AHRQ Grant Final Report

Title of Project:
Enabling Sleep Apnea Patient-Centered Care Via an Internet Intervention

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Abstract

Purpose: The objective of this project was to examine the effect of a novel “Internet intervention” for patients with Obstructive Sleep Apnea syndrome (OSA) that integrated a telemetry treatment device and an Internet-based portal that facilitates patient-centered, collaborative management for patients prescribed the gold-standard treatment of continuous positive airway pressure (CPAP).

Scope: CPAP adherence is disappointingly low, especially early in therapy. The key advantage to this intervention was that the patient could access educational and clinical data when they want to, allowing for patient-centered, collaborative care.

Methods: The project was designed as a randomized, controlled clinical trial—Usual Care group (UC, control) vs. myCPAP group (intervention). An important methodological advantage of the project was the objective measurement of CPAP adherence (“the amount of time CPAP is used at prescribed pressure”).

Results: Participation in the myCPAP intervention resulted in higher CPAP adherence at the two-month time point relative to participation in the UC group (3.5 ± 2.4 and 4.2 ± 2.3 hrs/nt; p=0.04; mean ± SD). Nightly CPAP adherence measured at the 4-month period was 3.9 ± 2.3 vs. 4.4 ± 2.4 hrs/nt (p=0.14) for the UC and myCPAP groups, respectively. However, at 2-months the groups did not differ on a number of outcomes, including sleepiness, depressive symptoms, vigilance, and OSA-related quality of life. It may be that the difference in amount of CPAP use of almost 1 hour per night is not large enough to have an impact on these measures.

Keywords: Behavioral Change; Continuous positive airway pressure therapy; Sleep apnea syndromes; Telemedicine; Treatment adherence

Purpose

The objective of this proposal was to examine the effect of a novel interoperable "Internet intervention" for patients with Obstructive Sleep Apnea syndrome (OSA) that integrated a telemetry treatment device and an Internet-based portal that facilitated patient-centered, collaborative management for patients prescribed the gold-standard treatment, continuous positive airway pressure (CPAP). The project specifically focused on two aspects of patient-centered care: patient self-management and providing access to medical information to patients and their care providers.

Poor treatment adherence with CPAP therapy is well-documented. Because it is well-known that adherence patterns are established very early in treatment, myCPAP was designed to provide new CPAP users with education and support they require to get started on CPAP. The overarching aim of the project was to examine the effect of this patient-centered, collaborative care "Internet intervention" on increasing CPAP adherence to a clinically meaningful level and to examine the potential mediators of this effect. The central questions that encompassed the conceptual and empirical contours of the study: Did the myCPAP intervention have an effect on the patient's experience of care, CPAP adherence, and OSA outcomes relative to usual care, and if so, what are the possible mechanisms that account for the effect? To answer these research questions, and in the process address fundamental intervention efficacy and cost issues in telemedicine, the randomized, controlled trial aimed to achieve the following goals:

Aim 1: To examine the effect of the myCPAP intervention compared to Usual Care on the patient's experience of the quality of patient-centered, collaborative care (as measured by the Patient Assessment of Chronic Illness Care and the modified CAHPS Clinician & Group Survey). The hypothesis was that, controlling for severity of OSA, participants in the myCPAP group will experience a higher level of patient-centered, collaborative care compared to the Usual Care group over the 4-month follow-up period.

Aim 2: To examine the effect of the myCPAP Internet intervention compared to Usual Care on level of CPAP adherence. The hypothesis was that, controlling for severity of OSA, participants in myCPAP will exhibit higher levels of CPAP adherence compared to the Usual Care group over the 4-month follow-up period.

Aim 3: To examine the effect of myCPAP, compared to Usual Care, on obstructive sleep apnea outcomes (e.g., OSA symptoms and OSA-specific health-related quality of life [HRQOL]). The hypothesis was that participants in the myCPAP group will experience greater measurable improvements in self-reported OSA symptoms and HRQOL from baseline compared to the Usual Care group over the 4-month follow-up period.

Scope

Patient-Centered Care for Chronic Medical Conditons. Per the Institute of Medicine (IOM), an essential component of quality medical care is patient-centeredness,[1] a component that historically has been both underappreciated and underutilized, despite being described as early as 1969 as "patient-centered medicine" by Balint.[2] The IOM issued ten design rules for redesigning health care, and several incorporating the critical role of patient-centered care, including: the patient as a source of control of that care; shared knowledge and the free flow of information; care based on a continuous healing relationship; and, customization of care based on patient needs and values.[1] At its core, patient-centeredness includes both a) the patient's experience of, and contribution to, medical care, and b) the presence of an effective partnership between clinician and patient (i.e., the clinician as a "collaborator"). This partnership is the product of a relationship in which the clinician's recommendations are informed by an understanding of the individual patient's needs and context to improve the patient's ability to act on the information provided. Further, an effective clinician-patient partnership is characterized by informed, shared decision making and development of patient knowledge and skills needed for self-management of chronic conditions.[3] In no small part, what is being described can be considered "collaborative management" or "collaborative care." [4] There is much overlap between patient-centered care and the widely discussed Chronic Care Model described by Wagner and colleagues as well.[5] There is much research to support a patient-centered approach to care: patients who are involved with their care decisions and management have better outcomes than those who are not.[6-9] Patient self-management, particularly for chronic conditions, has been shown to be associated with improvements in health status and decreased

utilization of services and has been identified as a priority area for transforming health care by the Institute of Medicine (http://www.ahrq.gov/qual/iompriorities.htm).[10, 11]

Health IT and Patient-Centered Care. Applications of health IT can help build a patient-centered health care system in which patients share information and control along with (i.e., in collaboration) their providers. Early experience confirms that when patients are given the chance to bridge the information gap between themselves, their health data, and their health care providers, many people enthusiastically take a more active role.[12] A recent review of 24 randomized controlled trials of "interactive health communication applications" for patients with chronic illnesses found preliminary evidence that the applications improved behavioral and clinical outcomes, as well as medical knowledge, social support, and perceived self-efficacy. For example, such an approach has had positive effect on health outcomes for patients with low back pain[13] and helped improve smoking cessation rates.[14]

Obstructive Sleep Apnea. OSA is a prevalent and serious medical condition characterized by repeated complete or partial obstructions of the upper airway during sleep (apneas and hypopneas, respectively). It is prevalent in 2% to 4% of working, middle-aged adults,[15] and an increased prevalence is seen in the elderly (approximately 24%),[16, 17] veterans (approximately 16%),[18] and possibly African Americans.[19, 20] Obesity is a major risk factor for OSA, as the risk of OSA increases significantly with increased weight.[15] Over 75% of OSA patients are reported to be more than 120% of ideal body weight.[21] Estimates of health care costs for OSA patients are approximately twice that of matched, healthy controls.[22] This increased cost of care is directly related to OSA severity and is evident several years prior to the diagnosis.[23] OSA is associated with shortened survival (i.e., higher mortality rate) in prospective studies of coronary artery disease patients[24] and community dwelling elderly,[25] as well as in several large retrospective studies.[26-28]

Medical and psychosocial consequences of OSA. OSA is associated with several cardiovascular diseases, most notably, hypertension, ischemic heart disease, heart failure, stroke, cardiac arrhythmias, and pulmonary hypertension. Compared to the general population, OSA patients have twice the risk for hypertension, three times the risk for ischemic heart disease, and four times the risk for cerebrovascular disease.[29-31] The evidence supporting the link between OSA and hypertension is compelling, with OSA now officially recognized as an identifiable cause of hypertension.[32] Evidence shows that OSA bears a dose-response relationship to hypertension independently of other known risk factors,[29, 33-36] the incidence of hypertension in apneic patients is as high as 53%,[37] and OSA is highly likely to be present in drug-resistant hypertension patients.[38]

Alterations in sleep architecture cause sleep to be nonrestorative, resulting in mildly to severely excessive daytime sleepiness (EDS). EDS and/or hypoxia secondary to OSA are associated with a number of neurocognitive, mood, and behavioral consequences, including lowered health-related quality of life (HRQOL),[39-41] impaired cognitive performance,[42-44] impaired driving ability (2 to 7 times increased risk of a motor vehicle accident),[45-47] dysphoric mood,[48-51] psychosocial disruption (e.g., more impaired work performance and productivity, and higher divorce rates),[52] and disrupted sleep and impaired quality of life of spouses of OSA patients.[53, 54]

Continuous positive airway therapy (CPAP). The goal of OSA treatment is the elimination of breathing events and snoring, maintenance of high blood oxygen levels and improvement of symptoms. Nasal continuous positive airway pressure (CPAP)[55] is the treatment of choice for this condition,[56] with meta-analytic reports of numerous randomized controlled trials showing that CPAP improves both objectively and subjectively measured daytime sleepiness[57] as well as health-related quality of life.[58] CPAP has been shown to normalize sleep architecture[54] and reduce blood pressure.[59] CPAP has been shown to normalize sleep architecture[54] and reduce blood pressure.[59]

CPAP Treatment Adherence. In the case of OSA treatment and management, the need for close patient monitoring using objective data is now considered standard practice per a 2006 American Academy of Sleep Medicine Practice Parameter report and review.[60, 61] The main reason for these standards are the near universally low CPAP adherence levels, estimated in the suboptimal range of 3 to 5 hours per night, while the standard prescription is for use whenever asleep (i.e., approximately 8hrs).[62, 63] **Consequently, there is general consensus among OSA researchers that the earlier patients are closely monitored and**

supported, before they establish unacceptable patterns of CPAP use, the more likely an intervention designed to improve and sustain adherence will be successful.[62, 64-66]

Methods

Study Design Overview. The design was a randomized parallel group trial with blinded evaluation that compared an Internet intervention based on the wireless telemonitoring of CPAP data (i.e., Internet-based positive airway pressure care, or **myCPAP**) versus a usual care CPAP treatment protocol (i.e., Usual Care, or **UC**). Subjects participated in the study by completing a sequence of six assessment and intervention phases: (I) recruitment, consent, and screening; (II) pre-intervention assessment; (III) intervention; (IV) post-intervention assessment; and (V) 4-month follow-up (Section D.4. below provides details on each phase). Participants underwent identical instruction and education on OSA and CPAP therapy and used identical CPAP units. Usual care was comprised of pre-determined clinical contacts while myCPAP was comprised of as-needed clinical contacts, based on objectively measured CPAP adherence and efficacy data and access to a patient-oriented Web site. The study was designed as a practical clinical trial that compared one clinical care method against another, with the goal of informing clinical decisionmaking.[67] It was comparing the effect of clinical care methods on a behavioral outcome (i.e., CPAP adherence) and was considered in large part a behavioral trial.

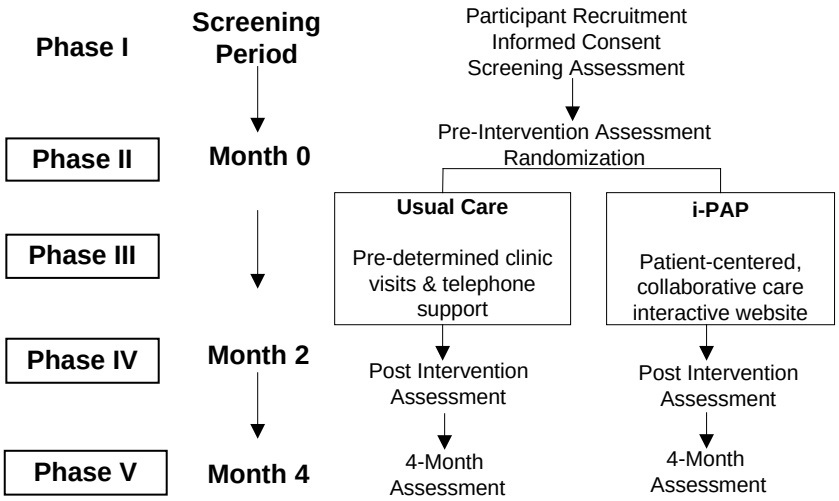

Figure 1: Overall Study Design

Study Participants. Two hundred and forty participants were planned to be recruited over the project period. A total of 555 potential participants were consented to contact and eligible for enrollment. The total enrolled was 241, with 115 to Usual Care and 126 to the myCPAP group). The total number of withdrawals during the course of the project was seven. These were due to CPAP intolerance and subsequent self-withdrawal from the study. Baseline rates of OSA patients with CPAP intolerance or refusal is estimated to be approximately 25% in clinical practice. In our project, this worked out to be approximately 3%, which appeared to be significantly lower. UCSD Medical Center was chosen as the primary recruitment site because of its status in San Diego County as the primary safety net provider, with an estimate of upwards of 45% of its patients being considered to be vulnerable. For our sample, vulnerable patients were defined as those who were of minority status, living in a household with income of less than $25,000, or had no insurance/were underinsured. Defined in that way, 44% of our sample was categorized as vulnerable.

Inclusion criteria. Our intent was to recruit a study population that was representative of the overall San Diego population of patients diagnosed with OSA. To this end, entry criteria were designed to be as inclusive as possible and were operationalized as follows: age $\geq$ 18 years; confirmed diagnosis of OSA; being newly prescribed CPAP therapy; having chronic symptoms as noted on screening symptom checklist; and fluency in English. OSA diagnosis by our VA Sleep Clinic has been and is currently consistent with published consensus statements [60] that CPAP treatment is indicated when the apnea-hypopnea index (AHI) is either (1) greater than or equal to 30 or (2) between 5 and 30 AND accompanied by documented sleep apnea symptoms, including excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, and documented cardiovascular diseases. Because mild OSA symptoms are, at best, modestly correlated with AHI, the research study focused on patients with moderate to severe sleep apnea, and therefore inclusion criteria required AHI to be greater than or equal to 15.

Exclusion criteria. Criteria for exclusion included residence in a geographical area outside of San Diego County (which could make regular contact difficult); fatal comorbidity (life expectancy less than 6 months as indicated by treating physician); significant documented substance/chemical abuse; or other participant circumstances that, in the opinion of a consensus of the study team, would interfere with the safety of a prospective participant or their need for treatment (i.e., clinical needs of patient outweighs needs of research study). No exclusion criteria or any other study design elements were used directly or indirectly to restrict study participation by women or members of minority groups. However, the project was unable to create a Spanish version and was therefore, limited to English speakers. Because men have a greater risk for OSA (and are identified and diagnosed at a greater rate) than women, a 4:1 ratio (men:women) was expected. Appendix 1 at the end of this document shows the enrollment table. The men:women ratio was in fact 2:1. The expected percentage of women was 20% while the actual percentage was 33%. Minorities were recruited approximately in the percentages expected (expected vs. actual): American Indian/Alaska Native (1.5% vs. 1.7%); Asian (8.0% vs. 9.2%; Native Hawaiian vs. Other Pacific Islander (0.5% vs. 0.0%); and Black or African-American (5.0% vs. 3.3%); while Whites were 85% vs. 84.6%. Participants from other (or unclassifed) races were not expected per original enrollment table, and per the study three (or 1.3%) participants reported their race as "other".

Procedures

Description of assessment and intervention phases. This section provides a detailed, sequential description of each of the five project phases during which all assessments and interventions took place. After informed consent was obtained, data was collected from study participants during the following phases: an Initial Screening Assessment (Phase I), at the Pre-intervention Assessment (Phase II), at the Post-intervention Assessment (Phase IV), and at the 4-month (Phase V). Figure 1 summarizes the overall study design by phase, project month, and activity. Data was also collected from chart review as part of the Phase I initial screening assessment.

Time frame. The maximum time required for each participant to be recruited into the study and complete the five assessment and intervention phases was 4 months. Participants were recruited and entered into the study at the approximate rate of 12 per month, with 6 participants assigned to UC and 6 assigned to myCPAP. We made every effort to keep to a minimum the amount of time from recruitment to intervention start so as to not prolong treatment start due to participation in this study. (Note: Our current work has shown that our research project routinely allows patients to start on treatment more quickly than they would have through normal clinical channels.) At a rate of 12 enrollees per month, it took approximately 17 months to complete enrollment. Project enrollment started in project month 3, and ended in project month 20. Given that each enrollee was part of the research study for 4 months (Phase I screening through Phase V, 4-month follow-up assessment), the first enrollee was completed in project month 7 (= project month 3 plus 4 months) and the last enrollee was completed in project month 24 (= project month 20 plus 4 months). This timeline allowed adequate time for recruiting each month and distributing the assessment and intervention workload over time. In addition, this timeline allowed for a small 3-month "cushion" should enrollment temporarily drop or should the project not get fully started at the beginning of month 3.

Phase I: Recruitment, Consenting, Screening Activities.

Location of Recruitment and Description of Sleep Apnea Population. Participant recruitment took place in the University of California, San Diego's (UCSD) Sleep Clinic, while central project activities were based in the Health Services Research & Development (HSR&D) Unit at VASDHS.

Randomization. Once patients agreed to participate in our study after completing the Phase II Pre-intervention Assessment, participants were assigned to UC or myCPAP using stratified randomization on both disease severity and on site (UCSD Sleep Clinic).

Phase II. Interventions.

Equipment. Because of its current availability, we used a wireless telemonitoring system developed by ResMed, Inc for this project. This study was designed to be an explicit test of a patient-centered, collaborative care Internet intervention, which, at its essence, was comprised of having daily access to CPAP adherence

and efficacy data and then acting on that data in a timely and effective way. In this way, patients were given access to their CPAP adherence and efficacy data.

For the provider Web-portal, we used the existing "Restraxx Data Center" (RDC), which is comprised of the Restraxx wireless module (which affixes to, and transmits data from, the CPAP flow generator) and the server/database, which houses the data and, fully compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), restricts access to authorized health care professionals. The wireless module connects to the flow generator via a docking mechanism that allows the connection to an existing 15-pin expansion port at the rear of the flow generator. The wireless module is approved by the U.S. Food and Drug Administration for use, and was approved for use in our pilot project by the UCSD Human Research Protections Program (HRPP). The Restraxx wireless module only fits compatible devices and, therefore, the Resmed S8 AutoSet flow generator unit and the associated humidifier unit was used in the study. The decision to use a humidifier at the outset of the study was based on the fact that most patients benefit from the option of using heated humidification,[68, 69] and we did not want this to become a confounding variable.

Patients randomized to UC were followed according to both the usual and standard care for OSA patients who are treated by the UCSD Sleep Clinic and by the published literature.[56] These standards include diagnostic sleep study, CPAP instruction and set-up by trained health care provider, and follow-up at pre-determined times (1-week, 1-month) by CPAP clinic staff. Beyond these pre-determined clinic contacts, patient were encouraged to call whenever they had a problem or concern. Adjustments or changes in the mask interface might be warranted at any point, so it is not uncommon for patients to switch from nasal to full-face masks or nasal pillows, for example. Pressure level changes are often warranted as well. If the patient brought in their CPAP unit, the data was downloaded and utilized.

Internet Intervention Positive Airway Pressure Group (myCPAP). The essence of the myCPAP intervention was (a) allowing both the patient and provider access to telemonitored adherence and efficacy data on a daily basis, (b) acting on that data collaboratively to guide CPAP management and troubleshoot problems early and effectively, and (c) emphasizing ways for the patient to express their preferences and needs. Below we describe both the patient and provider portals, which are set-up differently given the different needs of patients and providers. Patients randomized to myCPAP had objective CPAP data monitored as frequently as every day throughout the active 2-month treatment period. The frequency and nature of the clinical interactions was largely dependent upon patient-defined needs, subjective patient report of symptoms and progress, and the objectively measured nightly data values. The CPAP therapist assigned to carry out the myCPAP intervention was dedicated to myCPAP and had no contact with Usual Care participants. Every effort was made to minimize contact and discussions between the myCPAP therapist and the UC therapist.

myCPAP PATIENT PORTAL: The myCPAP patient portal for the intervention group consists of several components, all of which are designed with patient-centered, collaborative care as the central feature. These components are listed and described in Table 1. A dedicated myCPAP therapist could be contacted by the patients by telephone.

Table 1: Descriptions of the Components of the myCPAP patient portal

Component	Description
The Learning Center	Basic education to inform patients about sleep apnea, CPAP, and collaborative management.
My Charts	Easy-to-read charts that show adherence; efficacy data (disease severity and amount of air leak); and changes in weight, sleepiness, and physical activity over time.
Troubleshooting Guide	Interactive guide that allows patient to select the CPAP problem they are having; possible causes are discussed and solutions are listed.
My Assessments	This section includes both easy-to-complete individual items for patients to track (e.g., sleepiness level, weight, physical activity) and research questionnaires.
Sleep Apnea Resources	This component is comprised of two features: 1) a list of popular sleep apnea related Web sites (e.g.. American Sleep Apnea Association, National Sleep Foundation, and Medline Plus) and 2) sleep apnea news.

The myCPAP Provider Portal: We next describe the myCPAP provider portal, which was largely based on the Web site design created by ResMed, Inc as part of their Restraxx Data Center. The reason for this is that this portal is specifically designed for the provider that is managing a large number of OSA patients – should the intervention prove efficacious, we wanted a Web site that could handle large numbers of patients and have

broad appeal. Specifically, a calendar format with visual coding allows for the rapid inspection of "exceptions" (i.e., patients who are not well managed with CPAP). We provided great detail on the provider portal, because while we are emphasizing the patient's role in CPAP management (above), we cannot under-estimate the role that the CPAP provider can have in care management. This myCPAP intervention was unique in that essentially it provided both patient and provider with daily data on treatment adherence and efficacy. While the charts and pathways that were provided below would seem to indicate that the providers are the primary drivers of CPAP management, we wanted to make clear to the reader that our experiences to date clearly show that patients have control of the pace at which care progresses (i.e., by their initiative in contacting their provider by phone or returning phone calls). While our original intention was to include email contact, our local UCSD and VA research policies and procedures made it difficult to do it in a way that protected the privacy and confidentiality of the participants. Therefore, this component, along with forums for enrolled participants, were not included in this iteration of the intervention. The myCPAP intervention allowed the patients and providers to come together and act collaboratively with the best information each can have.

myCPAP Provider Parameters and Thresholds. Telemonitoring included review of both adherence and efficacy data. **Adherence data** provided detail on how many total hours the CPAP was used each night at therapeutic pressure. **Efficacy data** consists of both amount of mask leak (liters per minute) and apnea-hypopnea index (AHI: total number of apneas and hypopneas per hour of sleep). Thresholds for each parameter can be set for each patient using the password-secured, interactive Web site, the "Restraxx Data Center" (or RDC). The main purpose for setting these thresholds was to function as an aid for visual inspection of the data. The thresholds for each parameter were set to the following values per Table 2 at left.

Table 2: Threshold Specification for Each Parameter

Parameter	Threshold
CPAP adherence	< 4 hours/night
Apnea-Hypopnea Index	> 10 events per hour of sleep
Mask Leak	> 0.4 L/sec

Study Measures

Rationale for variable selection. The principal study goal was to determine whether the predictor variable (assignment to myCPAP vs. UC) was associated with differences in the patient experience of patient-centered, collaborative care, CPAP adherence and OSA outcomes post-intervention, and whether differences persisted at 4 months. Instruments used at each assessment are summarized in Table 3. The project questionnaire packet was comprised of a variety of measures, and we grouped them according to category of interest, per the specific aims of the study. Only one clinic was used for this study, so the CAHPS was modifed. The modified CAHPS was comprised of items 13-20; 23-25; DC1-7; CC1; DR1; and SD1-3 and was asked over the timeframe specific to the length of time in the study.

Table 3: Overview of Study Measures

Category	Measures	Screen	Base-line	Post-Interv.	4-mo Follow-up
Baseline					
	Demographics		X		
Demographics					
Sleep Study Outcomes	Sleep study data (e.g., apnea severity)		X		
Patient-Centeredness	Modified CAHPS			X	X
	Patient Assessment of Chronic Illness Care			X	X
	Patient preferences		X	X	X
OSA-related	OSA symptoms		X	X	X
	Epworth Sleepiness Scale (ESS)		X	X	X
	Pittsburgh Sleep Quality Index (PSQI)		X	X	X
	Sleep Apnea Quality of Life Index (SAQLI)		X	X	X
	Psychomotor Vigilance Task (PVT)		X	X	X
Social-Cognitive	Self-efficacy, Outcome expectations, & Social Support		X	X	X
CPAP Treatment	CPAP adherence		X	X	X
General HRQOL	SF-12; Quality of Well-Being-SA		X	X	X
Other	Center for Epidemiological Studies – Depression		X	X	X
	Self-reported physical activity		X	X	X
	Self-reported medical utilization		X	X	X
	Patient Satisfaction/qualitative interview			X	X

CAHPS = Consumer Assessment of Healthcare Providers and Systems; **CPAP** = continuous positive airway pressure therapy; **HRQOL** = health-related quality of life; **OSA** = obstructive sleep apnea

Results

Specific Aim 1: To examine the effect of the myCPAP intervention, compared to Usual Care, on the patient's experience of the quality of patient-centered, collaborative care (as measured by the Patient Assessment of Chronic Illness Care and the modifed CAHPS Clinician & Group Survey). The hypothesis was that, controlling for severity of OSA, participants in the myCPAP group will experience a higher level of patient-centered, collaborative care compared to the Usual Care group over the 4-month follow-up period.

Patient Assessment of Chronic Illness Care (PACIC). The PACIC was not assessed at baseline given that it was intended to measure differences of chronic illness (OSA) care. The two groups did not differ on this measure at either the 2-month or 4-month time point (see Table 4). For exploratory purposes, the scale was re-scored according to two alternative methods (1) the scoring method described in Glasgow et al (2005)[70] for consistency with the "5A approach," and (2) the scoring method described in a new study that factor analyzed the PACIC and suggested it was comprised of two factors: (a) shared-decision making/self-management (SDM) and (b) process of change (PC) (Taggart et al 2011). The two interventional groups did not differ on any of these alternative forms of PACIC subscales. Table 4 provides the means, SD and p-values for these analyses. Relative to other published studies of the PACIC in chronic illnesses, our PACIC total score was lower (2.4) than that obtained in those with diabetes in three separate studies (3.1[71]; 3.2[72]; and 3.2[70]).

Sleep Apnea Quality of Life Index (SAQLI). The SAQLI is an OSA-specific measure of health-related quality of life. It is comprised of several sections: (1) Domain A: 14-item measure of daily activities, social interactions, and emotional functioning; (2) Domain B: OSA symptom list; and (3) Domain C: treatment-related symptom list. At baseline, the SAQLI total score is comprised of domains A and B. Once on therapy, domain C is assessed and included in the total score. The two groups did not differ at baseline, which meant that randomization worked in that the groups were similar on the SAQLI total score and its subscales (see Table 4). However, the two groups did not differ at 2-months or 4-months on the SAQLI total score, or on any SAQLI subscale, meaning that the intervention did not have an effect on OSA-specific quality of life. That said, the SAQLI user manual suggests that a change of 0.1 is a clinically meaningful change. If this is indeed the case, then both groups improved a clinically meaningful amount (each improved by 0.2 points on the SAQLI total score).

Consumer Assessment of Healthcare Providers and Systems (CAHPS): The modified CAHPS overall score reflects patients experience with their healthcare providers. The two groups did not differ on this measure at either the 2-month or 4-month time point (see Table 4).

Table 4: Effect of group assignment on Patient Assessment of Chronic Illness Care, Sleep Apnea Quality of Life Index and Consumer Assessment of Healthcare Providers and Systems

		Baseline			2 month Visit			4 month visit		
Measure	**Subscale**	UC	myCPAP	p-value	UC	myCPAP	p-value	UC	myCPAP	p-value
PACIC - Total					2.4±0.9	2.4±0.8	0.93	2.6±1.0	2.4±0.9	0.36
	Patient Activation				2.6±1.2	2.7±1.0	0.65	2.8±1.2	2.8±1.0	0.72
	Decision Support				2.9±1.1	2.9±1.0	0.80	3.0±1.1	2.9±1.0	0.58
	Goal Setting				2.4±1.0	2.5±0.9	0.47	2.6±1.1	2.3±1.0	0.11
	Problem-Solving				2.7±1.3	2.5±1.1	0.41	2.7±1.4	2.6±1.1	0.65
	Follow-up and Coordination				1.9±0.9	1.9±0.9	1.0	2.1±1.1	1.9±0.9	0.34
SAQLI - Total		3.3±1.1	3.2±1.0	0.52	3.1±1.3	3.1±1.4	0.89	3.1±1.5	3.1±1.2	0.79
	Daily Activity	3.9±1.6	3.6±1.4	0.09	5.1±1.7	4.9±1.5	0.33	5.2±1.6	5.1±1.5	0.31
	Social	4.3±1.3	4.1±1.3	0.19	5.5±1.2	5.3±1.2	0.22	5.6±1.2	5.4±1.3	0.30
	Emotional	4.6±1.7	4.3±1.5	0.13	5.3±1.5	5.0±1.5	0.11	5.6±1.4	5.3±1.4	0.27
	Energy	3.5±1.8	3.1±1.5	0.06	4.9±1.8	4.6±1.8	0.29	5.0±1.9	4.9±1.7	0.52
	OSA symptoms	2.6±1.2	2.6±1.1	0.58	3.0±1.1	2.9±1.4	0.45	2.8±1.5	2.7±1.4	0.66
CAHPS					3.4±1.0	3.5±0.8	0.40	3.3±1.0	3.4±0.8	0.98

CAHPS = Consumer Assessment of Healthcare Providers and Systems; **PACIC** = Patient Assessment of Chronic Illness Care; **SAQLI** = Sleep Apnea Quality of Life Index

Specific Aim 2: To examine the effect of the myCPAP Internet intervention compared to Usual Care on level of CPAP adherence. The hypothesis was that, controlling for severity of OSA, participants in myCPAP will exhibit higher levels of CPAP adherence compared to the Usual Care group over the 4-month follow-up period.

Nightly CPAP adherence measured at the 2-month time point was 3.5 ± 2.4 and 4.2 ± 2.3 hrs/night (p=0.04) (mean ± SD) and at the 4-month time point was 3.9 ± 2.3 and 4.4 ± 2.4 hrs/night (p=0.14) for UC and myCPAP, respectively (see figure 2 and 3 below; figures include SEM bar).

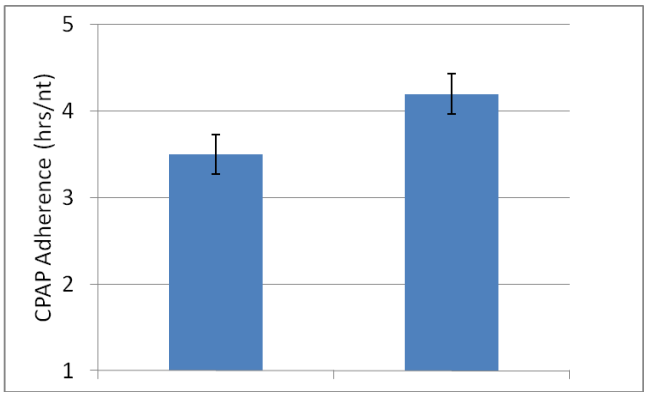

Figure 2: CPAP Adherence level (in hrs/nt) between UC and myCPAP at 2-months

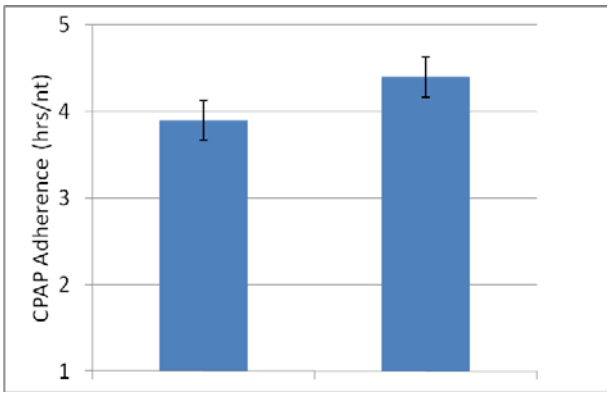

Figure 3: CPAP Adherence level (in hrs/nt) between UC and myCPAP at 4-months

We also examined the adherence data obtained across the first 14 nights for both groups. Night 1 CPAP adherence was 4.3 ± 3.4 and 4.5 ± 3.2 hrs/night (p=0.62) and Night 7 adherence was 3.5 ± 3.0 vs. 4.4 ± 2.9 hrs/night (p=0.03). This means that the randomization appears to have worked, given that no difference in adherence was seen between the groups on night 1 of CPAP use. However, after one-week (on night 7), the groups differed significantly on CPAP adherence, suggesting an intervention effect. See Figure 4 below.

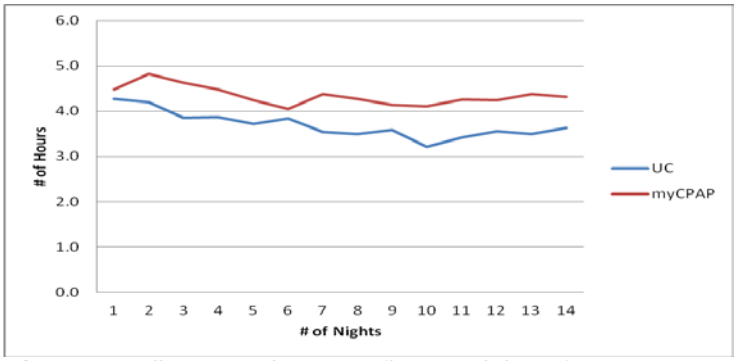

Figure 4: Adherence data over first 14 nights of CPAP usage

Specific Aim 3: To examine the effect of myCPAP intervention, compared to Usual Care, on obstructive sleep apnea outcomes (e.g., OSA symptoms and OSA-specific health-related quality of life [HRQOL]). The hypothesis was that participants in the myCPAP group will experience greater measurable improvements in self-reported OSA symptoms and HRQOL from baseline compared to the Usual Care group over the 4-month follow-up period.

There were no differences at baseline on any of the measured questionnaires, suggesting that randomization appeared to have worked (see Table 5 below). However, there were few differences at the 2-month and 4-month time points, suggesting that the intervention did not have an effect on these symptom measures. The significantly different values are bolded. Unexpectedly, at 4-months, the Epworth Sleepiness Scale was higher in the myCPAP group than in the Usual Care group. Both were in the normal sleepiness range of values, but the two groups still differed by 1.4 points with the myCPAP group rating slightly higher sleepiness levels. This difference may not be clinically meaningful. However, one explanation might be that the myCPAP group have

more interactions with their provider about tracking symptoms, and may have been more aware of their sleepiness levels than those in the Usual Care. In short, there may be a paradoxical effect related to greater awareness of sleepiness. This may be true for the findings related to the CESD as well. We have found the CESD to be a sensitive measure to treatment-related changes in OSA. Like the ESS findings in this study, those in the myCPAP group had statistically signficantly higher self-reported depressive symptoms than those in the Usual Care group (difference of approximately 1.5 points).

Table 5: Effect of group assignment on Epworth Sleepiness Scale, Obstructive Sleep Apnea Symptoms, Sleep Apnea Quality of Life Index, Pittsburgh Sleep Quality Index, Center for Epidemiological Studies-Depression, Psychomotor Vigilance Task, General Health, General Health Symptoms, and Quality of Well-Being

		Baseline			2 month Visit			4 month visit		
Measure	**Subscale**	UC	myCPAP	p-value	UC	myCPAP	p-value	UC	myCPAP	p-value
ESS		10.5±5.4	10.7±5.2	0.75	6.4±4.2	7.2±4.2	0.23	5.7±3.6	7.1±4.5	**0.02**
OSA Symptoms	Day	2.6±0.8	2.7±0.6	0.24	1.9±0.8	2.0±0.6	0.21	1.7±0.7	1.9±0.7	0.11
	Night	14.6±3.2	14.7±3.2	0.95	11.2±3.2	11.4±0.3	0.60	11.3±3.3	11.5±3.3	0.69
SAQLI	OSA Symptoms	2.6±1.2	2.6 ±1.1	0.58	3.0±1.1	2.9±1.4	0.45	2.8±1.5	2.7±1.4	0.66
	Treatment Symptoms				2.2±1.3	2.2±1.3	0.96	2.0±1.4	2.1±1.2	0.86
PSQI	Total	8.3±2.6	8.5±2.3	0.55	6.0±2.8	6.4±2.6	0.33	5.2±2.7	5.8±2.6	0.08
	Sleep Duration	1.1±0.6	1.2±0.7	0.39	1.0±0.7	1.0±0.8	0.81	0.6±0.7	0.7±0.8	0.38
	Sleep Disturbance	1.8±0.7	2.0±0.7	0.29	1.6±0.6	1.7±0.6	0.45	1.6±0.6	1.6±0.6	0.49
	Sleep Latency	1.2±0.8	1.1±0.8	0.60	0.9±0.8	1.0±0.9	0.70	0.8±0.9	0.9±0.8	0.42
	Daytime Dysfunction	2.1±0.8	2.2±0.8	0.65	1.3±0.8	1.5±0.7	0.13	1.2±0.8	1.4±0.8	0.17
	Sleep Efficiency	0.8±0.6	0.9±0.6	0.47	0.4±0.6	0.4±0.6	0.86	0.2±0.5	0.3±0.6	0.30
	Sleep Quality	0.6±1.1	0.6±1.1	0.68	0.5±1.0	0.6±1.0	0.47	0.6±1.1	0.5±1.0	0.87
	Use of Sleep Medication	0.6±1.0	0.7±1.0	0.87	0.3±0.6	0.3±0.5	0.92	0.2±0.6	0.4±0.8	**0.04**
CESD		11.0±6.0	11.4±5.2	0.67	8.2±5.3	8.8±5.4	0.40	7.1±4.9	8.6±5.5	**0.04**
Simple PVT	Total Mean	0.5±0.2	0.5±0.1	0.42	0.5±0.1	0.5±0.1	0.20	0.5±0.1	0.5±0.1	0.45
	False Start	0.7±1.2	0.7±1.1	0.97	0.5±0.9	0.5±0.9	0.93	0.4±0.8	0.6±0.1	0.25
	Major Lapse	0.3±1.4	0.09±0.3	0.08	0.1±0.4	0.1±0.5	0.95	0.1±0.3	0.6±3.9	0.21
Complex PVT	Overall	0.8±0.2	0.7±0.1	0.22	0.7±0.2	0.7±0.2	0.57	0.7±0.2	0.7±0.2	0.86
	False Start	0.1±0.4	0.1±0.4	0.70	0.1±0.4	0.2±0.7	**0.05**	0.1±0.4	0.2±0.4	0.65
	Major Lapse	0.1±0.5	0.1±0.5	0.92	0.1±0.5	0.0±0.3	0.29	0.2±1.3	0.2±0.6	0.90
	Incorrect Target	0.5±0.7	0.4±0.7	0.80	0.3±0.5	0.3±0.5	0.42	0.3±0.8	0.4±0.6	0.30
General Health		2.9±0.97	2.9±0.89	0.73	2.6±0.86	2.7±0.86	0.45	2.8±0.87	2.9±0.87	0.42
General Health - Symptoms		1.7±1.1	1.7±0.99	0.73	1.4±1.0	1.5±1.0	0.75	1.5±1.0	1.7± 1.1	0.13
QWB	QWB Total	0.7±0.11	0.7±0.13	0.47	0.8±0.16	0.8±0.15	0.13	0.82±0.1	0.78±0.1	**0.027**
	Acute and Chronic Symptoms	0.3± 0.10	0.3±0.11	0.60	0.2±0.15	0.2±0.14	0.18	0.18±0.1	0.2±0.1	**0.022**
	Mobility	0.0±0.00	0.0±0.00	0.73	0.0±0.00	0.0±0.00	0.32	0.0±0.0	0.0 ±0.0	n/a
	Physical Activity	0.0±0.03	0.0±0.03	0.44	0.0±0.01	0.0±0.02	0.31	0.0±0.02	0.0±0.01	0.85
	Self Care	0.0±0.01	0.0±0.01	0.20	0.0±0.00	0.0±0.01	**0.05**	0.0±0.01	0.0±0.00	0.87

CESD = Center for Epidemiological Studies – Depression; **ESS** = Epworth Sleepiness Scale; **PSQI** = Pittsburgh Sleep Quality Index; **PVT** = Psychomotor Vigilance Task; **QWB** = Quality of Well-Being; **SAQLI** = Sleep Apnea Quality of Life Index

Secondary Analyses:

1. CPAP Adherence

Table 6: CPAP adherence correlations with Questionnaires

CPAP Adherence		
Measure	**r**	**p-value**
CESD	-0.247	<0.001
ESS	-0.251	<0.001
SAQLI	-0.293	<0.001
OSA_Day	-0.311	<0.001
OSA_Night	-0.347	<0.001

Our group has been interested in the relationship between CPAP adherence level and outcomes. We took the opportunity to analyze the data across the entire group. The table to the right shows that higher CPAP adherence is significantly associated with lower sleepiness scores (ESS); depressive symptoms (CESD); improved OSA-related quality of life (SAQLI) and OSA symptoms both experienced during the day and at night. Not shown in the table was the fact that CPAP adherence was not associated with health-related quality of life (QWB) or patient-centered care (PACIC or modified CAHPS).

The Figure to the right shows a scatterplot of ESS and CPAP adherence, both measured at the 2-month time point. The line of best fit is included, and shows that the higher the adherence with CPAP, the greater the reduction in ESS.

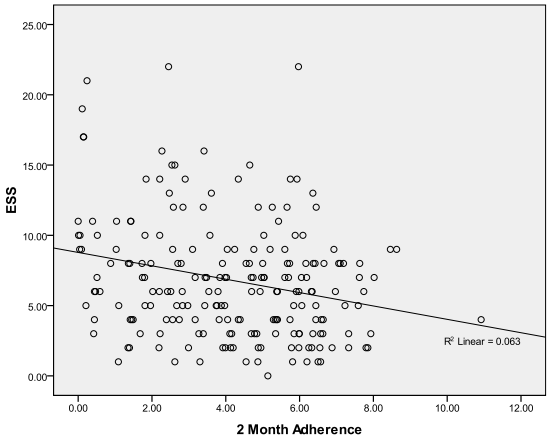

Figure 5: Scatter plot of CPAP adherence and ESS at 2-month timepoint, with line of best fit

2. Effect of CPAP on Sleep Quality

An interesting question that has come up during the course of the project is one of sleep quality while on CPAP. While it is expected that sleep architecture would be normalized based on published studies, there are some findings that suggest sleep architecture is not completely normalized in OSA patients prescribed CPAP therapy. The premise is that 1) CPAP is not used the entire night, so OSA can cause disruptions to sleep when therapy is not used and 2) even when CPAP is used, it may be that it can cause disruptions as well to sleep, possibly resulted in increased arousals, through suboptimal control of OSA.

To examine this issue, we first looked to the Pittsburgh Sleep Quality Index (PSQI) as a subjective measure of sleep quality. The PSQI has 2 relevant subscales: 1) sleep quality (one-item measure that asks, “during the past one month, how would you rate your overall sleep quality?”) and 2) sleep disturbance (9-item subscale that assesses how often have you had trouble sleeping because you . . .”). Each PSQI subscale is anchored with 0 = better and 3 = worse. Then, the responses to each specific item are tailored to that item. So, for example, the responses for the one-item sleep quality rating are: 0=very good; 1=fairly good; 2=fairly bad; and 3=very bad.

The following data are based on the total group of OSA patients. At baseline, 71.6% rated their sleep as “very good.” On CPAP therapy at 2 months, however, that percentage decreased to 62.2%. In other words, at baseline approximately 28% rated their sleep as less than “very good,” and on CPAP therapy at 2 months, that percentage increased to approximately 38%. The identical percentage at 2 months held at 4 months (approximately 38% rating their sleep as less than “very good”). This did not appear to differ by interventional group, and appears to be more related to CPAP therapy itself.

In terms of the sleep disturbance scores, not one of the 240 patients had a sleep disturbance score in the lowest (i.e., least disturbed, score = 0) group, leaving 3 levels of this subscale. At baseline, only 28% were in the lowest half of sleep disturbance (i.e., score = 0 or 1). At 2 months and 4 months, this percentage increased to 40% and 45% respectively. **However, this means that on CPAP therapy at 2 months, 60% of the group still had self-reported disturbed sleep, even while on CPAP therapy.**

3. Re-Scoring of the SAQLI

Careful attention to scoring instructions for the SAQLI revealed a potential improvement to the scoring methods for this questionnaire. Domain B concerns OSA symptoms. First, the participant is asked to indicate whether or

not they have experienced any of the 22 listed symptoms. There is also the opportunity to add symptoms that they might experience that are not on the list. Next, they are asked to list their top 5 most signicant symptoms (and they are allowed to provide 0, 1, 2, 3, 4, or 5 symptoms). For those up to 5 symptoms, they are then asked to rate how much of a problem each symptom has been over the last one month, with 1 = no problem and 7 = a very large problem. This Domain is then scored by summing the responses and dividing by 5. This methodology has the advantage of the number of symptom data, but has the unintended consequence reversing it! The following table shows the problem (keeping in mind that higher SAQLI scores, including in this domain, are associated with higher QOL/less problems) – it provides the case where the response is always 4. Regardless, those OSA participants who report identical level of ratings, but have greater number of symptoms, have a higher mean for Domain B. But more symptoms should be associated with lower SAQLI scores. It would appear that scoring the SAQLI per instructions would result in an artificially high SAQLI score.

Our group considered the obvious solution of simply using the number of reported symptoms as the denominator. However, this results in identical means when the responses are held constant across the varying number of symptoms. In other words, that potential solution explicitly does not take into consideration the number symptoms.

There does appear to be a solution in the form of a correction factor. One notices that the number of symptoms is the missing data, and by either adjusting the denominator or leaving it fixed does not work. Also, dividing by 1 does not work, nor does using a sum total score (given that this would be highly dependent on the reported number of symptoms). Given identical responses, what results are adjusted mean scores that are lower for higher number of symptoms. And this occurs in the same ratio as the original instructions, simply reversed. It is believed that this results in an improvement in the accurace of the scoring for SAQLI Domain B.

Table 7: Potential Improvement in the Scoring of SAQLI Domain B – OSA Symptoms

# items	Response	Sum	Mean (Sum/5)	Correction Factor	Adj Mean	
5	4	20	4.0	0.2	0.8	
4	4	16	3.2	0.5	1.6	
3	4	12	2.4	1.0	2.4	
2	4	8	1.6	2.0	3.2	
1	4	4	0.8	5.0	4.0	

Discussion

The main finding of the present study was that the myCPAP intervention resulted in higher adherence relative to the Usual Care group. This difference was almost 1 hour per night. However, the difference of one hour per night did not appear to result in a difference in the measured symptoms related to OSA when compared between the interventional groups.

The key advantage to the myCPAP intervention was the availability of resources important to the patient, including the Learning Center, the Troubleshooting Guide, and the data tracking. In the development of the myCPAP intervention, we ran into some issues related to what we could and could not do on the Web site, due to privacy and confidentiality concerns related to our local policies. These included (1) setting up an email contact system between patient and provider; (2) setting up a forum or bulletin board for enrolled participants; and allowing for greater tracking possibilities. Health-related behavior change is in large part modifiable due to several key behavioral change techniques, including: goal-setting, self-monitoring, peer support and efforts to increase self-efficacy. It may be that by not including peer support, the intervention lost out on a potentially efficacious component. In a previous studies of ours, a group self-management program had as one of its core components the peer support piece, and had a slightly larger effect. That study was limited by the ability of a clinic to enroll patients in a group format in a timely manner. The key advantage to the myCPAP intervention is the ability to provide OSA patients with the information they need, when they need it, which is consistent with a patient-centered, collaborative care approach. The myCPAP intervention provides the core of future interventional efforts using this technology.

This study also raised questions about the quality of sleep when using the gold-standard CPAP therapy for OSA. CPAP is generally considered efficacious when the residual AHI is less than 10 events per hour when on therapy. There are many well-controlled randomized trials of CPAP versus various forms of placebo to support

the efficacy of CPAP. However, true effectiveness studies have not been performed. A key limitation of CPAP therapy is how much it is used in clinic populations, and its suboptimal use is well-documented. Our study shows that in this large clinical sample, that self-reported sleep quality was low in 60% of the group, despite being using what is considered the most effective therapy for OSA. Remarkably few studies have specifically examined sleep architecture when using CPAP. The first study to do so found that CPAP did not have an effect[73]. Other studies have shown that some aspects of sleep architecture do improve on CPAP, including less stage 1 sleep and more rapid eye movement (REM) sleep (but no effect was shown on stage 2 sleep or deep sleep)[74].

The key issue for CPAP users is support. Many sleep clinics outsource the follow-up support to home health care companies. Low reimbursement is a key issue for conducting the necessary follow-up to help provide the support that is needed to allow for high adherence rates.

The dose-response studies that have been performed to date all suggest that to the extent that CPAP is used more, benefits increase. So, for example, our group published a study of CPAP users that found a linear relationship between CPAP adherence and improvement in apnea-hypopnea index (AHI), the arousal index (ArI) and the oxygen desaturation index (ODI)[75]. Weaver and colleagues found a linear relationship between CPAP adherence and improvements in subjective sleepiness (Epworth Sleepiness Scale) and objective sleepiness (multiple sleep latency test, as well as for functional outcomes related to sleep[76]. Importantly, across our total sample, we also found significant relationships between higher CPAP adherence and lower sleepiness, lower OSA symptoms, improved OSA-related quality of life, and lower levels of depressive symptoms.

The myCPAP Internet intervention did take advantage of wireless CPAP data transmission that allowed the provider to act on adherence and efficacy data in a timely, proactive way. This form of “telemonitoring” is not routinely available in clinical populations due to its cost. However, some home health care provider organizations are now offering this to each of their patients, so it would appear that a trend might be starting because of research projects such as this and other similar projects that show that these data are important for both patient and providers to use and act upon. When combined with research results that show that CPAP adherence patterns are established early in the treatment initialization process, the need for close telemonitoring early is very important. The principle of self-monitoring or tracking is a key component to behavior change, because in order to change a behavior, it is important to monitor the data that can show change.

Our main concern about CPAP therapy, and the impetus for this project, was that CPAP is used suboptimally in clinical practices. Our interventional group was designed to provide both automated and “live” support early in the CPAP initialization process. Unfortunately, clinical practices often do not follow patients even according to our Usual Care protocol (one-week phone call, one-month clinic visit). The main reason is because the large volume of new CPAP diagnoses takes precedence over the follow-ups. Based on the findings of this research study, it would appear that in order to obtain approximately 3.5 of hours of CPAP use per night (Usual Care group) at the 2-month time point, at a minimum a one-week phone call and one-month clinic visit with data download is required. To improve adherence, providing patients with extra education, clinical support, and behavioral change support is required. Our concern is that some clinics who are providing care that is less than that provided in the Usual Care group would result in adherence levels that do the patients a disservice, and in fact, make less than optimal use of health care resources. CPAP therapy is a complex medical regimen and requires appropriate education, clinical support and behavioral change support in order to maximize its potential as a therapy for the clinical management of OSA.

Conclusions

The myCPAP intervention has the potential to increase CPAP adherence over the short-term (approximately 2-months). The key advantage to such an intervention is that the patient can access educational and clinical data when they want to, and at a pace that is convenient to them, allowing for patient-centered, collaborative care.

Significance and Implications

Internet interventions, such as the myCPAP Web site for OSA, have the potential to “off-load,” or automate, some of the important clinical education and support components that may or may not be currently performed

by clinical staff. The fact that this Internet intervention can have a moderate effect on adherence with a complex treatment regimen is highly encouraging, especially in light of the fact that the intervention as implemented did not contain all of the possible components that might be make it more effective. Future research would do well to include some or all of the other components to make the intervention as robust as possible.

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Appendix 1: Enrollment Table

Study Title: **Enabling Sleep Apnea Patient-Centered Care Via an Internet Intervention**

Total Planned Enrollment: 241

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	5	18	23
Not Hispanic or Latino	76	141	217
Ethnic Category: Total of All Subjects *	81	159	240***
Racial Categories			
American Indian/Alaska Native	3	1	4
Asian	9	13	22
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	6	8
White	67	136	203
Other**	0	3	3
Racial Categories: Total of All Subjects *	81	159	240***

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”
**3 of the 239 participants marked Other as their racial category (1 reported “mixed”; 2 reported “other” but did not specific racial category
***1 of the 241 enrolled did not report ethnicity