

Effect of Telemedicine Education and Telemonitoring on CPAP Adherence: The Tele-OSA Randomized Trial

Short title: The Tele-OSA Randomized Clinical Trial

Dennis Hwang, MD¹; Jeremiah W. Chang, MS¹; Adam V. Benjafield, PhD²; Maureen E. Crocker, MBA²; Colleen Kelly, PhD³; Kendra A. Becker, MD¹; Joseph B Kim, MD¹; Rosa R. Woodrum, BA¹; Joanne Liang, BA¹; Stephen F. Deroose, MD^{1, 4}.

¹Southern California Permanente Medical Group, Division of Sleep Medicine

²ResMed Science Center, ResMed Corp

³Kelly Statistical Consulting

⁴Southern California Permanente Medical Group, Department of Research & Evaluation

From

Corresponding Author:

Dennis Hwang, MD
9961 Sierra Ave, Fontana, CA 92335
Dennis.x.hwang@kp.org
Phone: 909-427-4432
Fax: 909-427-5664

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Impact of Research:

The Tele-OSA study investigates the use of remote and automated telemedicine mechanisms as potential cost-effective solutions to improve healthcare delivery. The impact of these mechanisms on patient engagement, reflected in improved therapy adherence, addresses a critical

challenge in sleep medicine. Furthermore, these mechanisms may be generalizable to improving management and outcomes of other chronic disease conditions.

AT A GLANCE COMMENTARY

Scientific Knowledge on the Subject

While continuous positive airway pressure (CPAP) therapy is effective at improving outcomes and considered the treatment of choice for obstructive sleep apnea (OSA), optimizing adherence remains challenging. Strategies to improve adherence typically focus on enhancing OSA education and providing accountability through follow-up care; however, these activities are labor-intensive and difficult to deliver cost-effectively. Telemedicine is understood to be a necessary solution for the evolving healthcare environment. This study investigates whether telemedicine platforms with automated functions to provide education and accountability can be cost-effective solutions for sleep medicine.

What This Study Adds to the Field

The results of this 4-arm randomized clinical trial demonstrates that CPAP telemonitoring (that provides automated patient messaging feedback based on CPAP use) significantly improved 90-day adherence. Furthermore, the improvement was observed without requiring additional provider intervention. In contrast, a remotely delivered automated education program did not improve adherence. However, it did improve attendance rates to appointments, demonstrating improved patient engagement despite no overt impact on CPAP use. The results suggest that these telemedicine mechanisms may be cost-effective solutions for the care of patients with OSA; furthermore, these mechanisms may be generalizable as solutions for other chronic diseases.

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Abstract

Rationale– Automated telemedicine interventions could potentially improve adherence to continuous positive airway pressure therapy (CPAP).

Objective–Examining the effects of telemedicine-delivered obstructive sleep apnea (OSA) education and CPAP telemonitoring with automated patient feedback messaging on CPAP adherence.

Methods–This 4-arm, randomized, factorial-design clinical trial enrolled 1455 patients (51.0% women, age 49.1 ± 12.5 years) referred for suspected OSA. 956 underwent home sleep apnea testing and 556 were prescribed CPAP. Two telemedicine interventions were implemented: (a) web-based OSA education (Tel-Ed); (b) CPAP telemonitoring with automated patient feedback (Tel-TM). Patients were randomized to (1) Usual Care, (2) Tel-Ed added, (3) Tel-TM added, or (4) Tel-Ed and Tel-TM added (Tel-Both).

Measurements–Primary endpoint was 90-day CPAP usage. Secondary endpoints included attendance to OSA evaluation, and change in Epworth Sleepiness Scale score.

Main Results– CPAP average daily use at 90 days was 3.8 ± 2.5 , 4.0 ± 2.4 , 4.4 ± 2.2 and 4.8 ± 2.3 hours in Usual Care, Tel-Ed, Tel-TM and Tel-Both groups. Usage was significantly higher in the Tel-TM and Tel-Both groups versus Usual Care ($p=0.0002$ for both) but not for Tel-Ed ($p=0.10$). Medicare adherence rates were 53.5%, 61.0%, 65.6% and 73.2% in Usual Care, Tel-Ed, Tel-TM and Tel-Both groups (Tel-Both vs Usual Care, $p=0.001$; Tel-TM vs Usual Care, $p=0.003$; Tel-Ed vs Usual Care, $p=0.07$). Telemedicine education improved clinic attendance compared to no telemedicine education (show rate 68.5% vs 62.7%; $p=0.02$).

Conclusions—The use of CPAP telemonitoring with automated feedback messaging improved 90-day adherence in OSA patients. Telemedicine-based education did not significantly improve CPAP adherence but did increase clinic attendance for OSA evaluation.

Trial Registration—clinicaltrials.gov; NCT02279901

Abstract (244 words; max 250)

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Introduction

Obstructive sleep apnea (OSA) represents a significant disease and public health burden given its high prevalence, impact on quality of life (QOL) and association with cardiovascular disease.^{1,2}

Continuous positive airway pressure (CPAP) therapy is considered the gold standard treatment for OSA and is recommended as first-line therapy in the majority of patients.^{3,4} CPAP significantly decreases the number of respiratory events, improves daytime symptoms, quality of life and neurocognitive function, reduces the risk of traffic accidents,⁵⁻¹¹ and has beneficial effects on a number of cardiovascular comorbidities.¹²⁻¹⁹ However, regular and consistent device usage is required for the benefits of CPAP therapy to be realized, and optimizing CPAP adherence remains a significant challenge.¹⁴ Three months after initiation of therapy the proportion of patients who remain adherent to CPAP is typically only about 50 or 60%.^{20,21}

Improvements in CPAP device technology have had little effect on improving adherence.

Instead, interventions designed to enhance adherence have largely focused on engaging psychosocial factors that emphasize patient education and follow-up care.²²⁻²⁶ However, these approaches are labor-intensive making them potentially difficult to deliver cost-effectively.

Availability of sleep medicine specialists and over-burdened primary care physicians create additional challenges.

Telemedicine – the remote delivery of care with the use of technology – is a potential solution for efficient delivery of education and enhanced follow-up care. Advances in CPAP technology have integrated wireless capabilities that enable transfer of CPAP data via a cellular signal for remote monitoring by medical providers. Furthermore, automated algorithms can analyze these data and send automated, individualized patient messages when use is suboptimal. In addition,

web-based programs that inform patients about OSA can enable education outside the clinical setting.

The Tele-OSA study evaluated the impact of two telemedicine interventions (web-based OSA education and CPAP telemonitoring program with automated feedback messaging), alone and in combination, on CPAP adherence in patients with OSA. Some of the results of this study have been previously reported in the form of abstracts.³⁶⁻³⁸

Methods

Study design and participants

The Tele-OSA study was a 4 arm, randomized, factorial-design clinical trial conducted at a single sleep center that serves a large medical center in Southern California, USA. The study was conducted within the context of the sleep center's usual clinical care procedures for the diagnosis and management of OSA (Figure 1). Most patients are referred by primary care physicians, and a sleep medicine physician triages appropriate patients to HSAT after review of the referral information and electronic health record chart. HSAT classes (up to 13 people) are led by a sleep-trained respiratory therapist and sleep technologist and provide interactive OSA education and individualized HSAT setup. After a one-night test, patient return for an individual appointment with a respiratory therapist to review the results. Those with OSA are recommended to undergo a one-week CPAP trial followed by an individual return appointment with a respiratory therapist to review CPAP data and patient experience. Patients willing to commit to CPAP therapy are immediately dispensed a device; otherwise CPAP troubleshooting or alternative treatments are discussed. Sleep medicine-boarded physicians supervise the

workflow and review all sleep study and CPAP data. Clinicians providing routine care and study analysts were blinded to study arm assignment. The study protocol was approved by the Kaiser Permanente Southern California Institutional Review Board. Written informed consent requirement was waived after review determined that the study involved no more than minimal risk to subjects and that the waiver would not adversely affect the rights and welfare of subjects.

Consecutive patients referred to the Kaiser Permanente Fontana Sleep Disorders Center (California, USA) for evaluation of suspected OSA and triaged to home sleep apnea testing (HSAT) between November 2014 to August 2015 were enrolled into the study. Eligible patients were aged ≥ 18 years, had no previous sleep testing nor trial of OSA therapy, and were eligible for HSAT. Patients were excluded if they were at risk of other sleep disorders (e.g. severe insomnia), had significant cardiopulmonary disease (e.g. heart failure, chronic respiratory failure), or did not indicate English as their preferred language.

All patients that were prescribed CPAP were provided an auto-titrating device (AirSense 10; ResMed Corp) capable of wirelessly transmitting CPAP data daily via a cellular signal into a cloud database (U-Sleep, ResMed Corp).

Randomization and masking

To conform to the sleep center's usual care procedures, groups of patients were randomized with all participants in each HSAT class following the same treatment arm. Classes were randomized (1:1:1:1) to be managed using (1) Usual Care alone, (2) Usual Care plus telemedicine web-based education (Tel-Ed), (3) Usual Care plus CPAP telemonitoring with automated feedback messaging based on usage data for 90 days (Tel-TM), or (4) Usual Care plus both telemedicine-

based education and telemonitoring with feedback messaging (Tel-Both). Randomization was performed for each HSAT class (not in blocks) using a computerized random number generator.

Interventions

The Usual Care pathway is shown in Figure 1. Briefly, all patients attended a 1-hour, small-group education class with HSAT setup. During the session, sleep apnea education was provided, CPAP therapy was briefly described, and the HSAT setup procedure was taught. Patients with an apnea-hypopnea index (hypopneas were associated with $\geq 4\%$ oxygen desaturation) of at least 5 per hour ($AHI \geq 5$) were provided a CPAP trial, typically for one week. After the trial, those willing to continue CPAP were prescribed therapy and scheduled for a 3-month follow-up appointment.

The two telemedicine interventions in this study were designed to target different psychosocial factors: education and accountability. Two OSA-specific educational programs were used, developed by a company specializing in providing user-friendly patient education programs (Emmi; Emmi Solutions Inc.). In the Tel-Ed arm, patients were emailed a link to the OSA program 2 weeks prior to their HSAT class. All patients in all study groups received an appointment reminder call at that time. The first program included education about the pathophysiology of OSA (including animated videos depicting airway narrowing), health-related risks such as cardiovascular disease and impact on daytime vigilance, an introduction to CPAP therapy, and details of the assessment process. In patients eventually determined to have OSA, a link to a second education program was emailed during their one week CPAP trial with focused education on how to properly use CPAP, potential benefits of treatment on health and daytime vigilance, methods of acclimating, and equipment care instructions (see example in Supplementary Figure S1). The education sessions are interactive and typically last 15 minutes,

although patients were able to proceed at their preferred pace. Links to both programs were emailed to the patient with a personalized invitation that required date of birth verification for activation.

The Tel-TM intervention was based on automatic processing of device data by the cloud-based application (U-Sleep, ResMed Inc). When receiving their CPAP device, patients were educated about the automated feedback process and asked to state their preferred method for receiving messages (text messaging, email, phone call, or a combination). During the three-month study period, if CPAP usage thresholds were met, a message was automatically sent to the patient providing encouragement to improve use or positively reinforcing successful adherence (Supplementary Table S1).

Patients randomized to the Tel-Both arm received both the web-based education programs and the automated feedback messaging.

Assessments and outcomes

Patient demographic and clinical characteristics were determined at baseline, and sleep study findings were recorded. Patients completed the Epworth Sleepiness Scale (ESS) and Functional Outcomes of Sleep Questionnaire (FOSQ-10) at baseline and their 3-month follow-up appointment. CPAP usage data at 90 days was collected wirelessly from all patients. Also recorded was the 95th percentile of CPAP pressure, median mask leak and residual AHI for population description. For patients in the Tel-Ed and Tel-Both groups, educational program viewing status was determined for each patient. The number of clinical encounters (including office and telephone encounters) also was recorded.

The primary outcome was CPAP usage (days used, hours/day). Other adherence metrics were assessed including whether Medicare adherence (defined as a 30-day period during the first three months of therapy in which CPAP use was ≥ 4 hours/night on $\geq 70\%$ of days) was achieved.

Secondary endpoints were attendance rates to the HSAT class and change in ESS and FOSQ-10 scores at 3-month follow-up. In a post-hoc analysis, we examined long-term outcomes up to 360 days to determine if the observed treatment effect persisted longer than the planned 90 days.

Statistical analysis

To detect a 0.5-hour increase in average nightly CPAP usage with a standard deviation of 2.2 hours (as found in the Fox et al. study²⁸) with 80% probability, it was estimated that 283 patients per group would be required at the 0.05 significance level. Power was estimated in Power Analyses and Sample Size Software (PASS) Version 14 using the One-Way Analysis of Variance F-Tests Procedure.

Mixed effect general linear models were used to assess the effects of the interventions on the percentage of days that CPAP was used ≥ 4 hours in the first 90 days, the average hours of CPAP usage per day (all days) for the first 90 days, the average hours of CPAP usage per day (on days with CPAP use) for the first 90 days, change in ESS score and change in FOSQ-10 score. The Tel-Ed and Tel-TM interventions were treated as fixed effects and the HSAT class in which the patient was enrolled was treated as a random effect nested in the treatment group (to account for potential correlations within classes). Similarly, mixed-effects logistic regression models were used to assess the effects of the intervention on Medicare adherence rates and HSAT class attendance rates, with effects as described above. An interaction term between Tel-Ed and Tel-TM was investigated for all outcome variables, but was not statistically significant (p -value > 0.05) for any variable and thus was not retained in the model. HSAT class attendance

rates were compared between patients with the telemedicine education intervention and those without.

The “% Days CPAP Used” was compared between the combined groups with telemonitoring (TelTM and Tel-Both) and the combined groups without telemonitoring (Usual Care and Tel-Ed) at 30-day intervals up to 360 days. After 90 days, the telemonitoring arm divided into two arms (feedback messaging continued versus messaging discontinued). Means at each time point were compared with Student’s t-tests adjusted with a Bonferroni correction. Relative changes in percent days with CPAP use were calculated between time point “a” (0-30 days) to point “b” (30-60 days), and between point “b” (30-60 days) to point “c” (60-90 days). Relative changes were then compared with Student’s t-test and adjusted with a Bonferroni correction. A p-value of <0.05 was defined as statistically significant. All statistical analyses were performed using SAS versions 9.3 and 9.4 (Cary, NC USA)

Results

Study population

1873 patients were referred to the sleep center for suspected OSA and triaged to HSAT from November 2014 to August 2015. Recruitment closed when targeted accrual appeared to be reached. After excluding 418 patients who did not meet eligibility requirements (usually due to prior sleep study or CPAP use), 162 HSAT classes – accounting for 1455 patients – were randomized (Figure 1). Overall, 66% showed up to the HSAT class and were tested, and 81.1% of those tested were diagnosed with OSA ($AHI \geq 5$). 556 (38.2% of all randomized patients; 71.7% of all patients with OSA) were eventually prescribed CPAP, all of whom had 90-day usage data to be included for analysis. Baseline demographics, clinical characteristics, sleep study results, and CPAP trial data are shown in Table 1a while data for those prescribed CPAP therapy are shown in Table 1b. Rate of CPAP prescriptions (of those randomized) and baseline characteristics for those prescribed CPAP were similar between the four arms.

Patient-selected formats for automated messages in the Tel-TM and Tel-Both groups were email (31.7%), text messaging (17.5%), phone (2.3%), or a combination (40.3%); 22 patients (8.4%) declined messaging but were included in the analysis for each group. Likewise, although the two education programs were accessed by only 27-34% of patients (Figure 1), all were also included in the analysis. The mean number of telemonitoring messages was 18 (median 8).

CPAP usage and adherence

CPAP adherence results are reported in Table 2. The effect of Tel-Ed was not statistically significant for any primary outcome (p -values > 0.05). In contrast, Tel-TM and Tel-Both had a statistically significant increase on the *average usage across all days* compared to the Usual Care

group (4.4 and 4.8 hours vs 3.7 hours; $p=0.0002$). Tel-TM and Tel-Both also showed a significant increase compared to Usual Care on the proportion of days that CPAP was used compared to Usual Care (76.6% and 78.3% vs 64.8%; $p<0.0001$ and 0.0004) and in Medicare adherence rates (65.6% and 73.2% vs 53.5%; $p=0.003$ and 0.001). The odds of achieving Medicare adherence were 2.4 times higher (95% CI 1.4-4.0) in the Tel-Both group and 1.7 times higher in the Tel-TM group (95% CI: 1.2-2.4) than in the usual care group.

Self-reported sleep symptoms

There were improvements in all study arms in the self-reported sleep symptoms (the ESS and the FOSQ-10) over three months (Table 2). Analyses did not reveal any differences in the change in ESS or the FOSQ-10 scores in any intervention study arm vs Usual Care.

Healthcare utilization

Attendance to the HSAT class was 1.3 times higher in patients who received the telemedicine education program compared to those who did not (Tel-Ed + Tel-Both attendance 68.5% vs Usual Care + Tel-TM attendance 62.7%; $p=0.02$). The telemedicine program did not affect CPAP dispensation rates for patients with OSA, which ranged from 82-85% of those undergoing a CPAP trial across study arms (Figure 1). The number of sleep center encounters (office visits or telephone calls) during the 90-day follow-up period was low and did not differ significantly between intervention groups. The median number of encounters per patient was zero, and all means were ≤ 0.5 per person.

Temporal analysis of usage

Time trends in CPAP days used were examined (Figure 2) for combined telemonitoring groups (Tel-TM+Tel-Both) and combined non-messaging groups (Usual Care+Tel-ED). Telemonitoring

with automated messaging had an early impact (0-30 days) with a higher percentage of days used (83.3% vs 76.2% of days; $p=0.002$) (Figure 2). The CPAP usage rate declined in all groups, though more slowly (from 0-30 Days to 30-60 Days) in the groups with versus the groups without telemonitoring (-5.8% vs -17.1% ; $p=0.04$). The rate of decline from 30-60 to 60-90 Days was similar between groups, suggesting that the impact of telemonitoring with automated feedback messaging was primarily during the first 60 days after CPAP dispensation. Other usage metrics (e.g. % of days used ≥ 4 hours, hours use per day) showed similar findings (not shown).

In a post hoc analysis, we decided to examine CPAP usage and adherence data at one year after CPAP dispensation (Figure 2). In doing so, we discovered that 73 patients had tele-messaging continued past the 90-day study outcome date because of a failure to turn off messaging. Insofar as we can tell, these errors were an arbitrary process (i.e. staff forgetting as rolling study completion dates were passed). In Figure 2, CPAP usage in patients who had automated feedback messaging discontinued after 90 days gradually declined to levels that appeared the same as patients who never had automated feedback messaging. In contrast, the 73 patients who mistakenly continued to receive automated feedback messaging appeared to sustain greater CPAP use than patients who never received messaging or had messaging discontinued (% Days Used at 330-360 Days was $58.4\% \pm 41.1\%$ vs $48.1\% \pm 43.9\%$, $p=0.05$).

Discussion

The Tele-OSA study showed that telemedicine-based automated feedback messaging improved 90-day CPAP use after therapy was prescribed. In contrast, telemedicine-based patient education had no significant effect on 90-day CPAP use, although the study was not powered to detect

potentially small effects. Moreover, telemedicine education did increase attendance to the HSAT class even though the programs were not frequently accessed.

These findings suggest that accountability may be more effective than educational interventions at inducing changes in adherence behavior, although other factors could have contributed to the results. The timing of the intervention may be important, given that telemedicine-based feedback occurred during the follow-up period whereas telemedicine-education was provided before CPAP was prescribed. Another factor may have been the number of patient contacts for each intervention; access to education was provided twice, while automated feedback messaging was delivered as many times as usage threshold criteria were met. Furthermore, patients could choose whether to view the educational material when they received the telemedicine-based prompt, whereas the automatic nature of messaging in the telemonitoring groups meant that patients always received messages, whether they wanted to or not. It is possible that higher viewing rates of the education programs could have improved the impact. Finally, the two telemedicine interventions could differ in their direct impact on behavioral psychology. While education is likely necessary to provide foundational knowledge for behavior change, information and advice may not be enough to induce significant or sustained behavior changes.²⁷ Instead, addition of motivational elements such as accountability (represented by the automated messaging in our study) or other methods such as personalized goal-setting may be essential. Similar differences in effect of education and accountability have been seen in previous trials related to adherence to CPAP or other medical interventions. The TEXT ME trial reported that patients receiving four text messages per week (with advice and reminders on lifestyle changes) had improved low-density lipoprotein cholesterol levels at six months compared with controls.²⁸ In a CPAP study, Fox et al. demonstrated that patients randomized to CPAP remote monitoring

had significantly improved three-month adherence versus usual care.²⁹ In that study, sleep medicine personnel manually reviewed CPAP use every weekday and contacted the patient to troubleshoot if use was <4 hours for two consecutive nights. On the other hand, there was no significant improvement in three-month CPAP use in a study of an intensive 36-hour CPAP educational program that included individualized in-person discussions, focused workshops, and inclusion of spouses.³⁰

Another significant implication of the Tele-OSA study is that technology improved adherence without additional provider intervention, thus demonstrating the cost-effectiveness of this strategy. Follow-up care and education are labor-intensive, and automated tools such as those used in this study are likely to contribute to more efficient care delivery in the future. Although Fox et al showed improved CPAP adherence with remote monitoring,²⁹ their personnel-based approach would not be feasible in most clinical settings because of the high level of manual input and personnel time required. In contrast, our study showed benefits with automated feedback messaging without any resulting increase in patient encounters. This finding is supported by other recent studies demonstrating that telemedicine had equivalent CPAP outcomes to traditional follow-up but with reduced labor requirements, including one that compared a similar automated feedback messaging mechanism to personnel-based follow-up.³¹⁻³⁴ While the overall improvement in adherence with telemonitoring in this study was substantial, the degree of response varied between individual patients. Thus, the use of technology-based approaches should be considered as one solution among a larger set of management strategies to personalize the care for individuals.³⁵ Finally, tele-monitoring was well accepted by patients considering only a small minority of patients refused to receive messages, and no patients requested to discontinue messaging throughout the follow-up period.

This study applied two different interventions sequentially, allowing their relative impact on CPAP adherence to be assessed. Another strength of the study is the use of an established CPAP telemonitoring mechanism with established CPAP usage metrics to reliably and accurately collect objective data. There are a number of limitations that need to be taken into account. First, group rather than individual randomization was performed; nevertheless, treatment arm baseline characteristics were similar and within group correlations were taken into account in analyses. Second, because randomization occurred prior to the initial diagnostic visit, there was a substantial number of “drop-outs” between randomization and CPAP prescription (primarily patients who did not have OSA or elected for non-CPAP therapies), thus limiting the ability to perform an intention-to-treat analysis and potentially introducing bias. However, the “drop-out” rate and baseline characteristics of patients prescribed CPAP were similar in the four arms and is appropriately reflective of clinical care in which many patients referred for suspected OSA are not eventually prescribed CPAP. Third, this study was performed at a single center and health system which may limit generalizability of these results to other health sites and systems; however, this study had broad inclusion criteria and study participants were representative of the sleep center’s typical patient population.

A number of important questions remain unanswered, including the impact of automated feedback messaging beyond the initial three-month period. Longer term CPAP adherence past 90 days with ongoing automated feedback messaging was not formally assessed. Informally, in post hoc analyses, it appeared that continuation of messaging may be the optimal approach for sustained adherence. Additional questions include the potential impact of changing thresholds to increase message frequency or adding new triggers to provide more positive reinforcement, the possibility of personalizing automated messages for each patient based specifically on what

would motivate them the most, and whether the addition of mobile health applications that allow for individualized goal setting and self-direction of care would further enhance therapy adherence. It would also be useful to know whether implementing patient education during the follow-up period (rather than prior to treatment initiation) would be more effective. Data from future trials in this new and evolving area of healthcare will help provide insight into these issues.

In conclusion, the use of CPAP telemonitoring with an automated feedback messaging mechanism linked to CPAP use improved three-month CPAP adherence in patients with OSA. In this study, telemedicine-based education did not improve CPAP use to a statistically significant degree, but did improve adherence to OSA evaluation. This study supports the value of implementing automated telemedicine mechanisms into clinical sleep medicine and suggests that similar mechanisms may be useful in managing other chronic diseases.

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Figure legends

Figure 1. Study flowchart.

APAP, auto-titrating continuous positive airway pressure; CPAP, continuous positive airway pressure; DME, durable medical equipment; HSAT, home sleep apnea testing; OSA, obstructive sleep apnea; PAP, positive airway pressure; PSG, polysomnography.

Figure 2. CPAP usage over 360 days.

Because impact on CPAP adherence was limited to automated feedback messaging, this figure collapses four treatment arms into two arms in order to directly compare all patients with versus all patients without CPAP telemonitoring+automated feedback messaging. Feedback messaging was arbitrarily not discontinued after 90 Days in 73 patients.

Text tables

Table 1a. Baseline Characteristics of Study Patients

	All	Usual Care	Tel-Ed	Tel-TM	Tel-Both
Demographics	(n = 1455)	(n = 354)	(n = 380)	(n = 375)	(n = 346)
Male, n (%)	713 (49.0)	163 (46.0)	186 (48.9)	193 (51.5)	171 (49.4)
Age, years	49.1±12.5	50.2±12.7	49.1±12.2	47.2±12.5	49.7±12.3
Ethnicity, n (%)					
African American	48 (3.3)	8 (2.3)	12 (3.2)	13 (3.5)	15 (4.3)
Asian	89 (6.1)	25 (7.1)	17 (4.5)	26 (6.9)	21 (6.1)
Caucasian	782 (53.8)	191 (54.0)	212 (55.8)	194 (51.7)	185 (53.5)
Hispanic	517 (35.5)	125 (35.3)	136 (35.8)	137 (36.5)	119 (34.4)
Other	19 (1.3)	5 (1.4)	3 (0.8)	5 (1.3)	6 (1.7)
Clinical Data	All	Usual Care	Tel-Ed	Tel-TM	Tel-Both
	(n = 956)	(n = 225)	(n = 261)	(n = 232)	(n = 238)
BMI, kg/m ²	34.0±7.9	33.3±7.8	34.8±7.9	34.5±8.4	33.5±7.6
Sleep history:					
Sleep time*, h	6.4±1.3	6.3±1.2	6.5±1.2	6.4±1.4	6.5±1.4
Sleep latency*, min	27.8±29.3	30.3±27.5	27.1±30.6	28.8±31.1	25.4±27.2
Wake instances*, n	2.7±1.8	3.1±2.1	2.7±1.9	2.4±1.6	2.5±1.6
Caffeine servings*, n	1.9±1.2	1.8±1.0	1.9±1.2	2.0±1.3	1.9±1.1
ESS score	9.1±5.4	8.8±5.1	9.4±5.5	9.5±5.7	8.5±5.2
FOSQ-10 score	25.5±10.2	26.9±9.5	25.5±9.9	24.8±10.6	25.0±10.5
Sleep Study Results	All	Usual Care	Tel-Ed	Tel-TM	Tel-Both
	(n = 956)	(n = 225)	(n = 261)	(n = 232)	(n = 238)
AHI, /h	22.7±23.9	22.0±23.4	22.6±23.8	22.8±25.2	23.2±23.1
Supine AHI, /h	32.7±31.9	32.1±36.9	33.7±30.7	32.6±31.4	32.1±28.5
Non-supine AHI, /h	17.3±24.1	16.6±23.3	17.4±23.2	18.0±27.4	17.2±22.4
ODI, /h	20.3±22.3	19.8±22.2	20.6±22.9	20.3±23.0	20.4±21.3
T90, %	13.9±20.0	12.9±17.8	14.6±20.4	14.2±21.7	13.8±19.8
Minimum SO ₂ , %	79.3±9.0	80.1±8.1	78.8±9.5	79.5±8.7	78.9±9.6
Auto CPAP Trial	All	Usual Care	Tel-Ed	Tel-TM	Tel-Both
	(n = 672)	(n = 157)	(n = 194)	(n = 153)	(n = 168)
Duration, days	9.9±11.3	10.0±8.3	8.5±5.3	11.0±18.2	10.2±10.6
Days used, n	7.1±4.5	7.1±5.2	7.2±4.2	7.1±4.1	7.0±4.3
Days used, %	85.4±24.9	81.9±28.5	87.7±20.7	86.5±24.4	85.1±26.0
Days used for ≥4h, %	63.0±34.6	60.1±36.6	64.8±32.7	60.2±36.1	66.3±33.4
Average usage on all days, h	4.9±2.5	4.6±2.5	5.1±2.5	4.8±2.4	5.1±2.4

Average usage on days used, h	5.3±2.2	5.0±2.4	5.5±2.1	5.1±2.2	5.5±2.1
95 th percentile pressure, cmH ₂ O	10.3±2.5	10.0±2.6	10.6±2.3	10.2±2.5	10.4±2.4
Median leak, L/min	3.5±6.8	4.0±10.8	2.9±5.0	3.7±5.1	3.6±5.0
Residual AHI, /h	2.9±3.2	2.6±3.3	3.0±3.2	3.0±3.2	3.1±3.3

Values are mean ± standard deviation, or number of patients (%).

*Self-reported.

AHI, apnea-hypopnea index; BMI, body mass index; ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; ODI, oxygen desaturation index; SO₂, oxygen saturation; T90, time with oxygen saturation <90%; Tel-Ed, telemedicine-based education; Tel-TM, telemedicine-based telemonitoring; Tel-Both, telemedicine-based education and telemonitoring.

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Table 1b. Baseline Characteristics of Participants Prescribed CPAP

	All (n = 556)	Usual Care (n = 129)	Tel-Ed (n = 164)	Tel-TM (n = 125)	Tel-Both (n = 138)
Demographics					
Male, n (%)	325 (58.5)	73 (56.6)	91 (55.5)	76 (60.8)	85 (61.6)
Age, years	50.5±12.1	51.9±13.1	50.3±11.8	48.8±11.8	50.7±11.7
Ethnicity, n (%):					
African American	22 (4.0)	3 (2.3)	5 (3.0)	7 (5.6)	7 (5.1)
Asian	39 (7.0)	11 (8.5)	9 (5.5)	7 (5.6)	12 (8.7)
Caucasian	301 (54.1)	72 (55.8)	88 (53.7)	68 (54.4)	73 (52.9)
Hispanic	189 (34.0)	41 (31.8)	62 (37.8)	43 (34.4)	43 (31.2)
Other	5 (0.9)	2 (1.6)	0 (0.0)	0 (0.0)	3 (2.2)
Clinical Data					
BMI, kg/m ²	34.5±7.7	33.4±7.4	35.4±8.0	34.8±7.8	34.3±7.5
Sleep history:					
Sleep time, h	6.4±1.3	6.3±1.2	6.5±1.3	6.4±1.3	6.5±1.3
Sleep latency, min	27.6±30.0	30.0±27.5	26.7±32.1	28.9±32.0	25.6±27.8
Wake instances, n	2.7±1.8	3.1±1.9	2.8±2.0	2.3±1.3	2.7±1.6
Caffeine servings, n	1.9±1.3	1.8±1.0	1.9±1.4	2.0±1.5	1.9±1.2
ESS score	9.6±5.2	9.5±4.9	9.6±5.2	10.4±5.5	8.7±5.2
FOSQ-10 score	25.8±9.8	27.6±8.8	25.2±10.0	25.6±9.7	25.2±10.3
Sleep Study Results					
AHI, /h	31.9±25.8	31.5±25.5	30.2±25.9	33.5±27.1	32.6±24.7
Supine AHI, /h	42.8±30.1	41.7±30.8	41.1±30.4	45.8±31.0	43.3±28.3
Non-supine AHI, /h	24.4±27.6	23.6±27.1	22.8±26.3	26.2±31.7	25.4±25.7
ODI, /h	28.5±24.5	28.1±24.3	27.9±25.3	29.3±25.2	28.9±23.3
T90, %	18.8±21.9	17.0±18.5	18.7±22.2	20.0±23.7	19.5±22.8
Minimum SO ₂ , %	76.5±9.2	77.8±7.5	76.3±10.0	76.0±9.0	75.8±10.0
Auto CPAP Trial					
Duration, days	8.2±5.3	8.7±6.4	8.4±5.1	7.8±4.4	8.0±5.2
Days used, n	7.4±4.3	7.6±4.9	7.5±4.2	7.1±3.9	7.3±4.3
Days used, %	92.6±14.1	92.0±14.7	91.7±15.2	93.7±12.8	93.2±13.4
Days used for ≥4h, %	71.9±28.1	71.7±28.5	69.6±29.3	70.2±29.3	76.4±25.0
Average usage on all days, h	5.5±2.0	5.4±2.0	5.4±2.3	5.4±1.9	5.7±1.9
Average usage on days used, h	5.8±1.8	5.8±1.8	5.7±1.9	5.6±1.8	6.1±1.6
95 th percentile pressure, cmH ₂ O	10.7±2.3	10.4±2.4	10.8±2.3	10.7±2.2	10.8±2.2
Median leak, L/min	3.4±5.0	3.2±4.8	3.0±5.0	3.8±5.2	3.6±5.1
Residual AHI, /h	2.9±2.9	2.6±2.7	2.8±2.9	3.1±3.3	3.0±2.9

Values are mean ± standard deviation, or number of patients (%).

AHI, apnea-hypopnea index; BMI, body mass index; ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; ODI, oxygen desaturation index; SO₂, oxygen saturation; T90, time with oxygen saturation <90%; Tel-Ed, telemedicine-based education; Tel-TM, telemedicine-based telemonitoring; Tel-Both, telemedicine-based education and telemonitoring.

Table 2. CPAP Use and Subjective Outcomes 90-Days after CPAP Dispensation

	Usual Care (n=129)	Tel-Ed (n=163)	Tel-TM (n=125)	Tel-Both (n=138)	Tel-Ed Effect (95% CI) p-value	Tel-TM Effect 95% CI p-value	Tel-Both Effect 95% CI p-value
Days used, %	64.8±34.2	68.6±31.3	76.6±28.3	78.3±28.3	2.8 (-2.3, 7.9) 0.28	10.6 (5.5, 15.7) <0.0001	13.4 (6.1, 20.8) 0.0004
Average usage on all days, h	3.8±2.5	4.0±2.4	4.4±2.2	4.8±2.3	0.3 (-0.1, 0.7) 0.10	0.8 (0.4, 1.15) 0.0002	1.1 (0.5, 1.7) 0.0002
Average usage on days used, h	5.2±1.8	5.2±1.8	5.3±1.7	5.8±1.6	0.2 (-0.1, 0.5) 0.13	0.4 (0.1, 0.7) 0.006	0.6 (0.2, 1.0) 0.003
Medicare adherence, n (%) ¹	69 (53.5)	100 (61.0)	82 (65.6)	101 (73.2)	1.4 (1.0, 2.0) 0.07	1.7 (1.2, 2.4) 0.003	2.4 (1.4, 3.9) 0.001
	(n=83)	(n=113)	(n=90)	(n=93)			
Change in ESS score ²	-3.7±4.7	-2.8±6.4	-3.7±5.2	-3.0±3.7	0.8 (-0.2, 1.9) 0.13	-0.14 (-1.2, 0.9) 0.80	0.7 (-0.9, 2.3) 0.38
Change in FOSQ-10 score ²	-14.2±10.3	-9.9±12.9	-10.9±11.2	-11.3±12.8	1.9 (-0.8, 4.5) 0.16	0.6 (-2.0, 3.3) 0.64	2.5 (-1.3, 6.4) 0.20

Values are mean ± standard deviation or number of patients (%).

AHI, apnea-hypopnea index; ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; Tel-Ed, telemedicine-based education; Tel-TM, telemedicine-based telemonitoring; Tel-Both, telemedicine-based education and telemonitoring.

¹ Effect is the odds-ratio.

² While CPAP usage data was available for all patients, ESS and FOSQ-10 were available for only those that kept their 3-month follow-up appointment.