

ENHANCING PATIENTS' SELF-REGULATION OF OBSTRUCTIVE  
SLEEP APNEA: THE EFFECT OF SELF-MONITORING AND  
OBJECTIVE MONITORING

by

ROGER F. PEACH

A dissertation submitted to the Graduate Faculty in Educational Psychology  
in partial fulfillment of the requirements for the degree of Doctor of  
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This manuscript has been read and accepted for the Graduate Faculty in Educational Psychology in satisfaction of the dissertation requirement for the degree of Doctor of Philosophy.

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## Abstract

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SLEEP APNEA: THE EFFECT OF SELF-MONITORING AND  
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by

Roger F. Peach

Advisor: Professor B.J. Zimmerman.

Self-monitoring has been shown to increase adherence to chronic treatment regimens and is one aspect of behavioral self-regulation. A four-phase cognitive-behavioral model of self-regulation (disease symptom avoidance, disease acceptance, disease compliance, and disease self-regulation in sequentially improving order) has predicted treatment adherence in children with chronic asthma (Zimmerman, Bonner, Evans, & Mellins, 1999). The purpose of this study was to test the hypothesis that self-monitoring of continuous positive airway pressure (CPAP) use and/or greater self-regulation would improve CPAP adherence in patients with obstructive sleep apnea (OSA).

Patients newly diagnosed with OSA were prescribed their successfully titrated levels of CPAP using a machine that monitored hours of nightly use at the prescribed pressure (ResMed, Elite), then randomly assigned to either a self-monitoring (S) or non-self-monitoring (NS) condition. For the first 30 days, the S group was asked to record nightly CPAP use. The NS group received identical clinical instruction and

counseling, but was not asked to self-monitor. For the second 30 days, the experimental conditions were reversed. Phase of OSA self-regulation at follow-up was assessed by analysis of responses to a qualitative research instrument, the OSA Self-Regulatory Development Interview (OSASRDI).

At 30-day follow-up the S group used CPAP for more hours per night than the NS group. In addition, OSA self-regulatory patients used CPAP for more hours per night than both OSA compliant, and OSA acceptant patients. In general, those patients who self-recorded and were OSA self-regulatory used CPAP more than all other sub-groups.

At 60-day follow-up, the effects of self-recording had dissipated. OSA self-regulation phase at 60-days was a significant predictor of CPAP use at 60-days. Of those variables measured at 30-day follow-up, OSA self-regulatory phase at 30-days was the sole significant predictor of hours of nightly CPAP use at 60-days.

OSA self-regulatory behavior, coupled with self-recording, was particularly effective in establishing early adherence to CPAP. Therefore, self-recording should be introduced and monitored with, or very soon after, the provision of CPAP. Similarly, self-regulation training should be provided at about the same time, and in a manner appropriate to the OSA self-regulation phase of each patient.

## Frontispiece

”Do but consider what an excellent thing sleep is: it is so inestimable a jewel that, if a tyrant would give his crown for an hour’s slumber, it cannot be bought: of so beautiful a shape is it, that though a man lie with an Empress, his heart cannot beat quiet till he leaves her embracements to be at rest with the other: yea, so greatly indebted are we to this kinsman of death, that we owe the better tributary, half of our life to him: and there is good cause why we should do so: for sleep is that golden chain that ties health and our bodies together.”

THOMAS DEKKER. (1570-1632)

(From: *The Gull’s Hornbook*, p. 25, 1609)

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I must also thank Professor David Rindskopf for turning a statistical sow's ear, if not into a silk purse, at least into a serviceable portmanteau. Any failure to develop sheen is due to my pig-headedness not his superb teaching.

Professor Carol Kehr Tittle stepped into the breach and urged me forward at a time when my sprits could have easily flagged. Her well-chosen words had the knack of stiffening my resolve, and her insightful comments on my work enhanced it immensely.

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## Chapter I.

### INTRODUCTION

Obstructive sleep apnea (OSA) is a serious chronic breathing disorder characterized by partial or complete blockage of the upper airway during sleep. It can lead to life threatening arrhythmias, hypertension, stroke, congestive heart failure, and sudden death as well as daytime drowsiness that can lead to accidents and poor performance. Although assessments vary, the prevalence of OSA in the general population has been estimated to be about seven percent, and has been shown to be even higher in senior citizens, and certain minority populations in the United States (Ancoli-Israel, 1989; Kripke, Ancoli-Israel, Klauber, et al., 1997). It has also been shown to be widely under-diagnosed (Young, Palta, Dempsey, et al., 1993).

To treat this disease, surgical corrections have been employed, but they have significant downsides. As a result, many doctors have sought alternative treatments. The most widely used nonsurgical treatment involves the use of a continuous positive airway pressure (CPAP) mask that is worn during sleep (Faccenda, Mackay, Boon, & Douglas, 2001; Hedner, Darp, Ejnell, Carlson, & Caidahl, 1995; Sullivan, 1981). Air pressure delivered via the CPAP mask is designed to keep the throat open during sleep. Despite the effectiveness of CPAP as a treatment for OSA when used consistently, patients' adherence rates generally are considered to be low,

and self-reported adherence has been found consistently to overestimate measured adherence (Chervin, 1997; Kribbs, Pack, Kline, et al., 1993). There is a strong need to develop interventions that can improve CPAP adherence, and a promising model, tested in research on asthma, focuses on patients' development of self-regulatory techniques. The present research will examine the effectiveness of self-regulatory training in improving CPAP adherence by OSA patients.

### *Obstructive Sleep Apnea and its Effects*

Obstructive sleep apnea (OSA) is a chronic disorder characterized by partial or complete occlusions of the upper airway during sleep. While the OSA sufferer is asleep, the uvula and soft pallet collapse on the back wall of the upper airway. Then the tongue falls backward, also collapsing on the back wall of the upper airway. The tongue forms a tight blockage, preventing any air from entering the lungs. The effort of the diaphragm, the chest, and the abdomen to continue breathing, only causes the blockage to seal tighter. In order to breathe, the sufferer must arouse or awaken, causing tension in the tongue that in turns opens the airway allowing air to pass into the lungs.

OSA leads to a decline in blood oxygen saturation, and an increase in blood carbon dioxide. When the blood oxygen saturation drops, the heart pumps more blood with each beat. As the blood oxygen saturation decreases further, the heart beats faster and faster. As the carbon dioxide level in the blood increases, brain activity occurs that is designed to

encourage breathing. As a result, the effort and activity of the abdomen and chest increase. This action can become severe enough to cause arousal. The blockage is then cleared, and normal breathing returns. However, on returning to sleep, the whole process begins again. Thus, during sleep apneic periods, it is common to see an increase in premature ventricular contractions and other arrhythmias, because oxygen saturation drops, sometimes dropping as low as 40%.

Each cycle of blockage, cessation of breathing, and subsequent arousal that lasts at least ten seconds is classified as an OSA event according to The American Sleep Disorder Association. The Association considers the average number of OSA events per hour to be the patient's Respiratory Distress Index (RDI). An RDI of over 40 is considered severe. However, some RDIs are well above 100, with events lasting up to 120 seconds. However, many OSA sufferers are not aware of their nighttime cessations of breathing and arousals.

OSA has been estimated to affect up to 7% of the middle-aged population, and 40% of community dwelling adults over the age of 65 in the United States (Ancoli-Israel, 1989; Young et al., 1993). It is often associated with hypertension, stroke, congestive heart failure and sudden death (Lavie, Herer, Peled, et al.1995). According to the National Center for Sleep Disorders Research (1993), some 38,000 cardiovascular deaths occur in the United States of America as a result of OSA annually.

OSA has not only been associated with life-threatening arrhythmias and systemic hypertension but also obesity and diabetes. In addition, repetitive obstructive events during sleep cause fragmentation of sleep which can lead to increased daytime sleepiness, irritability, decreased concentration and memory, decreased energy, enuresis, sexual dysfunction, depressive symptoms and increased traffic accidents (e.g. Faccenda, et al., 2001; Lavie, Herer, Peled, et al., 1995; Teran Santos, et al., 1999).

Obstructive sleep apnea is also either underdiagnosed (Young, Evans, Finn, & Palta, 1997), or its diagnosis is delayed (Rahaghi & Basner, 1999). Undiagnosed OSA sufferers have been shown to be heavy users of health care resources in the decade preceding their diagnosis, to the extent that undiagnosed OSA has been estimated to cause \$3.4 billion in excess health care costs in the United States of America each year (Kapur, 1999).

Although the etiology of obstructive sleep apnea is unclear, there are several treatments currently available for OSA patients. These include: behavioral interventions (sleeping in a lateral position), diet and exercise programs, medications, mandibular advancing dental devices, continuous positive airway pressure (CPAP), and a variety of surgical procedures. Different degrees of success are claimed for each of these treatments. However, several studies claim that CPAP is a proven, effective treatment for sleep apnea, and it is certainly the principal nonsurgical treatment in use at present (Faccenda, et al., 2001; Hedner, et al., 1995; Sullivan, 1981).

The CPAP acts a pneumatic splint to prop the airway open passively. The positive pressure is generated and controlled by a portable machine that is run electronically. It can be positioned at the patient's bedside. The positive pressure is delivered to the patient through a transparent plastic mask, which is attached to the CPAP machine by tubes. Ideally, the mask is to be worn every night, for as long as the patient is asleep, but a minimum of five hours use per night is considered desirable. It is not the case that a continuous period of use can build up a patient's reserve of capacity so that the mask can be dispensed with for a few days. The machine has to be used all night, every night to be fully effective.

In the Cardiopulmonary Sleep and Ventilatory Disorders Laboratory of Columbia University (Director: Dr. R. Basner), in which this research is based, CPAP is the treatment of choice for OSA. This sleep laboratory serves a large population in New York City, and its clients are mainly drawn from a low socioeconomic status, ethnically diverse group.

#### *CPAP Adherence and Its Enhancement*

Despite the effectiveness of CPAP, used consistently, as a treatment for OSA, adherence rates, both for clients of the Columbia University Sleep Laboratory, and for the USA generally are considered to be low, and self-reported adherence has been found to consistently overestimate measured adherence (Chervin, 1997; Kribbs, Pack, Kline, et al., 1993). The reasons for the relatively low rates of adherence are not well understood.

Anecdotal evidence from the Columbia University Sleep Laboratory suggests that clients who do not have a spouse/partner living with them are less likely to adhere than are those who do. It also indicates that patients who have some self-involvement in their referral to the Sleep Laboratory are more likely to adhere to CPAP than those who are referred by their doctor alone. There have also been differences reported in the reasons OSA sufferers and the spouses/partners of OSA sufferers give for lack of adherence. OSA sufferers tended to describe barriers to CPAP use that centered around physiological problems (e.g. nasal stuffiness, oral dryness, and machine noise), whereas their spouses/partners tended to focus on psychosocial issues (e.g. staying out late, forgetting to use the machine, and being out of town without the machine) (Smith, Mayer, Metsker, et al., 1998).

To date efforts to increase adherence to CPAP in OSA patients have almost exclusively focused on biomedical determinants of continuing CPAP tolerance, such as disease severity, and physiological side effects, rather than psychological determinants. Engleman and Wild (2003), in their review of the CPAP adherence literature, argue that one reason for this is that researchers and clinicians in the area have generally adopted a “compliance” model of behavior, rather than an “adherence” model.

The two models view the health professional-patient relationship differently. In the “compliance” model, patients are expected to receive and carry out treatment instructions from a knowledgeable authority figure.

Thus, poor compliance is assumed to stem either from the authority figure's failure to communicate the treatment instructions adequately, or the patient's failure to comprehend the treatment instructions, or the patient's deviance from the instructions, if understood, or some combination of the three factors (Donovan & Blake, 1992).

By contrast, the "adherence" model de-emphasizes passive obedience to medical instructions, and puts a premium on the active participation of the patient in controlling their own illness. Thus, the emphasis of the "adherence" model is on active self-regulation of health behavior (Engelman & Wild, 2003; Leventhal, 1993; Myers & Midence, 1998).

In any event, the "compliance" model has increasingly been seen as limited in its scope and usefulness. In addition, there have been contradictory findings regarding both the nature of compliance and the predictors of compliance in studies that have focused on biomedical determinants (Engelman & Wild, 2003).

In various medical areas there have been attempts to move away from "compliance" models, and towards "adherence" models. Most of these attempts have been based on various psychological models. One early model, which still has some following among the medical profession is the fear reduction model.

*Fear reduction model.* Fear appeals have been used in an attempt to change attitudes and behaviors in relation to health issues such as

periodontal disease (Beck & Lund, 1981), and smoking (Maddux & Rogers, 1983), under the assumption that the more fearful of the consequences of non-adherence the sufferer became, the more motivated she or he would be to adhere to a medical regimen. However, both Beck and Lund (1981) and Maddux and Rogers (1983) showed that fear appeals varied widely in their effectiveness from person to person. Based on this finding, and data resulting from the measurement of other psychological factors, they argued that cognitive factors, including self-efficacy beliefs, were mediating factors in the effectiveness of fear appeals as a method of increasing adherence.

*Health belief model.* In contrast to the fear reduction model, the health belief model was developed from a social-psychological perspective (Rosenstock, 1974). It was one of the earliest theoretical models that outlined in detail the factors hypothesized to contribute to patient behavior. In its original conception the model proposed that the likelihood of a person carrying out a particular health behavior was a function of their beliefs about the perceived threat of the disease and an assessment of the costs or benefits of the prescribed course of action. Thus, according to the health belief model, patients' adherence was based on general health motivations, perceived seriousness of the disease, perceived susceptibility to it, their faith in medical care, and perceived characteristics of the treatment regimen.

One advantage of the health belief model is that it stresses adherence rather than compliance. In the health belief model the sufferer was seen as an autonomous, responsible person who could take charge of their own

health issues and work cooperatively with the treatment provider to effect positive outcomes.

Unfortunately, no strong correlations between health beliefs and subsequent adherence to treatment programs have been found (e.g. Bruhn, 1983). There is little or no evidence for the effectiveness of the model as a predictor of adherence, but rather, health beliefs tend to develop along with adherence rather than before it. In addition, the model tends to focus on internal cognitive factors to explain motivation to adhere (i.e. personal beliefs) while ignoring both external factors like the influence of the social environment in which patient has to operate, and behavioral factors like the patient's monitoring of their own efforts to control the disease and the effect of these efforts on disease symptoms.

*Protection motivation theory.* This theory (Rogers, 1975) sought to explain medical adherence as a source of protection against adverse health outcomes. Rogers and Mewborn (1976) found that as health recommendations were presented as more effective, patients' intentions to adopt them increased. They argued that this was because patients saw effective treatments as a means by which they could control a real threat. Therefore, protection motivation theory emphasized response efficacy (the perceived contingency between the performance of the recommended action and the reduction of the depicted threat) as a central variable in adherence. However, by putting emphasis on response efficacy, protection motivation theory failed to include a mechanism by which personal intentions and/or

beliefs about the effectiveness of a course of action could be translated into actual behavior. Thus, personal efficacy, or the person's perceived ability to perform a recommended action, was not included in the model. Yet, as was noted above, personal efficacy has been found to be a strong predictor of adherence behavior (Beck & Lund, 1981; Kaplan, Atkins & Reinsch, 1984; Maddux & Rogers, 1983).

*The theory of reasoned action, and the theory of planned behavior.*

The Theory of Reasoned Action (Ajzen & Fishbein, 1980), as its name suggests, attempted to suggest how cost-benefit decisions are translated into action. The theory proposed that the formation of intentions precedes and predicts behavior, and that attitudes towards and subjective norms about the behavior determine intentions.

The Theory of Planned Behavior (Ajzen, 1985) is an extension of the Theory of Reasoned Action. In it, the concepts of perceived behavioral control, and perceived barriers to action have been added to the Theory of Reasoned Action. In this way, the Theory of Planned Behavior attempts to account for individual differences in feelings of personal control over a behavior. However, there is little evidence to suggest that intentions alone are good predictors of behavior, no matter how they are determined.

*Bandura's social cognitive theory.* One approach that includes personal efficacy or self-efficacy as a central concept, while also stressing social influences on behavior is Bandura's social cognitive theory. This theory takes a transactional view of the individual and society wherein

personal factors (e.g., cognitive, affective, and physiological), behavior, and the environment all interact bidirectionally (Bandura, 1997; Zimmerman, 1989).

A further tenet of the theory is that human change is embedded in social systems, which provide constraints and resources for human functioning. In addition, unlike the approaches mentioned above, the social cognitive approach stresses the need for the active development of appropriate behavioral repertoires. In fact, in this approach, enactive experiences are considered to enhance patients' perceptions of self-efficacy (Bandura, 1977; 1997).

The concept of self-efficacy is based on the notion that people expect that a particular set of actions in specific situations will lead to certain outcomes. If a person also believes that she or he can successfully perform the behavior required to bring about the particular outcome in a specific situation, then the person is said to have developed a positive self-efficacy expectation about their performance in that situation (Bandura, 1977). Therefore, self-efficacy expectations are assumed to affect both the initiation and persistence of performance in particular situations.

In view of the fact that self-efficacy is assumed to affect initiation of behavior, performance and persistence of behavior, it has been hypothesized that self-efficacy plays an important role in self-regulatory health-related behaviors (Bandura, 1997). Self-regulatory efficacy has predicted positive outcomes in the areas of reduction of blood pressure levels and diabetes

(Bandura, 1997), arthritis (Lorig, & Holman, 1993), and asthma (Palen, Klein, & Seydel, 1997; Zimmermann, Bonner, Evans, & Mellins, 1999).

In the area of OSA, to my knowledge, there have only been two studies to date reported in the English language journals that have examined the role of self-efficacy in CPAP adherence. The first (Stepnowsky, Marler, & Ancoli-Israel, 2002) compared a social-cognitive model with a transtheoretical model (see below) as predictors of CPAP compliance. The second (Weaver, Maislin, Dinges, et al., 2003) developed a new instrument, the Self-Efficacy Measure for Sleep Apnea (SEMSA) that was specifically designed for OSA. This latter study, however, collected no data on patients' actual CPAP use, and thus it could not relate self-efficacy to CPAP adherence.

*The transtheoretical (stages of change) model.* This model attempts to account for the fact that cognitions and behavior change over time. It suggests that the maintenance of health behavior occurs in five progressive stages of change: pre-contemplation, contemplation, preparation, action, and maintenance (Prochaska, & DiClemente, 1983). In the pre-contemplation stage the person might not be aware of the need to change, nor may think they are not capable of change, and so may not even be thinking of changing. In the contemplation stage the person may be thinking of changing, but not be fully committed to making the change. In the preparation stage the person is assumed to have a plan of action and be intending to put it into practice. In the action stage active attempts are made

to change behaviors. Finally, in the maintenance stage, attempts are made to prevent relapse. The model's proponents suggest that progress through the stages is more likely to be recursive than linear, with many backtrackings and partial successes before behavior change is established.

The model has been shown to predict behavior in the areas of smoking cessation (DiClement, Prochaska, Fairhurst, et al., 1991), weight control (Curry, Kristal & Bowen, 1992), and exercise (Marcus, Selby, Niaura, & Rossi, 1992). The one study in the area of OSA that compared the transtheoretical model with the social-cognitive model (Stepnowsky, Marler, & Ancoli-Israel, 2002) found that there was not a significant difference between the two models in predictive capacity.

*Self-regulatory models.* A major assumption of the self-regulatory approach is that ultimately the responsibility for the effectiveness of any treatment rests with the sufferer. Thus, the patient is seen as being actively engaged in dealing with her or his own health issues. To these extents, self-regulatory models can be seen as “adherence” rather than “compliance” models.

One self-regulatory model of illness was generated by Leventhal (1993). In it the patient initially generates cognitive representations of a health threat, then develops and implements coping procedures to deal with the perceived threat, and finally appraises the outcome of the coping procedures. In this model the three stages of processing are thought to occur in parallel, thus creating a dynamic interaction between representation,

coping, and appraisal. However, this self-regulatory model fails to take account of the changes in social context in which this dynamic interaction is likely to occur.

An alternative self-regulatory model of health behavior was developed by Zimmerman, Bonner, Evans and Mellins (1999). In this model the patient is also seen as an active problem solver, but a problem solver who interacts with others (e.g. a spouse/partner, children, friends, their physician) in relation to their health problem. Thus, in this model, self-regulation is envisioned as embedded within a social context.

The self-regulatory model of Zimmerman et al. (1999) was developed from Bandura's social-cognitive model. In his model Bandura argued that self-regulation operated through a set of sub-functions, self-observation, self-reaction, and self-judgment that had to be developed for behavioral change to occur (see: Bandura, 1986a).

Self-monitoring, a formal manifestation of one of these sub-functions, self-observation, has been shown to enhance adherence and health outcomes in a variety of areas. The areas include; obesity, diabetes, smoking cessation, exercise, and nutrition (Burke, Dunbar-Jacob, & Hill, 1997; Kamarak & Lichtenstein, 1988; Karter, et al., 2001; Miller, Wallace, Eggert, & Lindeman, 1993; Perri, McAllister, Gange, et al., 1988).

The Zimmerman et al. (1999) model postulated that self-regulatory disease control occurs in four phases. The first phase is symptom avoidance. The second phase is disease acceptance. The third phase is

disease compliance, and the fourth phase is disease self-regulation. In the disease avoidance phase, the patient may perceive disease symptoms but does not attribute these symptoms to an inherent physiological vulnerability with serious health-threatening consequences if untreated. In the disease acceptance phase, the patient accepts the disease as a serious health problem, but they respond to the disease non-preventively. For example, they tend to react only to acute episodes. In the disease compliance phase, the patients tend to follow the physician's treatment recommendations, but are unskilled at making adjustments in treatment use to respond preventively to changing circumstances. In the disease self-regulation phase, the patient can adjust their treatment regimens in response to changing circumstances. The model predicts that patients will be more adherent to treatment as they move through the four phases from avoidance to self-regulation.

According to Zimmerman et al., (1999) in order for patients to be able to adjust their treatment in response to changing circumstances (i.e. be in the self-regulatory phase) one of the things they must do is be self-observant. In other words, they must exhibit self-regulatory efficacy as proposed by Bandura (1986).

While Zimmerman et al.'s (1999) model is similar to the transtheoretical model (Prochaska, & DiClemente, 1983) to the extent to which it postulates phases of self-regulatory disease control, one of its main differences is that it proposes that self-regulatory efficacy is the driving

force which moves people through the phases, whereas the transtheoretical model invokes concepts like willpower.

In addition, the Zimmerman et al. (1999) model also subsumes both the “compliance” and “adherence” models in one model. It argues that the “compliance” phase and “adherence” phase are distinct, but that often people move through the “compliance” en route to the “adherence” (self-regulatory) phase. It also predicts that patients who are fully self-regulatory should be more adherent than those who are compliant.

In a test of their model with families that had a child who had chronic asthma, Zimmerman, Bonner, Evans and Mellins (1999) found that results supported the presence of four distinct but sequentially ordered phases of disease self-regulation. In addition as patients/families became more self-regulatory in their disease control, so the severity asthma symptoms declined.

Zimmerman et al. (1999) argued that their results suggested that asthma self-regulation is a complex developmental process rather than a simple educational one. This implies that to be successful, a self-management program firstly needs to identify an individual’s stage of compliance, and then develop an intervention appropriate for that stage of development.

Such a self-management program was designed and tested by Bonner, Zimmerman, Evans, Irigoyen, Resnick, and Mellins (2002). The authors hypothesized that the intervention would lead to improved health

outcomes among patients with asthma. A key component of the program was self-monitoring, to the extent that participants were trained in keeping asthma diaries and monitoring peak flow meters. Results showed that the intervention group was more adherent to asthma treatment than controls, and that this group showed a significant decrease in symptom persistence. In addition, the intervention group was more likely to be asthma compliant or self-regulatory at follow-up than the non-intervention group. Members of the intervention group were also more likely to exhibit phase change towards the self-regulatory phase during the course of the study than those in the control group.

#### *Research Questions*

The main purpose of this research is to extend the findings of Zimmerman et al. (1999) regarding chronic asthma to another chronic respiratory disease, obstructive sleep apnea. A major research question will be whether a sequential, four-phase self-regulatory model of adherence underlies adherence to CPAP treatment for OSA, as it did for adherence to asthma treatment.

Self-monitoring (e.g. recording of one's progress towards a specific goal) has been shown to be a powerful strategy when used in an attempt to improve academic, sporting, and health-related performance (Bandura, 1986b). Another aim of this research is to determine whether OSA sufferers who monitor their nightly CPAP use and their sleepiness during the following day will show greater adherence to CPAP than those who do not.

A follow-up question is whether patients' self-recorded use of CPAP matches the data recorded by the CPAP machines that can be downloaded to a computer.

Finally, it is asked, are patients at a more advanced phase of OSA self-regulatory development more accurate in monitoring their CPAP use than those who are less advanced?

## Chapter II

### REVIEW OF THE LITERATURE

#### *Prevalence of Obstructive Sleep Apnea (OSA).*

Sleep apnea is thought to affect about seven percent of the adult population. However, estimates of the prevalence of obstructive sleep apnea (OSA) have varied widely, as have the methods, sample sizes, and sample types employed to obtain these estimates. For example, Kripke, Ancoli-Israel, Klauber, Wingard, Mason, and Mullaney (1997) used random telephone dialing between 1990 and 1994 to recruit participants for a prevalence survey of sleep-disordered breathing in San Diego adults. The participants were equipped with home recording instruments that monitored, usually for three consecutive nights, events that resulted in blood oxygen desaturations of greater than or equal to four percent. Among 190 women ages 40-64 years, a median of 4.3 desaturation events per hour of sleep was observed. A higher median of 6.7 events per hour was observed among 165 men. From their data, the authors estimated that 4.9 percent of non-Hispanic Whites ages 40-64 had 20 sleep-disordered breathing events per hour or more. But, they also found that frequencies were much higher among members of minority groups, leading to a standard estimate that 16.3 percent of U.S. Hispanics and racial minorities have 20 sleep-disordered events per hour or more. Kripke, et al. (1997), therefore concluded that sleep-disordered breathing is more common in the population, especially among minorities, than had been previously believed.

In addition, it is likely that a large proportion of OSA in the general population goes undiagnosed. For example, Young, Palta, Dempsey, Skatrud, Weber, and Badr (1993) concluded that the prevalence of undiagnosed sleep-disordered breathing was high among men and much higher in women than previously reported. They based their conclusion on data from the Wisconsin Sleep Cohort Study, a longitudinal study of the natural history of cardiopulmonary disorders of sleep. The Wisconsin Sleep Cohort Study drew a random sample of 602 employed men and women. Their ages ranged from 30 to 60 years, and they were studied by overnight polysomnography to determine their apnea-hypopnea index (AHI). An abnormal breathing event during objectively measured sleep was defined according to the commonly used clinical criterion of either a complete cessation of airflow lasting 10 seconds or more (apnea) or a discernible reduction in respiratory airflow accompanied by a decrease of 4 percent or more in oxyhemoglobin saturation (hypopnea). The AHI measures the frequency of episodes of apnea and hypopnea per hour of sleep. The investigators found that the estimated prevalence of sleep-disordered breathing, defined as an AHI score of 5 or higher, was 9 percent for women and 24 percent for men.

In a further study, using a much larger sample, Young, Evans, Finn, and Palta (1997) surveyed a large sample of 4,925 employed adults. They followed up questionnaire data on doctor-diagnosed sleep apnea to ascertain the prevalence of diagnosed sleep apnea. They also used in-laboratory

polysomnography on a subset of 1,090 participants to estimate screen-detected sleep apnea. They estimated that in this subset, that presumably did not have obvious barriers to health care for sleep disorders, that 93 percent of the women, and 82 percent of the men who were assessed as having moderate to severe sleep apnea as a result of the polysomnography had not been clinically diagnosed.

Although people across the age range can suffer from OSA, there are indications that its prevalence increases with age. For example, from the results of their study mentioned above, Young, Evans, Finn, and Palta (1997) estimated that 2 percent of women and 4 percent of men in the middle-aged (35-50 years) work force met the minimal diagnostic criteria for the sleep apnea syndrome. However, this figure is somewhat lower than that reported by Kripke, Ancoli-Israel, Klauber, Wingard, Mason, and Mullaney (1997), above, for an older age group of non-Hispanic Whites. In addition, Enright, Newman, Wahl, Manolio, Haponik, and Boyle (1996) set out to describe the prevalence of snoring, observed apneas, and daytime sleepiness in men and women aged 65 and older, and to describe the relationships of these sleep disturbances to health status and cardiovascular disease. They employed a cross-sectional design to study sleep problems, cardiovascular disease, general health, psychosocial factors, and medication use. Participants were drawn from the Cardiovascular Health Study, which included 5,201 adults, who were recruited from a random sample of Medicare enrollees in four communities in the United States of America.

Observed apneas were reported by 13 percent of men, and four percent of women.

*OSA, Mortality and Hypertension*

There is evidence that there is an increased risk of mortality in people with OSA. A retrospective study by Lavie, Herer, Peled, Berger, Yoffe, Zomer, and Rubin (1995) found that of 1,620 adult men and women who had been diagnosed with sleep apnea syndrome between 1976 and 1988, and who had been monitored in sleep laboratories, fifty-seven had died by 1990. Of these, fifty-three percent of deaths were due to respiratory-cardiovascular causes. The mortality rates revealed excess mortality of male patients under 70 years old. Lavie, et al. (1995) found that age, body mass index (BMI), hypertension, lung disease, and heart disease were significant predictors of mortality from all causes. In addition, age, being overweight, lung disease, and hypertension predicted deaths from myocardial infarction. The authors interpreted these results as suggesting that sleep apnea syndrome affects death indirectly, most probably by being a risk factor for hypertension.

In an earlier study, using a smaller sample, Lavie (1983) had found evidence of a link between OSA and hypertension. He drew seventy-eight workers from a population of 1502 presumably healthy workingmen who were interviewed about sleep habits and sleep disorders. They also underwent polygraphic recordings for at least one night. Lavie found a significant association between the complaint of excessive daytime

sleepiness and the incidence of sleep apnea. He also found that workers with more than 10 apneas per hour of sleep complained significantly more about loud snoring, hypermotility in sleep, and frequent headaches. In addition, they had significantly more hypertension.

Jelic, Bartels, Mateika, Ngai P, DeMeersman, and Basner (2002) also noted that obstructive sleep apnea appears to be a risk factor for diurnal systemic hypertension. But they pointed out that the specific biologic markers for this association have not been well established. They suggested that increased arterial stiffness is a predictor of cardiovascular morbidity and may precede the onset of systemic hypertension. However, arterial stiffness had not previously been measured in association with obstructive apneas in patients with OSA, nor related to systemic blood pressure activity in this setting. Therefore, these authors tested the hypothesis that arterial stiffness may be utilized as a sensitive measure of arterial vasomotor perturbation during obstructive events in patients with OSA. They tested forty-four normo- and hypertensive adult patients diagnosed with moderate to severe OSA. Beat-to-beat blood pressure was recorded from the radial artery by applanation tonometry during nocturnal polysomnography. The Arterial Augmentation Index (AAI), a measure of arterial stiffness, was calculated while the participants were awake, and during the first 10 ("early apnea") and last 10 ("late apnea") cardiac cycles of obstructive events, and the first 15 cardiac cycles following apnea termination ("post apnea").

Jelic, Bartels, Mateika, Ngai P, DeMeersman, and Basner (2002) found that mean AAI for the group was significantly increased during non-rapid-eye-movement (NREM) sleep from early apnea to late apnea. During rapid-eye-movement (REM) sleep, for 20 patients, mean AAI significantly increased from early apnea to late apnea. Conversely, neither mean systolic blood pressure nor mean arterial blood pressure was significantly changed from early apnea to late apnea in NREM. Since the authors found that arterial stiffness increased acutely in association with obstructive apneas in both NREM and REM sleep, and that such an increase in stiffness occurred in the absence of acute blood pressure increase, they concluded that arterial stiffness may be a sensitive measure of acute arterial vasomotor perturbation and may have implications concerning cardiovascular sequelae in patients with OSA.

#### *OSA and Coronary Heart Disease*

Koehler, and Schäfer (1996), in a prospective study of 74 men aged from 39 to 78 years of age, who had significant stenosis of one or more coronary arteries, revealed an association between coronary heart disease and OSA. Thirty-five percent of their group of coronary heart disease patients had OSA. This was compared with results from general population studies that estimate the prevalence of OSA at about four to five percent (see: Kripke, et al., 1997; Young et al., 1993). In similar vein, but this time in the area of chronic obstructive pulmonary disease, Weitzenblum, Krieger, Oswald, Chaouat, Bachez, and Kessler (1992) found that of 264 unselected

sleep apnea patients who had undergone detailed pulmonary function tests, 30, or 11 percent, had obstructive ventilatory defect.

#### *Obesity and OSA*

Sleep-disordered breathing has been shown to be related to obesity. Young, Evans, Finn, and Palta (1997) in their study to assess the prevalence of OSA found that obesity was strongly associated with sleep-disordered breathing, and Kripke, Ancoli-Israel, Klauber, Wingard, Mason, and Mullaney (1997) also found that obesity indicated by body-mass index was the most important demographic predictor of sleep-disordered breathing. Other clinical and epidemiological studies have also demonstrated a strong association between obesity and OSA (see: Strobel, & Rosen, 1996, for a review). However, it is difficult to show a causal relationship between obesity and OSA because most studies have methodological limitations. It has been hypothesized that obesity in people with OSA could put them at increased risk of cardio-vascular disease. Obesity has also been associated with diabetes.

#### *A Link with Diabetes*

In its turn, diabetes has been linked to OSA. Enright, Newman, Wahl, Manolio, Haponik, and Boyle (1996) observed apneas were associated with diabetes in women, and Strohl (1996) has argued that real and potential links exist between the risk factors for and co-morbidity associated with diabetes and sleep apnea. Strohl gave the common occurrence of obesity, hypertension, and disorders of metabolism in both

diabetes and OSA as an example. Strohl hypothesized that the events in OSA trigger different adaptations in metabolic processes involving insulin action and glucose regulation.

#### *Work-Related Accidents and Traffic Accidents*

Although OSA has been linked to a variety of physiological factors that result in morbidity or mortality, it has also been linked to environmental factors. For example, Melamed and Oksenberg (2002) tested for an association between excessive daytime sleepiness and risk of occupational injuries, using injury data taken from organizational archives. In what was both a retrospective and prospective study, they covered injury occurrence during two years prior to a sleep disorder assessment/education procedure and injury occurrence in the following year.

Melamed and Oksenberg (2002) drew a sample of 532 non-shift, daytime workers from eight industrial plants. These workers were provided with lectures and small-group discussions on sleep disorders, treatment, implications for safety, and quality of life. Participants completed a sleep assessment questionnaire before the commencement of the lecture/discussion sessions. Of the workers studied 22.6 percent had excessive daytime sleepiness. Of these, almost all said they had experienced it for the past two years or more, and over half of them had experienced it for ten years or more. In the two years prior to study participation, excessive daytime sleepiness was associated with an increased risk of sustaining a work injury, even after controlling for factory category, job and

environmental conditions. However, in the year after study participation, the injury rate decreased by one-third in the workers with EDS, making the association between EDS and injury no longer significant. Nevertheless, the authors concluded that, prior to intervention, workers with excessive daytime sleepiness had more than twice the risk of sustaining an occupational injury than workers without it.

Earlier, in a retrospective study, Aldrich (1989) had reviewed data on sleep-related accidents from 70 control subjects and 424 adults with four categories of sleep disorders: sleep apnea, narcolepsy, other disorders of excessive sleepiness, and sleep disorders without excessive sleepiness. Aldrich found that the proportion of individuals with sleep-related accidents was 1.5 to 4 times greater in the hypersomnolent patient groups than in the control group, and that apneics and narcoleptics accounted for 71 percent of all sleep-related accidents. In addition, the proportion of severe apneics who had sleep-related accidents was almost twice that of patients with mild or moderate apnea.

Obstructive sleep apnea has certainly been implicated in motor vehicle accidents. George and Smiley (1999) used a large population of OSA patients to determine the rate of automobile accidents using objective data from the Ministry of Transportation of Ontario (MTO). All cases of OSA were polygraphically confirmed. Cases of OSA were a priori divided into groups based on the apnea-hypopnea index (a measure of apneas and hypopneas per hour of sleep), and driving records were obtained from the

MTO. Age and sex matched controls were selected at random from drivers in the MTO driver database who held passenger vehicle licenses. Analysis was restricted to drivers with the same license class. The primary outcome measure was accidents in the five years preceding diagnosis. The secondary outcome was citations during the same period. George and Smiley found there was a significantly greater percentage of OSA patients with one or more accidents compared with controls for the same time period. The rate of accidents per year, for the preceding five years, was also greater for OSA patients than controls. The difference was accounted for by an increased accident rate in OSA patients with the highest apnea-hypopnea index. In addition, OSA patients had twice as many citations as controls.

Similarly, Garbarino, Nobili, Beelke, De Carli, and Ferrillo (2001) evaluated the contributing role of sleepiness in Italian highway vehicle accidents between 1993 and 1997. Accidents were ascribed as either sleep related, or non-sleep related by investigating police officers. The authors then assessed the relation between accidents and sleepiness as derived from a 24-hour sleep propensity curve. They discovered a close relationship between the curves of non-sleep ascribed accidents and sleep-ascribed accidents. This led them to suggest that the rate of non-sleep ascribed accidents was closely related with sleep propensity since it bore a strong similarity to the pattern of sleep-ascribed accidents. The ratio between the quota of accidents that were considered as sleep affected and those actually ascribed to sleepiness, was calculated as 5.83. The researchers found that 3.2

percent of all recorded accidents were ascribed to sleepiness by reporting police officers. Thus, multiplying this base rate by the ratio between the quota of accidents that were considered as sleep affected and those actually ascribed to sleepiness, they calculated that 18.7 percent of those accidents not officially ascribed to sleepiness were, in fact, sleep influenced. Thus, they reached an estimate that 21.9 percent of Italian highway vehicle accidents during the period were related in some way to sleepiness.

However, this study did not distinguish between those accidents in which the driver might be suffering from OSA, and those that might have been due to other fatigue factors. Nevertheless, extrapolating from the results of research cited above, it is safe to say that a sizeable proportion of drivers involved in sleep-influenced accidents were most likely suffering from OSA.

Finally, Horstmann, Hess, Bassetti, Gugger, and Mathis (2000) analyzed the frequency of motor vehicle and working accidents in 156 Swiss sleep apnea syndrome patients, and in 160 age-gender matched controls. About four times as many drivers in the sleep apnea syndrome group had motor vehicle accidents than in the control group. A difference that was statistically significant. Patients with severe sleep apnea had significantly more motor vehicle accidents than either patients with mild sleep apnea, or the control group.

It is also likely that sleep apnea patients under-report episodes of driving impairment, as well as other symptoms such as sleepiness.

Engleman, Hirst and Douglas (1997) attempted to assess this likely under-reporting by obtaining repeated ratings from 99 patients with OSA of unintended napping, driving impairment and mood, first at presentation and then after treatment with CPAP for about 22 weeks. Unintended napping was rated as significantly more severe on retrospective assessment (after CPAP treatment) than at baseline. In addition, driving impairment due to sleepiness was initially reported by 23% of all drivers and retrospectively by 37%, with 25% of initial deniers retrospectively admitting compromised driving ability before continuous positive airway pressure.

#### *OSA Adversely Affects Quality of Life*

Since OSA appears to be associated with increased morbidity and mortality, especially as a result of cardiovascular impairment, diabetes, sleep disorders, excessive daytime sleepiness, obesity, and industrial and vehicular accidents, it is not surprising that researchers in the area have investigated the effect of OSA on general quality of life. Baldwin, Griffith, Nieto, O'Connor, Walsleben, and Redline (2001) assessed the extent to which sleep-disordered breathing, difficulty initiating and maintaining sleep, and excessive daytime sleepiness were associated with impairment of quality of life using the Medical Outcomes Study SF-36 Health Survey (SF-36). They examined data from 5,816 participants who were enrolled in a nation-wide population-based Sleep Heart Health Study. They found that individuals with severe sleep disordered breathing indicated significantly poorer quality of life ratings on several SF-36 scales. Both difficulty

initiating and maintaining sleep, and excessive daytime sleepiness were strongly associated with reduced quality of life.

In a study which used more precise measurements of OSA, but a much smaller sample, Yang, Hla, McHorney, Havighurst, Badr, and Weber (2000) investigated the effects of sleep apnea on quality of life by conducting a prospective study of quality of life in patients with and without sleep apnea. Participants were drawn from university-based outpatient clinics, and consisted of primary care patients followed in a general internal medicine clinic as well as those referred to a sleep disorders clinic. Using the AHI, participants were classified into 3 groups of subjects. The first group consisted of 46 patients without sleep apnea. The second group comprised 16 patients with mild sleep apnea, and the third group, 21 patients with moderate to severe sleep apnea. Like the previous study, quality of life was assessed with the SF-36. Health history and demographic data were obtained via structured interview and medical record review. After controlling for age, gender, body mass index, and number of comorbid conditions, the association between sleep apnea and quality of life was significant in the domains of physical functioning and role limitation due to physical health problems. Patients with both mild and moderately severe sleep apnea scored significantly worse than did patients without sleep apnea in physical functioning and in role limitations due to physical-health. Moderate to severe sleep apnea participants scored significantly worse in vitality than did participants without sleep apnea. Participants with moderate

to severe sleep apnea had significantly lower scores than those without sleep apnea in positive affect, current health perceptions and vitality.

Obstructive sleep apnea has also been associated with loud snoring in many studies. Loud snoring can have a major impact on the quality of life of the spouses/partners, other family members, and associates (e.g. traveling companions) of the OSA sufferer. Adverse feedback from these sources regarding the OSA patient's snoring, can also impact negatively on her or his own quality of life.

#### *Health Care Costs of OSA*

Certainly, the health care costs associated with OSA appear to be high. Kapur, Blough, Sandblom, et al. (1999), in a retrospective study, assessed the medical costs of a consecutive series of 238 cases in the year prior to their being diagnosed as having sleep-disordered breathing. Among cases, mean annual medical cost prior to diagnosis was \$2720 versus \$1384 for age and gender matched controls. This difference was statistically significant. Higher annual medical costs were also significantly related to increased severity of sleep-disordered breathing when age, gender, and body mass index were controlled for. Using available data on the prevalence of undiagnosed moderate to severe sleep apnea in middle-aged adults, the authors estimated that untreated sleep apnea might result in \$3.4 billion additional medical costs in the United States of America.

In a Canadian study, Kryger, Roos, Delaive, Walld, and Horrocks (1996) compared the health care utilization of 97 obese patients diagnosed

with OSA, and 97 matched control subjects. Over a two-year period that ended two years prior to initial diagnosis, the OSA group had 251 nights in hospital, compared to 90 nights for the control group. During the same two-year period, total expenditures from physician claims were \$82,238 (Canadian dollars) in the OSA patients as opposed to \$41,018 in the control group. The authors estimated that during the same two-year period, the 97 OSA patients utilized between \$100,000 and \$200,000 more in services than their control counterparts. Since the cost of utilization of health services by OSA patients was calculated prior to diagnosis, the authors concluded that OSA sufferers are already heavy users of health care resources even before they are clinically determined to have OSA.

One question that remained from the previous study was, “What, then are the extent of health care costs for OSA sufferers after they have been diagnosed with OSA?” In an attempt to answer this question, Bahammam, Delaive, Ronald, Manfreda, Roos, and Kryger (1999) documented changes in health care utilization by OSA patients two years after diagnosis and treatment. Health care utilization was operationalized as physician claims and hospitalizations. The study was again carried out in Canada where 344 OSA patients on whom there were utilization data were selected from a University-based sleep disorders center, while gender- and age-matched controls were selected from the general population. Results showed that the difference in physician claims between the patients and their matched controls two years after diagnosis and treatment was significantly

less than the difference in the year before diagnosis. But that this result only held true for the subgroup of OSA patients who were adhering to treatment. A similar result occurred when hospital stays was the variable of interest. Thus the authors concluded that the cost of health care utilization by OSA sufferers does decrease following diagnosis and treatment, but diagnosis alone is not sufficient to bring about the reduction, it has to be accompanied by adherence to treatment on the part of the OSA patients.

#### *Treatments for OSA*

As noted in Chapter One, there are several treatments available for OSA, ranging from diet and exercise programs to surgical interventions. One of these treatments is continuous positive airway pressure (CPAP). CPAP is the treatment of choice in the study reported here. Several studies claim that CPAP is a proven, effective treatment for sleep apnea, and it is certainly the principal non-surgical treatment in use at present (Faccenda, et al., 2001; Hedner, et al., 1995; Sullivan, et al., 1981).

CPAP acts a pneumatic splint to prop the airway open passively. The positive pressure is generated and controlled by a portable machine that is run electronically. It can be positioned at the patient's bedside. The positive pressure is delivered to the patient through a transparent plastic mask, which is attached to the CPAP machine by tubes. Ideally, the mask is to be worn every night, for as long as the patient is asleep, but a minimum of five hours use per night has been considered desirable.

While CPAP is an effective treatment for OSA, it is not necessarily a simple matter to get accustomed to using the equipment. The machine has to be set up near the patient's bed, and the equipment has to be cleaned regularly. In addition, the OSA patient has to habituate to wearing a mask with its attached tubing every night during sleep. Although most CPAP machines are quite light and portable, patients have to remember to transport the machine when they travel, and feel confident about setting up and using the equipment in possibly unfamiliar surroundings while they are away from home. It is highly likely, therefore, that for these and other reasons people with OSA might use CPAP sub-optimally.

#### *Adherence to CPAP*

It is perhaps not surprising that one of the major problems in the successful treatment of OSA is that sufferers do not always comply with their prescribed treatment (Bahammam, Delaive, Ronald, Manfreda, Roos, & Kryger, 1999). Chervin, Theut, Bassetti, and Aldrich (1997) had previously noted that while continuous positive airway pressure (CPAP) had proved effective as a treatment for OSA, it is limited by poor compliance. In another study, Engleman, Martin, and Douglas (1994) assessed compliance with CPAP in 54 OSA patients. The patients were studied over the first 1-3 months after starting CPAP therapy. In all cases CPAP usage was monitored by hidden time clocks that indicated for how long the machines were switched on. Engleman and colleagues found that the mean nightly CPAP usage time was 4.7 hours, a little less than the recommended

minimum, and they also discovered that patients who experienced side effects, such as mask discomfort and oral dryness from CPAP, used their CPAP machines significantly less than those who did not.

Similarly, Kribbs, Pack, Kline, Smith, Schwartz, Schubert, Redline, Henry, Getsy, and Dinges (1993) reported that only 46 percent of their sample of 35 OSA patients met the criteria for regular CPAP use over an average period of 106 days. In this study, regular use was defined as at least 4 hours of CPAP use on 70 percent of the days monitored, again somewhat less than the recommended minimum usage. In addition, Kribbs et al. (1993) also found that patients' self-reports of CPAP usage significantly overestimated actual use as measured by a microprocessor inside their CPAP machines.

### *The Concept of Adherence*

Before continuing to outline some of the problems associated with assessing adherence to CPAP treatment, it is necessary to pause to consider the concept of adherence. This will be of importance later when various psychological models that have been proposed to explain adherence to medical regimens are outlined and discussed.

Almost all the literature cited in this chapter that deals specifically with OSA, uses the term "compliance" rather than "adherence" when referring to the on-going use of CPAP as a treatment for OSA. At first glance, it might be considered that the two words could be used

interchangeably as essentially describing the same thing. However, Engelman and Wild (2003) in their clinical review of the literature on CPAP adherence in patients with OSA argue that the adoption of a “compliance” model of behavior stems from a biomedical approach to CPAP use. In turn, they argue, that this approach inevitably leads to a focus efforts to increase adherence to CPAP on biomedical determinants of continuing CPAP tolerance, such as disease severity, and physiological side effects, rather than psychological determinants.

In addition, the physician-patient relationship is viewed differently in the “compliance” model than it is in the “adherence” model. In the “compliance” model patients are expected to receive and carry out treatment instructions from a knowledgeable authority figure (usually a medical doctor) (Haynes, 1979). In turn, poor compliance is assumed to result either from the authority figure’s failure to communicate the treatment instructions adequately, or the patient’s failure to comprehend the treatment instructions, or the patient’s deviance from the instructions, if understood, or some combination of the three factors (Donovan & Blake, 1992).

The compliance model has, however, been seen to be increasingly limited as patients become more concerned with managing their own health issues, and have increasing access to health information from a variety of sources. For that reason, the term “adherence” is increasingly being used in place of “compliance” when referring patients’ use of medical regimens. One reason for the increasing adoption of the term “adherence” is that it

implies a more active, and collaborative involvement of the patient in implementing and maintaining a particular course of treatment. Thus, the adherence model represents a shift away from emphasizing passive obedience to medical instructions, and towards emphasizing active self-regulation of health behavior (Engelman & Wild, 2003; Leventhal, 1993; Myers & Midence, 1998).

As has been seen, in the area of CPAP as a treatment for OSA the biomedical-compliance model still tends to hold sway. However, adherence models are beginning to be developed (Engelman & Wild, 2003). This development mirrors the trend in other illnesses, where biomedical models of behavior are being superseded by adherence models that incorporate psychosocial and cognitive factors in order to explain individual differences in reactions to medical regimens.

I will argue below that a psychological model of behavior that incorporates both the “compliance” and “adherence” models, and that has previously been successfully used in studying adherence in children with chronic asthma (Zimmermann, Bonner, Evans, & Mellins, 1999), can usefully be applied to the area of adherence to CPAP in OSA patients. First, however, I will attempt to show that the focus of the “compliance” model on biomedical determinants of CPAP adherence has led to confusion rather than clarity. Hence, practitioners are still uncertain about how best to increase adherence.

*Contradictory findings and conflicting interpretations of the same findings.*

In a relatively early study, Nino-Murcia, McCann, Bliwise, Guilleminault, and Dement (1989) treated 144 patients with nasal CPAP and observed them for periods of as long as 25 months. They reported compliance rates were between 65 percent and 83 percent, depending on the patient population considered. They found that demographic factors such as age, sex, and the presence of a housemate were unrelated to discontinuing to use CPAP. However, they did find that better-educated patients were less able to tolerate the equipment. This finding was to some extent contradicted by the results of Engleman, Martin, and Douglas's (1994) study, which showed that patients with a higher education level were more compliant with CPAP treatment. Nino-Murcia et al. (1989) found that dry throat and nose and sore eyes were commonly reported side effects, and that these side effects tended to inhibit CPAP use. To the extent that Engleman et al. (1994) reported that patients who experienced side effects such as mask discomfort and oral dryness from CPAP, used their CPAP machines significantly less than those who did not, there is some concordance between the two studies.

In view of the adherence rates Nino-Murcia et al. (1989) obtained, the authors concluded their study on an optimistic note, for intermediate-term use at least. But they also suggested that it remained to be seen whether adverse consequences occur over longer periods of time.

Using an even smaller sample of 44 French OSA patients, Meurice, Dore, Paquereau, Neau, Ingrand, Chavagnat, and Patte (1994) attempted to address the question of long-term acceptability of CPAP treatment. However, they suggested that results obtained at 14 months follow-up represented long-term adherence, whereas Nino-Murcia et al. (1989) had indicated that results obtained at follow-up periods of as long as 25 months represented only intermediate-term adherence. Thus, one of the problems in CPAP adherence research is highlighted; namely the lack of consistency across studies of the operational definitions of what constitutes short-, medium-, and long-term adherence. Nevertheless, Meurice et al. (1994) found that of their sample of 44 OSA patients, 30 (68 percent) were adherent (characterized by use of the apparatus every night throughout the night, for more than 5 hours per night). The daily use of nasal CPAP was significantly associated with initial AHI, as well as with the percentage of light sleep and slow-wave sleep during the initial polygraphic recording. Thus, patients used CPAP much more if they had an initial significant clinical handicap and if they were aware of the beneficial effects of CPAP. Under these conditions, patients tended to use the apparatus for the optimal length of time, regardless of the side effects linked to the treatment. They also concluded that relatively simple intervention such as using a time counter, as well as regular encouragement of patients to use the treatment as long as possible each night, would lead to what they considered to be good adherence.

Sin, Mayers, Man, and Pawluk (2002) also investigated long-term compliance to CPAP. They studied 296 Canadian OSA patients. The patients were supplied with a CPAP device equipped with a monitoring chip. Within the first week, daily telephone contacts were made. Patients were seen at 2 weeks, 4 weeks, 3 months, and 6 months. Sin et al. found that the mean duration of CPAP use was 5.7 per day at 2 weeks, and at 4 weeks, 5.9 hours per day at 3 months, and 5.8 hours per day at 6 months. The percentage of patients using CPAP for 3.5 hours per day was 89.0 percent at 2 weeks, 86.6 percent at 4 weeks, 88.6 percent at 3 months, and 88.5 percent at 6 months. The authors argued from these results that a relatively simple intervention like daily telephone contacts during the first week of CPAP use could enhance long-term compliance. However, the study did not have a control group of patients who did not receive the intervention, and while the mean durations indicated acceptable compliance, 3.5 hours per day of CPAP use, on which the percentage compliance rates were based, is somewhat below what is considered adequate usage (5-6 hours per day). Thus the authors may have overestimated the effectiveness of the intervention as a means of increasing CPAP compliance.

In contrast to the previous studies, Teran Santos, Quintana Gonzalez, Morato Arnaiz, Lazaro Asegurado, and Garcia Arroyo (1999) considered previously reported adherence rates to be generally low, thus illustrating another problem in the CPAP-adherence literature. That problem is that there has been no commonly agreed upon criterion, or set of criteria, as to

what constitutes acceptable CPAP adherence rates, either at the individual or group level. In their study that assessed the factors associated with adherence to CPAP, and the secondary effects of its use, Teran Santos et al. (1999) used a sample of 88 Brazilian patients diagnosed with OSA who were undergoing CPAP treatment. Individuals in this sample were followed for a period of 29 months, on average. Results showed seventy percent adherence. Adherence was associated with drowsiness degree, AHI, and mean pressure of CPAP. However the authors found that subjective evaluations of adherence by patients overestimated the actual use of the CPAP device as measured by time-counters. They also discovered that secondary effects were not a limiting factor for compliance. Although the adherence rate obtained in this study was similar to that of Meurice et al. (1994), the authors did not indicate whether they considered this to indicate good adherence to CPAP. However, they did suggest that the therapeutic approach adopted should be tailored to individual circumstances in order that a good acceptance level might be achieved, thus implying, both that an adherence rate of 70 percent could be improved upon, and that psycho-sociological factors might play a role in CPAP adherence.

Hoffstein, Viner, Mateika, and Conway (1992) had previously explicitly stated that CPAP adherence might be limited by what could be termed social-psychological factors. They pointed out that CPAP treatment of OSA involves the long-term, nightly use of relatively cumbersome equipment. So they suggested that adherence may be influenced not only by

the objective improvement in sleep apnea but also by the patient's subjective perception of the cost-benefit trade-off, bedmate or family support, and perceived side effects. Therefore, they tabulated the responses of 148 Canadian patients with OSA to a detailed mailed questionnaire.

Questionnaires were returned by 96 (67 %) of participants, and a further 42 were contacted by telephone. Of these 138 patients, 105 continued to use CPAP at a mean follow-up time of 17 months. The majority of patients (81 percent) perceived CPAP as an effective treatment of the disorder, 5 percent were unsure, and 14 percent believed that CPAP was ineffective, despite the resolution of sleep apnea on polysomnography. Subjective improvement as reported by the patients was also observed by the family members in 83 percent of the patients.

The most common complaint, voiced by 46 percent of the patients, was nocturnal awakenings. Nasal problems, such as dryness, congestion, and sneezing, were the second most frequent complaint present in 44 percent of the responders. Despite the avowed intent of the previous study's authors to examine the social-psychological factors involved in adherence, in essence the study's emphasis was on the effect of various side effects such as nasal problems on CPAP adherence.

In fact, there have been very few studies of CPAP that have examined the role of psychological factors in CPAP usage. One that did was carried out by Edinger, Carwile, Miller, Hope, and Mayti C. (1994). They assessed 38 male patients with OSA using the Minnesota Multiphasic

Personality Inventory (MMPI). The participants were asked to complete 2 weeks of rating symptoms, physical examination, diagnostic polysomnography, and MMPI testing prior to being placed on CPAP. Six months later, 26 (72.2 %) of the 36 subjects available for follow-up showed continued compliance. A regression analysis conducted with those 28 subjects who completed all pretreatment measures showed that continued therapy was predicted by such pretreatment measures as patients' body mass index, ratings of daytime sleepiness and nocturnal sleep quality, and MMPI Depression (D) and Hypochondriasis (Hs) scale scores. Eventual compliers had a higher body mass index, reported less daytime sleepiness and better nocturnal sleep quality, and scored lower on the MMPI D and Hs scales prior to treatment than did the non-compliers. However, the MMPI was originally developed to assess people with possible psychological disorders, and its validity as a tool for predicting CPAP adherence is questionable.

Pieters, Collard, Aubert, Dury, Delguste, and Rodenstein (1996) took a view similar to Nino-Murcia, et al. (1989) and Meurice, et al. (1994), arguing that although some previous studies had generally shown poor effective long-term adherence to CPAP in OSA patients, results from their retrospective study of patients treated with CPAP for more than one year showed high and stable adherence rates. They defined adherence as the average number of hours of CPAP use per day, where hours of use were obtained from a time-counter built into the CPAP machine. Pieters, et al. (1996) presented data from 95 patients, with an average follow-up period of

slightly over 2 years for the whole group. The group averaged 5 hours of use per day over that period. In addition, of 192 patients who were followed-up over a three-year period, only 21 quit treatment, mainly due to intolerance or cure. The authors claimed that these results contradicted those obtained in earlier studies, and indicated that in a nonselected group of OSA patients a high and stable adherence level can be achieved.

Fleury, Rakotonanahary, Tehindrazanarivelo, Hausser-Hauw, and Lebeau (1994) carried out a study of both acute and long-term adherence to CPAP in 31 patients diagnosed by polysomnography as suffering from OSA. Twenty of the 31 patients were treated at home, and four of those 20 (20 percent) interrupted their treatment during the first month because of discomfort. The remaining 16 were followed for an average of 285 days, and their average daily rate of CPAP use was 6.7 hours.

In order to increase knowledge about adherence to CPAP, Chervin, et al. (1997) performed a randomized, controlled clinical trial among 33 subjects of two interventions to improve compliance. One group of subjects received weekly phone calls to uncover any problems and encourage use, another received written information about sleep apnea and the importance of regular CPAP use, and a third served as control subjects.

Chervin and colleagues (1997) found that both interventions improved CPAP compliance relative to controls, and that the effect was particularly strong when intervention occurred during the first month of CPAP treatment. However, the sample size was small, and did not allow for

definitive investigation of other explanatory variables. Nevertheless, the authors concluded that simple, inexpensive efforts to improve adherence to CPAP can be effective, especially when applied at the start of CPAP treatment. They did caution that optimal intervention may vary with certain patient characteristics. This suggests that psychological factors have a role to play in adherence to CPAP.

By contrast, Hoy, Venelle, Kingshott, Engleman, and Douglas (1999) argued that it is necessary to provide more intensive programs and nursing support in order to increase CPAP adherence, which, they suggested is disappointingly low. Therefore, they randomized eighty consecutive, new patients with OSA to receive either usual support or additional nursing input including CPAP education at home and involving their partners, a 3-night trial of CPAP in their institution's sleep center, and additional home visits once they had begun CPAP. They found that CPAP use over a six-month period was significantly greater among patients receiving intensive support than among those receiving standard support.

In a more recent Swedish study, Janson, Noges, Svedberg-Randt, and Lindberg (2000), attempted to characterize patients who were unable to tolerate CPAP treatment as opposed to those who continued using CPAP. They performed a case-control study in which the cases comprised of 40 patients who had been started on CPAP treatment but had found the treatment unacceptable and had ceased to use CPAP. The controls comprised of 63 patients with OSA who had been prescribed CPAP and

were still using it (follow-up period 18 months to 10 yr). The patients who stopped CPAP treatment had a higher mean age, and had a lower mean oxygen desaturation index (ODI) than patients who continued using CPAP. The two most common reasons for non-compliance were problems in the nose or pharynx and lack of subjective effect by the treatment. Older age was an independent risk factor for non-compliance because of problems in the nose or pharynx. The authors also found that patients with less severe OSA were more likely to discontinue CPAP treatment, and that the risk of experiencing nasal and pharyngeal side effects of such severity that the patient stops using CPAP increased with age.

McArdle, Devereux, Heidarnejad, Engleman, Mackay, and Douglas (1999) investigated the level of long-term CPAP use, and the factors influencing such usage in a prospective study spanning eleven years. They examined determinants of objective CPAP use in 1, 211 consecutive Scottish patients with OSA who were prescribed a CPAP trial between 1986 and 1997. Prospective CPAP use data were available in 1, 155 (95.4 percent), with a median follow-up of 22 months. Fifty-two (4.5 percent) patients refused CPAP treatment, while 1,103 patients took CPAP home. During follow-up 20 percent of these stopped treatment, primarily because of a lack of benefit. Methods of survival analysis showed that 68 percent of patients continued treatment at 5 years. They found that average nightly CPAP use within the first three months was strongly predictive of long-term use, with higher average nightly usages predicting greater long-term use.

Independent factors associated with long-term CPAP usage were disease severity and subjective sleepiness.

One problem when estimating CPAP is that self-reported adherence tends to be greater than objectively measured adherence, thus casting doubt on some of the reported adherence rates obtained from measures such as questionnaires and telephone interviews. For example, Rauscher, Formanek, Popp, and Zwick (1993) studied 63 OSA patients and found that objective adherence as measured by a built-in time counter of the patients' devices showed an average usage time of 4.9 hours per night, while subjective adherence as reported in a self-administered questionnaire showed an average of 6.1 hours per night for the same period of time. Because the authors discovered that it was generally the participants with poor adherence who misestimated daily use time, the authors concluded that self-reports were unable to distinguish between adherent and nonadherent patients.

Krieger, Kurtz, Petiau, Sforza, and Trautmann (1996) conducted a prospective study aimed at objectively evaluating compliance with CPAP treatment. They recruited 728 obstructive sleep apnea patients and 98 nonapneic snorers. Of those, 575 OSA patients and 33 nonapneic snorers underwent CPAP therapy and were followed-up for an average of 1,176 days (range: 27 to 4,203 days). Compliance to treatment was measured by the mean rate of use of the CPAP device obtained from a built-in time counter. The acceptance of CPAP was greater than 90 percent at 3 years

and greater than 85 percent at 7 years in OSA patients. It was greater than 60 percent at 3 years in nonapneic snorers. The mean rate of CPAP use was 5.7 hours per day in OSA patients and 5.6 hours per day in snorers who were still on CPAP on October 1, 1995. Usage was correlated positively with age, body mass index, and AHI. The authors claimed that their results showed that CPAP therapy was reasonably accepted by OSA patients as well as by nonapneic snorers, and that objective disease severity (as measured by the respiratory event index and daytime and nighttime hypoxemia), rather than patients' symptoms or complaints, seemed to play a role in the quality of compliance to treatment.

Massie, Hart, Peralez, and Richards (1999) concluded that compliance with CPAP can be enhanced when used in conjunction with heated humidification. The authors thought that this was probably due to a reduction in side effects associated with upper airway symptoms and a more refreshed feeling upon awakening. They suggested that compliance gains may be realized sooner if patients are started with heated humidity at CPAP initiation. They based these conclusions on the results of a study that employed a randomized, crossover design. In it, data were collected on 38 OSA patients. The interventions were: heated humidity, cold passover humidity, and a washout period without humidity. Patients were titrated with heated humidity or cold passover humidity in the laboratory and subsequently initiated on humidity. Objective compliance, self-report of factors affecting CPAP use, satisfaction with CPAP, feeling upon

awakening, and daytime sleepiness were assessed at the completion of each 3-week treatment period and a 2-week washout period. Significant main effects were observed for compliance, satisfaction with CPAP, and feeling refreshed on awakening. CPAP use with heated humidity was greater than CPAP use without humidity, and only heated humidity resulted in patients feeling more refreshed on awakening. Specific side effects such as dry mouth or throat and dry nose were reported less frequently when CPAP was used with heated humidity compared to CPAP use without humidity.

#### *Psychological Models of Adherence*

*The fear reduction model.* As mentioned in the preceding chapter, one early attempt to explain adherence to treatment from a psychological perspective was the fear reduction model. Fear appeals have been used in an attempt to change attitudes and behaviors in relation to various health issues (Maddux & Rogers, 1983). The notion underlying the fear reduction model is that the more fearful the sufferer becomes of the possible consequences of failing to adhere to the prescribed treatment regimen, the more motivated she or he would be to adhere to it.

Fear appeals have been shown to be effective in producing attitude change with some groups of people, but ineffective with others. For example, Maddux and Rogers (1983) found that, using student smokers as participants, those with a high self-efficacy belief about their ability to give up smoking exhibited greater behavioral intentions to quit, than those students who had low self-efficacy expectations, despite the fact that both

groups were given the same warnings about the adverse health consequences of continuing to smoke. Thus, the authors argued, cognitive factors, including self-efficacy beliefs, were mediating factors in the effectiveness of fear appeals as a method of increasing adherence.

Similarly, Beck and Lund (1981) gave 80 dental patients a pre-test scale measuring health locus of control, and then exposed them to persuasive communication designed to manipulate their ideas about the seriousness of periodontal disease and their susceptibility to it. They found that those who were exposed to persuasive communication which emphasized the high seriousness of periodontal disease increased their fear level of the consequences of failure to floss regularly, and increased their reported intentions and compliance with a flossing regimen. However, the authors noted that perceived personal efficacy for the recommended behavior was the most important predictor of subsequent behavior.

*The health belief model.* In contrast to the fear reduction model, the health belief model was developed from a social-psychological perspective (Rosenstock, 1974). It was one of the earliest theoretical models that outlined in detail the factors hypothesized to contribute to patient behavior. It was similar to the fear reduction model in so far as it proposed that the likelihood of someone carrying out a health behavior was related to her or his perceived threat of the disease. Perceived threat was defined as beliefs about the seriousness of the disease and beliefs about susceptibility to it. The health belief model differed from the fear reduction model in so far as it

postulated that an individual also weighs up the perceived costs and benefits of a health-related course of action.

The model has undergone several revisions. According to the latest version of the model, patients' adherence is based on general health motivations, personal attributes that are assumed to be stable across time, susceptibility to illness, faith in medical care, and characteristics of the treatment regimen. One advantage of the health belief model is that it stresses adherence rather than compliance. Compliance was seen as simply doing what you're told as a patient, whereas adherence was seen as functioning as an equal partner with the health care professional to bring about changes in your health. Thus, in the health belief model the sufferer was seen as an autonomous, responsible person who could take charge of their own health issues and work cooperatively with the treatment provider to effect positive outcomes.

As mentioned in Chapter 1, no strong correlations between health beliefs and subsequent adherence to treatment programs have been found (e.g. Bruhn, 1983). Health beliefs tend to develop along with adherence rather than predict it, thus there is little or no evidence for the effectiveness of the model as a predictor of adherence. In addition, the model tends to look to internal factors to explain motivation to adhere (i.e. personal beliefs) while ignoring external factors like the influence of the social environment in which the disease sufferer has to operate.

*Protection motivation theory.* Rogers (1975) developed protection motivation theory as an extension of the health belief model. In protection motivation theory, response efficacy is defined as the perceived contingency between the performance of the recommended action and the reduction of the depicted threat. Response efficacy is thus similar to the notion of perceived benefits of action, which is one of the central variables in the health belief model.

Rogers and Mewborn (1976) found that as health recommendations were presented as more effective, intentions to adopt them increased. They also found that fear was unrelated to intentions to adopt a health regimen. The important factor in intentions to adhere was the extent to which communication about health issues depict a real, but controllable threat. It was, therefore, suggested that increasing the fear response in the patient might lead him or her to perceive the threat as uncontrollable and thus reduce motivation to emit the appropriate health behaviors.

As mentioned earlier, Rogers' protection motivation theory, while emphasizing response efficacy, fails to include personal efficacy, or the person's perceived ability to perform a recommended action, in the model of motivation. Yet personal efficacy has been seen to be a strong predictor of adherence behavior (Beck & Lund, 1981; Kaplan, Atkins & Reinsch, 1984; Maddux & Rogers, 1983).

*The theory of reasoned action and the theory of planned behavior.*

Although neither the Health Belief Model, nor Protection Motivation

Theory take account of social influences on behavior or suggested how cost-benefit decisions are translated into action, the Theory of Reasoned Action (Ajzen & Fishbein, 1980) attempted to do just that. This theory proposed that the formation of intentions precedes and predicts behavior, and that attitudes towards and subjective norms about the behavior determine intentions. Attitudes are seen as the product of beliefs about the likely outcome of the behavior and the perceived value of that outcome. Subjective norms comprise beliefs about others views of the behavior.

The Theory of Planned Behavior (Ajzen, 1985) is an extension of the Theory of Reasoned Action. In it, the concepts of perceived behavioral control, and perceived barriers to action have been added to the Theory of Reasoned Action. In this way, the Theory of Planned Behavior attempts to account for individual differences in feelings of personal control over a behavior. The extent to which a person feels in control of a behavior is dependent on control beliefs such as the perception of both internal and external resources. This concept has been considered to be similar to Bandura's (1977) concept of self-efficacy (Schwarzer & Fuchs, 1996).

*Bandura's social cognitive theory.* One theory that includes personal efficacy or self-efficacy as a central concept is Bandura's social cognitive theory. Social cognitive theory takes a transactional view of the individual and society. In this view, personal factors such as cognitive, affective, and physiological events, behavior, and the environment all interact bidirectionally (Bandura, 1997). For example, if people perceive

themselves as capable of taking their medication according to a treatment regimen (a cognition), they will be more likely to adhere to the regimen even in circumstances that might discourage the behavior (e.g. in the presence of a peer group). This action will confirm their self-perception (behavior-person feedback) and it may lead to their peers not teasing them for needing to self-medicate in a future similar circumstance (environmental change). This change may enhance the person's belief that they can bring about desirable environmental changes (environment-person feedback). This view, therefore, postulates a triadic reciprocity in causation (Bandura, 1997; Zimmerman, 1989).

A further tenet of the theory is that human change is embedded in social systems that provide constraints and resources for human functioning. One of the resources that social systems provide is modeling. According to the theory, social models are a source of vicarious experience for the individual. Learners can acquire an entirely new skill (e.g. OSA self-management) through observing a model. Thus, unlike the operant hypothesis, social cognitive theory suggests that people can learn behaviors in the absence of explicit reinforcement. However, vicarious learning alone would not be sufficient to account for individuals' unique and generative behavioral repertoires. One concept which Bandura has put forward to explain how behavior that was initially learnt vicariously comes increasingly under personal control is self-efficacy (Bandura, 1977; 1997).

The concept of self-efficacy is based on the notion that people expect that a particular set of actions in specific situations will lead to certain outcomes. If a person also believes that she or he can successfully perform the behavior required to bring about the particular outcome in a specific situation, then the person is said to have developed a positive self-efficacy expectation about their performance in that situation (Bandura, 1977).

The social cognitive view also assumes that there is a distinction between self-efficacy and motivation. A person might believe that they are capable of performing a set of actions in a particular situation, but unless they perceive that these behaviors will lead to a valued goal, they might not exhibit the behaviors. The perception that a set of behaviors will lead to a valued goal is termed outcome expectancy, and is similar to the notion of response efficacy in protection motivation theory. Just as there is an assumed distinction between self-efficacy and motivation, so there is a distinction between outcome expectancy and motivation, for even though a person might expect that a certain set of behaviors will lead to a valued goal, unless they perceive themselves as capable of performing those behaviors, they might not emit them.

Despite this theoretical separation of self-efficacy from motivation, self-efficacy expectations are assumed to affect both initiation and persistence of performance in particular situations. People tend to initiate behavior in situations in which they feel self-efficacious, and avoid those situations in which they feel they are unable to behave self-efficaciously.

Similarly, people who feel self-efficacious in certain circumstances will tend to continue to perform in those situations in order to achieve a valued goal, despite setbacks along the way or delay in reaching ultimate goal. On the other hand, those who feel less self-efficacious will not persist as long in order to achieve a goal.

In view of the fact that self-efficacy is assumed to affect initiation of behavior, performance and persistence of behavior, it has been hypothesized that self-efficacy plays an important role in self-regulatory health-related behaviors (Bandura, 1997). Self-regulatory efficacy has predicted positive outcomes in the areas of reduction of blood pressure levels, diabetes (Bandura, 1997), arthritis (Lorig, & Holman, 1993), and asthma (Palen, Klein, & Seydel, 1997; Zimmermann, Bonner, Evans, & Mellins, 1999).

*The transtheoretical (stages of change) model.* The transtheoretical model is a multidimensional approach to behavior change that integrates behavior change processes and principles from across leading theories (i.e. *transtheoretical*). This model attempts to account for the fact that cognitions and behavior change over time. As outlined previously, this model suggests that the maintenance of health behavior occurs in five progressive stages of change: pre-contemplation, contemplation, preparation, action, and maintenance (Prochaska, & DiClemente, 1983). In the pre-contemplation stage the person might not be aware of the need to change, or think they are not capable of change, and so may not even be thinking of changing. In the contemplation stage the person may be thinking of changing, but not be

fully committed to making the change. In the preparation stage the person is assumed to have a plan of action and be intending to put it into practice. In the action stage active attempts are made to change behaviors. Finally, in the maintenance stage attempts are made to prevent relapse.

Shifts from stage to stage are thought to occur through overt (behavioral) or covert (cognitive) processes of change. Each process is conceived of as a broad category encompassing multiple techniques and methods. Some of the processes include self-reevaluation, consciousness raising, and reinforcement management. Not surprisingly, more cognitive processes of change are supposed to be used in the earlier (contemplative) stages of change, while more behavioral processes are used to move through the later (more action oriented) stages. Unlike Bandura's social cognitive model, the transtheoretical model invokes willpower rather than self-efficacy as the spur to action (Prochaska, DiClemente, & Norcross, 1992).

The model further asserts that patients tend to draw up a mental "balance sheet" that weighs potential gains of engaging in a particular set of behaviors ('pros') against potential losses ('cons'). The balance between the 'pros' and the 'cons' is thought to vary depending on the stage the person is at. The model's proponents suggest that progress through the stages is more likely to be recursive than linear, with many relapses and partial successes before behavior change is established. They also argue that it is necessary for treatment to be matched with stage of change for it to be effective (Prochaska, et al., 1992). The model has been successfully applied in the

area of smoking (DiClemente, et al.,1991), weight control (Curry, Kristal & Bowen, 1992), and exercise (Marcus et al., 1992).

*Comparison of the social cognitive model with the transtheoretical model as predictors of CPAP adherence.* In the first of only two studies of the relationship of self-efficacy with adherence to CPAP in OSA sufferers published in English language journals, Stepnowsky, Marler and Ancoli-Israel (2002) compared a social-cognitive model with a transtheoretical model as predictors of CPAP compliance (the authors' term). The social-cognitive (SC) model used by the authors led them to hypothesize that OSA patients with higher perceived self-efficacy, higher outcome expectancies for CPAP, greater functional social support, and greater knowledge will be more compliant with CPAP. By contrast, the transtheoretical model led them to hypothesize that those patients with more pros than cons and who use more processes of change will be more compliant with CPAP.

Stepnowsky et al. (2002) recruited 51 OSA sufferers who were prescribed CPAP treatment to their study. The CPAP machines were fitted with a downloadable internal clock counter that recorded usage data. CPAP compliance was defined as the average nightly use (hours per night) over a 1-month time period. The authors generated and validated scales to assess the dimensions of both the SC and the TM models. These scales were cast in the form of pencil-and-paper questionnaires that were administered at CPAP fitting, one week post CPAP fitting, and one month post CPAP fitting. Compliance data were downloaded at one-month post CPAP fitting.

Results showed that neither the SC variables nor the TM variables measured on the day of CPAP-fitting were associated with CPAP compliance at one month. However, both SC and TM variables measured at one-week post CPAP fitting were highly associated with CPAP compliance measured at one month. These results suggest that instruments designed to predict CPAP adherence are best administered after patients have had some experience of using CPAP, since only then can they give informed answers to the items contained in the questionnaires. Although both the SC and the TM models, assessed at one week, were predictive of CPAP use at one month, the authors do not report a significant difference between the two models in predictive capacity. Hence, the suggestion is that the models are equally useful as predictors of adherence.

Weaver, Maislin, Dinges, Younger, Cantor, McCloskey, and Pack (2003), in what appears to be the second study in the English literature that examines adherence to CPAP using Bandura's social cognitive theory, suggested that Stepnowsky et al.'s (2002) research was limited because in the appraisal of outcome expectancy only two outcomes associated with CPAP use were assessed, and because no assessment of patients' perception of risk was included. Perception of risk, Weaver and colleagues argued, is a key component of Bandura's model. Therefore, they developed a new instrument, the Self-Efficacy Measure for Sleep Apnea (SEMSA) that was specifically designed for OSA, and measured perception of risk as well as self-efficacy and outcome expectancy.

In the SEMSA, perceived risk was measured by items, rated on a four-point scale, that ask the patient the degree of threat posed to them by risks associated with OSA. Outcome expectancies were assessed, again on a 4-point scale, by responses of potential general outcomes if CPAP is or is not used. Self-efficacy was evaluated by asking respondents to rate on a 4-point scale the level of validity of statements regarding their confidence in using CPAP despite certain challenges such as travel or nasal stuffiness.

The authors recruited 213 newly diagnosed OSA patients who completed the SEMSA either prior to, or upon completion of their diagnostic study in the sleep laboratory. In order to evaluate test-retest reliability, a subset of 20 patients completed the SEMSA a second time one week later at home prior to beginning CPAP therapy. Results from this subsample estimated test-retest reliability to be 0.68. Confirmatory factor analysis based on the results of the entire sample validated the three subscales of the SEMSA (risk perception; outcome expectancy; and treatment self-efficacy).

More than 60 percent of respondents perceived falling asleep during the day and having high blood pressure as threats associated with having OSA. However, less than 50 percent identified being depressed, having an accident, or having problems with sexual desire or performance as perceived risks. Most respondents indicated that they expected that CPAP treatment would produce positive outcomes, particularly in the areas of feeling better, not snoring, and being more active. As far as CPAP self-efficacy was

concerned, three quarters or more of participants said that they would use CPAP even if it took longer to get ready for bed, they traveled, or they felt embarrassed. However, fewer than 60 percent said they would use it if it made their nose feel stuffy, made them feel claustrophobic, or disturbed their bed partner's sleep.

A major problem with the above research is that no measure of CPAP usage is reported, so it is impossible to know to what extent responses to any or all of the three components of the SEMSA predicts actual adherence. However, the authors did say that they have undertaken an investigation of this question.

*Self-regulatory models.* A major assumption of the self-regulatory approach is that ultimately the responsibility for the effectiveness of any treatment rests with the sufferer. Thus, the patient is seen as being actively engaged in dealing with her or his own health issues. These models are similar to Bandura's social-cognitive model to the extent that they emphasize coping appraisal processes and the effect of the resultant feedback on cognition, emotion, and behavior. To these extents, self-regulatory models can be seen as "adherence" rather than "compliance" models.

One self-regulatory model of illness was generated by Leventhal (1993). In it the patient initially generates cognitive representations of a health threat, then develops and implements coping procedures to deal with the perceived threat, and finally appraises the outcome of the coping

procedures. In this model the three stages of processing are thought to occur in parallel, thus creating a dynamic interaction between representation, coping, and appraisal. However, this self-regulatory model fails to take account of the changes in social context in which this dynamic interaction is likely to occur.

An alternative self-regulatory model of health behavior was developed by Zimmerman, Bonner, Evans and Mellins (1999). In this model the patient is also seen as an active problem solver, but a problem solver who interacts with others (e.g. a spouse/partner, children, friends, their physician) in relation to their health problem. Thus, in this model, self-regulation is envisioned as embedded within a social context.

The self-regulatory model of Zimmerman et al. (1999) was developed from Bandura's social-cognitive model. In his model Bandura argued that self-regulation operated through a set of sub-functions that had to be developed for behavioral change to occur (see: Bandura, 1986a). These sub-functions are: self-observation (e.g. self-monitoring of performance along various dimensions); self-judgment (e.g. comparing the observed performance with personal goals); and self-reaction (e.g. evaluating the difference between observed performance and personal goals either negatively or positively). Thus, the development of self-regulatory efficacy is dependent on the development of these three sub-functions.

*Self-regulation and self-monitoring.* As was mentioned in Chapter 1, one of these three sub-functions, self-observation has been shown to play a

major role in the development of self-regulatory efficacy (Bandura, 1986a). In essence, self-observation focuses attention on the behavior that is to be changed, and the antecedents and consequences of that behavior. This direction of attention on the behavior to be changed is crucial because, according to Bandura (1986a), people need to know what they are doing in order to exert control over their actions. Therefore, achieving self-regulation depends in part on consistent and temporally proximate self-monitoring.

Consistent and temporally proximate self-monitoring can provide information about what conditions led to particular behaviors or feeling states. Thus, in the case of using the CPAP mask, self-monitoring could not only help OSA patients discover under which conditions they either do or do not use the mask, but also see how increased use of the CPAP mask increases feelings of psychological and physiological well-being.

Self-monitoring can also act as a self-motivating device by encouraging people to set goals of progressive improvement for themselves, even though they have not been explicitly asked to do so. In addition, it can provide informative feedback about progress towards those goals and general performance.

Self-recording is the formal manifestation of self-monitoring. Usually, self-recording involves noting behavioral occurrences on a recording sheet, along with such features as the time, place, and duration of occurrence (Schunk, 2001; Zimmerman, Bonner, & Kovach, 1996). It has

been used as a component of many successful, multi-faceted behavior change programs in a wide range of areas. Generally, these programs followed behavioral-cognitive models. It has also been shown to be effective, either on its own, or over and above other components in a program.

In the academic area, self-monitoring significantly increased students' time on task, self-efficacy, and achievement in mathematics (Sagotsky, Patterson, & Lepper, 1978; Schunk, 1983). In the area of sports, it has enhanced the development of complex motor skills (Martin & Anshel, 1995; Zimmerman & Kitsantis, 1996).

In health-related fields, a simple self-monitoring tool assisted obese men and women to achieve a healthy life-style (Miller, Wallace, Eggert, & Lindeman, 1993), and more frequent self-monitoring of blood glucose levels has been associated with better glycemic control in diabetics (Karter, et al., 2001). For both smoking cessation (Kamarak & Lichtenstein, 1988) and weight control (Perri, McAllister, Gange, et al., 1988), long-term maintenance has been associated with self-monitoring during treatment. In a cardiovascular risk-reduction program that comprised of four elements; pharmacological therapy, exercise, nutrition, and smoking cessation, self-monitoring improved compliance with the program in all four areas (Burke, Dunbar-Jacob, & Hill, 1997).

*A phase model of self-regulation.* As mentioned in Chapter 1, the Zimmerman et al. (1999) model postulated that self-regulatory disease

control occurs in four phases: disease avoidance; disease acceptance; disease compliance; and disease self-regulation. In the disease avoidance phase, the patient may perceive disease symptoms but does not attribute these symptoms to an inherent physiological vulnerability with serious health-threatening consequences if untreated. In the disease acceptance phase, the patient accepts the disease as a serious health problem, but they respond to the disease non-preventively. For example, they tend to react only to acute episodes. In the disease compliance phase, the patient tends to follow the physician's treatment recommendations, but is unskilled at making adjustments in treatment use to respond preventively to changing circumstances. In the disease self-regulation phase, the patient can adjust their treatment regimens in response to changing circumstances. The model predicts that patients will be more adherent to treatment as they move through the four phases from avoidant to self-regulatory.

According to Zimmerman et al., (1999) in order for patients to be able to adjust their treatment in response to changing circumstances (i.e. be in the self-regulatory phase) they must be able to be self-observant, make self-judgments, and be self-reactive. In other words, they must exhibit self-regulatory efficacy as proposed by Bandura (1986a).

Zimmerman et al.'s (1999) model is similar to the transtheoretical model (Prochaska, & DiClemente, 1983) in that both postulate distinctive phases of self-regulatory disease control. However, the former model assumes that self-regulatory efficacy is the driving force that moves people

through the phases whereas the transtheoretical model invokes concepts like willpower. In addition, the Zimmerman et al. (1999) model also subsumes both the “compliance” and “adherence” models in one model. It argues that the “compliance” phase and “adherence” phase are distinct, but that often people move through the “compliance” en route to the “adherence” (self-regulatory) phase. It also predicts that patients who are fully self-regulatory should be more adherent than those in the compliant phase.

*A test of the four-phase model.* As outlined in the first chapter, in order to test their model, Zimmerman, Bonner, Evans and Mellins (1999) developed a qualitative research instrument, the Asthma Self-Regulatory Development Interview (ASRDI). They tested whether responses to the ASRDI formed a continuum or clustered into four distinct phases. They also examined the predictive validity of the phase measures against asthma outcome measures. They found that the hypothesized four-phase model proved to be the best fit for the phase items, while subsequent analyses of the phase scores revealed a high degree of sequential ordering. That is, families were asthma avoidant (did not accept that their child had asthma or a disease) before they became asthma accepting (recognized the chronicity of their child's asthma) and were asthma accepting before they became asthma compliant (were willing to seek medical help), and became asthma compliant before they became asthma self-regulatory. Thus, the model that postulated the presence of four distinct but sequentially ordered phases of disease self-regulation was supported. In addition, phase differences were

negatively related with asthma severity. Thus, as patients became more self-regulatory in their disease control, so the severity asthma symptoms declined. The authors also found that self-efficacy increased as the family became increasingly self-regulatory until families reached the final self-regulatory phase.

Zimmerman et al. (1999) argued that their results suggested that asthma self-regulation is a complex developmental process rather than a simple educational one. This implies that to be successful, a self-management program firstly needs to identify an individual's stage of compliance, and then develop intervention appropriate for that stage of development. They also proposed that an optimal intervention should include powerful cognitive strategies, refined behavioral skills, and strong social support systems.

In an attempt to put the proposal into practice, Bonner, Zimmerman, Evans, Irigoyen, Resnick, and Mellins (2002) developed an intervention based on Zimmerman et al.'s (1999) four-phase model of asthma self-regulation. The authors hypothesized that the intervention would lead to improved health outcomes among patients with asthma.

The intervention was delivered by a trained, bilingual (Spanish and English) Family Coordinator. The Family Coordinator delivered asthma education to families, provided individualized support as families monitored their children's asthma-usage diaries, and coached them to present detailed asthma histories to their doctors. The Family Coordinator also conducted

three group educational workshops at one-month intervals. These workshops followed the learning sequence identified in the four-phase asthma self-regulation model. In the first workshop, families were trained to use asthma diaries and peak flow meters. In the second workshop, patients' diary records were used as illustrations of the effectiveness of controller medicines in preventing asthma symptoms over time, and in the third workshop, managing pharmacotherapy was taught using illustrations from participants' diary records.

The intervention also included three additional components interspersed around the workshop schedule. Between the first and second workshops, the Family Coordinator prepared families for their doctor visit. Between the second and third workshop, allergy testing was performed to help families identify asthma triggers, and following the third workshop, the Family Coordinator conducted home environment assessment and suggested strategies for reducing asthma triggers.

For the purposes of the study, 119 families were randomized at baseline either to receive the intervention (outlined above) or the usual medical care. Of the 119 families, 100 were available three months later for follow-up interviews.

Results showed significant improvements at three-month follow-up for the intervention group on, among other things, self-efficacy, self-regulatory skill, and adherence. This group also showed a significant decrease in symptom persistence. In particular, although there was no

significant difference in self-regulatory phase between the intervention and control groups at baseline, there was at follow-up. At follow-up, in a blind assessment, 66 percent of the intervention group was considered to be either asthma compliant or asthma self-regulatory, whereas only 28 percent of the control families were classified as asthma compliant, and none were deemed asthma self-regulatory. In addition, there was a significant relationship between improved outcome and phase change, with 24 intervention families improving one phase from baseline to follow-up, and 15 improving two or more phases, whereas 11 of the control group improved one phase, and one improved two or more phases.

#### *Purpose of Research*

The main purpose of this research was to extend the findings of Zimmerman et al. (1999) regarding chronic asthma to another chronic disease, OSA. To this end, an instrument similar to the asthma self-regulation scales was developed to assess OSA self-regulatory development. This instrument, the OSA Self-Regulatory Development Interview (OSARDI) (Appendix E) was related to both objective and subjective CPAP use and clinical outcomes.

Because self-monitoring has been shown to play a major role in the development of self-regulatory efficacy (see above), the effectiveness of self-recording CPAP usage, and corresponding daily alertness was assessed. To this end, participants in the research were randomly divided into two groups. One group was asked to self-monitor their CPAP use and

subsequent alertness for the first thirty days following allocation of the CPAP machine, and then not to monitor for the next thirty days. The other group was not asked to self-monitor for the first thirty days following CPAP acquisition, but to self-monitor for the thirty days thereafter. It was hypothesized that self-monitoring would enhance CPAP use when follow-up phase is controlled for.

CPAP machines are now available to the Cardiopulmonary Sleep and Ventilatory Disorders Laboratory of Columbia University Sleep Laboratory, which are capable of monitoring the number of hours per night in which the proper positive airway pressures were delivered, and these data can be downloaded to a computer and displayed numerically or graphically, and can be stored for up to one year. Daily CPAP use can also be recorded manually by the user. In view of previously reported discrepancies between subjective and objective monitoring of CPAP use, a further purpose of this research was to determine whether patients' self-recorded use of CPAP matched the objective records of the CPAP machine.

It was also hypothesized that OSA patients who were further advanced in their OSA self-regulatory behavior, as measured by the OSASRDI, would be more adherent to CPAP than those who are less advanced. That is to say, patients who were fully OSA self-regulatory would be more adherent than those who were OSA compliant, while those who were OSA compliant would be more adherent than those who were

OSA acceptant. In turn, those who were at the OSA acceptance phase were hypothesized to be less adherent than those who were OSA avoidant.

Finally, it was hypothesized that those who were further advanced in their OSA self-regulatory behavior would be more likely to use self-monitoring (self-recording), and be more accurate in their self-monitoring.

## Chapter III

### METHOD

#### *Ethical Approval*

Ethical approval was obtained from the Institutional Review Boards (IRBs) of Columbia University and the Graduate Center of the City University of New York.

#### *Participants*

The study sample was drawn from adult patients diagnosed with obstructive sleep apnea (OSA) in the Columbia University Cardiopulmonary Sleep and Ventilatory Disorders Laboratory and considered candidates for treatment with continuous positive airway pressure (CPAP). The initial sample comprised 72 patients with a mean age of 48.6 ( $\pm 11.5$ ) years who gave informed consent to participate in the study. There were 25 females and 47 males. The females had a mean age of 49.2 ( $\pm 12.9$ ) years, and the males a mean age of 48.3 ( $\pm 10.7$ ) years. There was no significant age difference between the females and males:  $t(70) = 0.30, p = .76$ .

The sample was made up of 13 African-Americans (mean age = 49.2 ( $\pm 12.2$ ) years), 19 Hispanics (mean age = 47.7 ( $\pm 10.7$ ) years), three Asian-Americans (mean age = 44.7 ( $\pm 20.5$ ) years), 36 Caucasians (mean age = 49.4 ( $\pm 11.3$ ) years), and one Jamaican (aged 40 years). There was no significant age differences among the ethnic groups:  $F(4,67) = 0.30, p = .88$ .

There was no dependency between ethnic group and gender:  $\chi^2 (4) = 2.16, p = .71$ .

### *Inclusion in Sample*

All patients referred to the sleep laboratory for suspected OSA were considered potential participants. They underwent standard clinical diagnostic nighttime polysomnography. OSA was diagnosed by the treating physician in patients with at least 5 obstructive events (apneas and hypopneas) per hour in association with compatible clinical symptoms (e.g. excessive daytime sleepiness, loud interrupted snoring). Apnea was defined as cessation of oronasal airflow for a minimum 10 seconds along with continued respiratory effort. Hypopnea was defined as discernable and discrete decrease in airflow as measured by a nasal pressure transducer and/or oronasal thermistor.

Titration to CPAP was carried out on the same study night as the diagnostic polysomnography. In order for a patient to be included in the study, the titration polysomnography had to demonstrate definite improvement in sleep and breathing so that the treating physician recommended CPAP as the preferred method of treatment.

All patients, previously naïve to CPAP, diagnosed with OSA and successfully titrated with CPAP were recruited for this research. The recruitment took place in the morning following the CPAP titration. Patients were asked by the author to indicate whether they might be interested in taking part in the research. Patients who indicated an interest

were taken though the recruitment protocol and consent procedure by the author. (See Appendix A for copy of recruitment protocol and informed consent form).

### *Procedures*

*Baseline.* All patients were prescribed their successfully titrated levels of CPAP using a machine (ResMed, Elite) that monitors time used at the prescribed pressure. Machines were installed at patients' homes by a representative of the suppliers. Instructions on usage and maintenance of the machine were given during installation. Costs of providing and maintaining the machine were borne by the insurance companies of the participants.

As part of the protocol and consent procedure all potential participants were told that part of the study involved being randomly assigned to a 'self-monitoring first' (S) or 'non-self-monitoring first' (NS) condition. They were be told that the S condition involved self-monitoring their CPAP usage and daytime alertness for thirty days, and then not self-monitoring for 30 days, while the NS condition involved the reverse procedure.

Those patients who gave their informed consent to participate were randomly assigned to either the S or the NS conditions. Randomization was carried out by drawing lots. The treating clinician was blind to the randomization.

After randomization all patients were given an open-ended interview, The Baseline Patient Questionnaire (Appendix B), which was designed to assess the development of the disease. All patients were then shown a CPAP machine similar to the one they were to receive at home. The machines are designed to record the number of hours of usage per night at the correct pressure. The data are stored in a microprocessor in the machine, and are computer downloadable. The cumulative number of hours of use is also visually available.

All participants were asked to check with the supplier's representative that the machine was computer-downloadable when they received it at home. They were also instructed to do this, in the main, by asking the representative to show them that the machine had a 'digital window' in which the hours of CPAP use could be displayed. They were also asked to make an appointment for a 30-day follow-up visit to the Sleep Laboratory immediately on receipt of their machine.

*The S condition.* Patients in the S condition were shown how to read the hours of nightly usage from the display on the CPAP machine. They were also given recording sheets (The Good Sleep Checklist, Appendix C) on which to record their nightly CPAP usage and their daytime alertness for each day for the first four weeks of usage.

For each day, the Good Sleep Checklist contained two scales. The first scale gave a number corresponding to hours of CPAP use, from 0-8. Participants were asked to circle the number that corresponded to their hours

of use for each night to the nearest hour. If they used CPAP for more than eight hours on any night, they were instructed to write the number of hours of use next to the scale. The second scale (0-8) indicated how sleepy or alert the patient felt during the day following CPAP use. Zero on the scale indicated, 'very sleepy all day', and 8 indicated, 'wide awake all day'. Participants were instructed to circle the number that corresponded to their perceived alertness for each day.

Patients in the S condition were instructed how to complete the Good Sleep Checklist. They were told that they could read the number of hours of CPAP use, to the nearest whole hour, directly from the CPAP machine each day, and record that number on the Good Sleep Checklist. They were asked to bring their CPAP machine and recording sheets with them when they returned for their 30-day follow-up visit.

*The NS condition.* Patients in the NS condition were not asked to record nightly CPAP usage nor given recording sheets. They were asked to bring their CPAP machine with them to their 30-day follow-up visit.

*30-day follow-up.* All patients had a consultation with the treating physician. All participants were given the follow-up protocol (Appendix D) and, if willing to continue in the study, the Barriers to CPAP Use Questionnaire (Appendix E). This instrument formed the basis of the OSA Self-Regulatory Development Interview (OSASRDI). This interview was given prior to the computer data being downloaded. The patients then had their nightly usage data downloaded from their CPAP machines. These data

were stored on computer file. Computer printouts of these data were made available to the patients and the treating physician. The treating physician and the author discussed the computer printouts independently with the patients. All participants were asked to make an appointment for their 60-day follow-up visit at the conclusion of the session.

*The S condition.* Patients in the S condition had photocopies made of their recording sheets. They were then told that they need not record their nightly CPAP usage, or daytime alertness for the next 30-days. They were asked to bring their CPAP machine with them on their return for their 60-day follow-up visit.

*The NS condition.* Patients in the NS condition were now explicitly shown how to read the hours of nightly usage from the display on CPAP machine. They were also given recording sheets (The Good Sleep Checklist, Appendix C) on which to record their nightly CPAP usage and their daytime alertness for each day for the next 30 days of usage. They were instructed how to complete these recording sheets. They were asked to bring their CPAP machine and recording sheets with them when they return for their 60-day follow-up visit.

*60-day follow-up.* All patients had a consultation with the treating physician. All participants were given the Barriers to CPAP Use Questionnaire. Then, all patients had their nightly usage data downloaded from their CPAP machines. These data were stored on computer file. Computer printouts of these data were made available to the patients and the

treating physician and discussed with them by the treating physician and the author independently. All patients were told that their participation in the study was now at an end, and thanked for their participation.

*The NS condition.* Participants in the NS group had photocopies made of their recording sheets.

### *Design*

The study employed a randomized cross-over design. Participants were randomly assigned to either the ‘self-monitoring first’ (S) condition (i.e. self-monitoring for the first 30 days of CPAP use, followed by 30 days of non-self-monitoring), or the ‘non-self-monitoring first’ (NS) condition (i.e. non-self-monitoring during the first 30 days of CPAP use, followed by 30 days of self-monitoring).

### *Baseline Measures*

*Development of OSA prior to CPAP use.* This was assessed by the Baseline Patient Questionnaire (Appendix B). From the baseline questionnaires the following variables were derived; major presenting problem; primary referral source; referral decision; awareness of OSA prior to polysomnography; and subjective seriousness of OSA. Responses relating to primary referral source were categorized as indicating one of two referral sources; either the patient’s doctor alone, or all other sources and possible combinations (e.g. the patient’s spouse and doctor in combination). Similarly, referral decisions were categorized as being made with some self-

involvement on the part of the patient, or no self-involvement. These two variables were categorized in this way because there are indications that OSA patients who were referred for treatment solely by their general practitioner, or had no self-involvement in the referral decision were less adherent to CPAP, than the other two groups. Patients were also classified as being aware or unaware of some of the symptoms and effects of OSA prior to referral to the sleep clinic. Subjective seriousness of OSA was assessed on a scale of 1–10, with 1 being “not at all serious”, and 10 being “extremely serious”.

*Severity of OSA.* Severity of OSA at baseline was assessed by the following measures independently: Apnea/Hypopnea Index (AHI) as measured by apneas/hypopneas per hour; nadir percentage oxygen saturation (nadir SAO<sub>2</sub>); CPAP pressure level (centimeters of water); and daytime sleepiness as measured by the Epworth Sleepiness Scale (ESS) (Johns, 1991). An AHI of 20 events or more per hour indicates OSA, and an AHI of 40 events or more indicates severe OSA. For nadir SAO<sub>2</sub>, greater disease severity is indicated by a lower percentage oxygen saturation. Greater CPAP pressure indicates greater disease severity, while a person with a total score of nine or more on the ESS (scale 0-24) is advised to see a sleep specialist.

*Obesity.* Patients’ Body Mass Index (BMI) was collected. This measure was recoded in kilograms per meter squared. BMI is positively related to overweight. A BMI of 30 or greater is considered obese.

*Demographics.* The following demographic data were collected: age in years; gender; ethnicity; and whether or not the patient lived with another adult in the home.

*Prescription.* Records were kept regarding whether patients were prescribed a humidifier or not.

### *30-day and 60-day Follow-up Measures*

*Self-regulation.* All participants were administered the OSA Self-Regulatory Development Interview (OSASRDI) at 30-day and 60-day follow-ups to assess phase of OSA self-regulation (Appendix E). The content of this instrument was based on barriers to CPAP use previously reported in the literature (e.g. Smith, Mayer, Metsker, et al., 1998), and anecdotal evidence regarding perceived barriers to CPAP use garnered from the Director and staff of the Cardiopulmonary Sleep and Ventilatory Disorders Laboratory of Columbia University. The questions in the OSASRDI were phrased in a way that required respondents to disagree with the statement contained in each item in order to pass the item. This was to prevent participants from passing items by giving answers that appeared to conform to the opinions expressed in the items.

The OSASRDI consisted of three sections. The first section contained eight questions designed to assess whether or not the respondent was at the OSA acceptant self-regulatory phase. These questions assessed whether the patients believed they had OSA, whether they believed their

OSA was serious, and whether they believed that failure to use CPAP every night might result in serious health consequences, such as hypertension, reduced oxygen supply to the brain, and sleepiness and serious accidents. Failure to pass this section resulted in the respondent being assessed as OSA avoidant.

The second section of the OSASRDI contained ten questions designed to assess whether participants continued to use CPAP despite possible barriers such as, mask discomfort, equipment noise, difficulty of using and maintaining the equipment, nasal stuffiness, oral dryness, and failure of their quality of life to improve. Failure to pass this section resulted in the respondent being assessed as OSA acceptant.

The final section of the OSARDI contained eight questions designed to assess patients' ability to continue and adjust their CPAP use in the face of changing conditions, for example, whether respondents took and used CPAP when traveling away from home, whether they could adjust the mask when it was uncomfortable, whether they still used CPAP after falling asleep unexpectedly at night, and whether they used it after a change in daily routine.

*CPAP usage.* Usage data from all CPAP machines were downloaded, and a hard copy printed out. The print-outs listed the date of each day of use or non-use, and the number of hours and minutes of use at the prescribed pressure for each day to the nearest tenth of an hour. The primary data of interest derived from these print-outs were: mean hours of

nightly usage over each 30-day period; percentage of nights on which CPAP was used over the 30-day period; and mean hours of nightly usage on nights when CPAP was actually used over the 30-day period.

*Self-monitoring.* Photocopies of patients' recording sheets, the Good Sleep Checklist, were made. The estimated hours of CPAP use for each day were recorded, as was estimated alertness. The estimated hours of use were compared with the objective hours of use recorded by the CPAP machines. A discrepancy score was created by subtracting the patient-estimated number of hours from the machine-recorded number of hours.

#### *Data Analyses*

*The S condition vs. the NS condition.* Differences in mean hours of nightly CPAP usage over each 30-day period; percentage nights used; and mean hours of nightly usage on nights when CPAP was actually used between the Self-monitoring (S) and the Non-self-monitoring (NS) conditions were assessed independently at the 30-day follow-up periods using independent samples *t*-tests, analysis of variance (ANOVA), and multivariate analysis of variance (MANOVA). Continuous baseline variables were controlled for using a general linear regression model of covariance. The relationship between categorical baseline variables and the experimental groups was assessed using non-parametric statistics (Pearson's chi-square).

Differences among self-recording sub-groups, participants at different OSA self-regulatory phases, and self-recording by self-regulatory

sub-groups at both 30- and 60-day follow-ups were assessed by using general linear model regression analysis in addition to the above methods.

Differences within and between participants across the two follow-up periods were analyzed using ANOVA and paired comparison *t*-tests.

*Differences between self-recording and objective recording.*

Differences between participants' recorded hours of CPAP use per night and the actual hours of usage as recorded by the CPAP machine were calculated. Participants were assessed using a global discrepancy score, based on the degree to which their self-recorded usage deviates from actual usage, and allowing for the fact that participants were only asked to record their usage to the nearest whole hour.

*Analysis of the OSASRDI.* Initially, for each participant, responses to each item of the OSASRDI, were scored "Pass" or "No Pass" according to the scoring criteria (Appendix F) by two independent raters. Inter-rater reliability was assessed using Cohen's kappa statistic. Patients were considered to have passed a phase if they passed 75 per cent or more of the applicable items in that phase. The self-regulatory phase in which a participant was considered to be, was the most advanced phase for which she or he passed 75 per cent or more of the applicable items, assuming he or she had passed 75 per cent or more of the applicable items for the preceding phases.

The sequentiality of the self-regulatory phases was examined using Guttman scaling procedures, Menzel (1953). A coefficient of scalability,

Cs, was calculated. The coefficient of scalability is the standard method for assessing whether a set of items form a Guttman scale. By convention, Cs should be .60 or higher to consider a set of items Guttman scalable.  $Cs = 1 - (E/X)$ , where E is the number of Guttman errors and X is the number of errors expected by chance. This method of analysis determines the degree to which patients passing higher phases had in fact successfully passed lower phases.

*The Baseline Patient Questionnaire and Demographic Data.*

Responses to the baseline questionnaire were grouped and categorized. In particular demographic variables were generated, as well as major presenting problem, perceived seriousness of OSA, primary source of referral to the Sleep Laboratory, and whether there was self-involvement in referral to the Sleep Laboratory. The data generated were analyzed using the parametric and non-parametric methods given above.

*Change in CPAP Use Over Time.* For each of the first four weeks of CPAP use, average weekly use was calculated for each participant. Differences in CPAP use across the four weeks were assessed for self-recording by self-regulation sub-groups using a multilevel linear regression analysis. Change in CPAP use, if any, within each group across the four-week period was assessed using the same method.

*General Methods of Data Analysis.* The multilevel linear regression analyses were performed using the HLM 5 program (Raudenbush, Bryk, & Congdon, 2002). All other statistical analyses were conducted using the

SPSS statistical package (SPSS, Inc., 2002). All hypothesis testing was two-tailed, and used a significance level of  $\alpha = 0.05$ .

## Chapter IV

### RESULTS

#### *Baseline*

At baseline, 35 participants were randomly assigned to the S group, and 37 to the NS group. Baseline differences between the two groups as a function of the clinical, demographic, and patient questionnaire variables are given below.

#### *Clinical and Demographic Variables*

Tables 1 and 2 show that there were no significant differences between the S and the NS groups at baseline on any of the clinical or demographic variables. Table 1 demonstrates that, on average, participants in both the S and the NS groups had AHI scores that indicated severe OSA. In addition, mean ESS total scores were indicative of the necessity of seeing a sleep specialist. Mean BMI scores suggested that, on average, participants were obese. Table 2 shows that women made up about a third of the sample (35%), and ethnic minorities constituted 50 percent of the sample.

#### *Baseline Patient Questionnaire*

*Major Presenting Problem.* The major presenting problems that ultimately led to referral to the sleep laboratory for the participants are listed in Table 3. The percentage of participants with each major presenting problem is given separately for the S and the NS groups in Table 3. A Pearson chi-square test showed that the sort of major presenting problem

reported by the participants did not depend upon the group to which they were randomized:  $\chi^2(15) = 14.12, p = .52$ .

**Table 1:** Comparison of S and NS groups on OSA severity measures and age.

Baseline variable	S Group (n = 35)		NS Group (n = 37)		T (df)	p
	Mean	SD	Mean	SD		
AHI (events per hour) <sup>a</sup>	56.1	29.7	50.6	28.4	.80(68)	0.43
Nadir SaO <sub>2</sub> (%) <sup>b</sup>	79.8	7.0	78.5	10.2	.64(64)	0.52
CPAP pressure <sup>c</sup>	11.6	2.5	11.2	2.7	.62(68)	0.54
Body Mass Index (BMI) <sup>d</sup>	39.0	8.4	37.4	10.7	.69(68)	0.49
Total ESS score <sup>e</sup>	12.3	6.0	12.0	5.4	.20(65)	0.84
Age (years)	48.2	12.8	49.0	10.3	-.30(70)	0.76

*Notes:* <sup>a</sup>Apnea-Hypopnea Index. 20 events or more indicate OSA. <sup>b</sup>Nadir percent blood-oxygen saturation. <sup>c</sup>Expressed in centimeters of water (cmH<sub>2</sub>O). <sup>d</sup>Calculated in kilograms per meter squared. A BMI of 30 or greater is considered obese. <sup>e</sup>Epworth Sleepiness Scale (Scale 0-24). Total score of 9 and up should see sleep specialist. SD = Standard deviation. T = t-test value, df = degrees of freedom, p = probability of obtaining no difference between the means (p < .05 indicates a statistically significant difference).

It is worth noting that only 5.7 percent of the S group and 8.1 percent of the NS group reported that OSA was their major presenting problem. Overweight and being overweight to the extent of needing gastro-bypass surgery were reported as the major presenting problem by more than 20 percent of the S group, and more than ten percent of the NS group. This result is consistent with the obtained mean BMI values indicating obesity (Table 1, above). Respiratory problems, snoring, and fatigue were reported as major presenting problems by a sizable percentage of both groups.

**Table 2:** Comparison of S and NS groups on demographic variables.

Baseline variable	S Group (n = 35)		NS Group (n = 37)		$\chi^2$ (df)	p
	Number	Percent	Number	Percent		
Gender					.84(1)	0.36
Female	14	40.0	11	30.0		
Male	21	60.0	26	70.0		
Ethnicity					6.72(4)	0.15
African-American	7	20.0	6	16.0		
Hispanic	6	17.0	13	35.0		
Asian-American	3	9.0	0	0.0		
Caucasian	19	54.0	17	46.0		
Other (Jamaican)	0	0.0	1	3.0		
Living with another adult in household	21	60.0	21	58.0	.01(1)	0.92
Prescribed humidifier	13	37.0	18	49.0	.97(1)	0.32

Notes:  $\chi^2$  = Pearson's chi-square test value, *df* = degrees of freedom, *p* = probability of no dependency between the variables (*p* < .05 indicates a statistically significant dependency).

*OSA Awareness.* Although fewer than nine percent of each experimental group mentioned that OSA was their major presenting problem, Table 4 shows that 71 percent of the S group and 81 percent of the NS group were aware of OSA and some of its associated symptoms at baseline. The ten percent difference between the groups in participants who were OSA aware was not significant,  $\chi^2(1) = .93$ , *p* = .34.

*Subjective Seriousness of OSA.* When asked to rate the seriousness of their OSA on a scale of 1-10, with 1 being “not at all serious”, and 10 being “extremely serious”, the S group, on average, rated it as 7.88, and the NS group as 6.83. Levene’s test showed that equality of the variances of the means for the two groups could not be assumed:  $F(1) = 7.16, p = .01$ , and a t-test using adjusted degrees of freedom to account for this inequality indicated that the mean ratings for the S and NS groups were not significantly different:  $t(61.89) = 1.78, p = .08$ .

**Table 3:** Major presenting problem by self-recording group at baseline.

Major presenting problem	S Group (n = 35)		NS Group (n = 37)	
	Number	Percent	Number	Percent
Gastro-bypass surgery	5	14.2	4	10.8
Overweight	4	11.4	1	2.7
Fatigue	4	11.4	4	10.8
Other	4	11.4	3	8.1
Heart problems	3	8.6	1	2.7
Snoring	3	8.6	8	21.6
Falling asleep while driving	3	8.6	1	2.7
Respiratory problems	3	8.6	5	13.6
OSA	2	5.7	3	8.1
Choking	2	5.7	1	2.7
Migraine/Headache	1	2.9	1	2.7
Dizziness	1	2.9	0	0.0
Ear, nose and throat	0	0.0	2	5.4
Epilepsy	0	0.0	1	2.7
Hepatitis C	0	0.0	1	2.7
Cancer	0	0.0	1	2.7

*Primary Source of Referral to the Sleep Laboratory.* For the S group, 37 percent said that their primary source of referral to the sleep laboratory was a physician: either their general practitioner or a specialist. A further 23 per cent said that the decision to make a referral to the sleep laboratory was instigated by themselves and their doctor in conjunction. Fourteen percent said the referral decision was instigated by themselves alone, and an additional 14 percent said that their spouse or partner, or other family or friends instigated the referral. The remaining 12 percent said the referral decision was initiated either by themselves and their spouse/partner jointly, or by their doctor and their spouse/partner jointly, or by themselves and their spouse/partner and their doctor in conjunction.

For the NS group, 46 percent said that their primary source of referral to the sleep laboratory was a physician: either their general practitioner or a specialist. A further 6 percent said that the decision to make a referral to the sleep laboratory was instigated jointly by themselves and their doctor. Fourteen percent said the referral decision was instigated by themselves alone, while eight percent said that their spouse or partner, or other family or friends instigated the referral. Fourteen percent said the referral decision was initiated by their doctor and spouse/partner jointly, and the remaining 12 percent said that referral was initiated either by themselves and their doctor jointly, or by themselves and their spouse/partner jointly, or by themselves and their spouse/partner and their doctor in conjunction. A

Pearson chi-square test showed that referral source did not depend upon the group to which participants were randomized:  $\chi^2(6) = 7.62, p = .27$ .

These data were collapsed, firstly to compare the frequencies of those whose primary referral source was the physician alone with all other possible categories of referral source (Doctor only vs. All others), and secondly to compare those participants who had some self-involvement in their referral, either alone or in combination with others, with those who had no self-involvement in their referral (Self-involvement vs. No self-involvement). The results for both the S and NS groups are given in Table 4. Table 4 shows that in neither case was there a dependency between the variable and the group to which the participants had been randomized.

**Table 4:** Primary referral source, referral decision, and OSA awareness for S and NS groups.

Baseline variable	S Group (n = 35)		NS Group (n = 37)		$\chi^2$ (df)	p
	Number	Percent	Number	Percent		
Primary referral source					.74(1)	0.39
Doctor only	13	37.0	17	46.0		
All others	22	63.0	20	54.0		
Referral decision					1.73(1)	0.19
Self-involvement	19	54.0	26	69.0		
No self-involvement	16	45.0	11	31.0		
OSA awareness					.93(1)	0.34
Aware	25	71.0	30	81.0		
Unaware	10	29.0	7	19.0		

Notes:  $\chi^2$  = Pearson's chi-square test value, *df* = degrees of freedom, *p* = probability of no dependency between the variables (*p* < .05 indicates a statistically significant dependency).

### *30-day Follow-up*

Fifty-four participants, 75 percent of the 72 who enrolled at baseline, attended their 30-day follow-up appointment. Of these, 25 were from the S group (71.4% of the S group), and 29 were from the NS group (78.4% of the NS group). However, four of the NS group, and three of the S group had been provided with non-downloadable CPAP machines, in error. A further three participants, two from the NS group and one from the S group, were not equipped with downloadable machines because their insurance policies did not cover such provision. Thus, no objective CPAP usage follow-up data could be gathered from these 10 patients. For that reason, their baseline data were included with that of the 18 non-attendees in the “no CPAP data” group when comparisons were made between that group and the “CPAP data” group, below. In all, there were 21 participants from the S group, and 23 from the NS group who provided analyzable CPAP usage data. For these 44 patients, attendance at 30-day follow-up did not depend on the experimental group to which they had been randomized,  $\chi^2(1) = .04, p = .85$ .

### *Comparison of “CPAP data” and “no CPAP data” groups*

*Clinical and demographic variables at baseline.* Table 5 and Table 6 show that there were no significant differences between the “CPAP data”

and “no CPAP data” groups at baseline on the clinical or demographic variables.

**Table 5:** Comparison of “CPAP data” and “no CPAP data” groups on OSA severity measures and age.

Baseline variable	CPAP data (n = 44)		No CPAP data (n = 28)		T (df)	P
	Mean	SD	Mean	SD		
AHI (events per hour)	49.7	28.4	58.4	29.4	-1.24(68)	0.22
Nadir SaO2 (%)	79.7	9.4	78.3	7.8	.64(68)	0.52
CPAP pressure <sup>a</sup>	11.4	2.9	11.5	2.3	-.19(68)	0.85
Body Mass Index (BMI) <sup>b</sup>	38.2	10.5	38.2	8.4	-.02(68)	0.99
Total ESS score <sup>b</sup>	11.8	6.1	12.7	5.0	-.68(65)	0.50
Age (years)	49.0	11.4	48.0	11.8	.33(70)	0.74

Notes: <sup>a</sup>Apnea-Hypopnea Index. 20 events or more indicate OSA. <sup>b</sup>Nadir percent blood-oxygen saturation. <sup>c</sup>Expressed in centimeters of water (cmH2O). <sup>d</sup>Calculated in kilograms per meter squared. A BMI of 30 or greater is considered obese. <sup>e</sup>Epworth Sleepiness Scale (Scale 0-24). Total score of 9 and up should see sleep specialist. SD = Standard deviation. T = t-test value, df = degrees of freedom, p = probability of obtaining no difference between the means (p < .05 indicates a statistically significant difference).

*Major presenting problem at baseline.* The percentage of participants with each major presenting problem at baseline is given separately for the “CPAP data” and “no CPAP data” groups in Table 7. A Pearson chi-square test showed that the sort of major presenting problem reported at baseline by the participants did not depend upon whether or not they provided analyzable CPAP data at the 30-day follow-up,  $\chi^2(15) = 5.53$ ,  $p = .99$ .

**Table 6:** Comparison of “CPAP data” and “no CPAP data” groups on demographic variables.

Baseline variable	CPAP data (n = 44)		No CPAP data (n = 28)		$\chi^2$ (df)	p
	Number	Percent	Number	Percent		
Gender					.02(1)	0.89
Female	15	34.0	10	36.0		
Male	29	66.0	18	64.0		
Ethnicity					3.05(4)	0.55
African-American	8	18.0	5	18.0		
Hispanic	12	27.0	8	27.0		
Asian-American	3	6.0	0	0.0		
Caucasian	20	45.0	15	57.0		
Other (Jamaican)	1	2.0	0	0.0		
Living with another adult in household	27	61.0	16	56.0	.62(1)	0.43
Prescribed humidifier	20	46.0	11	39.0	.27(1)	0.61

Notes:  $\chi^2$  = Pearson’s chi-square test value, *df* = degrees of freedom, *p* = probability of no dependency between the variables (*p* < .05 indicates a statistically significant dependency).

*OSA Awareness, Primary Source of Referral to the Sleep*

*Laboratory, and Subjective Seriousness of OSA.* Table 8 indicates that OSA awareness did not depend on whether participants provided CPAP data or not, with over 70 percent of both groups being aware of OSA to some extent at baseline. Similarly, Table 8 shows that there were no significant differences between the “CPAP data” and “no CPAP data” groups on whether they were referred to the sleep clinic by a physician or not, or whether there was self-involvement in their referral. On average, those providing CPAP data rated OSA seriousness as 7.2 on a scale of 1-10, while

those who did not provide such data rated it as 7.5. The ratings of the two groups were not significantly different:  $t(68) = .52, p = .61$ .

**Table 7:** Major presenting problem for “CPAP data” and “no CPAP data” groups.

Major presenting problem	CPAP data (n = 44)		No CPAP data (n = 28)	
	Number	Percent	Number	Percent
Gastro-bypass surgery	5	11.0	4	14.0
Overweight	4	9.0	1	4.0
Fatigue	4	9.0	4	14.0
Other	4	9.0	3	10.0
Heart problems	3	7.0	1	4.0
Snoring	6	14.0	5	18.0
Falling asleep while driving	2	5.0	2	6.0
Respiratory problems	4	9.0	3	10.0
OSA	3	7.0	1	4.0
Choking	2	5.0	2	6.0
Migraine/Headache	1	2.0	1	4.0
Dizziness	1	2.0	0	0.0
Ear, nose and throat	2	5.0	1	4.0
Epilepsy	1	2.0	0	0.0
Hepatitis C	1	2.0	0	0.0
Cancer	1	2.0	0	0.0

**Table 8:** Primary referral source, referral decision, and OSA awareness for “CPAP data” and “no CPAP data” groups.

Baseline variable	CPAP data (n = 44)		No CPAP data (n = 37)		$\chi^2$ (df)	p
	Number	Percent	Number	Percent		
Primary referral source					.01(1)	0.93
Doctor only	13	58.0	17	57.0		
All others	22	42.0	20	43.0		
Referral decision					.11(1)	0.75
Self-involvement	19	60.0	26	64.0		
No self-involvement	16	40.0	11	36.0		
OSA awareness					.05(1)	0.83
Aware	25	77.0	30	75.0		
Unaware	10	23.0	7	25.0		

Notes:  $\chi^2$  = Pearson’s chi-square test value, *df* = degrees of freedom, *p* = probability of no dependency between the variables (*p* < .05 indicates a statistically significant dependency).

#### *Comparison of S and NS groups on CPAP usage*

Univariate *F*-tests showed that the S group used CPAP for significantly more hours per night during the first 30 days of usage than did the NS group (4.94 hrs. v. 3.43 hrs.,  $F(1,42) = 2.50, p = .04$ ). Similarly, the S group used CPAP for more hours per night on the nights when CPAP was actually used than did the NS group (5.55 hrs. v. 4.31 hrs.,  $F(1,42) = 2.09, p = .04$ ). However, the groups did not differ significantly on the percentage of nights CPAP was used during the first 30 days of use (S = 85.28% v. NS = 73.97%,  $F(1,42) = 1.58, p = .12$ ).

Multivariate analysis of variance (MANOVA) showed that there was no significant difference in CPAP usage between the S and NS groups when

all three usage variables were considered simultaneously, Wilk's  $\lambda(3, 40) = .90, p = .22$ .

*Comparison of S and NS groups at 30-day follow-up on baseline variables*

T-tests and Pearson chi-square tests showed that the S and NS groups that had analyzable data at 30-day follow-up did not differ significantly on any of the clinical or demographic variables that were collected at baseline (see Tables 9 & 10), nor did they differ on major presenting problems at baseline or baseline questionnaire variables (see Tables 11 & 12).

**Table 9:** Comparison of S and NS groups at 30-day follow-up on OSA severity measures and age.

Baseline variable	S Group (n = 21) 30-day follow-up		NS Group (n = 23) 30-day follow-up		<i>t</i> (df)	<i>p</i>
	Mean	SD	Mean	SD		
AHI (events per hour)	53.7	26.3	46.5	30.2	.81(40)	0.42
Nadir SaO2 (%)	80.8	7.1	78.7	11.0	.70(40)	0.49
CPAP pressure <sup>a</sup>	11.6	2.8	11.2	2.9	.41(40)	0.69
Body Mass Index (BMI) <sup>b</sup>	39.0	10.5	37.5	8.4	.46(40)	0.65
Total ESS score <sup>b</sup>	11.2	6.5	12.2	5.8	-.55(38)	0.59
Age (years)	48.5	11.7	49.4	11.3	.81(42)	0.81

*Notes:* <sup>a</sup>Apnea-Hypopnea Index. 20 events or more indicate OSA. <sup>b</sup>Nadir percent blood-oxygen saturation. <sup>c</sup>Expressed in centimeters of water (cmH<sub>2</sub>O). <sup>d</sup>Calculated in kilograms per meter squared. A BMI of 30 or greater is considered obese. <sup>e</sup>Epworth Sleepiness Scale (Scale 0-24). Total score of 9 and up should see sleep specialist. SD = Standard deviation. *T* = *t*-test value, *df* = degrees of freedom, *p* = probability of obtaining no difference between the means (*p* < .05 indicates a statistically significant difference).

**Table 10:** Comparison of S and NS groups at 30-day follow-up on demographic variables.

Baseline variable	S Group (n = 21) 30-day follow-up		NS Group (n = 23) 30-day follow-up		$\chi^2$ (df)	p
	Number	Percent	Number	Percent		
Gender					.01(1)	0.92
Female	7	33.0	8	35.0		
Male	14	67.0	15	65.0		
Ethnicity					4.45(4)	0.35
African-American	4	19.0	4	17.0		
Hispanic	5	24.0	7	30.0		
Asian-American	3	14.0	0	0.0		
Caucasian	9	43.0	11	48.0		
Other (Jamaican)	0	0.0	1	4.0		
Living with another adult in household	13	62.0	14	61.0	.01(1)	0.94
Prescribed humidifier	7	33.0	13	57.0	2.38	0.12

Notes:  $\chi^2$  = Pearson's chi-square test value, *df* = degrees of freedom, *p* = probability of no dependency between the variables (*p* < .05 indicates a statistically significant dependency).

*Breakdown of S group and comparison with NS group at 30-day follow-up*

Six participants from the S group had not self-recorded at all during the prior 30-day period. None of the NS group had, in fact, self-recorded. In view of these findings participants' data were reanalyzed by assigning them as coming from either those of the S group who actually recorded (Group1, n = 15), those in the S group who did not record (Group 2, n = 6), or the NS group (n = 23). Pearson's  $\chi^2$  tests showed that there were no significant dependencies between group membership and any of the categorical baseline variables.

**Table 11:** Major presenting problem for S and NS groups at 30-day follow-up.

Major presenting problem	S Group (n = 21) 30-day follow-up		NS Group (n = 23) 30-day follow-up	
	Number	Percent	Number	Percent
Gastro-bypass surgery	2	9.0	3	13.0
Overweight	4	19.0	0	0.0
Fatigue	2	9.0	2	9.0
Other	2	9.0	2	9.0
Heart problems	2	9.0	1	4.0
Snoring	2	9.0	4	17.0
Falling asleep while driving	2	9.0	0	0.0
Respiratory problems	1	5.0	3	13.0
OSA	2	9.0	1	4.0
Choking	1	5.0	1	4.0
Migraine/Headache	0	0.0	1	4.0
Dizziness	1	5.0	0	0.0
Ear, nose and throat	0	0.0	2	9.0
Epilepsy	0	0.0	1	4.0
Hepatitis C	0	0.0	1	4.0
Cancer	0	0.0	1	4.0

Group 1, those who were randomized to the self-recording group and actually recorded, used CPAP, on average, for 95.2 percent ( $\pm 7.9\%$ ) of nights during the 30 days, and for 6.12 hours ( $\pm 1.86$  hrs.) per night, and for 6.36 hours ( $\pm 1.66$  hrs.) per night on the nights they actually used the machine. Those who were randomized to the self-recording group but did not record (Group 2) used CPAP, on average, for 60.41 percent ( $\pm 35.4\%$ ) of nights during the 30 days, and for 1.98 hours ( $\pm 1.58$  hrs.) per night, and for

3.55 hours ( $\pm 2.19$  hrs.) per night on the nights they actually used the machine. The usage data for the NS group (Group 3) on these three variables was as reported above, i.e. 73.97 percent nights used ( $\pm 22.6\%$ ), for 3.43 hours per night ( $\pm 2.00$  hrs.), and 4.31 hours usage on nights actually used ( $\pm 1.75$  hrs.) (see Figures 1 and 2).

**Table 12:** Primary referral source, referral decision, and OSA awareness for S and NS groups at 30-day follow-up.

Baseline variable	S Group (n = 21) 30-day follow-up		NS Group (n = 23) 30-day follow-up		$\chi^2$ (df)	p
	Number	Percent	Number	Percent		
Primary referral source					.24(1)	0.63
Doctor only	13	61.0	17	55.0		
All others	22	39.0	20	45.0		
Referral decision					1.12(1)	0.29
Self-involvement	19	52.0	26	68.0		
No self-involvement	16	48.0	11	32.0		
OSA awareness					.03(1)	0.87
Aware	25	76.0	30	78.0		
Unaware	10	24.0	7	22.0		

Notes:  $\chi^2$  = Pearson's chi-square test value, *df* = degrees of freedom, *p* = probability of no dependency between the variables ( $p < .05$  indicates a statistically significant dependency).

A one-way analysis of variance (ANOVA) showed that the three groups differed significantly on percentage of nights CPAP was used,  $F(2,41) = 7.37, p < .01$ , mean hours of nightly usage,  $F(2,41) = 13.49, p < .01$ , and mean hours of usage on nights when CPAP was actually used,  $F(2,41) = 7.99, p < .01$ . Post-hoc tests (Tukey's *HSD*) showed that Group 1, those of the S group who actually self-recorded, used CPAP for a greater

percentage of nights than either Group 2, those of the S group who did not self-record, (Mean difference = 34.8%,  $p < .01$ ), or Group 3, the NS group (Mean difference = 21.3%,  $p = .01$ ). There was no significant difference between Group 2 and Group 3 in percentage of nightly CPAP use (Mean difference = 13.6%,  $p = .35$ ).

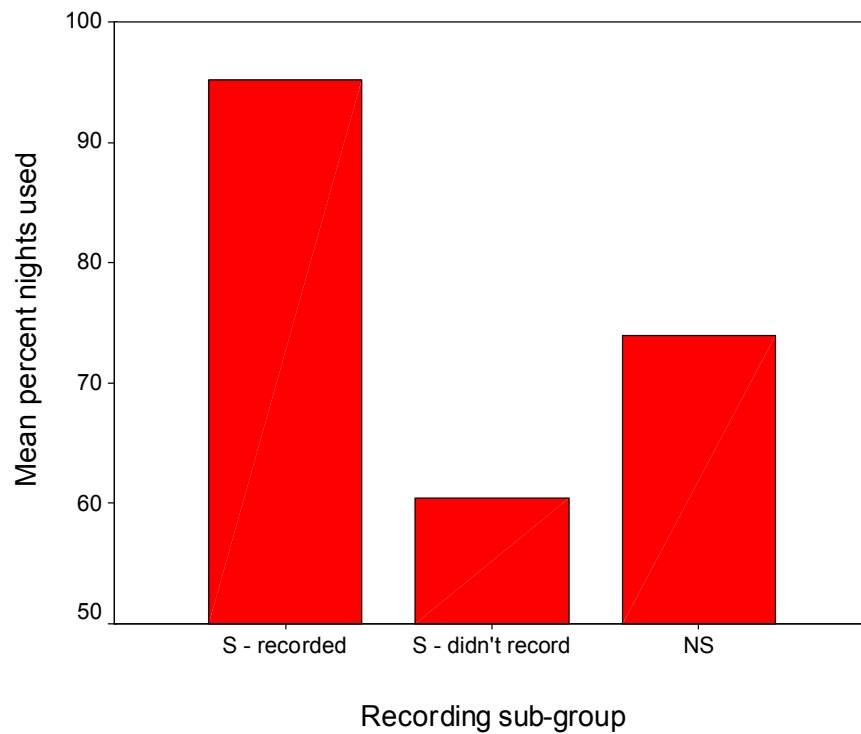


Figure 1. Mean percent of nights CPAP was used over the first 30 days for each self-recording sub-group.

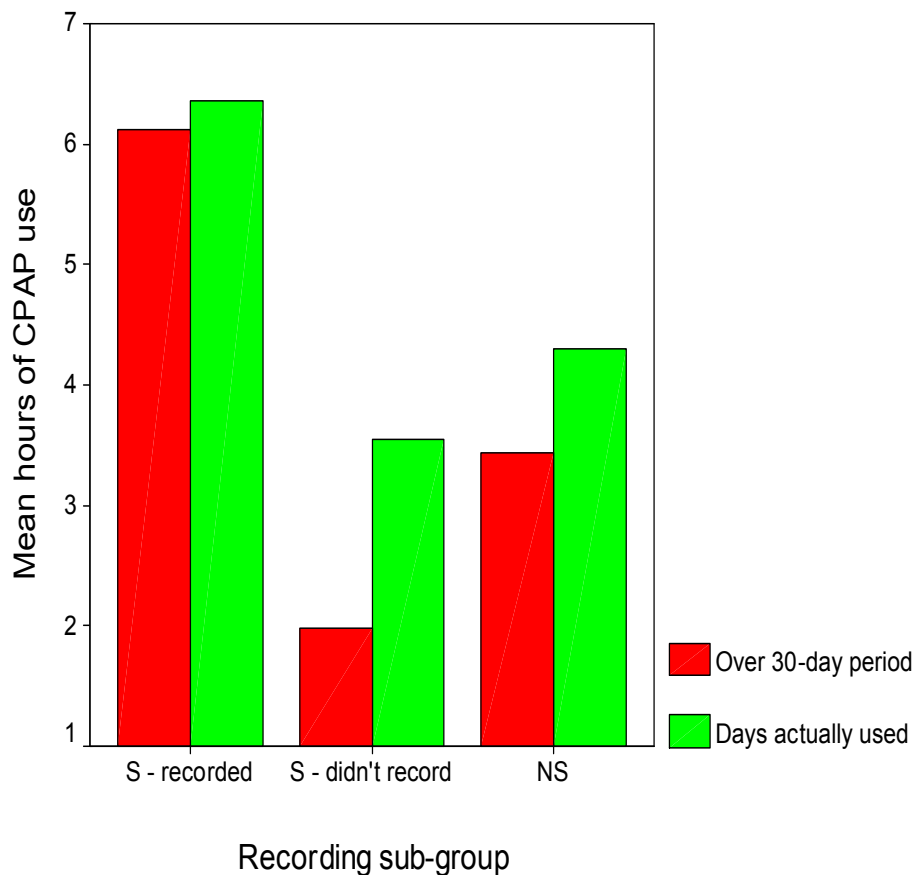


Figure 2. Mean hours of CPAP use over the 30-day period, and on nights CPAP was actually used for each self-recording sub-group.

A similar pattern of results emerged regarding hours of nightly CPAP usage. Participants in Group 1 used CPAP for more hours per night, on average, than did those in Group 2 (Mean difference = 4.14 hours,  $p < .01$ ), or Group 3 (Mean difference = 2.69 hours,  $p < .01$ ). There was no significant difference between Group 2 and Group 3 in nightly hours of CPAP use (Mean difference = 1.45 hours,  $p = .24$ ).

As might be expected from the previous results, participants in Group 1 used CPAP for more hours on the nights it was actually used than either those in Group 2 (Mean difference = 2.81 hours,  $p = .01$ ) or Group 3

(Mean difference = 2.05 hours,  $p = .01$ ). There was no significant difference between Group 2 and Group 3 in nightly hours of CPAP use (Mean difference = 0.76 hours,  $p = .63$ ).

When the three dependent variables were considered simultaneously MANOVA demonstrated that there was a significant difference among the three groups: Wilk's  $\lambda (6, 76) = .58, p < .01$ . A joint multivariate Bonferroni approach was used to compare Group 1 to the other two groups on each variable, and to identify the variables on which any differences might occur. The multivariate Bonferroni approach sets up 95 per cent confidence intervals (95%CI) around the parameter coefficients (differences between the groups on each variable). If the value 0 falls within the confidence interval, then there is no significant difference between the groups on that variable. It was found that Group 1 differed from Group 2 on percentage of days of CPAP use (95%CI = [1.78;40.72]), mean hours of nightly use (95%CI = [0.90;4.39]), and mean hours of nightly usage on nights CPAP was actually used (95%CI = [0.37;3.64]), with Group1 having greater usage than Group 2.

Dummy variables were then constructed using 1, 0 coding so that the Groups 2 and 3 were compared to Group 1. These dummy variables were firstly entered into a linear regression equation to predict variation in the percentage of nights on which CPAP was used. Results confirmed that those participants in the self-recording group who actually recorded used CPAP on a greater percentage of nights (Mean ( $B_0$ ) = 95.2%) than either

those who were in the non-self-recording group (Mean difference ( $B_1$ ) = -21.3%,  $p < .01$ ) or those in the self-recording group but who did not record (Mean difference ( $B_2$ ) = -34.8%,  $p < .01$ ). Variation in self-recording subgroup accounted for a significant 26.4 percent of the variance in percentage of nightly CPAP use ( $R^2 = .26$ ,  $F$  change(2,41) = 7.37,  $p < .01$ ).

The baseline clinical variables together with age and rating of OSA seriousness were then centered about their means. That is to say that the mean of each variable was subtracted from each individual's score for that variable. Thus an individual who scored at the mean of a particular variable would have a centered score of 0 for that variable. When centered variables are entered into a regression equation the intercept represents the score on the dependent variable for a person who has an average score on the centered variable. The slope value for the centered variable represents the amount of increase or decrease a person who is one unit above the mean of the centered variable is predicted to score on the dependent variable.

None of the baseline variables alone was a significant predictor of CPAP use. When they were entered into a regression equation one by one, together with the group by variable interaction terms, none of the baseline variables was a significant predictor of percentage of nights of CPAP use over and above self-recording sub-group. The interaction of BMI with being a member of the self-recording group who did not in fact self-monitor was the only other significant predictor of percentage of nights on which CPAP was used ( $B_3 = -2.65$ ,  $p < .01$ ). This result indicates that for every

point above average BMI (38.16) a person in Group 2 was they would use CPAP on 2.65 percent fewer nights than members of Group 1. When this interaction term was added to group membership in the regression equation it accounted for an additional 15.2 percent of the variance in percentage of nights on which CPAP was used:  $F \text{ change}(1,38) = 10.44, p < .01$ .

Similar regression analyses were performed for mean hours of CPAP use, and mean hours of CPAP use on the days on which CPAP was actually used. For mean hours of CPAP use, differences in group membership accounted for 39.7 percent of the variation in hours of CPAP use per night. The only other significant predictor of mean hours of CPAP use was nadir percentage blood-oxygen saturation (SAO2%) at baseline ( $B_3 = .079, p=.02$ ), and this variable predicted an additional 9.2% of the variance in mean hours of CPAP use:  $F \text{ change}(1,38) = 6.48, p = .02$ . This result indicates that, regardless of group, for every percentage point above average nadir SAO2% (79.1%) any participant was, she or he would use CPAP for approximately five minutes more per night than those participants at mean nadir SAO2%. By extension, a patient whose nadir SAO2% was ten percent above average would be predicted to use CPAP for fifty minutes more per night than those at mean nadir SAO2%.

For mean hours of CPAP use on those nights when CPAP was actually used, differences in group membership accounted for 28.0% percent of the variation in hours of CPAP use per night. As for overall mean usage, the only other significant predictor of mean hours of CPAP use on those

nights when CPAP was actually used was nadir percentage blood-oxygen saturation (SAO2%) at baseline ( $B_3 = .07, p = .03$ ), and this variable predicted an additional 9.4% of the variance in mean hours of CPAP use:  $F$  change(1,38) = 5.43,  $p = .03$ . This result indicates that for every percentage point above average nadir SAO2% (79.1%) she or he was, any participant, regardless of group, would be predicted to use CPAP for approximately four minutes more per night than those at mean nadir SAO2%. By extension, a patient whose nadir SAO2% was ten percent above average would be predicted to use CPAP for forty minutes more per night than those at mean nadir SAO2%.

#### *Assessment of self-regulation*

Participant's responses to OSASRDI were coded according to the scoring criteria given in Appendix F. Respondents were considered to have either passed (coded 1) or failed (coded 0) each item. If participants gave no response to an item, or it was considered to be not applicable, it was coded N/A. Coding of all questionnaires, both those administered at 30-day follow-up and 60-day follow-up, were coded independently by two graduate students of the City University of New York who were not involved in the study. The coders were blinded to participant details, experimental group, and time of follow-up. All questionnaires were coded. Inter-rater reliability was assessed by Cohen's Kappa and equaled 0.77. Coding disagreements were resolved by a third independent coder.

The total of passed items was calculated for each participant for each sub-section of the OSASRDI. These totals were then expressed as a percentage of all applicable, answered items in for each sub-section (OSA self-regulation phase). If a patient passed 75 percent or more of the applicable, answered items on a sub-section, she or he was considered to have passed that sub-section. Each participant was assessed as either passing or failing each phase of OSA self-regulation sequentially, so that if a patient failed Phase 2 (OSA acceptance) he or she was considered to be at the OSA avoidant phase. However, if the respondent passed both Phase 2 and Phase 3, then she or he was judged to be at the OSA compliant phase. If a patient passed Phases 2, 3, and 4, then she or he was deemed to be at the OSA self-regulated phase.

If the sequential phase model holds, then in theory participants should not fail an earlier phase in the sequence, yet pass a later phase. This theoretical position was tested by means of Guttman sequential test. The test resulted in a coefficient of scalability,  $C_s$ , of 0.83. A coefficient of 1.00 represents a perfect fit of the model, while a  $C_s$  of 0.60 or above indicates that the set of items are Guttman scaleable. There were two patients who were assessed as passing a later OSA self-regulatory after failing an earlier phase. These patients were assessed as being at the phase of self-regulation prior to the one they last passed.

*Self-regulation and CPAP use at 30-day follow-up*

At 30-day follow-up, no patients were assessed as OSA avoidant. Eight patients were assessed as OSA acceptant. Seven were judged to be OSA compliant, and the remaining 29 were assessed as OSA self-regulated.

Those participants who were at the OSA self-regulated phase used CPAP, on average, for 87.0 percent ( $\pm 20.2\%$ ) of nights during the 30 days, and for 5.18 hours ( $\pm 2.10$  hrs.) per night, and for 5.86 hours ( $\pm 1.64$  hrs.) per night on the nights they actually used the machine. Those who were at the OSA compliant phase used CPAP, on average, for 76.07 percent ( $\pm 26.48\%$ ) of nights during the 30 days, and for 3.08 hours ( $\pm 1.79$  hrs.) per night, and for 3.77 hours ( $\pm 1.57$  hrs.) per night on the nights they actually used the machine. Patients who were at the OSA acceptant phase used CPAP, on average, for 54.57 percent ( $\pm 19.59\%$ ) of nights during the 30 days, and for 1.36 hours ( $\pm 0.82$  hrs.) per night, and for 2.43 hours ( $\pm 0.98$  hrs.) per night on the nights they actually used the machine (see Figures 3 and 4).

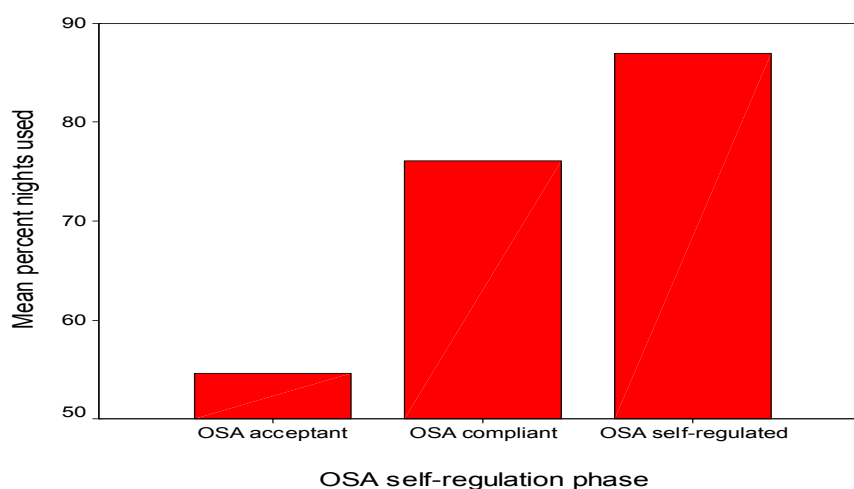


Figure 3. Mean percent of nights CPAP was used during the first 30-day period by self-regulation phase

A one-way ANOVA showed that the three groups differed significantly on percentage of nights CPAP was used,  $F(2,41) = 7.50, p < .01$ , mean hours of nightly usage,  $F(2,41) = 14.05, p < .01$ , and mean hours of usage on nights when CPAP was actually used,  $F(2,41) = 17.78, p < .01$ . Post-hoc tests (Tukey's *HSD*) showed that those who were OSA self-regulated used CPAP for a greater percentage of nights than those who were OSA acceptant (Mean difference = 32.4%,  $p < .01$ ).

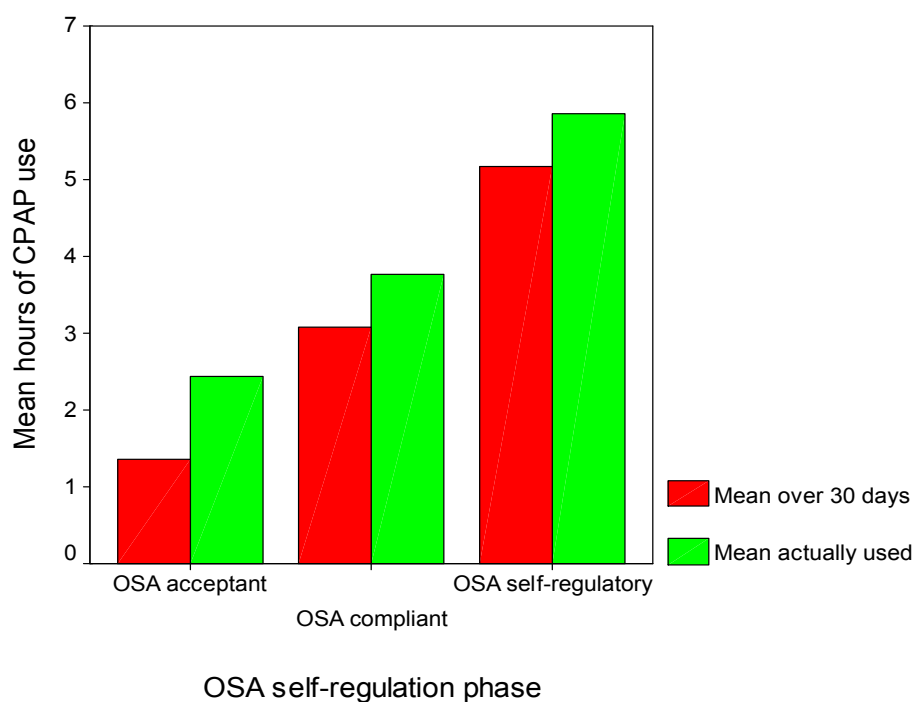


Figure 4. Mean hours of CPAP use over the 30-day period, and on nights CPAP was actually used by self-regulation phase.

A somewhat different pattern of results emerged regarding hours of nightly CPAP usage. OSA self-regulated patients used CPAP for more hours per night, on average, than both OSA compliant patients (Mean difference = 2.10 hours,  $p = .03$ ) and OSA acceptant patients (Mean difference = 3.81 hours,  $p < .01$ ).

Similar results were obtained when hours of CPAP use on nights when it was actually used were considered. OSA self-regulated patients used CPAP for more hours than either OSA compliant patients (Mean difference = 2.09 hours,  $p = .007$ ) or OSA acceptant patients (Mean difference = 3.42 hours,  $p < .001$ ).

When the three dependent variables were considered simultaneously MANOVA demonstrated that there was a significant difference among the three groups: Wilk's  $\lambda (6, 78) = .46, p < .01$ . A joint multivariate Bonferroni approach showed that OSA self-regulators differed from OSA acceptant patients on percentage of days of CPAP use (95%CI = [-55.80;-9.06]), mean hours of nightly use (95%CI = [-5.91; -1.72]), and mean hours of nightly usage on nights CPAP was actually used (95%CI = [-5.13;-1.72]). Those who were OSA self-regulatory also differed from OSA compliant patients on mean hours of nightly usage on nights CPAP was actually used (95%CI = [-3.89;-0.29]).

Linear regression analysis of self-regulation group differences was performed using the method outlined above. Results confirmed the significant group differences shown by ANOVA and post-hoc tests. They also showed the difference between the OSA compliant group (Mean = 76.1%) and the OSA acceptant group (Mean = 54.6%) in percentage of nights CPAP was used closely approached significance (Mean difference = -21.5%,  $p = .06$ ). Overall variation in self-regulation phase accounted for 26.8 percent of the variance in percentage of nightly CPAP use, 40.7 percent

of the variance in hours of nightly use across the 30-day period, and 46.4 percent of the variance in hours of nightly use on those nights when CPAP was actually used.

*Self-regulation and self-recording at 30-day follow-up*

Both actual self-recording group and self-regulation phase independently accounted for a large proportion of the variance in the three dependent variables. A non-parametric test of association showed that there was a significant association between actual self-recording and self-regulation phase,  $\chi^2(4) = 11.87, p = .02$ , with the non-recording group having most (87.5%) of those patients in the OSA acceptant phase and those who were in the self-recording group but did not self-record having only 6.9 percent of OSA self-regulatory patients. Therefore, sub-groups were constructed that reflected the interaction between OSA self-regulation phase and actual self-recording group. No patients in the self-recording group who actually recorded were assessed as being OSA acceptant. The other sub-groups are as follows:

Sub-group 1 (n = 13): OSA self-regulated patients who recorded

Sub-group 2 (n = 02): OSA self-regulated patients who were assigned to the recording group, but did not record

Sub-group 3 (n = 14): OSA self-regulated patients in the NS group

Sub-group 4 (n = 02): OSA compliant patients who recorded

Sub-group 5 (n = 03): OSA compliant patients who were assigned to the recording group, but did not record

Sub-group 6 (n = 02): OSA compliant patients in the NS group

Sub-group 7 (n = 01): OSA acceptant patients who were assigned to the recording group, but did not record

Sub-group 8 (n = 07): OSA acceptant patients in the NS group

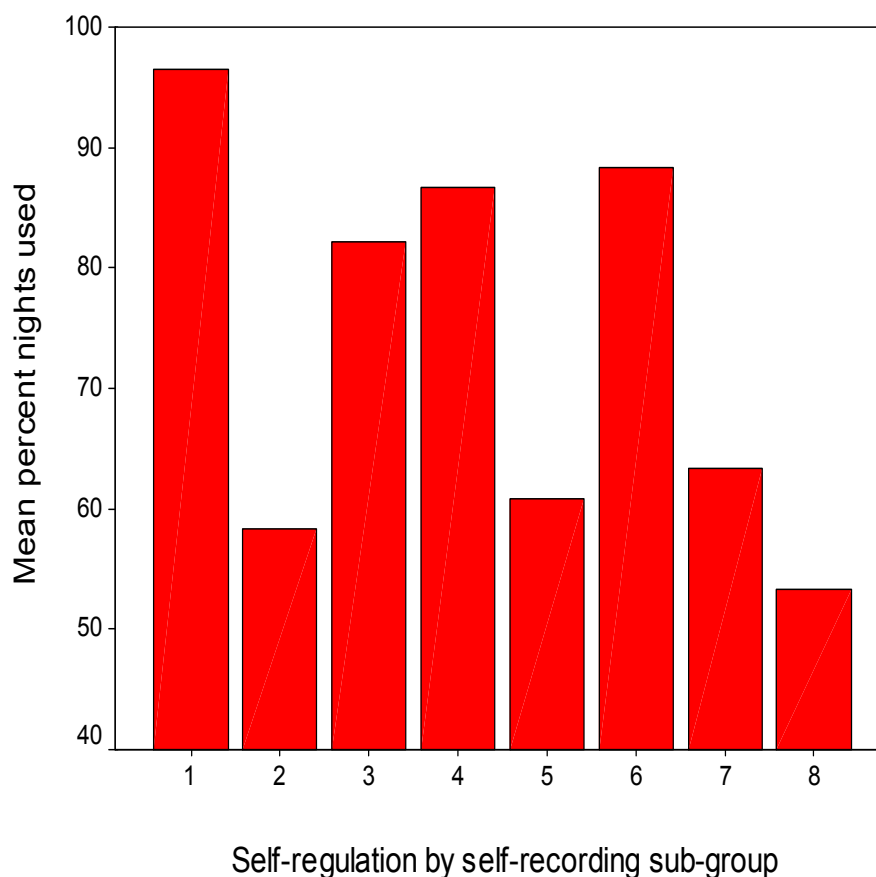


Figure 5. Percent of nights CPAP was used for each self-recoding by self-regulation phase sub-group.

The sub-group means for percentage of nights of CPAP use are shown in Figure 5 and for mean hours of CPAP use across the 30-day period in Figure 6. Only one patient in the self-recording group who did not actually record was assessed as being OSA acceptant. This patient's data were omitted from further analysis. There were no significant associations

between categorical baseline variables and the sub-groups formed from the self-regulation by self-recording interaction.

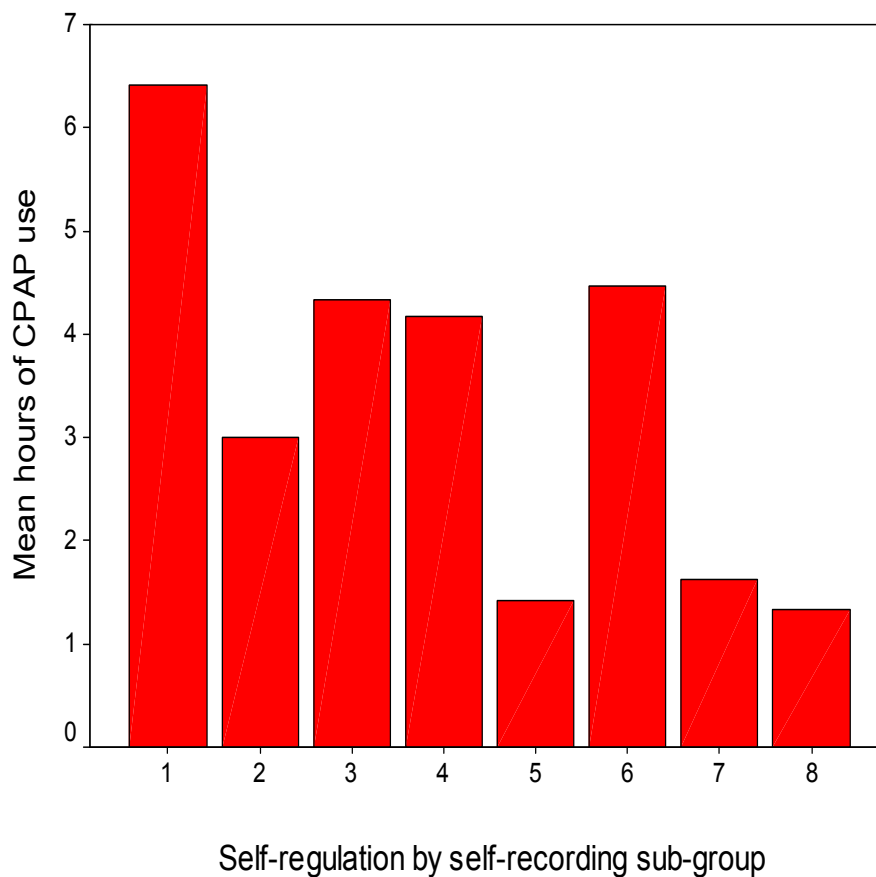


Figure 6. Mean hours of CPAP use across the 30-day period for each self-recording by self-regulation sub-group.

The sub-groups were dummy coded, using 1, 0 coding, and entered into linear regression equations to predict the variation in each of the three dependent variables separately. Using this method of dummy coding, the unstandardized coefficient for the intercept ( $B_0$ ) represents the mean score of the sub-group against which all other sub-groups are compared. The unstandardized coefficients for the respective slope values ( $B_n$ ) represent the

difference between each sub-group's mean score and the comparison group's mean.

Results showed that OSA self-regulated patients who also self-recorded ( $n = 13$ , mean = 96.5%) used CPAP for a greater percentage of nights than the OSA self-regulated patients who were in the self-recording group but did not record ( $n = 2$ , mean difference = -38.2%,  $p = .015$ ). However, although OSA self-regulated patients who actually recorded tended to use CPAP for a greater percentage of nights than OSA self-regulated patients in the non-recording group ( $n = 14$ ), this difference was not significant (Mean difference = -14.3%,  $p = .09$ ). They also used CPAP for a significantly greater percentage of nights than those who were OSA compliant and did not record even though they were in the recording group ( $n = 3$ , mean difference = -35.7%,  $p = .01$ ) and those who were OSA acceptant and in the non-recording group ( $n = 7$ , mean difference = -43.2%,  $p < .01$ ). The interaction between self-regulation phase and actual recording group membership accounted for 42.7 percent of the variance in percentage of nights CPAP was used.

The interaction between self-regulation phase and actual recording group membership accounted for 59.4 percent of the variance in average nightly CPAP use across the follow-up period. For this dependent variable, OSA self-regulated patients who also recorded used CPAP for significantly more hours per night than all other sub-groups with the exception of OSA

compliant patients who also recorded, and OSA compliant patients who were in the non-recording group (see Table 13).

**Table 13:** Comparison of those in the S group who were OSA self-regulatory and who actually recorded with all other self-regulation by self-recording sub-groups on mean hours of CPAP use over the 30-day follow-up period.

<b>Sub-group mean differences</b>	<b><i>B</i>(hours per night)</b>	<b><i>T</i></b>	<b><i>p</i></b>
Sub-group 1 (n=13) mean (intercept)	6.19	12.63	<.01
Sub-group 2 (n=2) – Sub-group 1	-3.19	-2.44	.02
Sub-group 3 (n=14) – Sub-group 1	-1.73	-2.72	.01
Sub-group 4 (n=2) – Sub-group 1	-2.02	-1.57	.13
Sub-group 5 (n=3) – Sub-group 1	-4.78	-4.38	<.01
Sub-group 6 (n=2) – Sub-group 1	-1.73	-1.34	.19
Sub-group 7 (n=7) – Sub-group 1	-4.62	-6.01	<.01

*Notes:* *B* = Unstandardized regression coefficient, *T* = *t*-test value, *p* = probability of obtaining no difference between the means (*p* < .05 indicates a statistically significant difference).

For average nightly usage on those nights when CPAP was actually used, the interaction between self-regulation phase and actual recording group membership accounted for 58.9 percent of the variance. OSA self-regulated patients who also recorded used CPAP for significantly more hours per night than the OSA self-regulated patients who were in the non-recording group (n =14, mean difference = -1.4 hours, *p* = .02), OSA compliant patients in the recording group but who did not record (n = 3, mean difference = -4.35 hours, *p* < .01), and OSA acceptant and in the non-recording group (n = 7, mean difference = -4.12 hours, *p* < .01).

Those OSA self-regulated patients who were in the non-recording group used CPAP for a greater percentage of nights than OSA acceptant patients in the same group (Mean difference = -28.9%,  $p < .01$ ). Although using CPAP for fewer hours per night than OSA patients who self-recorded (see above), these patients used CPAP for more hours per night than OSA compliant patients in the recording group who did not record (mean difference = -2.91 hrs,  $p = .01$ ), and those in the non-recording group who were OSA acceptant (mean difference = -3.01 hrs,  $p < .01$ ). Similar relationships among the mean differences were found when hours of nightly use on those nights when CPAP was actually used served as the dependent variable.

Patients in the non-recording group who were OSA acceptant used CPAP for a significantly fewer percentage of nights than all other groups, with the exception of those patients, regardless of their OSA phase, who were in the self-recording group but did not record. A similar pattern of mean differences was found when hours of nightly CPAP use across the thirty day period was used as the dependent variable.

When the centered baseline variables were entered into the regression equations (see above) none was found to be a significant predictor of variation in percentage of nightly CPAP use over and above the self-regulation phase by self-recording sub-group interaction. However, nadir percentage blood-oxygen saturation (SAO<sub>2</sub>%) at baseline significantly predicted mean hours of CPAP use ( $B = .09$ ,  $p < .01$ ), and mean hours of

CPAP use on the nights on which CPAP was actually used ( $B = .07, p < .01$ ) over and above the self-regulation phase by self-recording sub-group interaction.

These results mean that for every one percent above average nadir SAO2% a person was, they increased their average nightly CPAP use by 0.09 of an hour, or approximately 6 minutes. Similarly, on the nights CPAP was actually used, they increased their nightly usage by 0.07 of an hour, or approximately four minutes. These relationships held across the various self-regulation by self-recording sub-groups.

**Table 14:** Comparison of those in the S group who were OSA self-regulatory and who actually recorded with all other self-regulation by self-recording sub-groups on mean hours of CPAP use over the 30-day follow-up period, controlling for nadir SAO2%.

<b>Sub-group mean differences controlled for nadir SAO2%</b>	<b><i>B</i>(hours per night)</b>	<b><i>T</i></b>	<b><i>p</i></b>
Sub-group 1 (n=13) mean (intercept)	6.25	14.89	<.01
Sub-group 2 (n=2) – Sub-group 1	-4.11	-3.64	<.01
Sub-group 3 (n=14) – Sub-group 1	-1.61	-2.95	.01
Sub-group 4 (n=2) – Sub-group 1	-2.29	-2.08	.04
Sub-group 5 (n=3) – Sub-group 1	-5.07	-5.42	<.01
Sub-group 6 (n=2) – Sub-group 1	-2.37	-2.13	.04
Sub-group 7 (n=7) – Sub-group 1	-4.79	-7.27	<.01
Nadir SAO2% <sup>a</sup>	0.09	3.68	<.01

*Notes:* <sup>a</sup>Nadir percent blood-oxygen saturation. *B* = Unstandardized regression coefficient, *T* = *t*-test value, *p* = probability of obtaining no difference between the means ( $p < .05$  indicates a statistically significant difference).

For mean hours of CPAP use, nadir SAO<sub>2</sub>% predicted an additional 12.0 percent of the variance:  $F$  change(1,33) = 13.88,  $p < .01$ . Similarly, baseline nadir SAO<sub>2</sub>% predicted an additional 10.5 percent of the variance in mean hours of CPAP use on the nights when it was actually used:  $F$  change(1,33) = 11.37,  $p < .01$ . Taken together the self-recording by self-regulation interaction and baseline nadir SAO<sub>2</sub>% predicted 71.4 percent of the variance in mean hours of CPAP use per night across all thirty nights, and 69.4 percent of the variance in mean hours of CPAP use on nights when CPAP was actually used.

When differences in baseline nadir SAO<sub>2</sub>% was controlled for across the sub-groups, the adjusted means showed that OSA self-regulated patients who recorded used CPAP for more hours per night averaged across the thirty day period than all other sub-groups (see Table 14). When average nightly CPAP use on those nights when CPAP was actually used was considered, OSA self-regulated patients who recorded used CPAP more than all other sub-groups except for both OSA self-regulated and OSA compliant patients who were in the recording group but did not record.

OSA self-regulated patients who did not record used CPAP for more hours per night than OSA self-regulated patients who were in the recording group but did not record and OSA acceptant patients who chose not to record. Controlling for baseline nadir SAO<sub>2</sub>% and adjusting the means did not significantly alter the other previously reported relationships among the sub-groups.

*Change in CPAP use over time for 30-day follow-up*

Figure 7 shows average weekly CPAP use in hours for self-regulation by self-recording sub-groups. Sub-group 1 represents those OSA self-regulated patients who also self-recorded. Sub-group 2 signifies those OSA self-regulated patients who were assigned to the S group but did not self-record. Sub-group 3 comprised those OSA self-regulated patients who were assigned to the NS group. Sub-group 4 indicates those OSA compliant patients who also self-recorded. Sub-group 6 contains those OSA compliant patients who were assigned to the S group but did not self-record, and sub-group 8 represents OSA acceptant patients assigned to the NS group.

Multilevel analysis demonstrated that there was significant variation among the sub-groups on average CPAP use at week one (Intercept variance component = 2.69,  $\chi^2(6) = 54.12$ ,  $p < .01$ ). However, there were no significant differences among the sub-groups when change in usage across the four weeks was considered (Slope variance component = 0.08,  $\chi^2(6) = 10.71$ ,  $p = .10$ ). The ordinary least squares intercepts (mean hours of CPAP use at week one) and slopes (increase or decrease in mean hours of CPAP use across the four week period) for each of the sub-groups are plotted in Figure 8.

Although an ordinary least squares regression analysis showed that patients in sub-group 2 declined on average in their use of CPAP by approximately one hour per week across the four weeks (Slope ( $B_1$ ) = -1.05), all other sub-groups maintained their CPAP use across the four weeks

at about the level it was at in week one (i.e. the slope values were close to zero). The average slope across all the sub-groups was  $-0.16$ , which was not significantly different from zero:  $t(26) = -0.50, p = .62$ .

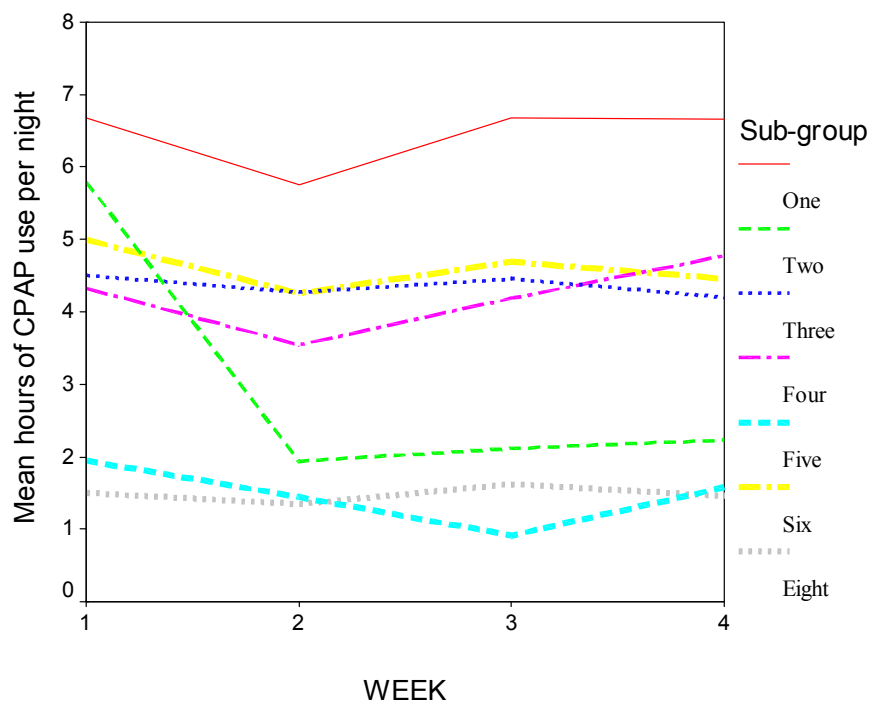


Figure 7. Mean hours of CPAP use for each of the first four weeks of use for each self-regulation by self-recording sub-group.

### *Self-regulation and accuracy of recording*

The accuracy of recording of those in the S group who recorded was assessed by calculating the discrepancy between the objectively and subjectively recorded hourly use for each of the first 28 nights of CPAP use. The mean discrepancy for the first 28 nights was then calculated. There was a wide range in daily discrepancy ( $-.30$  to  $5.35$ ). However, the mean discrepancy across the 28 nights of self-monitoring was  $0.86$ . Since patients were asked only to record CPAP use to the nearest whole hour, while the

objective data were recorded in tenths of an hour, an average tolerance level of 0.5 hours could reasonably be applied to the mean discrepancy. If the average tolerance level is subtracted from mean discrepancy then the resultant average discrepancy across the period is 0.36 of an hour. There was no significant difference between OSA self-regulated patients and OSA compliant patients in mean discrepancy of recording:  $t(13) = -.515, p = .62$ .

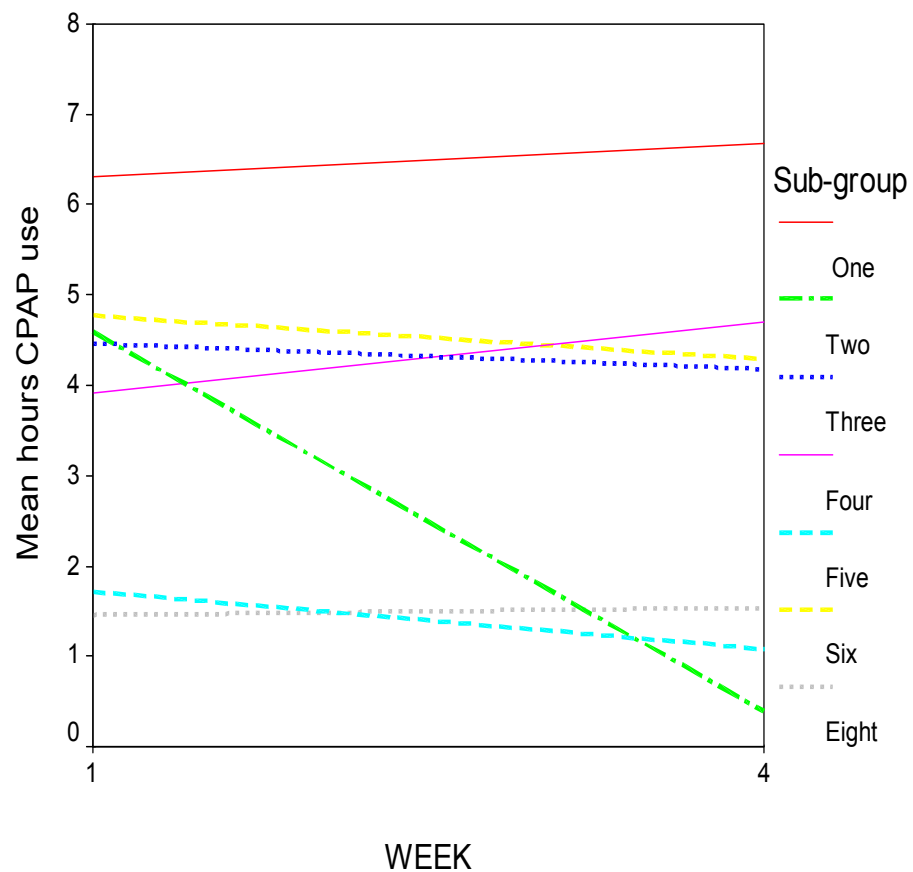


Figure 8. Ordinary least squares slopes for each of the self-regulation by self-recording sub-groups across the four weeks of the follow-up period.

#### *Self-recorded alertness*

Mean alertness scores, as recorded by OSA self-regulated patients for the first four weeks of the 30-day follow-up period are given in Figure 9.

There were insufficient patients at other OSA development phases who self-recorded to make comparisons meaningful. On the scale used, a rating of 8 signified high alertness, while a rating of 0 indicated extreme sleepiness. Ordinary least squares analysis showed that the mean rating of alertness at week one (5.6) did not change significantly across the four week period (Slope = 0.24,  $p = .15$ ). On average, across the four week period OSA self-regulatory patients rated their alertness as 6 on the scale. This indicates a state of high to very high alertness all day.

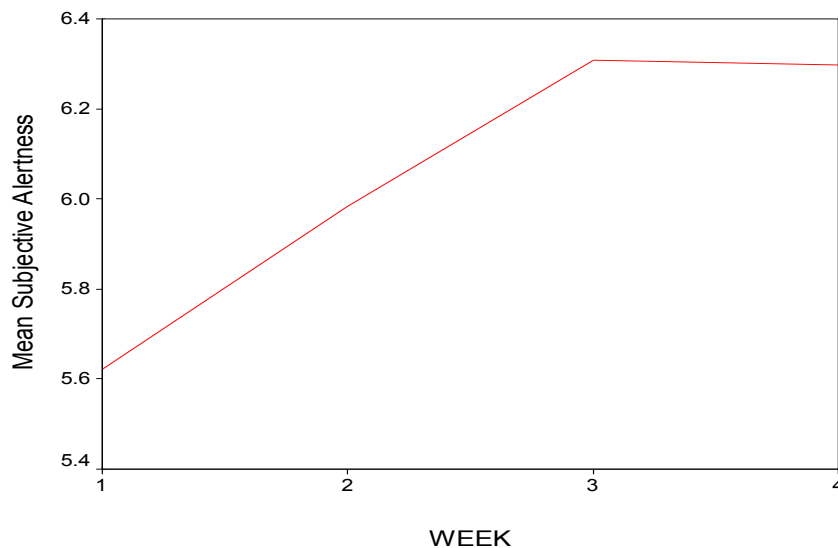


Figure 9. Mean alertness scores, as recorded by OSA self-regulated patients for the first four weeks of the 30-day follow-up period.

### *Sixty-day follow-up*

Thirty patients attended their 60-day follow-up visit. Of these 13 had self-recorded during the first 30-day period, but had not recorded during the second 30-day period. Seven had been in the NS group for the first 30 days, and had self-recorded during the second 30 days, while six had been in

the NS group originally, but had not recorded during the second thirty days. Four had been in the S group during the first thirty days, but had not self-recorded, and did not record during the second thirty-day period.

In all, 17 (81%) of the 30-day S group attended 60-day follow-up, while only 13 (57%) of the 30-day NS group attended. When the data from these patients were analyzed on an intention to treat basis, no significant differences were found between the two groups in percentage of nights CPAP was used, mean hours of CPAP use across the follow-up period, or mean hours of use on days when CPAP was actually used (see Table 15 below).

**Table 15:** Differences in CPAP use between the S and NS groups at 60-day follow-up.

CPAP use	S Group (n = 17)		NS Group (n = 13)		Significance of Difference	
	Mean	SD	Mean	SD	<i>t(df)</i>	<i>p</i>
Percent days used	89.0	14.4	85.1	15.6	0.7(28)	0.49
Mean hours of use	5.0	2.3	4.5	1.9	0.6(28)	0.54
Mean hours on days actually used	5.5	2.0	5.0	1.8	0.6(28)	0.56

Attendance at 60-day follow-up did not significantly depend on recording group at 30-day follow-up:  $\chi^2(1) = 3.02, p = .08$ . There were no significant differences between those who attended 60-day follow-up and those who attended 30-day follow-up but did not attend 60-day follow-up on

any of the baseline variables with two exceptions. Eighty-eight percent of patients who had some self-involvement in their referral to the sleep laboratory and who attended the 30-day follow-up session attended both follow-up sessions, whereas only 54 percent who had no self-involvement in their referral did:  $\chi^2(1) = 5.54, p = .02$ . In addition, only 50 percent of people who were referred to the sleep clinic by their doctor alone and attended the first follow-up session also attended at 60-day follow-up. By contrast, 80 percent of patients who were not referred by their doctor alone and attended the initial follow-up session also attended the second session:  $\chi^2(1) = 4.29, p = .04$ .

*CPAP use by self-recording sub-group (as treated analysis)*

Patients were re-categorized into four self-recording sub-groups at 60-day follow-up. The first group (SREC1) consisted of patients from the S group for the first thirty days who had self-recorded, but did not self-record during the second thirty days ( $n = 13$ ). The second group (SREC2) was made up of those originally in the S group, but who had not recorded and did not record for the second thirty-day period ( $n = 4$ ). The third group (SREC3) comprised those participants who were in the NS group at 30-day follow-up, and had self-recorded for the second thirty days ( $n = 7$ ). The final group (SREC4) comprised NS patients at 30 days who had not recorded during the second 30-day period ( $n = 6$ ).

Patients in the SREC1 sub-group used CPAP, on average, for 90.6 percent ( $\pm 15.0\%$ ) of nights during the period, and for 5.6 hours ( $\pm 2.3$  hrs.)

per night, and for 6.0 hours ( $\pm 2.0$  hrs.) per night on the nights they actually used the machine. Those who were in the SREC2 sub-group used CPAP, on average, for 85.3 percent ( $\pm 13.9\%$ ) of nights during the 30 days, and for 3.7 hours ( $\pm 1.7$  hrs.) per night, and for 4.3 hours ( $\pm 1.6$  hrs.) per night on the nights they actually used the machine. Patients who in the SREC3 sub-group used CPAP, on average, for 92.9 percent ( $\pm 10.6\%$ ) of nights during the 30 days, and for 5.3 hours ( $\pm 1.9$  hrs.) per night, and for 5.6 hours ( $\pm 1.6$  hrs.) per night on the nights they actually used the machine. The fourth sub-group (SREC4) used CPAP, on average, for 76.1 percent ( $\pm 16.2\%$ ) of nights during the 30 days, and for 3.6 hours ( $\pm 1.6$  hrs.) per night, and for 4.4 hours ( $\pm 1.9$  hrs.) per night on the nights they actually used the machine. The above means, together with the equivalent means for the sub-groups at 30-day follow-up are given in Figures 10 -12 below.

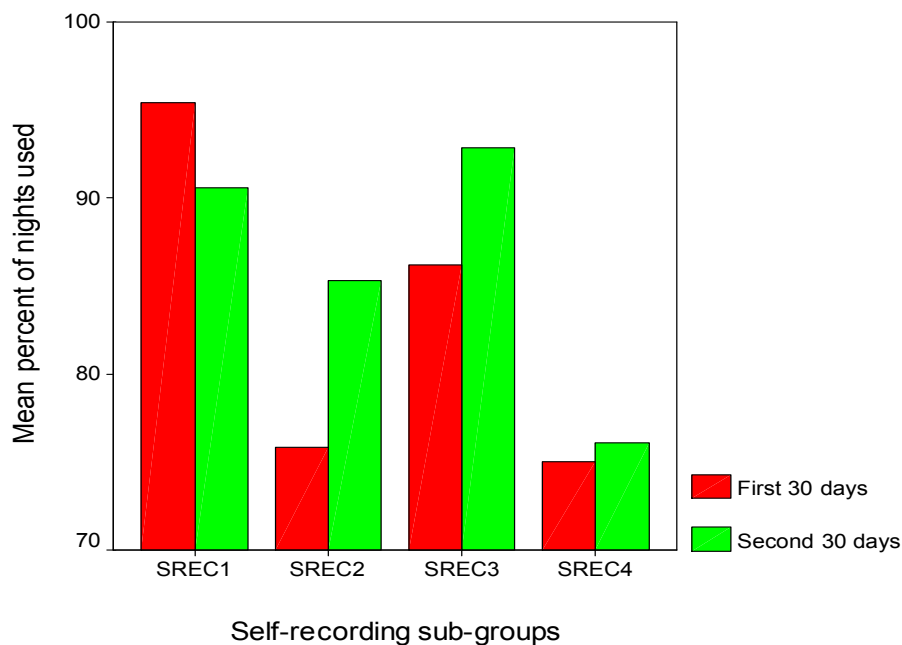


Figure 10. Mean percent of nights CPAP was used for first and second 30-day follow periods by self-recording sub-group at 60-day follow-up.

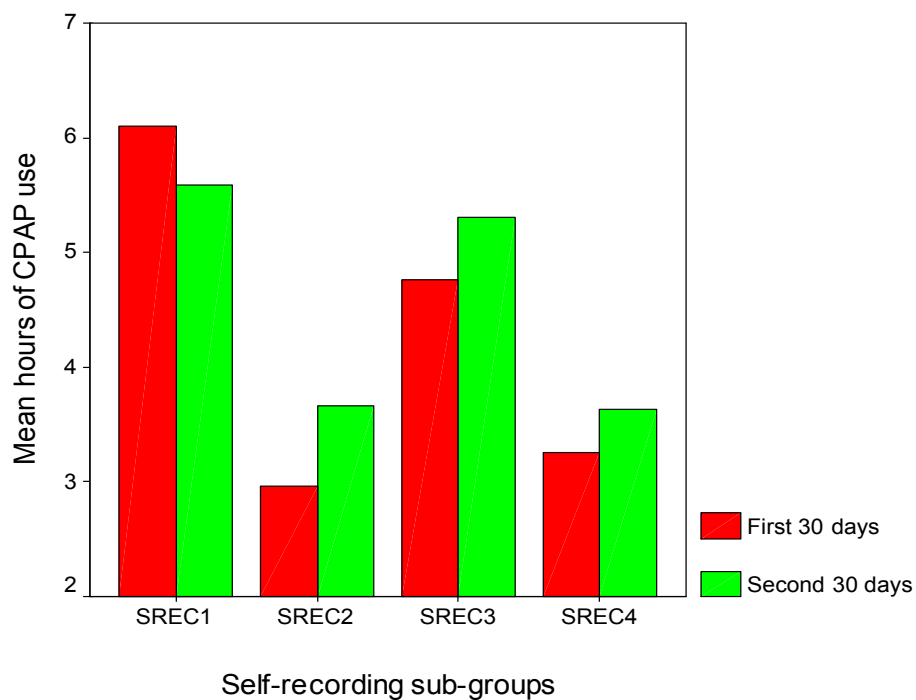


Figure 11. Mean hours of CPAP use for first and second 30-day follow periods by self-recording sub-group at 60-day follow-up.

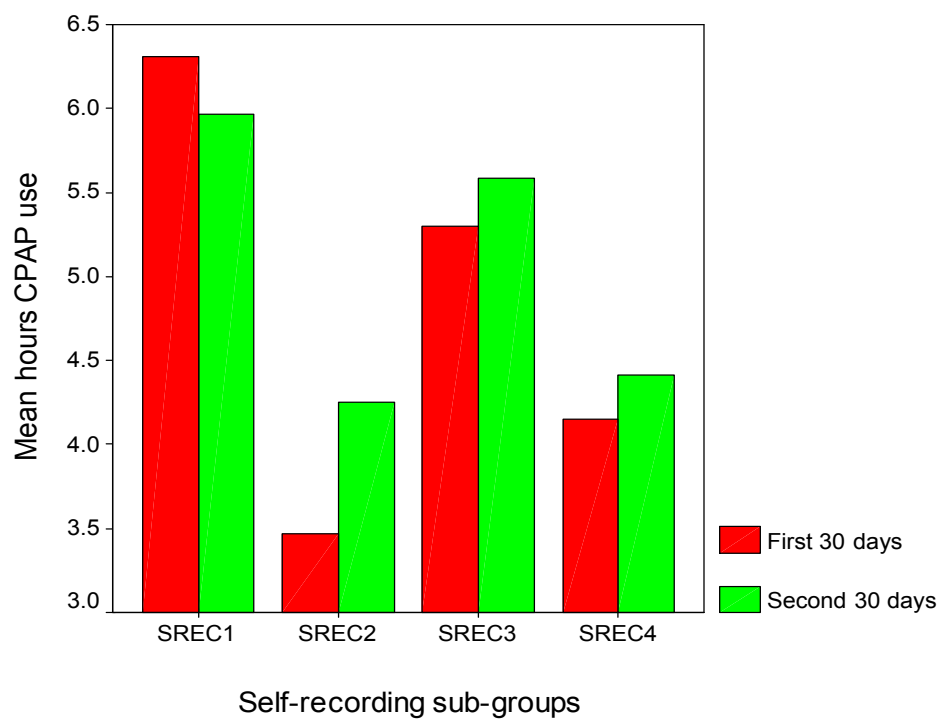


Figure 12. Mean hours of CPAP use on nights CPAP was actually used for first and second 30-day follow periods by self-recording sub-group at 60-day follow-up.

There were no significant differences among the four self-recording sub-groups at 60-day follow-up for percentage of nights used,  $F(3,26) = 1.85, p = .16$ , mean hours of CPAP use across the 30-day span,  $F(3,26) = 1.95, p = .15$ , and mean hours of CPAP use on nights when CPAP was actually used,  $F(3,26) = 1.57, p = .22$ . Among the sub-groups there were no significant differences in the change of CPAP use from 30-day follow-up for percent of nights used,  $F(3,26) = 1.67, p = .20$ , mean hours of CPAP use across the 30-day span,  $F(3,26) = 0.80, p = .50$ , and mean hours of CPAP use on nights when CPAP was actually used,  $F(3,26) = 2.50, p = .08$ .

Linear regression analysis showed that the differences in the self-recording sub-groups reported above accounted for 17.6 percent of the variance in percentage of nights on which CPAP was used, 18.4 percent of the variance in overall mean hours of CPAP use, and 15.4 percent of the variance in mean CPAP use on those nights when CPAP was actually used. For none of the three dependent variables was the percentage of the variance accounted for by difference in self-recording sub-group significantly different from zero.

CPAP use at 60-day follow-up was compared with that at 30-day follow-up within the self-recording sub-groups. Only those patients who were originally assigned to the S group, but who had not recorded and did not record for the second thirty-day period (SREC2) showed any significant change in CPAP use. On average, these participants increased their hours of

CPAP use on those nights when CPAP was actually used by about 45 minutes per night:  $t(4) = 2.86, p = .046$ .

*Protocol compliers only analysis at 60-day follow-up*

When those participants in the S and NS groups who complied with the experimental protocol (i.e. the SREC1 & SREC3 groups) were directly compared, a similar pattern of results emerged. Repeated measures ANOVA showed that CPAP use by participants who self-recorded for the first thirty days and discontinued thereafter tended to decline, while CPAP use by those who initially did not self-recorded and then self-recorded for the second thirty days tended to increase. However, the relative change in usage between the two groups across follow-up periods was not significant (see Table 16 below).

**Table 16:** Differences between S and NS groups for compliers only in change in mean scores from 30- to 60-day follow-up for CPAP use.

CPAP use	Compliers S Group (n = 13)			Compliers NS Group (n = 7)			Relative Change	
	Mean at 30-days	Mean at 60-days	Mean Change	Mean at 30-days	Mean at 60-days	Mean Change	<i>F(df)</i>	<i>p</i>
Percent days used	95.5	90.6	-4.9	86.2	92.9	6.7	2.6(1,18)	0.13
Mean hours of use	6.1	5.6	-0.5	4.8	5.3	0.5	2.7(1,18)	0.12
Mean hours on days actually used	6.3	6.0	-0.3	5.3	5.6	0.3	1.6(1,18)	0.22

There were no significant differences between compliers in the S and NS groups on baseline severity, demographic, or questionnaire variables, with one exception: significantly more of the NS compliers were prescribed

an humidifier at baseline:  $\chi^2(1) = 8.81, p < .01$ . There were no significant differences between the two groups in CPAP use at 30-day follow-up, nor self-regulation phase at either follow-up period.

*Protocol compliers vs. non-compliers at 60-day follow-up*

When those participants who had complied with the experimental protocol (i.e. the SREC1 & SREC3 sub-groups combined) were compared with non-compliers (i.e. the SREC2 & SREC4 sub-groups combined), results showed that protocol compliers used CPAP for a greater percentage of nights, for more hours per night across the thirty-day period, and for more hours per night when CPAP was actually used than non-compliers at both 60- and 30-day follow-ups (see Tables 17 & 18).

**Table 17:** Differences between protocol compliers and non-compliers in CPAP use at 60-day follow-up.

CPAP use	Compliers (n = 20)		Non-compliers (n = 10)		Significance of Difference	
	Mean	SD	Mean	SD	<i>t(df)</i>	<i>p</i>
Percent days used	91.8	13.0	78.3	14.5	2.6(28)	0.02*
Mean hours of use	5.5	2.1	3.4	1.3	3.0(28)	0.01*
Mean hours on days actually used	5.9	1.8	4.1	1.6	2.6(28)	0.02*

*Note:* \* indicates a statistically significant difference in mean score between the groups.

**Table 18:** Differences between protocol compliers and non-compliers in CPAP use at 30-day follow-up.

CPAP use	Compliers (n = 20)		Non-compliers (n = 10)		Significance of Difference	
	Mean	SD	Mean	SD	t(df)	p
Percent days used	92.3	12.6	73.2	25.7	2.2(11.2)	0.04*
Mean hours of use	5.6	2.1	2.9	1.9	3.5(28)	<0.01*
Mean hours on days actually used	5.9	1.8	3.6	1.7	3.4(28)	<0.01*

*Note:* \* indicates a statistically significant difference in mean score between the groups.

Significantly more OSA self-regulated patients (90%) were among the protocol compliers than among the non-compliers (40%):  $\chi^2(1) = 8.52$ ,  $p < .01$ . Similarly, significantly more (80%) of the protocol compliers were assessed as being OSA self-regulated at 30-day follow-up than non-compliers (30%):  $\chi^2(1) = 7.18$ ,  $p = .01$ . There were no other significant differences between the protocol compliers and non-compliers for any of the baseline severity, demographic, or questionnaire variables.

#### *Self-regulation at 60-day follow-up*

Of the 30 patients who attended 60-day follow-up, 26 were assessed as being at the same self-regulation phase as they had been at 30-day follow-up. Of the four who had changed their self-regulation phase over time, one was assessed as moving from OSA compliant to OSA self-regulatory, one changed from OSA acceptant to OSA self-regulatory, another changed from OSA compliant to OSA acceptant, and the fourth altered from OSA self-

regulatory to OSA compliant. In all, 22 patients were assessed as OSA self-regulatory, 5 as OSA compliant, and 3 as OSA acceptant. Attendance at 60-day follow-up did not depend on OSA self-regulatory phase at 30-day follow-up:  $\chi^2(2) = 4.58, p = 10$ .

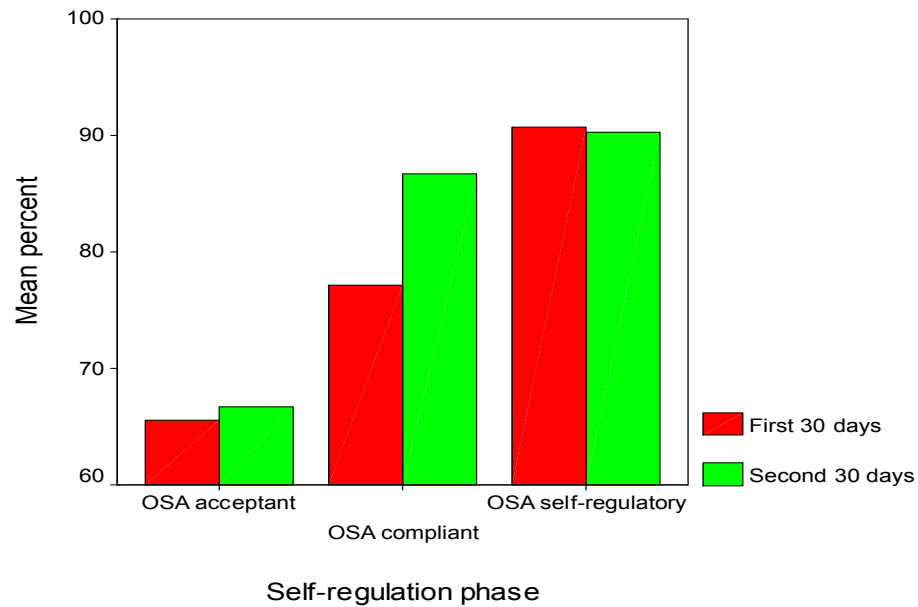


Figure 13. Percent of nights CPAP was used for first and second 30-day follow periods by self-regulation phase at 60 days.

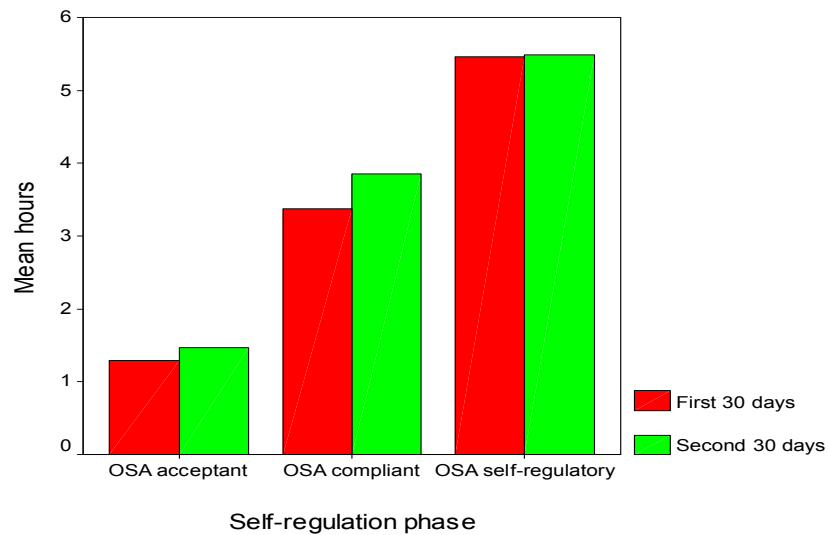


Figure 14. Mean hours of CPAP use across the 30-day period for first and second 30-day follow periods by self-regulation phase at 60 days.

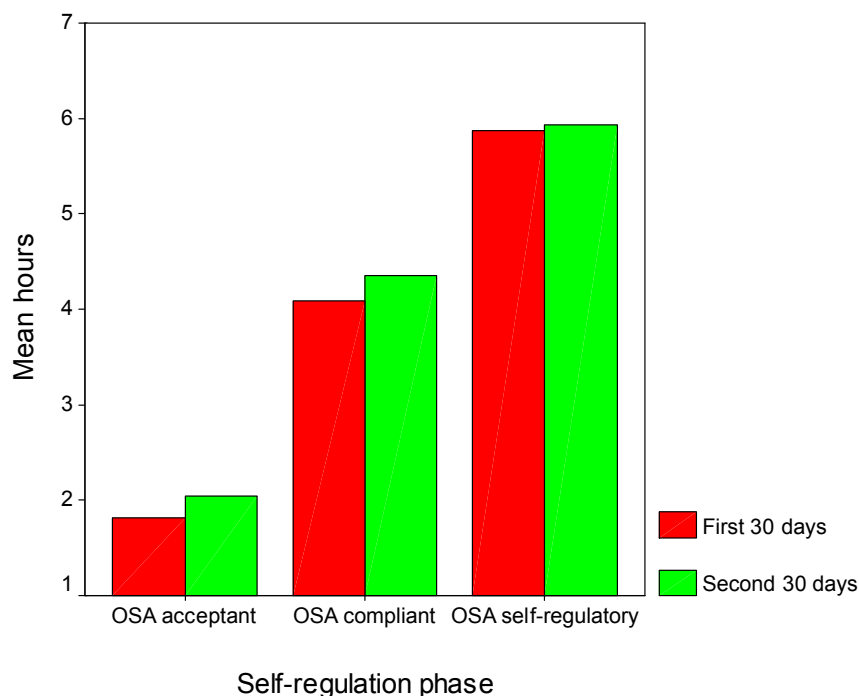


Figure 15. Mean hours of CPAP use on nights when CPAP was actually used for first and second 30-day follow periods by self-regulation phase at 60 days.

Those participants who were at the OSA self-regulated phase used CPAP, on average, for 90.3 percent ( $\pm 13.4\%$ ) of nights during the period, and for 5.5 hours ( $\pm 1.9$  hrs.) per night, and for 5.9 hours ( $\pm 1.6$  hrs.) per night on the nights they actually used the machine. Those who were at the OSA compliant phase used CPAP, on average, for 86.7 percent ( $\pm 12.7\%$ ) of nights during the 30 days, and for 3.9 hours ( $\pm 0.7$  hrs.) per night, and for 4.4 hours ( $\pm 0.9$  hrs.) per night on the nights they actually used the machine. Patients who were at the OSA acceptant phase used CPAP, on average, for 66.7 percent ( $\pm 15.3\%$ ) of nights during the 30 days, and for 1.5 hours ( $\pm 1.0$  hrs.) per night, and for 2.0 hours ( $\pm 1.2$  hrs.) per night on the nights they actually used the machine (see Figures 13 – 15).

A one-way ANOVA showed that over the second 30-day period the three groups differed significantly on percentage of nights CPAP was used,  $F(2,27) = 4.10, p = .03$ , mean hours of nightly usage,  $F(2,27) = 8.02, p < .01$ , and mean hours of usage on nights when CPAP was actually used,  $F(2,27) = 10.20, p < .01$ . Post-hoc tests (Tukey's *HSD*) showed OSA self-regulated patients used CPAP for a greater percentage of nights than OSA acceptant patients (Mean difference = 23.6%,  $p = .02$ ). They also used CPAP for more hours per night, on average, across the 30-day span than OSA acceptant patients (Mean difference = 4.02 hours,  $p < .01$ ), and used CPAP for more hours on the nights it was actually used than OSA acceptant patients (Mean difference = 3.89 hours,  $p < .01$ ). There were no other significant differences among the self-regulation phase groups. There were no significant within-group changes in percentage of nights CPAP was used or hours of CPAP use per night across the two follow-up periods.

Linear regression analysis showed that the differences in the self-regulation phase groups accounted for a significant percentage of the variance in all three dependent variables. Difference in self-regulation phase accounted for 23.3 percent of the variance in percentage of nights on which CPAP was used, 37.3 percent of the variance in overall mean hours of CPAP use, and 43.0 percent of the variance in mean hours of CPAP use on those nights when CPAP was actually used.

*30-day follow-up predictors of CPAP use at 60-day follow-up*

Linear regression analysis showed that the interaction between self-regulation phase and recording sub-group at 30 days accounted for 36.5 percent of the variance in percentage of nights on which CPAP was used, 33.9 percent of the variance in overall mean hours of CPAP use, and 33.6 percent of the variance in mean hours of CPAP use on those nights when CPAP was actually used. However, none of the percent variances accounted were significantly different from zero.

Self-regulation phase at 30-day follow-up was a more parsimonious predictor of CPAP use during the second thirty-day period than the interaction between self-regulation phase and self-recording sub-group at 30-day follow-up. Self-regulation phase at 30-day follow-up alone accounted for 17.3 percent of the variance in nights on which CPAP was used, 23.9 percent of the variance in overall mean hours of CPAP use, and 24.6 percent of the variance in mean hours of CPAP use on those nights when CPAP was actually used. Although, the percentage of variance in percentage of nights CPAP was used was not significantly different from zero, it approached significance ( $p = .08$ ). Self-regulation phase at 30-day follow-up significantly predicted variation in mean hours of CPAP use during the second thirty days of use ( $p = .03$ ), and in mean hours of CPAP use on those nights when CPAP was actually used ( $p = .02$ ).

Self-recording sub-group at 30-days alone did not account for a significant percentage of the variation in any of the three dependent

variables over the second 30-day period. None of the baseline variables accounted for significant variation in CPAP use at 60-days.

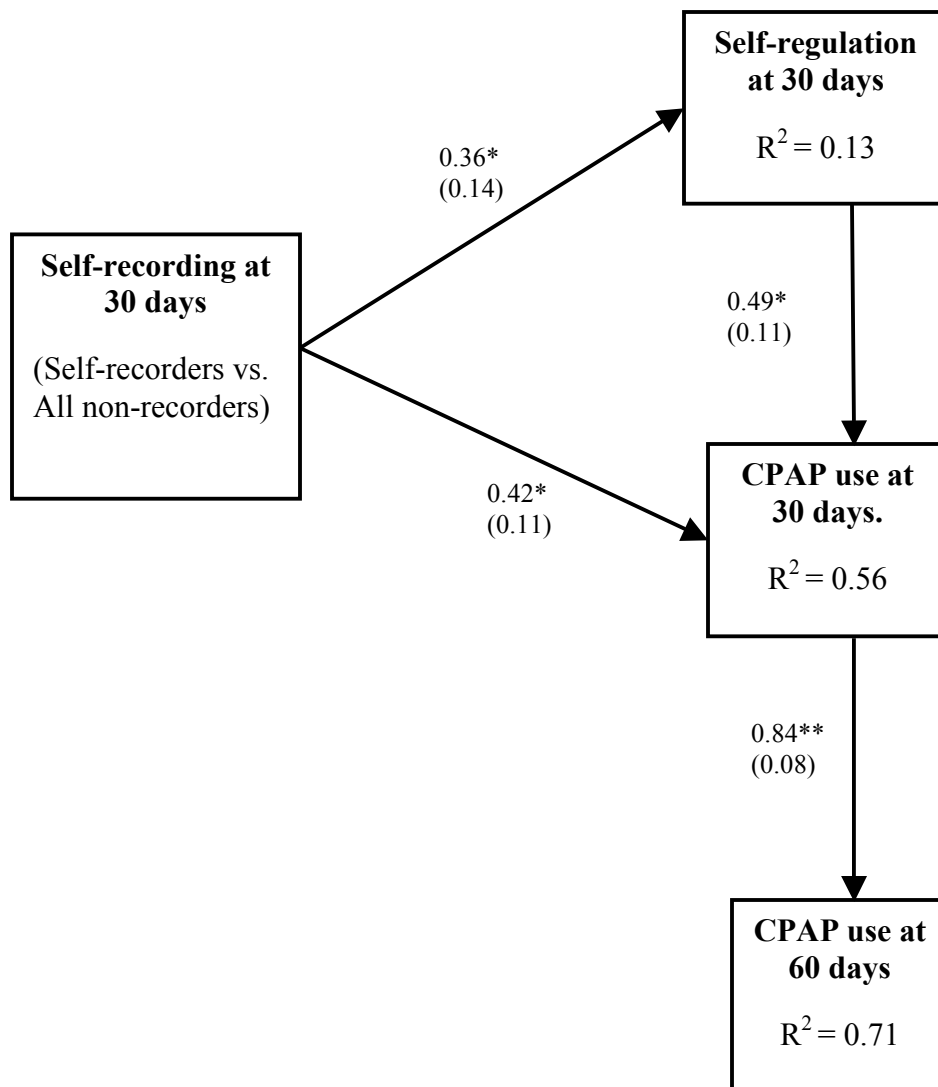
*Effects of self-recording on self-regulation, and self-regulation on CPAP use*

A path model with the following hypotheses was fit to the data using the LISREL-8.54 program (Jöreskog & Sörbom, 2003). The first hypothesis of the model was that when those who actually self-recorded at 30-days were compared with those who did not self-record (the NS group plus those in the S group who did not self-record), self-recording would have a direct positive effect self-regulation at 30-day follow-up and mean hours of CPAP use at 30 days. The second hypothesis was that self-regulation at 30-day follow-up would directly and positively effect mean hours of CPAP use at 30 days. The third hypothesis was that mean hours of CPAP use would have a direct positive effect on mean hours of CPAP use at 60-day follow-up. This model, together with the results, is given in Figure 16.

When evaluating model fit, the root mean square error of approximation (RMSEA) was considered. For RMSEA, values up to .05 indicate a close fit, values between .05 and .08 represent reasonable errors of approximation, values between .08 and .10 indicate mediocre fit, and values above .10 indicate poor fit. The goodness-of-fit index (GFI), the adjusted goodness-of-fit index (AGFI), and the comparative fit-index (CFI) were also considered. Index values of GFI, AGFI and CFI in the .90's indicate a good

fit. Additionally, the Likelihood Ratio Test statistic ( $\chi^2$ ) is reported. Figure 16 presents the significant paths (standardized coefficients with standard deviations in parentheses) resulting from the LISREL analysis.

Taken overall, the model was considered consistent with the data,  $\chi^2(2) = 5.39, p = 0.07$ , GFI = .94, AGFI = .71, CFI = 0.95, RMSEA = 0.20 and 90% Confidence Interval of RMSEA: [0.00, 0.41]. As hypothesized, self-recording had a direct positive effect on self-regulation at 30 days ( $\beta = .36$ ) and mean hours of CPAP use at 30-days ( $\beta = .42$ ). Self-regulation phase at 30-day follow-up also had a direct effect on mean hours of CPAP use at 30-days ( $\beta = .49$ ). Finally, mean hours of CPAP use at 30-days had a direct effect on mean hours of CPAP use at 60 days ( $\beta = .84$ ). Figure 16 also shows that self-recording account for 13 percent of the variance in self-regulation at 30-days ( $R^2 = .13$ ), and that self-recording at 30 days and self-regulation phase at 30 days together accounted for 56 percent of the variance in mean hours of CPAP use at 30 days ( $R^2 = .56$ ). Finally, mean hours of CPAP use at 30 days accounted for 71 percent of the variance in CPAP use at 60 days ( $R^2 = .71$ ).



Note: \*  $p < .05$ . \*\*  $p < .01$ .

Figure16. Path diagram showing effects of self-recording at 30-days on self-regulation and self-regulation on CPAP use.

## Chapter V

### DISCUSSION

This research had two main aims. One was to assess whether self-recording of CPAP use and corresponding daily alertness enhanced adherence to CPAP. The other was to assess the relationship, if any, between self-regulatory behavior and CPAP use. Since self-monitoring has been shown to play a role in the development of self-regulatory efficacy, it was further hypothesized that there would be a positive relationship between self-recording and self-regulatory behavior, and, therefore, adherence to CPAP.

#### *Self-Recording and Adherence to CPAP*

There was a positive relationship between self-recording and CPAP use, at least for the first month of CPAP use. Although at the first 30-day follow-up period patients in both experimental groups used CPAP for about the same percentage of nights over the period. Those patients in the self-recording (S) group had used CPAP for significantly more hours per night than those in the non-recording (NS) group. Indeed, the S group used CPAP for about one and a half hours more per night, on average, than the NS group. The S group's average CPAP usage of about five hours per night was at a level that is generally considered to be beneficial in relation to OSA. However, the NS group's average CPAP usage of three hours and twenty-five minutes per night is generally considered sub-optimal (Engleman, Martin, & Douglas, 1994; Kribbs, Pack, Kline, et al., 1993).

On the other hand, the NS group did use CPAP for four hours and twenty minutes, on average, on those nights when it was used. Four hours of CPAP per night has been considered beneficial for new CPAP patients by some investigators (Kribbs, Pack, Kline, et al., 1993). Nevertheless, the NS group used CPAP for about one hour and ten minutes less than the S group on those nights when CPAP was used. The S group still enjoyed a significant advantage in hours of CPAP use per night over the NS group when this measure of use was employed. The diminution in the gap between the groups on this measure is due to the fact that the NS group used CPAP on fewer, but not significantly fewer, nights over the 30-day period than the S group.

The positive relationship between self-recording and CPAP use was even more clearly demonstrated when the data from those six patients in the S group who did not self-record were removed from the S group and analyzed as a separate set. When these patients' data were compared with those of both the NS group and those people in the self-recording group who did actually record, the results were striking. Those who 'opted out' of the S group used CPAP for about four hours per night on 60 percent of nights in the time period. Thus, they had an average nightly usage of approximately two hours per night across the 30-day period. This meant that those patients who 'elected not to record' used CPAP considerably less than those patients who actually recorded. They also used CPAP at a level somewhat, but not significantly, lower than the NS group.

With the removal of the ‘elective non-recorders’ from the S group, the data demonstrated that those of the S group who actually recorded used CPAP for slightly over six hours per night on 95 percent of nights over the period. Naturally enough, when the reconstituted S group’s data were compared with those of the NS group, the differences between the two groups in favor of the new S group were larger than those between the original two groups. In addition, difference in sub-group allocation (i.e. the new S group, those in the self-recording group who elected not to record, and the original NS group) was a significant predictor of percentage of nights of CPAP use, and mean hours of CPAP use on nights it was actually used. In particular, variation in self-recording sub-group accounted for 40 percent of the variance in mean hours of CPAP use over the 30-day follow-up period.

All of the above findings suggest that self-recording is a powerful aid to CPAP adherence. Previous research has demonstrated that self-recording can be efficacious in academic areas (Sagotsky, Patterson, & Lepper, 1978; Schunk, 1983), the development of complex motor skills (Martin & Anshel, 1995; Zimmerman & Kitsantis, 1996), and, more relevant to this study, in health-related fields (Burke, Dunbar-Jacob, & Hill, 1997, Kamarak & Lichtenstein, 1988, Karter, et al., 2001, Miller, Wallace, Eggert, & Lindeman, 1993). At least as far as the initial stages of CPAP use is concerned, the results of this research extend the previous findings

regarding the efficacy of self-recording in developing adherence to the area of OSA and CPAP.

By the 60-day follow-up period the positive effects of self-recording seemed to have dissipated. When the data were analyzed on an “intention to treat” basis, there were no significant differences between the S and NS groups in CPAP use. However, several patients who attended the 60-day follow-up had not complied with the experimental protocol, either during the first or second follow-up periods. Therefore, the data were reanalyzed on an “as treated” basis. This was done by constructing four self-recording sub-groups at the 60-day follow-up period. The first of these sub-groups consisted of patients from the original S group who had self-recorded initially, but did not self-record during the second thirty days. The second comprised of those participants who were originally in the S group, but who had not recorded and did not record for the second thirty-day period. In the third group were those patients in the NS group at 30-day follow-up who had self-recorded for the second thirty days. The final group comprised NS patients at 30 days who had not recorded during the second 30-day period. At 60-day follow-up there were no significant differences among these sub-groups on percentage of nights CPAP was used, mean hours of CPAP use across the second 30-day period, or mean hours of CPAP use on the those nights when CPAP was actually used.

It could be argued that the failure to find significant differences among the self-recording sub-groups occurred because the sub-group that

had self-recorded during the second follow-up period had increased their CPAP use over that period, and in some way ‘caught up with’ those in the original S group who had originally self-recorded, but did not do so over the second follow-up period. Conversely, the latter group might have reduced its level of CPAP use to that of the other sub-groups over the second follow-up period because its members were no longer self-recording. The within-group comparisons show that this was not the case.

CPAP use at 60-day follow-up was compared with that at 30-day follow-up within the self-recording sub-groups. Only those patients who were originally assigned to the S group, but who had not recorded and did not record for the second thirty-day period showed any significant change in CPAP use across the two follow-up periods, and this was only for mean hours of CPAP use on the nights CPAP was actually used. Patients in this sub-group increased their usage by about three quarters of an hour on those nights. Thus, there was a significant increase in hours of CPAP use for a group that had never self-recorded across the whole sixty days of the study. In addition, the sub-group that did record over the second follow-up period, did not significantly increase its CPAP use in that period from levels in the previous period during which its members did not self-record.

The failure to find significant differences in CPAP use among the sub-groups might have been due to the small numbers in each of the self-recording sub-groups. Thus, it was likely that there was insufficient statistical power to detect differences between the groups. Nevertheless,

there was little evidence that self-recording during the second 60-day period contributed to enhanced CPAP use.

This diminution in the effectiveness of self-recording is not surprising for several reasons. On the one hand, those in the self-recording group for the first 30-days and who had actually recorded had already established a relatively high level of CPAP use and were likely to have appreciated the health benefits of using CPAP by that time. Indeed their CPAP use did not decline markedly over the second 30-day period, suggesting that self-recording was not sustaining their behavior over that time, even if it had during the first 30-day period. Similarly, those who had been randomly assigned to the non-recording group for the first 30-days had established a pattern of CPAP use during that time. Although this pattern of use was not at the level of the “self-recorders”, it was still at a level likely to have provided some health benefits. Indeed, very few members of this group actually recorded during the second 30-day period, and those that did showed little enhancement in CPAP use, possibly due to “ceiling” effects.

The fact that some participants deviated from the experimental protocol to which they were randomly assigned had the potential for introducing uncontrolled bias into the 60-day follow-up results. In an attempt to eliminate this possibility a “compliers only” analysis was conducted. Results of this analysis showed a pattern similar to those discussed above. Repeated measures ANOVA demonstrated that CPAP use by participants who self-recorded for the first thirty days and discontinued

thereafter tended to decline at 60-days, while CPAP use by those who initially did not self-recorded, and then self-recorded for the second thirty days tended to increase. However, the relative change in usage between the two groups across follow-up periods was not significant.

There were no significant differences between compliers in the S and NS groups on any of the baseline severity, demographic or questionnaire variables, with the exception that significantly more of the NS compliers were prescribed an humidifier at baseline. In addition, they did not differ significantly in OSA self-regulation phase at either follow-up period. Thus, it appears that when compliers only were considered the resulting S and NS groups were essentially unbiased.

When protocol compliers were compared with protocol non-compliers a somewhat different pattern emerged. Not only did protocol compliers use CPAP significantly more than non-compliers at both 30- and 60-day follow-up periods, significantly more of the compliers were OSA self-regulated than the non-compliers at both follow-up periods. There were no other significant differences between the protocol compliers and non-compliers for any of the baseline severity, demographic, or questionnaire variables. These findings strongly suggest that OSA self-regulation was a crucial factor in participants' compliance with the experimental protocol. Thus, OSA self-regulated patients were more likely to comply with the experimental protocol, and hence self-record. In consequence they were

likely to gain some advantage in CPAP usage from their self-monitoring, at least during the first 30-day period.

Membership in the ‘as treated’ self-recording sub-group at the initial follow-up period was a significant predictor of CPAP use over the second follow-up period, whereas membership in the ‘as treated’ self-recording sub-group at 60-days was not. Membership in the ‘as treated’ self-recording sub-group at the first 30-day follow-up period accounted for 37 percent of the variance in percentage of nights on which CPAP was used over the second 30-day period. It also accounted for 34 percent of the variance in mean hours of CPAP use over the second 30-day period, and in mean hours of use on those nights when CPAP was actually used over that same period. These findings indicate that self-recording at an early stage of CPAP use is an important aid to developing both short- and long-term adherence. However, self-recording is not likely to be as effective if introduced later in time, especially not after 30-days of CPAP use.

Self-recording is usually introduced at the initial stages of behavior change programs with the expectation that it will be phased out as changes in behavior become more established (e.g., Burke, Dunbar-Jacob, & Hill, 1997; Kamarak & Lichtenstein, 1988). The current research shows that self-recording is positively related to CPAP adherence, if it is introduced and carried out when patients are initially adjusting to CPAP as a form of treatment for OSA.

Self-recording also has the benefit of being a simple and relatively cheap technique. However, several patients who were randomly assigned to the self-monitoring group did not actually self-record, even though they had volunteered to participate in the research and knew that they were expected to self-monitor and to present their recording sheets at follow-up. This finding suggests that if self-recording is to be used effectively to enhance CPAP adherence, patients' use of any self-recording device should be monitored by a health professional, especially in the early stages of CPAP use.

According to social-cognitive theorists (e.g. Bandura, 1986a; Zimmerman et al., 1999), self-recording focuses attention on behavior that is to be changed, and the antecedents and consequences of that behavior. In addition, it is thought to enhance motivation to persist in a behavior by providing concrete feedback that can be used to evaluate progress towards goal attainment.

It is not clear, however, from this research why self-recording was effective in enhancing adherence to CPAP. When asked about the perceived usefulness of self-recording as a method of enhancing CPAP use, only three of those patients who self-recorded said that they felt it helped them to focus on their behavior in relation to CPAP, and helped to keep them motivated to use the machine. Most of the rest said that they didn't find any benefit from the self-recording, and only did it because they were asked to do so as part of research participation.

*Self-Regulation and Adherence to CPAP*

The above observation leads to the question whether self-recording, rather than leading to the development of self-regulatory efficacy, results from it. That is to say, whether the patients who self-recorded did so in the main because they were OSA self-regulatory, or at the very least OSA compliant. The results from the protocol compliers versus non-compliers analysis indicate that the latter may well be the case.

Results at 30-day follow-up showed that differences in phase of OSA self-regulation as assessed by the OSASRDI accounted for 27 percent of the variance in percentage of nightly CPAP use, 41 percent of the variance in hours of nightly use across the 30-day period, and 46 percent of the variance in hours of nightly use on those nights when CPAP was actually used. These results are similar to those for the self-recording sub-groups at 30-day follow-up for percentage of nights on which CPAP was used, and mean hours of CPAP use across the follow-up period. However, the self-regulation phase accounted for 18 percent more of the variance in hours of nightly use on those nights when CPAP was actually used than did self-recording sub-group membership.

The relationship between self-regulation phase and CPAP use was generally in the direction hypothesized. Those who were OSA self-regulated used CPAP for 32 percent more nights over the period than those who were OSA acceptant. In addition, OSA self-regulated patients used CPAP for significantly more hours per night, and more hours on nights

when CPAP was actually used, on average, than both OSA compliant patients, and OSA acceptant patients. In addition, OSA compliant patients used CPAP on 22 percent more nights than did OSA acceptant patients. This difference is in the direction hypothesized and closely approached statistical significance ( $p = .06$ ). It is possible that a statistically significant difference was not detected due to the small number of subjects in each of the groups (OSA compliant,  $n = 7$ ; OSA acceptant,  $n = 8$ ). The trend in the data was in the direction hypothesized for the other two dependent variables, although for these variables, the differences between the OSA compliant group and the OSA acceptant patients did not approach statistical significance as closely. For these variables too, larger numbers of participants at each self-regulatory phase might have resulted in statistically significant differences between the compliant and acceptant patients.

The above findings suggest that attainment of the self-regulation phase at 30-days is at least as good a predictor of CPAP use at 30-days as self-recording. Indeed, self-regulatory status is somewhat better at predicting mean hours of CPAP use on those nights when CPAP was actually used. Therefore, it is possible that those patients who were OSA self-regulated, not only used CPAP more than those in the other phases of self-regulation, but because they were highly self-regulatory were more likely to self-record than other patients.

Path analysis confirmed these results. Comparing those patients in the S group who actually self-recorded for the first 30 days with those in the

NS group plus those in the S group who did not self-record, self-recording for the first 30-days directly predicted both OSA self-regulation phase at 30-days, and CPAP use over the same time period. OSA self-regulation phase at 30-days also directly predicted mean hours of CPAP use at 30 days. Taken together self-recording at 30 days, and self-regulation at 30 days accounted for 56 percent of the variance in mean hours of CPAP use at 30 days. CPAP use at 30 days, in turn, directly predicted, and accounted for 71 percent of the variance in, mean hours of CPAP use at 60 days. Thus, self-recording plays some role in the development of OSA self-regulation, and both self-recording and the development of OSA self-regulation appear to be crucial in increasing adherence to CPAP.

At 60-day follow-up, attainment of the self-regulation phase at 60-days was the best single predictor of CPAP use. It accounted for 23 percent of the variance in percentage of nights on which CPAP was used, 37 percent of the variance in overall mean hours of CPAP use, and 43 percent of the variance in mean hours of CPAP use on those nights when CPAP was actually used. Self-recording over this 60-day period did not significantly predict CPAP use.

It is also worth noting that of those patients who attended the 30-day follow-up, those who had had some self-involvement in their initial referral to the Sleep Laboratory were more likely to attend 60-day follow up than those who had no self-involvement in their referral. Similarly, those patients who had not been referred to the Sleep Laboratory solely by their

doctor were more likely to attend the 60-day follow-up than those who had been referred by their physician alone.

These findings indicate that some self-involvement in the ‘remedial process’ is important for long-term follow-up attendance, and, more importantly, that self-regulatory behavior in relation to OSA and CPAP is a major influence on long-term CPAP adherence. Indeed, attainment of the self-regulation phase at 30-day follow-up was a better predictor of CPAP use at 60-day follow-up than either self-recording at 30-days or at 60-days, or the interaction between self-regulation and self-recording at 30-day follow-up. The relationship between this interaction and CPAP use is discussed below.

CPAP is a treatment for OSA but not a cure. In addition, the beneficial effects CPAP use cannot be built up by sustained daily use. To be maximally effective, therefore, CPAP has to be used every night for the rest of the lifespan. The present research has shown that the development of self-regulatory behavior in relation to CPAP use is crucial in maintaining adherence to CPAP over a relatively long period of time (60-days). Thus, there is need to develop methods to enhance CPAP self-regulation in order to promote long-term adherence, as discussed later.

#### *The Relationship between Self-Recording and Self-Regulation*

In an attempt to clarify the relationship between self-recording and self-regulation in relation to CPAP adherence, the 30-day follow-up data were examined to assess whether there was an interaction between the two

variables. Although no relationship between self-regulation phase and self-recording group was evident at the outset or at 30-day follow-up, there was a relationship between self-recording sub-group and self-regulation phase at 30-day follow-up. For example, there were no OSA acceptant patients who actually recorded, but 7 OSA acceptant patients who were in the NS group. Similarly, there were relatively more OSA self-regulated patients in the group that actually self-recorded than in the NS group.

When the nature of the interaction was assessed, it was found that patients in the OSA self-regulated phase (both those in the self-recording group who actually recorded, and those in the NS group) used CPAP for significantly more hours per night across the follow-up period than patients who were OSA acceptant, and those in the S group who were OSA compliant but did not self-record. This result suggests that attainment of OSA self-regulation phase skill was more crucial to CPAP adherence than self-recording. On the other hand, for this dependent variable, OSA self-regulated patients who also recorded used CPAP for significantly more hours per night than OSA self-regulated patients in the NS group. This finding suggests that self-recording had an effect on CPAP adherence over and above self-regulation phase, at least as far as OSA self-regulated patients were concerned.

OSA self-regulated patients who also recorded did not use CPAP for significantly more hours per night than OSA compliant patients who also recorded, and OSA compliant patients who were in the non-recording group.

This suggests that, for these groups, there was no effect either of self-regulation or self-recording. However, nadir percent blood oxygen saturation (SAO<sub>2</sub>%) at baseline was a significant covariate of the self-regulation phase by self-recording sub-group interaction for this variable. When differences in baseline nadir SAO<sub>2</sub>% were controlled for, differences among the adjusted means showed that OSA self-regulated patients who recorded used CPAP for significantly more hours per night than both OSA compliant sub-groups. Nevertheless, OSA self-regulated patients in the NS group did not use CPAP for more hours per night than the two OSA compliant groups when nadir SAO<sub>2</sub>% was controlled for. These results also indicate that self-recording has a beneficial effect on CPAP adherence over and above self-regulation phase.

By contrast, OSA compliant self-recorders and those in the NS group who were OSA compliant showed no significant differences in CPAP use whether nadir SAO<sub>2</sub>% was controlled for or not. This finding suggests that for OSA compliant patients, self-recording does not make a difference in CPAP use. The results for these sub-groups must be approached with caution however, as there were very few participants in the OSA compliant by self-recording sub-groups, making it less likely that differences between the groups would be detected.

Those OSA self-regulatory patients who chose not to record used CPAP significantly less than all other OSA self-regulatory patients, regardless whether the latter self-recorded or were in the NS group. In

addition, those OSA self-regulatory patients who self-recorded used CPAP more than those OSA self-regulatory patients who were in the NS group. These outcomes indicate that for OSA self-regulatory patients, at least, self-recording can lead to enhanced CPAP use over and above other self-regulatory behaviors in relation to CPAP use.

Those patients who were randomly assigned to the S group, but who did not self-record generally used CPAP less than their OSA self-regulatory development phase equivalents, whether the equivalents were those of the S group who did self-record, or from the NS group. Indeed, average hourly CPAP use for OSA compliant patients in the S group who did not record was at about the same level of OSA acceptant patients in the NS group. CPAP use for both these groups was low: slightly over one hour per night, on average. In addition, patients in the S group who did not record used CPAP for about the same percentage of nights across the follow-up period regardless of OSA self-regulatory phase. The level of CPAP use measured by this variable was also low: about 60 percent of nights across the period. Thus, those patients who ‘opted out’ of self-recording tended to use CPAP at a similar sub-optimal level, regardless of OSA self-regulatory phase.

It is clear that for S group patients who ‘opted out’, the decision not to record was associated with low CPAP adherence, but it is not clear that ‘choosing not to record’ lead directly to low CPAP adherence. It is not clear either that the decision not to record lead to a failure to develop OSA self-

regulatory behavior. Indeed, two of these patients were assessed as being OSA self-regulatory.

It may have been that patients in the S group who did not record generally started using CPAP spasmodically at low rates, and did not record because they were unwilling to ‘objectify’ their lack of success with the treatment. Moreover, numbers in this subgroup were low so it is difficult to draw definitive conclusions about the effect of ‘opting out of recording’ on OSA phase development and adherence to CPAP.

In view of the design of the study, self-recording could not be used as a direct measure of self-regulatory behavior. The assessment of OSA self-regulatory development phase was made using questions directly related to attitudes about OSA, and reported behavior in relation to CPAP use. Thus, it was perfectly possible for patients to be judged as OSA self-regulatory in the absence of self-recording, as the results demonstrated.

Although two of the patients in the S group who did not self-record, and a relatively large percentage of patients in the self-recording group and the non-recording group were assessed as being OSA self-regulatory, there were qualitative differences in their self-regulatory behavior that lead to the differences in CPAP use. It is also possible that the OSASRDI did not include a large enough range of questions related to CPAP use upon which to judge OSA self-regulatory phase. If this were so, then the OSASRDI was not sensitive enough to make finer-grained distinctions relative to OSA self-regulation phase, and needs to be refined in this regard.

Although the experimental manipulation in this study involved the concrete act of self-recording, it was also possible for the non-recording group to self-monitor in other ways. For ethical reasons, all participants regardless of group to which they were randomly assigned were shown at the outset how to read the number of hours of CPAP use from the ‘digital window’ in the CPAP machine. This was not an arduous task. It may have been that some participants in the non-recording group, particularly if they were self-regulatory, checked their progress visually without recording it, although none admitted to doing so at follow-up. However, if it is assumed that OSA self-regulated patients in the NS group did implicitly self-monitor their CPAP use, then these results provide evidence that for OSA self-regulatory patients explicit self-recording is more likely to be associated with early-stage CPAP adherence than implicit self-monitoring.

The question of the direction of influence of self-recording and self-regulation cannot be fully resolved from the data. Nevertheless the 30-day follow-up results clearly show that patients who are OSA self-regulated and self-record do better in their CPAP use than most other patients. The combination of self-regulation phase and actual recording group status was the best single predictor of CPAP use. It accounted for 43 percent of the variance in percentage of nights CPAP was used, 60 percent of the variance in average nightly CPAP use across the follow-up period, and 59 percent of the variance in average nightly usage on those nights when CPAP was actually used.

*Baseline variables and CPAP use*

None of the baseline variables alone significantly predicted variation in CPAP use at 30-day follow-up. Only nadir percentage blood-oxygen saturation (SAO<sub>2</sub>%) in combination with self-regulation by self-recording sub-group significantly predicted CPAP use at 30-days (see above). Nadir SAO<sub>2</sub>% at baseline significantly predicted an additional 12 percent of the variance in mean hours of CPAP use across the follow-up period and an additional 11 percent of the variance in mean hours of CPAP use on the nights when CPAP was actually used. In general, when differences in baseline nadir SAO<sub>2</sub>% were controlled across the sub-groups, and differences in the adjusted means were analyzed, the pattern of the relationship between the sub-groups did not change, with the exception of those discussed above.

*Changes in CPAP Use and Self-Regulation Phase across the Follow-up Periods*

Generally the weekly pattern of CPAP use over the four week first follow-up period did not change from that established in the first week of use, either within the self-recording and self-regulation sub-group or between such groups. The exception to this conclusion is the group of patients who are OSA self-regulated but who chose not to record. Their CPAP use declined over the first four-weekly period. For those patients

who attended the 60-day follow-up their CPAP use did not change significantly from its level at 30-day follow-up.

With the exception of four patients, the others did not change their phase of self-regulation from 30-day follow-up to 60-day follow-up. This result, taken together with the fact that CPAP average weekly CPAP usage did not change much over time from its level at week one, indicates that OSA self-regulatory behavior and corresponding CPAP use tend to be established in the very early stages of exposure to CPAP. Support for the view that levels of CPAP adherence are established in the early days of CPAP use is provided by the work of Weaver and her colleagues (Weaver, Kribs, Pack, et al., 1997) who found that CPAP use in the first four days of exposure significantly predicted use at 30 days. The implication to be drawn from these observations is that, as with self-recording, if interventions are to be introduced to enhance the development of OSA self-regulatory behavior, and hence CPAP adherence, they should be introduced at least as early as the first week of CPAP use.

Although OSA self-regulated patients who self-recorded and those in the non-recording group for the first 30 days used CPAP, on average, at a level that has been shown to provide beneficial effects, those who were OSA compliant used CPAP at a marginal level, and those who were OSA acceptant used CPAP sub-optimally. Other than by self-recording, this study did not directly attempt to enhance patients' OSA self-regulatory behavior. However, Bonner, Zimmerman, Evans, Irigoyen, Resnick, and

Mellins (2002) have shown in the case of families who have a child with chronic asthma that disease self-regulative behavior could be developed in two main ways. The first was through the use of a family coordinator who maintained contact with the family and helped them to develop strategies including self-monitoring to overcome adherence problems. The second was by developing ameliorative strategies appropriate to phase of self-regulatory development the family was at. A similar intervention approach could well benefit OSA sufferers in their adherence to CPAP.

Zimmerman, Bonner, Evans and Mellins (1999) in testing their model of asthma self-regulation found that their postulation of four distinct but sequentially ordered phases of disease self-regulation was supported. These phases were asthma avoidance (i.e. families did not accept that their child had asthma or a disease), asthma acceptance (i.e. families recognized the chronicity of their child's asthma but were unwilling to seek medical help or take action to control the disease), asthma compliance (i.e. were willing to seek medical help and take limited action to control the disease), and asthma self-regulation (i.e. they monitored their asthma and adjusted their behavior to control their asthma as circumstances changed).

The present research did not find any OSA patients who were OSA avoidant. That is to say that all patients accepted that they had OSA, and, in general, that it was a serious problem for them. They also generally believed that, in theory at least, CPAP should be used every night to be beneficial. This is not a surprising finding, as all patients in this study had

attended a sleep laboratory, had just had the results of their overnight polysomnography explained to them by a health care provider, and had the detrimental health effects of OSA explained to them.

However, a three phase model of OSA self-regulation fit the data well. It should be noted that patients in the OSA acceptant phase had sought medical advice, but they tended to take little action to control their OSA. For example, they tended to find the CPAP mask uncomfortable and make little effort to adjust it, or seek to relieve any nasal stuffiness or oral dryness as a result of using CPAP. OSA compliant patients generally did take some action to relieve any discomfort, but often tended to 'just put up with it'. They also tended not to take the CPAP equipment with them when they traveled, nor adjust their CPAP use to changes in daily routine. OSA self-regulatory patients did employ various strategies to make the mask more comfortable, including trying different types of masks. They also tended to take the machine with them when they traveled, even if they traveled overseas. They were also able to adjust their CPAP use to changes in routine, and if they lived with a spouse or partner, to use feedback to enhance their CPAP use. Thus, this research generally extends the model of disease self-regulation developed by Zimmerman and his colleagues (1999) to the area of OSA.

Zimmerman, Bonner, Evans and Mellins (1999) argued that their results implied that to be successful, a self-management program firstly needs to identify an individual's stage of self-regulation, and then develop

interventions appropriate for that stage of development. The present study lends support for that implication in the area of OSA.

It would be important to set up the equivalent of a family coordinator (see, Bonner, Zimmerman, Evans, Irigoyen, Resnick, and Mellins, 2002) who would act as a contact person for people newly using CPAP. This health professional should work with patients to assess their level of OSA self-regulation, and develop strategies to enhance OSA self-regulation appropriate to the patient's phase of development. For example, patients in the OSA acceptant phase could be given simple techniques to help overcome oral dryness (e.g. drinking water when they wake, or chewing gum). For patients in the compliant phase, suggestions could be given about ways to enhance mask comfort, and work around changes in schedule or location. Self-recording should be introduced to all patients and monitored in the early stages by the health professional.

#### *Barriers to CPAP use*

In general, the main reported barriers to CPAP use were: the discomfort of the mask when the CPAP system was in use; perceived nasal stuffiness and oral dryness that resulted from using CPAP; and the difficulty of using CPAP when traveling. For three people, the difficulty in using CPAP when traveling did not stem from any lack of portability of the machine, or any unwillingness to take it away from home. Rather the problem was that the patients vacationed at a location that did not have a source of electrical power (e.g., a camp site, and on board a yacht) for the

machine. It would be useful if CPAP machines could be developed with their own internal power source that would at least be sufficient for a few days use when external power sources are not available.

Although some patients said that they found nasal congestion and oral dryness barriers to CPAP use, others did not. Several participants reported that CPAP use had, in fact, helped to clear their nasal passages, and to reduce oral aridity. Some for whom oral dryness was a problem simply kept a glass of water by their bedside and took a drink when they woke each morning. They found this practice alleviated the problem.

Many patients managed to make adjustments to the mask or other CPAP equipment if they found it uncomfortable. For example, some used cream to ease chafing of the mask, while others adjusted the holding straps. One patient found the hose that delivered the air to the mask cold to the touch, so wrapped a sock around it to overcome this.

The ingenuity with which many of the participants overcame potential barriers to CPAP use suggests that an OSA patients' support group could be beneficial in helping patients in the early stages of CPAP use to overcome problems. The fact that 25 percent of initial enrollees in this study did not return for their 30-day follow-up visit, even though they were volunteer participants, suggests that such a support group might be difficult to organize and maintain. However, this might only be true of populations similar to the one sampled in this study.

### *Limitations of the Study*

One of the limitations of the study was that initial assessment of OSA self-regulatory phase did not occur until the first follow-up visit, 30-days after CPAP treatment had been instituted. Therefore, there was no baseline indication of participants' confidence levels about their ability to use CPAP prior to its introduction. The reason for this was that OSA self-regulatory phase has to be assessed after patients have had some experience of using CPAP.

Aloia and his colleagues (2004) have shown that self-efficacy at three months predicted 50 percent of the variance in CPAP use at three months. However, in that study baseline self-efficacy did not predict CPAP use. Nevertheless, self-efficacy has also been shown to be positively associated with the development of self-regulatory behavior. It may have been that those in the present study who were more self-regulatory and used CPAP more had higher perceived self-efficacy for CPAP at baseline than those who were less self-regulatory and used CPAP less. Weaver and her colleagues (2002) have developed an instrument for measuring OSA self-efficacy. Future research into OSA self-regulation and adherence to CPAP would benefit from the inclusion of measures of OSA self-efficacy at baseline, or at the early stages of CPAP use.

It may also have been that those who did not attend 30-day follow-up were less self-regulatory, or had lower perceived self-efficacy for CPAP adherence than patients who attended. Since these variables were not

measured at baseline it is impossible to tell whether this was the case or not. However, drop-outs from 30-day follow-up and 30-day follow-up attendees did not differ on any of the baseline variables that were collected. It would be surprising, therefore, if they differed only on perceived CPAP self-regulatory efficacy.

The relatively small number of patients who attended both follow-up periods presented a problem. Some sub-groups that were developed had exceedingly few participants. For example, there was only one OSA acceptant patient who was assigned to the recording group, but did not record, and two patients in both the ‘OSA compliant – NS’ sub-group, and the ‘OSA compliant – S who self-recorded’ sub-group. The small number of participants in some groups reduced the statistical power to detect differences among the sub-groups. Conversely, since statistical power was low, such statistically significant differences among groups and sub-groups as were obtained can be considered robust.

Similarly, it could be argued that because the numbers at follow-up were small, they were not representative of all patients who enrolled in the study. However, the fact that 30-day attendees and non-attendees did not differ significantly on any of the baseline variables suggests that those patients who attended follow-up were representative of the initial sample.

It is true that all participants in the study were volunteers, and therefore, may have been more motivated to use CPAP and attend follow-up than those who did not volunteer. This may account for the relatively high

number of participants who were assessed as being OSA self-regulatory at 30-day follow-up.

The sample may not have been representative of OSA patients in the general population. However, because of the nature of the population served by the Sleep Laboratory, the sample generally contained patients with severe OSA, as measured by their AHIs, nadir SAO<sub>2</sub>%s, and total ESS scores. The sample also tended to be severely overweight as shown by mean BMI. In addition, a large proportion of the sample attended the clinic to be screened for OSA before undergoing gastro-bypass surgery for obesity. The sample contained a large proportion of ethnic minorities, in particular Hispanics and African-Americans, and most of the sample were on Medicaid or Medicare. Therefore, the results of this study are generalizable to an ethnically diverse population of patients with severe OSA.

#### *General Conclusions and Future Research*

Engelman and Wild (2003) in their clinical review of the literature on CPAP adherence argued that the adoption of a biomedical, “compliance” model of behavior leads to efforts to increase adherence to CPAP that focus on biomedical determinants of continuing CPAP tolerance, such as disease severity, demographics, and physiological side effects, rather than psychological determinants. This biomedical focus has met with mixed results at best, and failure at worst.

The present study demonstrated that no clinical or demographic variable predicted adherence to CPAP. However, a psychological phase model of OSA self-regulatory behavior, together with self-recording, strongly predicted adherence to CPAP, both in the short and longer term. The research, therefore, provides empirical support for Engelman and Wild's (2003) view that in order to enhance CPAP use, the focus of such efforts should move away from the biomedical model and towards psychological models. In particular, this work has demonstrated the value of introducing self-recording, and other techniques to enhance self-regulatory behaviors at an early stage of CPAP use in order to increase adherence.

The present research has shown that such psychological techniques can be effective with ethnically diverse patients who have severe OSA. The development of self-regulatory behavior depends on a complex interrelationship of personal, behavioral, and environmental factors. Thus, sophisticated methods need to be employed in order to develop OSA self-regulation.

However, self-recoding is a simple and relatively cheap procedure. This is particularly important at a time when increasingly sophisticated computerized techniques are being developed to aid CPAP-use monitoring. It is possible that some of the patients in this study would not have had ready access to computers, nor sufficient expertise to use them. Therefore a simple, 'pencil-and-paper' method of self-monitoring such as used in this

study may be more cost-effective than more elaborate self-recording techniques.

The relationship between self-recording and the development of self-regulation was not entirely clear from the results of the present study. More work needs to be done to clarify this relationship. In addition, it should be emphasized that self-monitoring is but one component of self-regulation. As has been seen, OSA self-regulatory behavior can develop in the absence of self-recording. As well as self-monitoring, self-regulatory behavior includes, but is not limited to, elements such as: goal-setting; planning; and self-evaluation. This study did not assess differences between the groups on any of these factors. Further research is needed to see whether differences in any or all of these elements might account for differences in self-regulatory behavior and CPAP adherence.

As has been mentioned, an intervention program designed to increase self-regulatory behavior in relation to CPAP needs to be developed and tested. The intervention should include self-monitoring, and should be tailored to the self-regulatory phase appropriate for each individual. To this end, self-regulation phase should be monitored early in the intervention, and assessed at regular intervals. In conjunction with this, OSA self-efficacy needs to be assessed at baseline, and at follow-up. The intervention program could be implemented by a coordinator (e.g., Bonner, et al., 2002) who could model appropriate OSA self-regulatory behaviors and monitor participants' self-recording.

## Appendix A

### **Self-recording in the Treatment of OSA – Recruitment Protocol.**

My name is Roger Peach, and I am a Doctoral Student in the Educational Psychology Department of the City University of New York. I am collaborating with Dr. Basner, the Director of the Sleep Laboratory here at Columbia Presbyterian Hospital. I would like to talk to you about a research study I am doing, and then ask you if you would be willing to participate in it. You do not have to participate in it, and if you decide not to, your treatment here at Columbia Presbyterian will not be affected in any way. Do you have time and are you willing for me to talk to you about the research?

If ‘Yes’, continue as below. If ‘No’, then “thank you very much for letting me mention the research to you.”

I am inviting you to participate in a research study that is trying to find out what problems, if any, people might have in using the CPAP machine and mask. That’s the machine and mask like the one you used last night. And also whether recording the number of hours you use CPAP for each night, and how awake or sleepy you feel the next day helps you to keep on using CPAP.

You qualify as a possible participant in this study because from your sleep study last night, you have been found to have obstructive sleep apnea, and the CPAP treatment you had last night (the mask and the machine) was successful.

If you participate in this research, you will be provided with a CPAP machine that monitors the number of hours you use it for every night, but that will not affect your treatment in any way. If you choose not to participate your treatment will be exactly the same, except you won’t have a machine that monitors your nightly usage.

If you agree to participate, I will ask you to bring the machine back with you when you come for your follow-up visits so that I can download the data from it onto our computer. You would be expected to make the first follow-up visit as part of your treatment whether or not you participate in the study. There will be two follow-up visits, 30-days and 60-days after you receive the machine. The follow-up visits will be scheduled during regular clinic hours, and you will first see a sleep physician, and then I would like to ask you some questions about how you got on with CPAP. Each follow-up visit should take about an hour.

## Appendix A (continuation)

If you agree to participate, you will also be put into one of two groups, by chance. One of the groups I will ask to record the number of hours they use the machine for each night and how alert they feel the next day, on sheets I'll give them, for the first 30-days, and then for the second 30-days I will not provide recording sheets. For the second group, I won't provide sheets for the first 30-days, and won't ask them to record, but I will provide them with sheets and ask them to record for the second 30-days. I will explain how to use the recording sheets, if you agree to participate in the study.

If you agree to participate, I would also like to ask you some questions this morning about your sleeping or breathing problem, and how it has been affecting you and your family. It should take about 20 – 30 minutes.

There should be no risks to you for participating in this research. The only drawback is the extra time and effort you will spend answering my questions and monitoring your CPAP use, and bringing your machine back to be downloaded, as well as the extra 60-day follow-up visit.

You can discontinue your participation in the study at any time, and your treatment here at Columbia Presbyterian Hospital will not be affected.

Do you have any questions at this stage?

Do you think you might be willing to participate in this research? If you think you might be, then I will give you a consent form to read (see below). Please read it, and feel free to ask me any questions you have about it. If, when you have read it, you are still willing to participate in the study, then I will ask you to sign it. If you sign it, I will then ask you some questions about your sleep/breathing problem, and ask you to draw lots to see which group you will be assigned to.

(If unwilling to participate then: “thank you very much for letting me talk to you, and taking up your time. I appreciate it.”)

(If the informed consent form is signed) – I would now like to ask you some questions. You don't have to answer any question if you don't want to, and you don't have to give me a reason for not answering.

(ADMINISTER BASELINE QUESTIONNAIRE)

Thank you for answering my questions. Do you have any questions you'd like to ask me at this stage?

## Appendix A (continuation)

Now, I'd like you to take a slip of paper from this envelope to see which group you'll be in as far a recording for yourself the number of hours each night you use CPAP for.

**(If the 'Non-Recording' slip is drawn, then).** You don't have to record your CPAP usage for the first 30-days. I will explain about recording your usage when you come back in 30-days.

**(If the 'Recording' slip is drawn, then).** You've been chosen to monitor your CPAP usage for the first 30-days. I'd like you to use these forms (give forms). I'll explain how I'd like you to use them.

I'd like you to put your name on the sheet, and the date when you receive your CPAP machine. When you get your CPAP machine, I'd like you to use it normally the first night, and then the next morning see how many hours you used it for. The machine will show you the number of hours. They should appear in the window on the top of the machine. I'd then like you to circle the number on the upper scale corresponding to the number of hours you used the machine for, to the nearest whole hour for 'Day 1'. If you used the machine for more than 8 hours, please write the number of hours you used the machine for at the end of the scale for that day. Then I'd like you to just go about your day s you would normally, and then when you go to bed at night circle the number on the lower scale corresponding to how alert you felt during the day. If you felt very wide awake and full of energy you might circle an 8 or a 7. If you felt very sleepy, and maybe even fell asleep, you might circle a 0 or a 1. For something in between, you might circle an intermediate number. Please don't go beyond 8 on this scale. I would like you to do that every day for the 30-days after you receive your machine. Do you have any questions about that?

**Then for all participants.**

I will tell the Administrative Officer that you are participating in the study. She will arrange with the company to bring you a downloadable CPAP machine. The company will contact you by phone to arrange a time to set up the machine at your home. The company representative will show you how to set up the machine and mask. Please ask the representative to show you where the number of hours you use the machine is shown, and that the machine is downloadable. When you have received your machine, please call our Administrative Officer to schedule your 30-day follow-up visit. You should have your machine in a few days. If you have not heard from the company in a week's time, please call our Administrative Officer to

check what is causing the delay. If you have any problems with the machine or the mask you can call the Lab. Here, and/or the company who supplied  
Appendix A (continuation)

the machine. You do not have to wait until your 30-day follow-up visit to deal with any problems.

Thank you for participating, and giving up your time to talk with me today.

### **Informed Consent Form**

My name is Roger Peach. I am a Ph.D. student in Educational Psychology at the Graduate Center of the City University of New York. In order to complete the requirements of my degree, I am conducting a research study in which I would like you participate.

The purpose of the study is to find out the problems people have in using the CPAP mask and machine to help them deal with their sleep apnea, and how they overcome these problems. I would like to ask you some questions about your experiences with the CPAP mask and machine. The whole interview should take about 30 minutes.

Your participation is entirely voluntary. You can stop at any time if you wish, and you do not have to answer any question if you don't want to. If you refuse to participate in, or withdraw from, this study your medical care at Columbia-Presbyterian Medical Center, either now or in the future will not be affected.

You will not be identified by name in the study. All records of this study will be kept in a locked cabinet, and will only be accessible by me, Dr Robert Basner, Director of the Columbia University Cardiopulmonary Sleep and Ventilatory Disorders Laboratory, and my graduate advisor, Professor Barry J. Zimmerman, in the Educational Psychology Program at the Graduate School, City University of New York.

You will be somewhat inconvenienced by having to spend time on the interview, but no other risks or inconveniences are associated with the study. You may or may not benefit personally from the study, but its benefits to society may include more knowledge about how to make using the CPAP mask and machine easier.

If you have any questions about this research, please ask, and I will do my best to answer them. If you have any questions in the future you can reach me, Roger Peach at (917) 4594-663, or Dr. Basner at (212) 305-8625, or Professor Zimmerman at (212) 817-8285. If you have any questions regarding your rights as a participant in this study, you can contact Hilry

## Appendix A (continuation)

Fisher, Sponsored Research, Graduate Center/City University of New York,  
(212) 817-7523.

## CONSENT TO PARTICIPATE IN THIS RESEARCH

Study Title: An investigation into the barriers to the use of continuous positive airway pressure (CPAP) as a treatment for obstructive sleep apnea: A self-regulation approach.

Informed Consent: I, \_\_\_\_\_, agree to participate in this research project. I have read the description of the study. I understand that I can end my participation at any time during this study without penalty. I understand that I will receive a copy of this consent form. I understand and agree to all terms and conditions

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Name (Print) (Signature) (Date)

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(Signature of Researcher) (Date)

## Appendix B

**Baseline Patient Questionnaire**

I.D. Number: \_\_\_\_\_

Date of Birth:        /        /         
                  MM      DD      YY

Gender:    Male    Female

1.        When did your problems with sleep apnea or breathing begin?  
How did it start?
  
2.        What did you think the problem was?
  
3.        What made you decide to seek medical help for this problem?
  
4.        What kind of treatment for the problem have you had so far?
  
5.        How is this problem affecting you and your family?
  
6.        How do you feel about that?
  
7.        Has this problem affected your ability to work or carry out tasks of  
daily living?
  
8.        How do you feel about that?

## Appendix B (continuation)

9. What worries you most about your sleep (breathing) problem?
10. Do you have any other health problems?
11. Which of your health problems concerns you the most?
12. Which concerns you the least?
13. On a scale of 1-10, with 1 being least serious and 10 being of most serious, how serious a problem do you think your sleep apnea is?
14. What would you like to do now that you can't do because of this problem?
15. Some people try different ways to sleep better at night or stay awake during the day. What, if anything, do you do?
16. Have you ever been treated with a pump that provides air to you through a mask that you wear at night?

Yes

No

## Appendix C

## The Good Sleep Checklist

Name: \_\_\_\_\_ For week beginning: \_\_\_\_/\_\_\_\_/\_\_\_\_  
MM DD YY

**Please fill out the checklist twice a day. Each morning, read the hours that the CPAP mask was working properly from the machine, and mark the nearest hour on the checklist. Each evening, mark down how awake you felt during the day, using the scale below.**

0 1 2 3 4 5 6 7 8  
Very sleepy Wide awake  
all day all day

Day 1 morning	Hours of CPAP	0	1	2	3	4	5	6	7	8
Day 1 evening	Sleep-Awake	0	1	2	3	4	5	6	7	8

Day 2 morning	Hours of CPAP	0	1	2	3	4	5	6	7	8
Day 2 evening	Sleep-Awake	0	1	2	3	4	5	6	7	8

Day 3 morning	Hours of CPAP	0	1	2	3	4	5	6	7	8
Day 3 evening	Sleep-Awake	0	1	2	3	4	5	6	7	8

Day 4 morning	Hours of CPAP	0	1	2	3	4	5	6	7	8
Day 4 evening	Sleep-Awake	0	1	2	3	4	5	6	7	8

Day 5 morning	Hours of CPAP	0	1	2	3	4	5	6	7	8
Day 5 evening	Sleep-Awake	0	1	2	3	4	5	6	7	8

Day 6 morning	Hours of CPAP	0	1	2	3	4	5	6	7	8
Day 6 evening	Sleep-Awake	0	1	2	3	4	5	6	7	8

Day 7 morning	Hours of CPAP	0	1	2	3	4	5	6	7	8
Day 7 evening	Sleep-Awake	0	1	2	3	4	5	6	7	8

Comments:

## Appendix D

### **Protocol for Administering OSASRDI at Follow-up**

Thank you for coming back for your follow-up visit. I would like to ask you some questions about your experiences with the CPAP mask and machine. The whole interview should take about 30 minutes. Before we begin, I would like you to read, and if you agree to continue with the study, to sign a consent form which covers your ongoing participation in the study.

I want to remind you that your participation is entirely voluntary. You can stop at any time if you wish, and you do not have to answer any question if you don't want to. If you wish to withdraw from this study your medical care at Columbia-Presbyterian Medical Center, either now or in the future will not be affected.

You will be somewhat inconvenienced by having to spend time on the interview, but no other risks or inconveniences are associated with the study. You may or may not benefit personally from the study, but its benefits to society may include more knowledge about how to make using the CPAP mask and machine easier.

If you have any questions about this research, please ask, and I will do my best to answer them.

I would like to download the data from your CPAP machine, and then ask you the questions. (Then administer the OSASRDI Questionnaire.)

Thank you very much for answering my questions.

(If participant is in the 'Self-recording' group, ask permission to photocopy their recording sheets.)

(If participant is in the 'Non-self-recording' group, then give recording sheets and instructions for their use, as in "Recruitment Protocol")

Thank you very much for your continued participation in the study.

## Appendix E

**BARRIERS TO CPAP USE QUESTIONNAIRE****PHASE 1 - APNEA SYMPTOM AVOIDANCE**

(Note there are no questions for this phase – Participants whose answers to questions in Phase 2 indicate that they do not accept sleep apnea as a serious problem will be considered symptom avoidant)

**PHASE 2 - APNEA ACCEPTANCE**

Some people don't believe that failure to use CPAP every night might lead to hypertension and a heart attack. What do you believe?

Some people don't believe that failure to use CPAP every night might cut oxygen to the brain and lead to permanent damage. What do you believe?

Some people don't believe that failure to use CPAP every night might lead to sleepiness and a serious accident. What do you believe?

Some people believe that failure to use CPAP every night is alright because they think their sleep apnea is not a serious problem. What do you believe?

Some people believe that they don't need to use CPAP because their sleep apnea symptoms are gone. What do you believe?

Some people believe that they should use CPAP only when their sleep apnea symptoms are really bad. What do you believe?

Some people believe that they don't need to use CPAP every night because they don't really have sleep apnea. What do you believe?

Some people believe they no longer need to use CPAP every night because they have stopped snoring. What do you believe?

**PHASE 3 - APNEA ADHERENCE**

Some people don't use CPAP every night because it makes their nose feel stuffy. Is this true for you?

Some people don't use CPAP every night because it makes their mouth feel dry. Is this true for you?

Some people don't use CPAP every night because they still feel tired or fall asleep during the day. Is this true for you?

## Appendix E (continuation)

Some people don't use CPAP every night because they still feel depressed a lot of the time. Is this true for you?

Some people don't use CPAP every night because wearing the mask interferes with their sex life. Is this true for you?

Some people don't use CPAP every night because their general quality of life hasn't improved since they've used it. Is this true for you?

Some people don't use CPAP every night because the mask is uncomfortable. Is this true for you?

Some people don't use the CPAP machine every night because they forget to use it. Is this true for you?

Some people don't use CPAP every night because it makes a noise that stops them from sleeping. Is this true for you?

Some people don't use CPAP every night because the equipment is too much trouble to use. Is this true for you?

**PHASE 4 - APNEA SELF-REGULATION**

Some people can't remember and transport their CPAP machine when they travel? Is this true for you?

Some people don't feel able to use CPAP when they sleep in a room with an unfamiliar person? Is this true for you?

Some people can't adjust their CPAP mask when it is uncomfortable or not working properly? Is this true for you?

Some people can't adjust their CPAP use when they change their evening schedule or routine? Is this true for you?

Some people can't adjust their CPAP use when they arrive home late at night? Is this true for you?

Some people can't remind themselves to use CPAP when they fall asleep unexpectedly and wake up late at night? Is this true for you?

Some people can't use feedback from their spouse or partner to adjust and improve their CPAP use? Is this true for you?

## Appendix E (continuation)

Some people have trouble getting themselves to use CPAP when they are feeling depressed? Is this true for you?

## Appendix F

**BARRIERS TO CPAP USE QUESTIONNAIRE -  
RESPONSE CRITERIA**

**PHASE 1 - APNEA SYMPTOM AVOIDANCE**

(Note there are no questions for this phase – Participants whose answers to questions in Phase 2 indicate that they do not accept sleep apnea, as a serious problem will be considered symptom avoidant)

**PHASE 2 - APNEA ACCEPTANCE**

Some people don't believe that failure to use CPAP every night might lead to hypertension and a heart attack. What do you believe?

*Response Criterion:*

*Pass – I don't believe that/ I disagree/ No that's wrong/ I believe (think) it could lead to those things/ I know it can lead to those things. Or similar.*

*No Pass – I agree/ I don't believe it could lead to those things/ I'm not aware of the data/ the doctor says so, but I'm not sure. Or similar.*

Some people don't believe that failure to use CPAP every night might cut oxygen to the brain and lead to permanent damage. What do you believe?

*Response Criterion:*

*Pass – I don't believe that/ I disagree/ No that's wrong/ I believe (think) it could lead to those things/ I know it can lead to those things. Or similar.*

*No Pass – I agree/ I don't believe it could lead to those things/ I'm not aware of the data/the doctor says so, but I'm not sure. Or similar.*

Some people don't believe that failure to use CPAP every night might lead to sleepiness and a serious accident. What do you believe?

*Response Criterion:*

*Pass – I don't believe that/ I disagree/ No that's wrong/ I believe (think) it could lead to those things/ I know it can lead to those things. Or similar.*

*No Pass – I agree/ I don't believe it could lead to those things/ I'm not aware of the data/the doctor says so, but I'm not sure. Or similar.*

## Appendix F (continuation)

Some people believe that failure to use CPAP every night is alright because they think their sleep apnea is not a serious problem. What do you believe?

*Response Criterion:*

*Pass – My sleep apnea is a serious problem/ No, it is a serious problem/ I disagree. Or similar.*

*No Pass – I don't think it is a serious problem/ I agree/ I don't think it's a serious problem for me. Or similar.*

Some people believe that they don't need to use CPAP because their sleep apnea symptoms are gone. What do you believe?

*Response Criterion:*

*Pass – My symptoms have not gone and I still use it/ I know I have to use it every night even if I don't have the symptoms/ I'm getting better but I still use it/ I disagree. Or similar.*

*No Pass – I agree/ My symptoms are gone and I've stopped using it. Or similar.*

Some people believe that they should use CPAP only when their sleep apnea symptoms are really bad. What do you believe?

*Response Criterion:*

*Pass – You should use it all the time/ I disagree/ That's stupid. Or similar.*

*No Pass – I agree/ I have sometimes not used it when my symptoms were not severe. Or similar.*

Some people believe that they don't need to use CPAP every night because they don't really have sleep apnea. What do you believe?

*Response Criterion:*

*Pass – I know I have sleep apnea and I use it/ If you have sleep apnea you need to use it/ If the doctor tells them they have sleep apnea why wouldn't they use it?/ I disagree. Or similar.*

*No Pass – I agree/ I don't think I have sleep apnea. Or similar.*

## Appendix F (continuation)

Some people believe they no longer need to use CPAP every night because they have stopped snoring. What do you believe?

*Response Criterion:*

*Pass – I don't know whether I snore or not, but I still use it/ My partner says I've stopped snoring but I still use it/If I don't use it, I snore, so I try to use it/ I disagree. Or similar.*

*No Pass – I agree/ I never snored so I don't use it/ . Or similar.*

**PHASE 3 - APNEA ADHERENCE**

Some people don't use CPAP every night because it makes their nose feel stuffy. Is this true for you?

*Response Criterion:*

*Pass – It does (did) make my nose feel stuffy (dry, sore) but I still use it/ My nose is not as stuffy (dry) since I've been using it/ I don't have a problem with a stuffy (dry) nose/ Not true for me. Or similar.*

*No Pass – It made my nose stuffy (dry, sore) and I stopped using it/ It was too uncomfortable to use. Or similar.*

Some people don't use CPAP every night because it makes their mouth feel dry. Is this true for you?

*Response Criterion:*

*Pass – It does (did) make my mouth feel dry (sore) but I still use it/ My mouth is not as dry since I've been using it/ I don't have a problem with a dry mouth/ I just keep some water by my bed, and rinse my mouth when I wake up/ Not true for me. Or similar.*

*No Pass – It made my mouth dry and I stopped using it/ It was too uncomfortable to use. Or similar.*

Some people don't use CPAP every night because they still feel tired or fall asleep during the day. Is this true for you?

## Appendix F (continuation)

*Response Criterion:*

*Pass – I still use it/ I don't fall asleep during the day (feel as tired) since I've been using it/ I never fell asleep during the day before I had it, but I use it/ Not true for me. Or similar.*

*No Pass – I still feel tired (fall asleep), and I haven't been using it/ Or similar.*

Some people don't use CPAP every night because they still feel depressed a lot of the time. Is this true for you?

*Response Criterion:*

*Pass – I don't feel depressed and I use it/ I still use it/ Not true for me. Or similar.*

*No Pass – I have been feeling depressed (down, frustrated), and I haven't been using it all the time/ Or similar.*

Some people don't use CPAP every night because wearing the mask interferes with their sex life. Is this true for you?

*Response Criterion:*

*Pass – Not true/ You don't need to have the mask on to have sex/ I put the mask on afterwards/ My sex life has improved/ Or similar.*

*No Pass – I don't like the idea of having my partner seeing me in bed with the mask on/ It's not natural to have to but the mask on/ Or similar.*

Some people don't use CPAP every night because their general quality of life hasn't improved since they've used it. Is this true for you?

*Response Criterion:*

*Pass – My quality of life has improved/ I still use it even if I don't feel great some days/ Not true for me. Or similar.*

*No Pass – My quality hasn't improved much, and I haven't been using it/ Or similar.*

Some people don't use CPAP every night because the mask is uncomfortable. Is this true for you?

## Appendix F (continuation)

*Response Criterion:*

*Pass – It is (has been) uncomfortable but I still use it/ It was uncomfortable, but I adjusted it and it's fine now/ It was uncomfortable, but I got a new mask and it's fine now/ Not true for me. Or similar.*

*No Pass – I has been (is) uncomfortable, and I stopped using it. Or similar.*

Some people don't use the CPAP machine every night because they forget to use it. Is this true for you?

*Response Criterion:*

*Pass –I don't forget/ It's right there by the bed, how could you forget to use it?/ Not true for me. Or similar.*

*No Pass – Sometimes I forget (don't bother to) use it/ Or similar.*

Some people don't use CPAP every night because it makes a noise that stops them from sleeping. Is this true for you?

*Response Criterion:*

*Pass – There's no problem with noise/ The noise is sort of relaxing (soothing)/ It bothered me at first but now it's no problem/ Not true for me. Or similar.*

*No Pass – The noise stopped me from using it/ Or similar.*

Some people don't use CPAP every night because the equipment is too much trouble to use. Is this true for you?

*Response Criterion:*

*Pass – No it's not a problem to use/ Cleaning it is a problem, but I still use it/ Not true for me. Or similar.*

*No Pass – All the cleaning of the equipment (maintaining the equipment) is a hassle, and I don't use it/ Or similar.*

## Appendix F (continuation)

**PHASE 4 - APNEA SELF-REGULATION**

Some people can't remember and transport their CPAP machine when they travel? Is this true for you?

*Response Criterion:*

*Pass – I traveled with it and used it. It was no problem/ I went on vacation with it, and used it. Or similar.*

*No Pass – I don't take it when I travel because I'm afraid it will not work the same when I get back and I need it/ I didn't take it with me/ I went to Europe and they have a different system so I didn't take it/ I took it, but I couldn't use it (set it up) when I got there. Or similar.*

*Not applicable – I haven't traveled since I've had it. Or similar*

Some people don't feel able to use CPAP when they sleep in a room with an unfamiliar person? Is this true for you?

*Response Criterion:*

*Pass – I have done it. It was no problem/ I went on vacation with it, and used it. Or similar.*

*No Pass – I didn't like to use it when I was sharing a room with someone. Or similar.*

*Not applicable – I haven't had occasion to do this since I've had it. Or similar*

Some people can't adjust their CPAP mask when it is uncomfortable or not working properly? Is this true for you?

*Response Criterion:*

*Pass – I have adjusted it/ I have tightened (loosened) the straps/ I have adjusted the mask (got a new mask). Or similar.*

*No Pass – It's uncomfortable, but I still use it/ I couldn't adjust it, and I don't use it. Or similar.*

## Appendix F (continuation)

Some people can't adjust their CPAP use when they change their evening schedule or routine? Is this true for you?

*Response Criterion:*

*Pass – Not true for me/ I just keep it by the bed and use it/ Or similar.*

*No Pass – I sometimes forget to use it, if I'm late in, or have been doing something else. Or similar.*

*Not applicable – I don't change my evening schedule. Or similar*

Some people can't adjust their CPAP use when they arrive home late at night? Is this true for you?

*Response Criterion:*

*Pass – Not true for me/ I just keep it by the bed and use it/ Or similar.*

*No Pass – I sometimes forget to use it, if I'm late in, or have been doing something else. Or similar.*

*Not applicable – I don't change my evening schedule. Or similar*

Some people can't remind themselves to use CPAP when they fall asleep unexpectedly and wake up late at night? Is this true for you?

*Response Criterion:*

*Pass – Not true for me/ I have fallen asleep in front of the T.V. but I use it when I go to bed after that/ Or similar.*

*No Pass – Sometimes I don't put it on after I've fallen asleep in front of the T.V. Or similar.*

Some people can't use feedback from their spouse or partner to adjust and improve their CPAP use? Is this true for you?

*Response Criterion:*

*Pass – Not true for me/ My partner says I am better (have stopped snoring) since I have been using it, so I keep using it/ My partner reminds me to put it on if I forget. Or similar.*

## Appendix F (continuation)

*No Pass – My partner doesn't say anything about it/ I don't take any notice of feedback. Or similar.*

*Not applicable – No partner (significant other).*

Some people have trouble getting themselves to use CPAP when they are feeling depressed? Is this true for you?

*Response Criterion:*

*Pass – Not true for me/ I use it even if I am feeling depressed/ Or similar.*

*No Pass – I do feel depressed sometimes and don't use it. Or similar.*

*Not applicable – I don't feel depressed. Or similar*

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