Self- Management of Continuous Positive Airway Pressure Settings

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Background: Because of clinical demands, patients are often under-educated and under-supported about the features of their positive airway pressure (PAP) devices. The most engaged patients are ones who understand the details of their device and change the feature settings so that they can maximize the benefits of therapy. Features settings include humidification level, expiratory pressure relief, pressure ramping, mask alert, auto pressure start, among other important comfort features. Historically, patients have not been provided with access to alter or modify therapy pressure settings, which requires physician prescription. Allied medical staff can carry out subsequent pressure setting changes. It is clear that it is difficult for the healthcare system to engage in optimal chronic disease management and accommodate the needs of sleep apnea patients early in the treatment initialization process, which requires multiple visits/contacts to ensure that patients are maximizing the use of therapy.

Objectives and Aims: The overarching aim of the proposed project is to examine the effect of providing patients with the ability to adjust their PAP pressure levels on therapy adherence and outcomes. To answer these research questions, the proposed randomized, controlled two-group trial of Sleep Apnea Self-Management Program (SM) and SM plus Individualized Pressure Adjustment (IPA) has the following specific aims related to APAP adherence and efficacy, patient-reported outcomes, and utilization: (1) To examine the effect of Individualized Pressure Adjustment (IPA) of settings on treatment adherence and efficacy (i.e., mask leak and residual apnea-hypopnea index); (2) To examine the effect of SM+IPA versus SM on patient self-reported treatment outcomes; and (3) To describe the effects of SM-IPA and SM groups on utilization.

Significance: Sleep apnea is one of the most common chronic conditions in the VA. Positive airway pressure (PAP) therapy is the gold-standard therapy for sleep apnea, but adherence with PAP is suboptimal. VA sleep programs are understaffed relative to clinical demand for education and support. While adaption to PAP therapy has traditionally been achieved through sequential visits and pressure changes initiated by providers during office-based care, self-monitoring and individualized pressure adjustment is an important strategy that would empower Veterans to achieve better control of their OSA. The key impacts of this project are significant for both patients (improved outcomes) and the VA (improved staff efficiencies).

Innovation: While patients have control over a wide range of comfort features on their PAP devices, historically they have not been formally educated and supported to adjust pressure settings. The unique aspect of this study is the focus on individualizing pressure settings to allow for the maximizing therapeutic benefit, including increased PAP adherence. Importantly, this is done within the context of provider oversight.

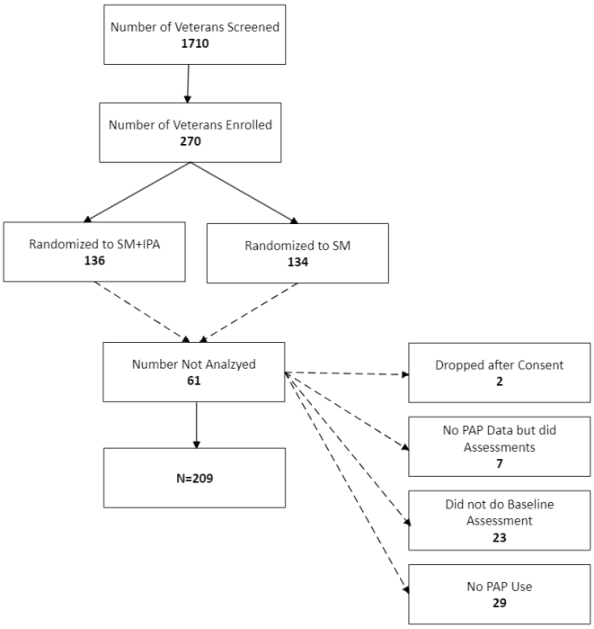
Methods: The proposed study is a 6-month randomized, controlled, non-blinded, single-center study comparing the Sleep Apnea Self-Management Program (SM) to SM plus Individualized Pressure Adjustment (IPA). Both groups will receive the SM protocol to ensure that they receive identical OSA and PAP education and support. Participants in the intervention arm will be provided with additional education and support that will allow them to adjust their PAP pressures.

Findings/ Progress: We are currently continuing recruitment of research subjects and engaging in follow up visits.

Expected Results: Positive findings from this study will result in a Toolkit that can be distributed through the VA Sleep Network and the American Sleep Apnea Association to provide patients and providers with the knowledge necessary to improve the clinical management of OSA.

Accomplishments Overview. Our primary accomplishment this past period was conducting our final analysis for the IMPRESS study. What follows is a summary of the data analyses.

Sample Recruitment. The diagram shows the patient flow through the study. Over 1,700 veterans were screened and 270 were enrolled in the study and then randomized into one of two interventional groups. Of those 270, 61 were not analyzed due to the reasons cited in the diagram, leaving an analyzable sample of 209 participants. The study received an extension due to not reaching the planned sample size due to COVID-19 and a national CPAP recall, which helps to account for the large number of screenings.



Results

Sample Characteristics. The study focused on patients diagnosed with OSA and prescribed CPAP therapy. The sample was (90% men; 10% women) from various ethnic backgrounds and with a full range of medical co-morbidities. At baseline, the sample was middle-aged (mean age = 47.3 ± 12.2), had moderate-severe OSA (mean apnea-hypopnea index (AHI) = 25.5 ± 22.4), and was overweight (mean body mass index (BMI) = 32.0 ± 5.3). All statistics are mean ± SD unless otherwise noted. Table 1 provides the sample characteristics at baseline for the total group and the two intervention groups.

Table 1 shows the sample characteristics across the total sample and then subdivided by the two study groups at baseline. The measures are grouped by category. The sample characteristics did not significantly differ between the intervention groups at baseline.

Table 1: Baseline Sample Characteristics

Category	Measure	Total	SM+IPA	SM	*p*-value
Demographics	Age	47.3 ± 12.2	48.1 ± 12.6	46.3 ± 11.8	0.09
	BMI	32.0 ± 5.3	32.0 ± 5.5	32.0 ± 5.0	0.59
OSA Severity	AHI	25.5 ± 22.4	26.3 ± 23.2	24.4 ± 21.6	0.43

Note: BMI: Body Mass Index; AHI: Apnea-Hypopnea Index.

Data Analyses. Data analyses were conducted by study aim. Aim 1 was focused on CPAP adherence and included measures of CPAP efficacy (mask leak and residual AHI) (Table 2). There were no significant differences between adherence, mask leak or residual AHI between the intervention groups.

Table 2: CPAP Adherence & Efficacy

Category	Measure	Total	SM+IPA	SM	*p*-value
Adherence	Adherence	2.13 ± 1.6	2.2 ± 1.6	2.1 ± 1.5	0.17
Efficacy	Mask Leak	15.2 ± 14.0	15.8 ± 14.7	14.4 ± 13.0	0.16
	Residual AHI	2.9 ± 2.6	3.1 ± 2.7	2.8 ± 2.5	0.17

Aim 2 focused on patient-reported outcomes (PROs). Table 3 provides the baseline PROs. There were no significant differences at baseline for the measures except for Epworth Sleepiness Scale and Outcome Expectations, with slightly higher baseline sleepiness and outcome expectation levels in the SM group.

Table 3: Baseline Patient-Reported Outcomes (PROs)

Category	Measure	Total	SM+IPA	SM	*p*-value
OSA	SASN	3.2 ± 0.7	3.2 ± 0.7	3.1 ± 0.7	0.59
	SAQLI	39 ± 1.3	56.3 ± 11.7	55.5 ± 10.1	0.80
Sleep	ESS	13.3 ± 5.3	12.9 ± 5.7	13.7 ± 4.7	0.01
	SI	11.2 ± 5.7	11.1 ± 5.6	11.3 ± 5.8	0.25
Social-Cognitive	SE	4.3 ± 0.7	4.3 ± 0.8	4.4 ± 0.7	0.35
	OE	4.6 ± 0.9	4.5 ± 1.0	4.8 ± 0.7	0.00
Other	CESD	1.5 ± 0.5	1.5 ± 0.5	1.6 ± 0.5	0.35
	BIPQ	55.9 ± 11	56.3 ± 11.7	55.5 ± 10.1	0.37

Note: SASN: Sleep Apnea Symptoms-Night; SAQLI: Sleep Apnea Quality of Life Index; ESS: Epworth Sleepiness Scale; SI: Sleep Condition Indicator; SE: Self-Efficacy Scale; OE: Outcome Expectations; CESD: Center for Epidemiological Studies Short Depression Scale; BIPQ: Brief Illness Perception Questionnaire.

Table 4: 2 Month Patient-Reported Outcomes

Category	Measure	Total	SM+IPA	SM	p-value
OSA	SASN	2.6 ± 0.8	2.6 ± 0.8	2.7 ± 0.9	0.66
	SAQLI	4.4 ± 1.4	4.5 ± 1.4	4.4 ± 1.4	0.94
Sleep	ESS	11.0 ± 5.3	10.5 ± 5.8	11.4 ± 4.7	0.04
	SI	14.4 ± 7.1	14.3 ± 7.3	14.6 ± 7.0	0.79
Social-Cognitive	SE	4.0 ± 0.8	3.9 ± 0.9	4.1 ± 0.8	0.52
	OE	4.2 ± 0.9	4.0 ± 0.9	4.4 ± 0.9	0.80
Other	CESD	1.3 ± 0.6	1.3 ± 0.6	1.3 ± 0.6	0.40
	BIPQ	51.8 ± 12	53.0 ± 11.9	50.4 ± 12.0	0.94
Patient Activation	PACIC	3.3 ± 1.1	3.2 ± 1.1	3.4 ± 1.1	0.79

Note: SASN: Sleep Apnea Symptoms-Night; SAQLI: Sleep Apnea Quality of Life Index; ESS: Epworth Sleepiness Scale; SI: Sleep Condition Indicator; SE: Self-Efficacy Scale; OE: Outcome Expectations; CESD: Center for Epidemiological Studies Short Depression Scale; BIPQ: Brief Illness Perception Questionnaire; PACIC: Patient Assessment of Chronic Illness Care.

Conclusions. The intervention did not appear to increase CPAP adherence and efficacy measures or patient-reported outcomes. It is not surprising that PROs were not improved because higher levels of CPAP use are typically needed to improve sleep and sleep quality to have an impact on the PROs. The levels of CPAP adherence found in this study are consistent with levels found in veterans in other studies. This study encountered two primary challenges: (1) COVID-19 and (2) a national CPAP recall. The primary impact of COVID-19 was the effect on in-person visits. The study went entirely virtual during this time period, including consenting procedures. One major lesson learned during this time was the importance of conducting hybrid studies to tailor study methods for our veterans. While we were forced to avoid in-person visits, future studies would do well to schedule at least 1-2 in-person visits to ensure study progress. Future studies on this topic may want to consider a more intensive intervention. It may be that patients require more contact or more encouragement and instruction. It may also be that a different study design is needed to evaluate individualized pressure adjustment because only a subset of patients may be initially interested in it. While individualized pressure adjustment may not be effective in large numbers, this does not mean that individual clinicians may not want to consider implementing IPA on a case-by-case basis in those patients who express interest.