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SCIENTIFIC INVESTIGATIONS

Effect of cloud-based sleep coaches on positive airway pressure adherence

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Study Objectives: Decreased early positive airway pressure (PAP) adherence is predictive of poor long-term adherence. We hypothesized that cloud-based sleep coaches (CBSC) providing protocol-driven live telephone contact with patients starting treatment would improve early adherence.

Methods: At PAP set-up patients were randomized to: (1) standard care (SC) including respiratory therapist PAP setup, wireless adherence monitoring, and elective use of a mobile adherence feedback application (PAPapp); or (2) SC+CBSC. Primary 3-month endpoints were adherence (all nights, nights used, % of nights ≥ 4 hours use, and % participants with ≥ 4 hours use on ≥ 70% of nights [% ≥ 4 ≥ 70%]) and secondary endpoints were change in Epworth sleepiness scale (ESS) and satisfaction with treatment and PAPapp use.

Results: Two hundred fifty participants were randomized (SC 126, SC+CBSC 124). Characteristics SC versus SC+CBSC (mean ± SD) for age (55.2 ± 13.4 versus 54.9 ± 11.5 years), diagnostic apnea-hypopnea index (36.7 ± 21.1 versus 36.6 ± 20.6 events/h), and ESS (10.8 ± 6.1 versus 11.2 ± 6.0) did not differ. At 3 months, the % of days with ≥ 4 hours of PAP use (SC: 48.1 ± 36.8% versus SC+CBSC: 57.9 ± 35.4%, $P = 0.032$), use all nights (SC:3.7 ± 2.7 hours versus SC + CBSC: 4.4 ± 2.6 hours, P=0.027), and PAPapp use satisfaction were greater with SC+CBSC (intention to treat analysis). The [% ≥ 4 ≥ 70%] did not differ between groups in the intention to treat analysis but was higher in those completing CBSC interventions. The ESS improvement and patient satisfaction did not differ between groups.

Conclusions: The CBSC system improved PAP adherence at 3 months.

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Early patient contact following the start of positive airway pressure (PAP) treatment to provide motivation and intervention for patient concerns is believed to improve adherence to treatment. The goal of this study was to determine if a systematic protocol to provide patient contact and support after PAP treatment initiation using cloud-based sleep coaches would improve PAP adherence compared to standard care.

Study Impact: The results of this study document that use of cloud-based sleep coaches can improve PAP treatment adherence when added to standard care after PAP treatment initiation.

INTRODUCTION

Positive airway pressure (PAP) therapy remains the first line treatment for obstructive sleep apnea (OSA).[1] While PAP treatment reliably reduces the apnea-hypopnea index (AHI), the effectiveness is limited by inadequate adherence in a substantial number of patients.[2–5] Maximizing adherence to PAP is a challenge, although strategies have shown promise in helping patients achieve an acceptable level of adherence to therapy. For example, a 2013 Veterans Administration (VA) Health Care System-based study indicated that peer (ie, patient to patient) driven intervention resulted in adherence and patient satisfaction that was greater than standard care.[6] A randomized controlled multicenter study involving a nurse-led management program resulted in adherence that was noninferior to a physician-led model,[7] indicating that properly trained nonphysician health care providers can help manage PAP treatment initiation in patients with OSA. Other studies have shown improvement in adherence using telemedicine, education, and motivational approaches.[8–10] Patient access to web-based information on their treatment has also been shown to improve adherence.[11–13]

In summary, patient engagement, management by nonphysicians, the use of technology and motivational enhancement all have demonstrated positive impact on adherence to PAP therapy.

Treatment of OSA in the VA Health Care System is challenging due to comorbid medical conditions and high demand relative to available resources.[14–16] A study of electronic medical records found the prevalence of OSA in the veteran population in 2018 was approximately 18% (over 1 million individuals).[15] A recent assessment of VA sleep services concluded that "most VA sleep programs are understaffed for their workload and have lengthy wait times for appointments".[15] Many VA sleep centers do not offer comprehensive sleep services.[16] Some VA systems outsource durable medical

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equipment (DME) services (PAP setup and interventions) to vendors in the private sector, whereas others have onsite respiratory therapists (RTs) that provide PAP setup and follow-up. The VA prosthetics service issues equipment and supplies directly to patients, to DME providers, or to in-house PAP respiratory services. Interventions for problems vary from dedicated sleep clinics with sleep physicians and RTs in more sophisticated programs to troubleshooting by prosthetics service clerks in less sophisticated systems. However, even in more comprehensive sleep programs, providing timely interventions for PAP issues and poor adherence is difficult. Remote monitoring of PAP adherence using wireless modems is increasingly used in VA sleep programs. The PAP wireless modems communicate with cloud-based programs that can be accessed by providers. Detailed adherence information, a residual device-identified AHI and leak estimates are available, and pressure changes can be performed remotely. However, unless available information about problematic adherence is noted and followed by an intervention, it cannot possibly improve PAP treatment outcomes. Using the wireless information is challenging given that CPAP RTs and sleep physicians are often busy providing clinic follow-up for an existing large population of PAP patients. Mobile applications (on telephone or computer) allow the patient to have daily feedback concerning their PAP adherence, mask fit, and treatment efficacy. This technology has the potential to improve adherence, but only if embraced by patients.

In the North Florida South Georgia VA health care system, most PAP care is provided at the Malcolm Randall VA Medical Center (MRMC) by sleep physicians and a cadre of VA RTs providing in-house DME services. Three peripheral sites offer only CPAP RT services (PAP treatment set-up and mask fitting). Diagnostic testing utilizes a combination of home sleep apnea testing and in-lab polysomnography (diagnostic and split night studies). Patients who are uncomplicated are usually started on auto-adjusting PAP or bilevel PAP devices without a preceding titration.[17,18] Polysomnography for PAP titration is used for complicated or very severe patients. Patients are setup on PAP devices in classes (3 to 6 patients) or individual appointments consisting of education, mask fitting, and setting PAP devices to the pressure ordered by sleep physicians. All devices contain wireless modems, and RTs monitor device information. Patients have telephone numbers to call for issues, and most patients are seen in sleep clinic within the first 3 to 12 months of treatment.

Although protocols are in place to react to problems with early adherence, the challenging overall workload and large number of incoming telephone calls from existing patients and difficulty contacting patients ("telephone tag") often results in absent or delayed interventions in patients with early poor adherence. Unlike the private sector, there is no requirement of adequate early adherence to enable individuals to continue to receive treatment in the VA system. If patients are not proactive in communicating PAP issues, interventions may be delayed for months after the start of CPAP treatment. Timely interaction with patients starting PAP treatment is especially critical as early adherence is predictive of long-term adherence.[19–22] Patient education and support delivered at the beginning of PAP treatment can improve PAP adherence.[23,24]

A patient adherence management service (PAMS, Philips Respironics, Murrysville, Pennsylvania) was introduced to provide communication and motivation for patients starting PAP treatment. The PAMS program relies on trained cloud-based sleep coaches (CBSC) to guide the patient through the process of initiating and becoming adherent to PAP therapy. The CBSC staff communicate with patients early in their PAP treatment and monitor early adherence, contacting the patient if adherence is not acceptable. Using motivational enhancement, they assist the patient in overcoming obstacles to adherence. Unresolved issues are escalated to cloud-based respiratory therapists (CB-RTs) or local providers based on provider-selected criteria. Assistance with using a mobile PAP application (PAPapp) named DreamMapper (formerly called SleepMapper, Philips Respironics, Murrysville, Pennsylvania)[12] is also provided.

We hypothesized that the addition of the CBSC service to standard care would improve early PAP adherence, self-reported sleepiness, and treatment satisfaction. A randomized controlled clinical trial was performed to test these hypotheses.

METHODS

A prospective randomized study design was used to compare two methods of follow-up after PAP treatment start: standard care (SC) and standard care plus the CBSC service (SC+CBSC). The primary study endpoints included nightly PAP adherence (all days), nightly adherence (days used), and the % of nights with use ≥ 4 hours and the % of participants meeting the Centers of Medicaid and Medicare Adherence Criteria[25] (≥ 4 hours of use on ≥ 70% of nights over 30 consecutive days during the first 90 days of PAP therapy).

Secondary endpoints included (1) improvements in self-reported sleepiness (Epworth Sleepiness Scale, ESS[26]), (2) patient satisfaction with treatment, and (3) satisfaction with use of the PAPapp. Patient satisfaction was to be determined via a participant questionnaire at 90 days (see supplemental material).

Initial screening and enrollment

At the MRMC, PAP education and device-setup classes (3 to 6 patients per class) are used to start PAP treatment on most patients with uncomplicated OSA. After diagnosis with home sleep apnea testing, diagnostic polysomnography (PSG) or split PSG, patients with uncomplicated OSA are routinely started on auto-adjusting CPAP or auto-adjusting bilevel PAP devices based on physician order. In all diagnostic testing, detection of hypopnea is based on a ≥ 3% arterial oxygen desaturation (or arousal if polysomnography is used).[27]

Consecutive patients attending the device set-up classes at the MRMC from 9/20/2017 to 12/20/2018 were informed about the study, and if they met inclusion/exclusion criteria and volunteered to participate, they were enrolled. Participants provided written, informed consent, and the project was approved by the University of Florida Investigational Review Board and the VA Human Research Protection Program. Inclusion and exclusion criteria are listed in **Table 1**. A total of 918 patients was screened (**Figure 1**) and 250 participants were

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Table 1—Inclusion and exclusion criteria.

Inclusions
• Age 21 to 75 years (men and women)
• Diagnostic apnea-hypopnea index ≥ 15 events/h (diagnostic polysomnography [PSG], diagnostic portion of split PSG, or home sleep apnea test)
• Eligible for treatment with automatically adjusting continuous positive airway pressure or bilevel positive airway pressure
• Residence in area covered by wireless network
Exclusions
• Participation in another interventional research study concerned with sleep disorders within the last 30 days
• Major uncontrolled medical condition that would interfere with the demands of the study, adherence to positive airway pressure (PAP), or the ability to commit to follow-up assessment including conditions such as poorly managed or controlled or advanced stages of pulmonary disease, cardiac disease, neurological disease, neuromuscular disease, cancer, and renal disease
• Prior PAP use within the previous 12 months
• Predominantly central apneas (≥ 50% central apneas) or Cheyne Stokes respiration (CSR) present during ≥ 20% of total sleep time
• Chronic respiratory failure or insufficiency with suspected or known neuromuscular disease, moderate chronic obstructive pulmonary disease, or any condition with an elevation of arterial carbon dioxide levels while awake or the requirement for continuous supplemental oxygen or mechanical ventilation
• Surgery involving the upper airway, nose, sinus, eye, teeth, or middle ear within the previous 90 days
• PAP therapy is otherwise medically complicated or contraindicated, such as those with a difficult to size or adjust interface (mask) resulting in facial pain, skin irritation or trauma, or excessive air leaks

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enrolled. Nearly all participants were PAP naive (99%), but if a participant had not used PAP treatment for more than a year, inclusion in the study was permitted.

Randomization

After undergoing screening and enrollment, participants were assigned to either SC follow-up or to SC+CBSC follow-up (**Figure 1**). A computer program controlling for potentially confounding variables generated the randomized treatment assignment. The randomization process was blinded (performed by the electronic data capture system [DATATRAK EDC, Mayfield Heights, Ohio] once the research coordinator clicked the "randomize" button). Randomization was stratified based on age (≤ 52, > 52 years) and AHI (≤ 30, > 30 to ≤ 50, > 50 events/h). The age cutoff is near the midpoint of the allowable age range in the protocol. The age and AHI cutoffs were based on information from previous adherence studies with a similar age distribution.

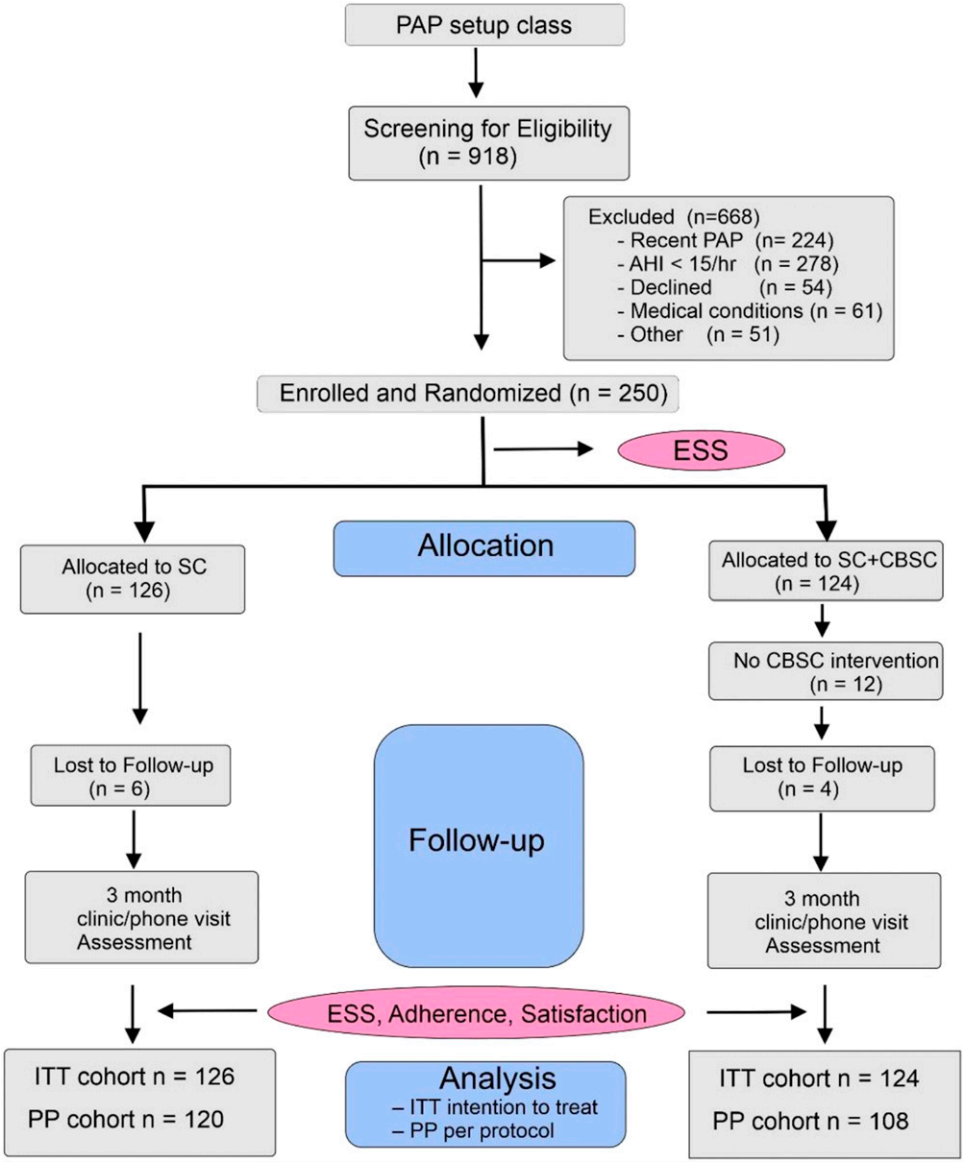
Standard care follow-up

Participants attending PAP setup classes were educated about use of their PAP device, including cleaning, ramp option, and humidification. All patients were encouraged to use therapy nightly for as long as they can, preferably for the entire time they sleep. Each participant was fitted with a mask based on physician order, participant preference, and the ability to obtain a good mask seal. The type of PAP device (auto-adjusting CPAP or auto-adjusting bilevel PAP) and pressure settings were determined by physician order. Participants practiced putting on their masks and turning on the PAP device. All devices were manufactured by Philips Respironics and contained wireless modems with information accessed via a cloud-based program (EncoreAnywhere [EA], Philips Respironics, Murrysville, Pennsylvania) that is password protected and compliant with Health Insurance Portability and Accountability Act compliant. Device data are uploaded into the EA database via wireless modems programmed to call in automatically. Device data are associated with the individual participant based upon the serial number of the device and modem entered by VA CPAP RT staff. All PAP devices had the ability to deliver heated humidification. At the PAP setup class, participants received information about the PAPapp (written information also supplied with each PAP unit). Participants were provided with telephone numbers for PAP supply replacement and for PAP treatment issues. They were also encouraged to use the secure messaging service "MyHealthy Vet" to facilitate communication with the sleep providers. Participants have a 6-week inspection of EA adherence and efficacy data if ordered by the physician reading the sleep study. Pressure settings can be changed remotely based on physician order. A participant may be scheduled for an individual mask fitting CPAP RT appointment if discomfort or leak issues are significant. A 3-month (90 to 120 days) sleep clinic visit with a sleep provider (physician or physician extender) was scheduled.

Cloud-based sleep coach follow-up

Participants randomized to SC+CBSC follow-up received all elements of standard care and, in addition, interaction/communication from the CBSC service. The CBSC follow-up program is outlined in **Table 2**. Participant contact information was entered into the EA database at the time of PAP setup, enrolling the participant in the CBSC program. The participants were informed that they would receive a telephone call from the CBSC system in 3 to 4 days to discuss their experience with therapy. Further contact from the CBSC could be expected if their adherence goals were not reached. All participants received calls on day 3 to 4 and on day 32 after PAP initiation. The participants were also provided with information on, and encouraged to use, the mobile application (PAPapp), allowing them to view their

Figure 1—Patient flow during the study.



Participants were recruited from a positive airway pressure (PAP) setup class and, if they met inclusion and exclusion criteria, were randomized to standard care (SC) or SC + the cloud-based sleep coach program (CBSC). In both follow-up arms, a few participants were lost to follow-up, and 120 participants in both groups completed the 3-month clinic or telephone appointment. The intention to treat (ITT) cohort included all participants randomized to a follow-up group. Due to operator error, 12 participants in the CBSC arm did not have timely sleep-coach telephone calls and were not included in the per protocol analysis. AHI = apnea-hypopnea index, ESS = Epworth Sleepiness Scale, PP = per protocol.

current adherence. Issues that could not be resolved by CBSC were escalated first to CB-RT and then to sleep providers at the MRMC, if indicated.

Data collection: baseline and 3-month clinic visit (SC and SC+CBSC)

At enrollment, age, sex, diagnostic AHI, height, weight (body mass index calculation), the ESS,[26] and a brief sleep history were obtained from all participants. For participants in the SC+CBSC follow-up group, documentations of each interaction with the CBSC or cloud-based RT were entered into EA.

Sleep center staff interactions with participants (both study arms) were entered into the VA computerized electronic medical record. Data from both follow-up groups were entered in a secure, Health Insurance Portability and Accountability Act-compliant Philips Respironics cloud-based electronic database. At 3 months (90 to 120 days), all participants (both study arms) were scheduled to attend a follow-up sleep clinic visit and complete an ESS questionnaire and patient-satisfaction survey (see supplemental material). All participants completing the study received a $50 travel compensation. For those individuals who could be not be scheduled for clinic, ESS and patient satisfaction information were obtained via a telephone call.

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Table 2—Cloud-Based Sleep Coach (CBSC) Program.

Days after PAP Setup	Description of Cloud-based Sleep Coach (CBSC) Interventions
Day 3 (±1)	First call made to participant. On this call CBSC introduces him/herself, discusses the therapy experience and mask fit so far, and determines if there are any treatment issues. The CBSC discusses therapy use expectations, provides motivation, instruction on PAP use, captures responses to goal setting and discussion of treatment importance (dependent of participant willingness), and sets adherence goals for future calls.
Day 7	SC reviews participant's adherence in EncoreAnywhere (EA) and notes from previous call. CBSC places calls to participants who are not meeting Centers for Medicare and Medicaid (CMS) adherence requirements* or they determine a call is necessary after viewing notes (eg, ongoing issues with treatment) and adherence trend (eg, irregular or decreasing use). Coach utilizes motivational instructional techniques to engage participant in therapy use.
Day 14	CBSC reviews patient's adherence in EA and notes from previous call. CBSC places calls to participants who are not meeting adherence requirements or they determine a call is necessary after viewing notes (eg, ongoing issues with treatment) and adherence trend (eg, irregular or decreasing use).
	Participants with at least 7 days of usage data, at least 1 live call contact, and a calculated 90% or greater probability of being adherent (determined by an adherence profiling algorithm) may have a live contact attempt eliminated or have the contact made with an interactive voice response call, email, or text.
Day 32	Live call made to all participants in the program. Compliant participants are encouraged to maintain adherence, provided with information on the process of PAP resupply. Participants who are not yet adherent receive a phone call every 15 days until day 90, as necessary.
	Day 30 call is placed on day 32 post set up date to ensure at least 30 days of usage.
Any time period	Problems not adequately handled by CBSC are escalated to cloud-based respiratory therapists (RT). If the problems remain unresolved (eg, requiring a mask or pressure change), the issues are escalated to physicians for interventions. Proposed solutions are communicated to local continuous positive airway pressure RTs for direct interventions.

*≥ 4 hours use for ≥ 70% of night during a consecutive 30-day period. PAP = positive airway pressure.

Adherence data were obtained from all participants via EA. Regardless of the exact clinic/telephone clinic date, the 3-month adherence was determined for the first 90 days following PAP set-up. The Centers for Medicare and Medicaid Service (CMS) criteria for adherence[28] (≥ 4 hours use ≥ 70% of nights during a consecutive 30-day over the initial 90 days of treatment) was used to determine the percentage of participants meeting CMS criteria.

Statistical analysis

Baseline variables were summarized with descriptive statistics. Continuous data were summarized with mean and standard deviation. An intention to treat (ITT) and a per protocol cohort (PP) were analyzed (**Figure 1**). The ITT cohort (SC and SC+CBSC) included all individuals randomized and started on PAP. Six participants in the SC and four participants in the SC+CBSC arm were lost to follow-up. When adherence data were not available, a value of 0 hours was used for adherence comparisons, except for average use (days used). For the SC study arm, the per protocol cohort consisted of the 120 participants who attended a 3-month clinic visit or had a telephone visit. The PP cohort for the CBSC group included 108 participants. This cohort consisted of all participants in the SC+CBSC ITT cohort (124) excluding four participants who did not complete the study and 12 participants who did not receive scheduled CBSC calls due to inadvertent removal from the EA group assigned for CBSC interactions. Continuous data tended to have symmetric distributions and were therefore analyzed with an independent-samples *t* test; in cases where the homogeneity of variance assumption was not met, the *P*-values were adjusted using the Satterthwaite method.[29] Proportions were compared between groups using the Fisher's exact test. The ESS values at 3 months were compared between the groups using analysis of covariance, where the preintervention ESS was included as a covariate to adjust for baseline differences. For the satisfaction survey, two groups were formed for comparison in each study arm: very satisfied/satisfied and neutral/dissatisfied/very dissatisfied. Adjustments for multiple comparisons were not performed.[30,31] All comparisons were conducted at a significance level of $P < .05$. Statistical computations were made using SAS Enterprise Guide 7.1., (Cary, North Carolina).

Sample size estimation

A power analysis was performed prior to study initiation using prior analysis of EA data showing proportions of patients meeting CMS criteria[26] to be between 40 and 50%. We used 45% for control and 67% for intervention (50% increase) with power of 90% and alpha of 0.05. By using the Test for Two Proportions procedure in PASS 11 (NCSS, Kaysville, Utah), the sample size in each group was 114 participants. On the basis of this analysis and anticipation of some participants lost to follow-up, a total target population of 250 participants was the study goal.

RESULTS

A total of 250 participants were randomized to the two methods of follow-up: SC (126) and SC+CBSC (124). Only 3 participants were not PAP naive. Home sleep apnea testing provided a diagnosis in 182 participants. Of these, 159 participants used the WatchPAT 200 (Itamar Medical, Israel), 15 used the Nox T3 (Carefusion, Yorba Linda, California), and 8 used various other

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home sleep apnea testing devices. Split-night polysomnography was used in 49 participants, and 19 underwent full-night diagnostic polysomnography. The majority of participants (SC group 86/126 and in the SC+CBSC group 94/124) were started on PAP without a preceding titration (either split sleep study or titration PSG). Even if participants had a titration, they were almost always started on an auto-adjusting PAP device. Treatment PAP mode included 2 participants with CPAP (SC), 9 with auto-bilevel PAP (5 in SC, 4 in SC+CBSC), and 239 with auto-adjusting continuous positive airway pressure (APAP). The participants randomized to the 2 methods of PAP follow-up did not differ with respect to age, body mass index, sex, diagnostic AHI, or baseline ESS (**Table 3**) in either the ITT or PP cohorts. Participants in the SC and SC+CBSC groups were obese, predominantly male, and had an average AHI in the severe range. The average ESS was slightly increased in both groups (normal ESS is ≤ 10).

Adherence and device data

In the ITT cohort the % days used, average daily use (all days), and the % of days with ≥ 4 hours use were significantly greater in the SC+CBSC group (**Table 4**). The average daily use (days used) as well as the % of participants with ≥ 4 hours use for ≥ 70% of days did not differ between the follow-up groups. In the PP cohort the average use (all days), average use (days used), % days used, % of days with ≥ 4 hours of use, and the percentage of participants meeting the CMS criteria were all greater in the SC+CBSC group. The residual AHI (PAP device estimate), the percentage of the night in large leak, and the 90% pressure did not differ between the groups in both the ITT and PP cohorts.

Epworth Sleepiness Scale and PAPapp usage data

The ESS at 3 months (using baseline value as a covariate) and the change from baseline did not differ between the follow-up groups (**Table 5**). In addition, the proportion of participants using the PAPapp did not differ between the SC and SC+CBSC groups.

Patient satisfaction survey

The patient satisfaction results are shown in **Figure 2**. Note that not all participants completing the satisfaction questionnaire

Table 3—Baseline characteristics.

	Intention to Treat Cohort			Per Protocol Cohort		
	Standard Care	Standard Care + Sleep Coaches	*P*	Standard Care	Standard Care + Sleep Coaches	*P*
n	126	124		120	108	
Age (years)	55.2 ± 13.4	54.9 ± 11.5	.848	55.3 ± 13.4	55.4 ± 11.5	.913
BMI (kg/m^2)	33.5 ± 6.2	33.1 ± 5.8	.621	33.4 ± 6.0	33.1 ± 5.7	.667
Male	89.7% (113/126)	88.7% (110/124)	.841	90.0% (108/120)	89.8% (97/108)	> .999
Female	10.3% (13/126)	11.3% (14/124)		10.0% (12/120)	10.2% (11/108)	
Diagnostic AHI (events/h)	36.7 ± 21.1	36.6 ± 20.6	.961	36.9 ± 21.4	37.5 ± 21.2	.825
ESS (pretreatment)	10.8 ± 6.1	11.2 ± 6.0	.661	10.8 ± 6.1	11.4 ± 6.0	.486

Data shown as mean ± standard deviation. Sex differences analyzed using Fisher exact test, others unpaired *t* tests. AHI = apnea-hypopnea index, ESS = Epworth Sleepiness Scale.

Table 4—Adherence and device data (initial 3 months).

	Intention to Treat Cohort			Per Protocol Cohort		
	Standard Care	Standard Care + Sleep Coaches	*P*	Standard Care	Standard Care + Sleep Coaches	*P*
n	126**	124		120	108	
Average use (all days) in hours	3.7 ± 2.7	4.4 ± 2.6	.027	3.8 ± 2.7	4.6 ± 2.5	.027
Average use (days used) in hours	5.1 ± 2.1	5.5 ± 2.0	.091	5.1 ± 2.1	5.6 ± 1.9	.046
% Days used	62.6 ± 35.1	73.6 ± 30.2	.008	64.7 ± 34.0	75.6 ± 28.6	.009
% Days > 4 hours	48.1 ± 36.8	57.9 ± 35.4	.032	49.7 ± 36.4	60.1 ± 34.3	.027
% Meeting CMS criteria	50.8 (64/126)	62.9 (78/124)	.057*	52.5 (63/120)	65.7 (71/108)	.045*
AHI on treatment (events/h)	4.4 ± 3.9	4.6 ± 4.3	.646	4.3 ± 4.0	4.5 ± 4.1	.701
Percent of night in large leak	5.5 ± 11.2	6.1 ± 13.1	.703	5.6 ± 11.3	6.7 ± 13.9	.544
90% pressure*** (cm H_2O)	10.6 ± 2.1	10.6 ± 2.4	.873	10.6 ± 2.1	10.7 ± 2.4	.830

Data are mean ± standard deviation. *Fisher exact test, other comparisons unpaired *t* tests. **2 patients had no data, value of 0 imputed except for average use (days used). For AHI on treatment, 90% pressure, and large leak n = 124. ***Continuous positive airway pressure (CPAP) used for patients on CPAP or average of 90% inspiratory and expiratory positive airway pressure for patients on auto-bilevel positive airway pressure. AHI = apnea-hypopnea index, CMS = Centers for Medicare and Medicaid.

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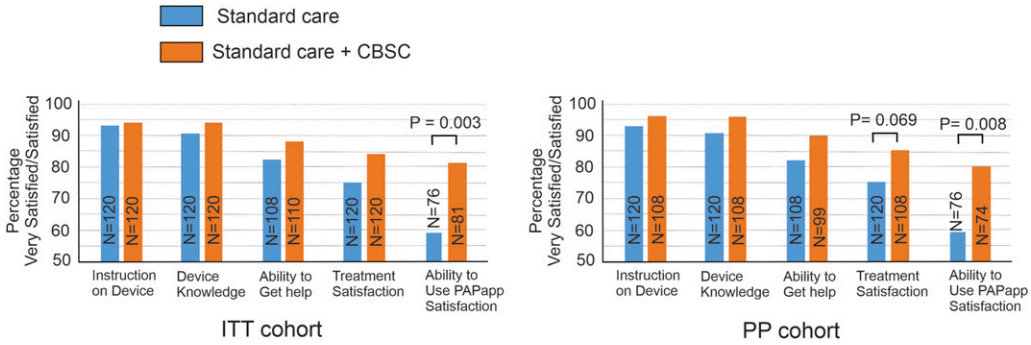
Table 5—Epworth Sleepiness Scale (ESS) and PAPapp use (initial 3 months).

	Intention to Treat Cohort			Per Protocol Cohort		
	Standard Care (n = 120)	+ Sleep Coaches (n = 120)	*P*	Standard Care (n = 120)	+ Sleep Coaches (n = 108)	*P*
ESS 3 months	8.3 ± 5.5	8.9 ± 5.4	.435*	8.3 ± 5.5	9.3 ± 5.5	.281*
Change in ESS	−2.5 ± 6.1	−2.1 ± 5.5	.655	−2.5 ± 6.1	−2.1 ± 5.7	.632
PAPapp use	76/120	81/120	.587**	76/120	74/108	.485**

*ESS = 3 months analysis of covariance with baseline ESS as covariate. **Positive airway pressure app (PAPapp) use = Fisher exact test, change in ESS by unpaired *t* test.

Figure 2—The percentage of participants very satisfied/satisfied in the intention to treat (ITT) and per protocol cohorts (PP).



The differences in treatment satisfaction between the SC and the SC+CBSC groups in the ITT and PP cohorts were not statistically significant. In both cohorts, a significantly greater percentage were satisfied with the ability to use the mobile positive airway pressure app (PAPapp) to follow adherence in the SC+CBSC group.

answered all the questions. In the ITT and PP cohorts, satisfaction with group PAP device instruction, knowledge of the PAP device, ability to get help with device issues, and treatment satisfaction were not different between the SC and SC+CBSC groups (**Figure 2**). Satisfaction with the ability to use the mobile application (PAPapp) was significantly greater in the SC+CBSC group in both the ITT and PP cohorts.

Cloud-based sleep coach interventions

There was an average of 5.0 ± 2.4 live coach to participant conversations in the PP cohort (n = 108). Essentially all were sleep coach initiated. To illustrate the challenges of telephone contact, there were 9.3 ± 3.7 call attempts per participant. Of note, there was also an average of 1.7 ± 1.1 calls to 52/108 participants in the per protocol cohort by a sleep coach RT. In contrast, an average of only 0.39 interactions were documented in the VA electronic medical record for participants in the SC protocol cohort (n = 120).

DISCUSSION

The main findings of this investigation are that the addition of a structured program of CBSC to SC increased the percentage of days of PAP use, average nightly use (all days), and % of nights ≥ 4 use for 30 consecutive days in the initial 3 months of treatment. The percentage of participants meeting the Medicare criteria in the SC+CBSC group was higher in the PP cohort but not in the ITT cohort. There was no evidence of improvement in patient satisfaction with instruction on use of the PAP device, PAP device knowledge, or the ability to get help with PAP issues. However, patient satisfaction was high in both groups. There was no difference in the proportion of participants using the PAPapp, but the satisfaction in using the application was significantly greater in the SC+CSB group (both ITT and PP cohorts).

Obtaining adequate adherence to PAP treatment is the major challenge of this type of therapy. Basically, PAP treatment is effective only if used. Poor early PAP use has been shown to be a risk factor for poor long-term adherence.[19–22] Therefore, we hypothesized that a program of early patient contact would improve adherence. We would contend that although the standard of care used in this study is not ideal, it is comparable to that available at many locales in both the VA and private sector. Of interest, nearly one-half of the participants in the sleep coach follow-up arm required the expertise of an RT with approximately 2 calls per participant. This highlights the need for expert intervention in a substantial number of patients started on PAP.

It is not surprising that satisfaction with class instruction or knowledge about the PAP device did not differ between the groups, as participants were not recruited until after instruction was completed. Satisfaction with the class and device knowledge was high in both groups as the standard of care provides standardized expert PAP device education and mask fitting.

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There was no difference in satisfaction with ability to get help with issues. The lack of a difference in ability the get help may have been due to the fact that both groups had PAP help telephone numbers and the ability to use secure messaging to notify providers of issues. Treatment satisfaction in both the intention to treat and per protocol cohorts was not statistically different in the CBSC group (**Figure 2**). It is possible that with a larger group of participants the difference would have reached statistical significance. The study design (target number of participants) was not based on a power analysis of treatment satisfaction. At PAP setup both groups received information about the PAPapp and literature was provided with the PAP units. Therefore, it might be expected that the number of participants using the mobile application did not differ between the groups. The higher satisfaction with the PAPapp in the CBSC group (both ITT and PP cohorts) might simply reflect an association with higher adherence or possibly encouragement or information about the application furnished by the sleep coaches.

Study strengths

The current study has several strengths. First, participants in both treatment arms received the same systematic PAP device instruction and mask fitting, as well as similar PAP treatment with similar devices. Enrollment and randomization followed the PAP setup class; therefore, the study arms did not affect the instruction or mask fitting. Both groups had standard VA PAP clinic contact information to get help with PAP issues. The device and treatment mode were similar in both study arms with the overwhelming majority using autoadjusting PAP. There was no difference in the device-determined residual AHI, amount of large leak, or 90% treatment pressure between the two study groups. Therefore, none of these factors can explain the difference in adherence between the groups. Third, all participants had wireless modems that allowed a complete dataset for adherence analysis. Only 6 participants in the SC and 4 in the SC+CBSC group were lost to follow-up. The VA CPAP RTs rendering PAP services were only aware that participants were part of a study but not the study arm assignment; consequently, we believe both groups received similar VA staff PAP care. In fact, participants had a high degree of satisfaction in both follow-up arms.

Study limitations

The current study had several limitations. The study population consisted of veterans who were predominantly male with moderate to severe sleep apnea. The study results might not generalize to nonveteran patients composed of more women and milder sleep apnea. However, if an intervention improves adherence in a group with known low adherence and challenging comorbid conditions, it is likely to be effective in other populations. Furthermore, the yearly cost to the VA prosthetics service for PAP equipment exceeded 200 million dollars in fiscal year 2018.[32] Therefore, the findings are of clinical and fiscal importance even if restricted to the veteran population. The veteran population has a high prevalence of posttraumatic stress disorder and insomnia.[15,33,34] Both of those disorders pose challenges to PAP treatment, and nightly adherence is often < 3 hours.[8,11] In most locales, the demand for PAP services far exceeds the available resources. A centralized cloud-based program provides the ability to target adherence after PAP initiation without the need to hire additional staff.

In the VA system, adequate adherence in the first 90 days is not required for continued PAP treatment. Conversely, patients in the private sector not meeting adherence standards usually surrender their PAP device unless they start another 90-day adherence trial. Therefore, given this difference, patient motivation to exhibit good early adherence might be lower in VA patients. On the other hand, our mean nightly adherence of 4.6 hours in the SC+CBSC group was similar to PAP adherence in a large multicenter trial of different CPAP modes in which participants were called at 7 and 14 days to intervene for PAP issues.[35]

Because DME services are integrated with the sleep program at our VA medical center, our results may not generalize to VA programs outsourcing DME services. Integrated DME services should theoretically reduce delay in the involvement of CPAP RTs and physicians to deal with PAP treatment issues, once identified. Even with integrated DME services, timely scheduling and communication are still obstacles to efficient care. Unfortunately, not all patients are proactive in dealing with PAP issues. It is not unusual for patients not to report treatment issues and stop using PAP treatment while awaiting an intervention at the first clinic visit.

Our results may also not apply to PAP set-up by DME services in the private sector. However, follow-up by DME companies in the private sector is not uniformly timely and, given limitations on reimbursement relative to costs, providing good DME care is increasingly challenging. Although wireless modem adherence monitoring is widely utilized, the information often does not reach physicians for several weeks. If physicians order a pressure or mask change, the implementation may also be delayed. Many DME providers do analyze early adherence and reach out to patients who are not doing well. Conversely, there is increasing economic pressure to limit the number of RTs employed by DME providers. Furthermore, even the best DME companies are unlikely to call new PAP patients an average of 9 times over the first 3 months. Therefore, it seems likely that a sleep coach program integrated with CPAP providers would also improve adherence in the private sector.

It might be argued that if our standard care follow-up had been more aggressive, this would have reduced the difference in adherence between SC with and without CBSC services. However, we would contend that the SC given to our participants is typical of real-life circumstances and reflects average or better PAP follow-up in the typical VA health care system. For example, in a large study[17] (216 participants) of PAP outcomes at an academic VA medical center comparing clinical pathways using ambulatory testing versus laboratory testing, the average nightly PAP use in the 2 study groups was 3.49 and 2.92 hours/night, respectively. The average nightly use (all nights) in the SC arm in the ITT cohort in the current study was 3.7 hours.

Nearly all our participants were treated with autoadjusting CPAP or autoadjusting bilevel PAP (most without a preceding PAP titration). This is common practice at our institution for uncomplicated OSA given limited resources. PSG titration

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studies are reserved for patients with central apneas, congestive heart failure, chronic obstructive pulmonary disease, supplemental oxygen, and parasomnias. Prior studies in VA patients suggest the approach results in adherence comparable to use of a polysomnography for diagnosis and/or PAP titration.[17,18] Studies have not documented improved adherence when autoadjusting PAP devices are used in consecutively recruited patients.[35] In any case, both the standard of care and CBSC follow-up arms received similar PAP devices, mask, and setup instructions. Thus, it seems unlikely that differences in PAP equipment or PAP treatment mode would influence the results.

Consideration of cost versus benefit is needed in considering the potential utility of an intervention. A reasonable concern is that the improvement in adherence with CBSC while statistically significant, might not be clinically significant. In the ITT cohort, the average nightly use (all days) was higher in the CBSC group (4.4 compared with 3.7 hours) by about 42 minutes. It could be argued that an average increase of 42 minutes nightly use might not be clinically significant. Indeed, we did not find a difference in improvement in the ESS in the CBSC group. However, we would contend that the 25.1% increase in the participants with ≥4 hours use on ≥70% of nights (per protocol cohort) is clinically important, as this level of use is often considered a threshold for clinical benefit.[36]

The current study sought to evaluate the utility of a CBSC service provided by a commercial entity (and manufacturer of PAP devices). The cost of a CBSC service can be bundled with PAP device cost (as commonly available for wireless modem service in the VA Health Care system). It is also certainly possible that the approach of early and frequent contact with patients recently started on PAP might be duplicated in house by trained personnel who are not CPAP RTs, such as trained nurse extenders. Another concern might be the feasibility of a service when an average of 9 telephone contacts attempts per participant were made. However, use of a cloud-based group of coaches whose only job is patient contact makes the program feasible. In addition, the number of missed telephone calls can be reduced by increasing use of electronic messaging.

Another limitation of our study was that adherence was followed over only the first 3-month period. Most of the CBSC interventions are designed for that time period. The fact that PAP adherence decreases with time is well documented. However, the decrease in adherence would be unlikely to differ in the two groups being compared in this study. Certainly, studies of sleep coach interventions over a longer duration (> 3 months) would be of interest.

The study design did not allow determination of which components of the CBSC program helped improve adherence. Indeed, many studies of interventions to improve PAP adherence have the same issue.[23] Possible reasons for improvement include direct human contact, motivation, reliability of communication (telephone calls answered by a person rather than an answering device), and rapid intervention for PAP issues. Indeed, different aspects of the program might well very in importance between patients. For example, a motivated patient may simply need quick access to address PAP issues.

Although the fraction of participants using the PAPapp and the satisfaction with the PAPapp were analyzed, our study was not designed to determine if use of the PAPapp had a role in adherence improvement. We determined PAPapp use and satisfaction entirely from the end-of-study satisfaction questionnaire. In retrospect, tracking the number of days the PAPapp was used and asking participants if the PAPapp helped them use their PAP more regularly or longer might have improved our study design.

In summary, this prospective randomized study found that the addition of a cloud-based sleep coach program (to standard care) for close adherence monitoring and motivation following PAP treatment initiation resulted in improvement in adherence and a trend toward greater patient treatment satisfaction in those completing the CBSC interventions compared with an integrated system of SC alone. This suggests that similar programs targeting early adherence may improve early PAP adherence in many patient settings.

ABBREVIATIONS

APAP, auto-adjusting positive airway pressure
BPAP, bilevel positive airway pressure
CBSC, cloud-based sleep coaches
CMS, Centers for Medicare and Medicaid Service
CPAP, continuous positive airway pressure
DME, durable medical equipment
EA, EncoreAnywhere (cloud-based adherence program)
ESS, Epworth Sleepiness Scale
ITT, intention to treat cohort
MRMC, Malcolm Randall VA Medical Center
PAPapp, mobile positive airway pressure app (tablet or telephone)
PP, per protocol cohort
PSG, polysomnography
OSA, obstructive sleep apnea
RT, respiratory therapist
SC, standard care
VA, Veterans Affairs

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