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SCIENTIFIC INVESTIGATIONS

Impact of patient and family engagement in improving continuous positive airway pressure adherence in patients with obstructive sleep apnea: a randomized controlled trial

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Study Objectives: The aim of the Improving CPAP Adherence Program was to assess the impact of a multidimensional treatment framework based on shared decision-making, patient activation, and caregiver engagement on improving long-term positive airway pressure (PAP) adherence in patients newly diagnosed with obstructive sleep apnea.

Methods: In this pilot study, patients aged ≥ 18 years with a new obstructive sleep apnea diagnosis who qualified for PAP treatment and lived with a caregiver were randomly assigned to receive either the multidimensional treatment (intervention, n = 28) or unrelated education (control group, n = 32). All patients and their caregiver participated in a group visit. The intervention group attended 4 structured sessions: interactive education, peer coaching, hands-on experience, and a semistructured motivational interview. The control group was educated on physical activity and lifestyle only. Objective PAP adherence data were obtained at baseline (day that they received PAP machine to group visit), group visit to 3 months, and 3–6 months.

Results: In an age-adjusted model, the mean daily use of PAP increased significantly over the 3 time periods (P = .03). Intervention-arm participants gained a mean 1.23 hours (95% confidence interval, 0.33–2.13) in PAP mean daily use between 3 and 6 months vs those in the control arm (P = .008). We saw no difference in the percentage of PAP adherence across time between the 2 arms.

Conclusions: A multifaceted patient-centered intervention with caregiver engagement improved PAP adherence vs control levels, a beneficial effect sustained for the 6 months. Our findings suggest that caregivers, with the appropriate training, can improve patients' PAP adherence by providing a socially supportive environment.

Keywords: obstructive sleep apnea, positive airway pressure, patient and caregiver engagement, multifaceted intervention, peer coaching, motivational interview

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Only 1 prior randomized controlled trial has provided evidence that a couple's engagement improves continuous positive airway pressure adherence in patients with obstructive sleep apnea. The purpose of this study was to assess the extent to which a multidimensional structured intervention that engages patients and their caregivers can improve positive airway pressure adherence.

Study Impact: This study expands upon prior knowledge by providing evidence that a multifaceted patient-centered intervention with caregiver engagement improves long-term positive airway pressure adherence.

INTRODUCTION

Obstructive sleep apnea (OSA) is a common public health problem that affects 34% of men and 17% of women.[1] Its prevalence is increasing because of increased obesity rates.[2] OSA is also an independent risk factor for hypertension[3–5] and other adverse cardiovascular outcomes.[6] Positive airway pressure (PAP), the mainstay treatment for OSA, has been shown to improve sleep quality, reduce daytime symptoms, and improve overall quality of life in patients.[7] Adherence to PAP is defined as PAP use ≥ 4 hours/night. PAP adherence improves OSA symptoms, including hypertension,[8–10] and most notably treatment-resistant hypertension.[11] Unfortunately, PAP adherence remains suboptimal despite marked improvement in mask technology and the development of several behavioral interventions in the last 20 years. Overall PAP adherence remains low at 66% and has improved by only approximately 1 hour per night over the past 20 years.[12]

The known relationship between PAP adherence and outcomes has underscored a need to develop interventions to enhance adherence,[13–18] using methods including telemonitoring,[19] patient engagement via mobile health interventions,[20,21] peer coaching,[22] and spousal involvement.[23] Evidence suggests that the social influence of partners or others who are close with patients can promote health-enhancing behavior change.[24] Surveys conducted by Baron et al[25] in patients with OSA revealed

that perceptions of collaborative spousal involvement were favorably associated with adherence. Likewise, Gentina et al[26] showed that a partner's encouragement of continuous positive airway pressure (CPAP) use and a stable, longstanding relationship were independent predictors for CPAP adherence. However, their work was an observational study only and was limited to couples.[26] Mendelson et al further classified couples into 3 clusters (young working couples, mature active couples, and retired couples) and found that patients in the retired couples cluster showed the highest CPAP adherence.[27]

Qualitative analyses conducted on couples and the partners of patients with OSA by Luyster et al[28] and Khan et al[29] have highlighted the importance of using couples-oriented interventions to improve PAP adherence. A randomized controlled trial (RCT) of couple-oriented interventions further supported this idea,[30] but the positive effect of partner engagement was not sustained (< 3 months), perhaps owing to the small sample size (only 5 patients in the couple-oriented group).

The present study was designed to expand and improve upon these findings of positive influences of social partners on PAP adherence. Our study, the Improving CPAP Adherence Program (I-CAP), aimed to determine the impact upon PAP adherence of a multidimensional treatment framework based on shared decision-making; a patient activation method focused on knowledge, skills, and building confidence to influence behaviors[31]; and caregiver engagement. Our approach included having a caregiver attend the intervention visit to help empower the patient and develop a shared understanding between caregiver and patient of the goals and benefits of PAP treatment and to facilitate each caregiver's provision of support to his/her care recipient (ie, the patient with OSA). In this pilot RCT, we assessed the impact of patient and caregiver engagement in improving long-term PAP adherence in patients newly diagnosed with OSA over 6 months.

METHODS

Design

The I-CAP study was a randomized, controlled, parallel-group clinical trial with intervention and attention control arms. Patients were randomized (1:1) in blocks of 4 using a computer-generated randomization program and were recruited from June 2016 through August 2018. The study was approved by the Michigan State University Institutional Review Board. Initially, patients were recruited from Sparrow Pulmonary Clinic (East Lansing, MI), but we later added 4 more recruitment sites including a sleep laboratory and 3 other clinics. Patients were mainly recruited from the Sparrow Pulmonary Clinic, the Mid-West Center for Sleep Disorders, and the Sparrow St. Lawrence Sleep Center (all in MI). The group visit was conducted in the Sparrow Hospital Professional Building. All the participants, including the caregivers, provided written informed consent.

Inclusion criteria

The inclusion criteria were as follows: (1) patients with newly diagnosed OSA who qualified for PAP therapy; (2) aged 18 years or older; (3) living with a caregiver, defined as the support person living in the same household as the index participant and including spouses, partners, significant others, parents, and siblings; (4) able to speak English; and (5) owning a cell phone.

Exclusion criteria

The exclusion criteria were as follows: (1) significant cognitive impairment or severe psychiatric disease, and (2) patient refusal or inability to give informed consent.

Conceptual framework

The I-CAP study was based on the relational coordination model[32] and the social-ecological perspective theory (**Figure 1**).[33] The relational coordination model provides an evidence-based framework that enhances coordination among providers and patients and has been shown to be associated with improved outcomes and quality of care.[34,35] According to the social-ecological perspective theory, health-related outcomes are determined by person and environment and are influenced by interrelationships in the social environment (actor-partner interdependence). In the I-CAP study, we combined the 7 dimensions of the relational coordination model with the social-ecological perspective theory to produce an effective PAP adherence program based on patient-centered intervention, caregiver engagement, and peer coaching to improve PAP adherence in OSA.

Study procedures

The clinic/laboratory staff asked patients if they would like to participate in a research study. Interested patients were directed to complete the permission to call form. The research assistant contacted patients via phone or email based on their preference and assigned the next available randomization assignment.

Group visit

The main study intervention was a 60- to 90-minute group visit, which was scheduled from 4–96 days (median 37) after participants received a PAP machine, for both the intervention and the control groups. There were 4 patients who did not participate in a group visit until day 112, 115, 119, and 254, respectively, after receiving the PAP machine, mostly because of scheduling issues (3 of 4 patients).

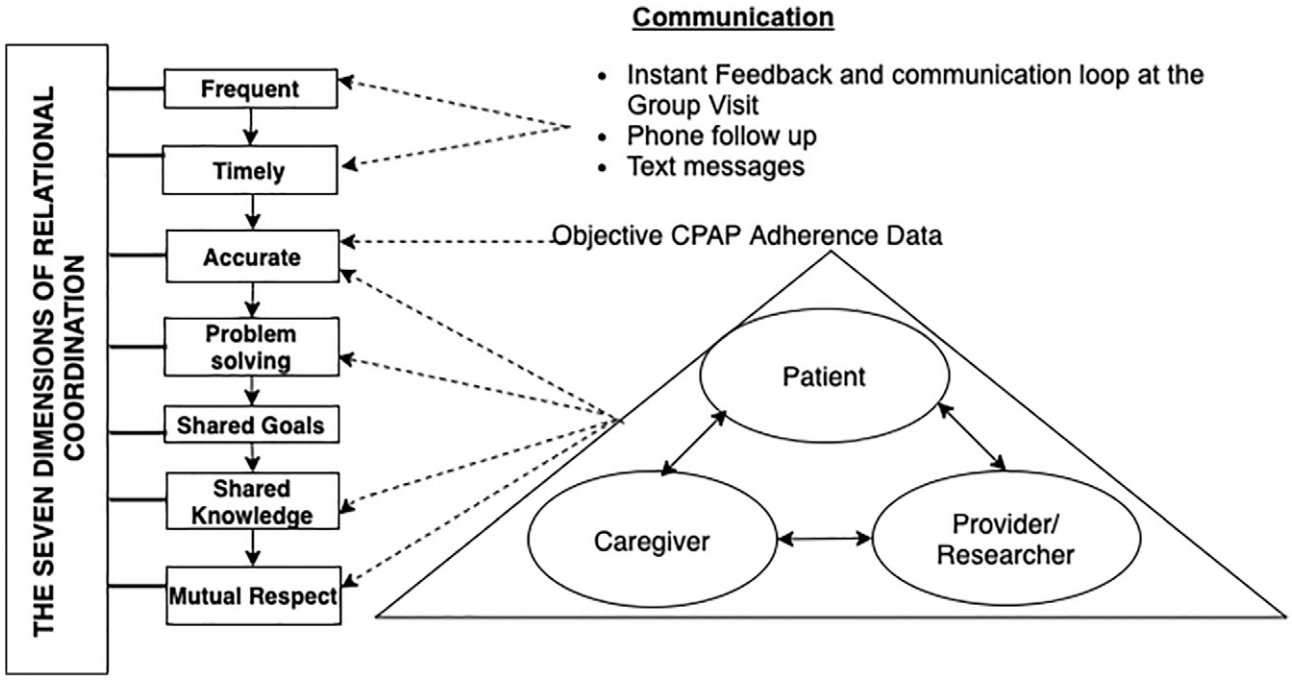
Intervention arm

During the group visit, all the intervention arm participants along with their caregiver participated in 4 structured patient-centered sessions: (1) interactive education that focused on educating participants on the effects of OSA on health and the benefits of using a PAP machine, (2) peer coaching from a patient with chronic OSA who used PAP, (3) hands-on experience with a respiratory therapist, and (4) a semistructured 1-on-2 motivational interview. The details of these sessions have been described previously.[29]

Attention control arm

During the group visit, the control arm participants and their caregiver were provided information on physical activity and lifestyle modification.

Figure 1—The relational coordination model and the social ecological perspective theory incorporated into the I-CAP study.



CPAP = continuous positive airway pressure, I-CAP = Improving CPAP Adherence Program.

Follow-up intervention

Approximately 1 month after the group visit, the research assistant contacted participants by phone to discuss any potential issues. The research assistant also encouraged PAP adherence for patients in the intervention arm only. We sent standard text messages to patients in the intervention arm at periodic intervals throughout the 6-month study to encourage them to use CPAP. Both groups received text message reminders to complete the surveys at 1, 3, and 6 months.

Outcomes

Primary outcomes

Primary outcomes included the mean daily usage of PAP (hours per night) and the percentage of PAP adherence during each of 3 intervals: (1) at baseline (from the day the PAP machine was received until the group visit), (2) group visit to 3 months, and (3) 3–6 months from the group visit. We used Medicare's definition of PAP adherence as the use of CPAP ≥ 4 hours per night on 70% of nights during each interval. Medicare uses adherence during the initial 90-day period to determine reimbursement for long-term PAP therapy. All patients were using a PAP device with remote monitoring capabilities. The adherence data were captured daily by the existing data-gathering server and were obtained from the PAP supplier for the 3 intervals described above.

Secondary outcomes

Secondary outcomes included the Epworth Sleepiness Scale (ESS),[36] CPAP tactics,[25] pre- and postassessment surveys, and the Combined Outcome Measure for Risk Communication and Treatment Decision-Making Effectiveness (COMRADE) survey.[37]

ESS: Measures the tendency to fall asleep in 8 different situations.[36] The responses for each of the 8 items are rated on a 0–3 scale, with higher scores indicating more chances of dozing off. The total score ranges from 0–24, with a score of 10 or more indicating excessive daytime sleepiness.

CPAP tactics survey: This survey was adapted from Baron et al.[25] It has 25 items and measures the perceptions of caregiver involvement. Both patients and their caregiver completed their respective sections and rated how often the caregiver used each strategy over the past week to encourage PAP use. The response ranged from 1 (never) to 5 (several times per day). The surveys were mailed at 1 month, 3 months, and 6 months after the group visit.

Pre- and postassessment surveys: These surveys were intended to measure the intervention's impact at the end of the group visit. The surveys were rated on a 4-point ordinal scale and assessed the patients' understanding of OSA and how it affects health; the role of PAP treatment, both post-I-CAP and pre-I-CAP; and the comfort with and satisfaction in making a treatment decision.

COMRADE survey: This survey measured the shared decision-making and the confidence in the decision made.[37] The 20-item survey uses a Likert response format (1 = strongly disagreed to 5 = strongly agree) and was administered at the end of the group visit.

Loss to follow-up on surveys (LTFU): Loss to follow-up was defined as when a participant stopped returning surveys to the study team, whether it occurred at 1, 3, or 6 months after the group visit. Data on CPAP adherence were still available on some of these patients.

Statistical analysis

Descriptive statistics were generated for baseline characteristics, including means and standard error for continuous variables, and frequencies and percentages for discrete variables. Pooled *t* tests and chi-square tests were used to compare these baseline characteristics between the 2 study groups. In addition, a Wilcoxon rank-sum test was conducted to compare the time lag between receiving a PAP machine and the group visit, for the control group vs the intervention group.

For primary outcomes, correlated data models were used to evaluate the intervention effect on mean daily usage (linear mixed-effects model) and the percentage of PAP adherence (generalized estimating equations models). For the linear mixed model, 2 sensitivity analyses were conducted. The first analysis used the model-based variance-covariance matrix as implied by the underlying random-effect specification to estimate the standard errors of the fixed effect parameter estimates. The second analysis treated the association structure resulting from the assumed random-effect specification as a working model, in which case a sandwich estimator was invoked to estimate these standard errors. Further, for each of these approaches, both the adjusted and unadjusted analyses were conducted.

For secondary endpoints such as CPAP tactics, generalized estimating equation models were used to describe the longitudinal profile of patients reporting at least once that their caregiver had engaged in the behaviors aimed at encouraging PAP use and to assess whether this frequency differed between the 2 study groups. In addition, linear mixed-effects models were used to describe the profile of the ESS across time, using both the model-based and the empirical standard errors. For the pre- and postassessment survey, an ordinal regression model for correlated data was used to assess the trend in ordered scores from pre-I-CAP to post-I-CAP. Because only a few patients scored 1 on the scale, ordinal variables pertaining to I-CAP assessments were then recoded by combining levels 1 and 2 to create ordinal variables with 2 ordered levels (1 and 2, 3 and 4). Proportional odds model assumptions with cumulative logits were assessed and adopted if deemed plausible.

Because there was little variability in the COMRADE survey data (ie, only a few patients reported level 3 or lower), we created binary versions of COMRADE survey endpoints combining levels 1, 2, 3, and 4 into a single level, which was then contrasted with level 5 (strongly agree).

For both the primary and the secondary outcomes, intention-to-treat analysis was adopted by including all study participants in the groups to which they were randomized, regardless of any loss to follow-up. In addition, the available case analysis method that also included patients with an incomplete profile across the 3 study visits was adopted to handle nonresponse. All analyses were performed using SAS software, version 9.4 in a Windows environment (SAS Institute Inc., Cary, NC).

RESULTS

A total of 235 patients completed the permission-to-call form; however, only 60 patients (28 in the intervention arm and 32 in the control arm) were enrolled in the study and participated in the group visit. The reasons patients chose to not participate are described in **Figure 2**. Overall, there were no differences in the baseline characteristics between the 2 arms except that the intervention arm patients were on average 8 years older than the control arm patients. More women (62%) participated in the study than men (**Table 1**). Thirteen intervention arm group visits (1 to 3 patients with their caregiver at each group visit) and 30 control arm group visits (1 or 2 patients with their caregiver at each group visit) were held during the course of the study (**Table 1** and **Table 2**). For the intervention arm, multiple couples were scheduled together because it involved coordinating with the peer coach and respiratory therapist and required the availability of 2 rooms to conduct semistructured interviews. Because the study focused on patients with a new diagnosis of OSA, we performed the primary and secondary outcome analysis after excluding the 4 patients who had exposure to PAP for more than 100 days. The interval in the scheduling of the group visits varied for patients in both the intervention and control arms because of challenges in having 2 or more couples (index participant and their caregiver) scheduled for the group visit sessions, which occurred only twice per week.

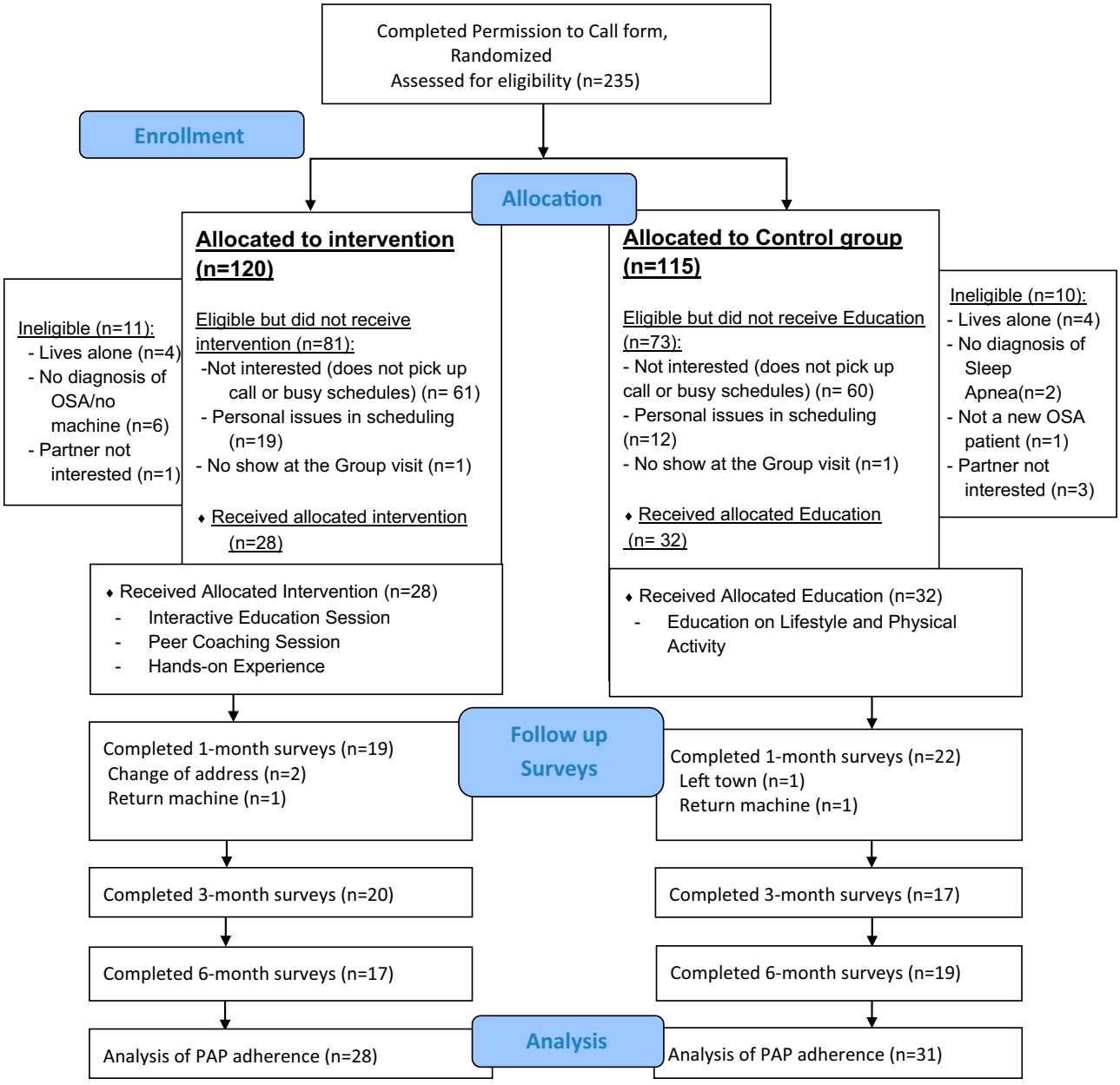
Follow-up and retention

Among the 60 patients, 24 (13 control arm and 11 intervention arm) patients stopped returning surevys during the course of the study for various reasons, including no interest, moving out of town, and stopping CPAP use. Among the 13 LTFUoS control arm patients (8 at 1 month, 4 at 3 months, and 1 at 6 months), 5 patients (including 1 patient who left town) did not have the CPAP adherence data available at 6 months. Among the 11 LTFUoS intervention arm patients (5 at 1 month, 3 at 3 months, and 3 at 6 months), 4 patients (including 2 patients who did not notify us of their changed address) did not have the CPAP adherence data available at 6 months.

For the 5 control group patients for whom the CPAP adherence data were not available at 6 months, 2 patients never used the CPAP machine and 3 (2 patients reported returning the machine) had used it for < 10% of days at 3 months from the group visit. For the 4 intervention group patients for whom the CPAP adherence data were not available at 6 months, their CPAP use was < 60% at 3 months from the group visit.

The retention rates were determined as the percentage of patients who completed either the 3-month or the 6-month follow-up survey, among those who were enrolled and attended the group visit. The 3-month retention rate was 61.6% (37/60), with 53% retention (17/32) in the control group and 71.4% retention (20/28) in the intervention group. The 6-month retention rate was 60% (36/60), with 59% retention (19/32) in the control group and 60.7% retention (17/28) in the intervention group. The overall retention rate (survey completed at 3 or 6 months) was 66.6% (40/60), with 62.5% retention (20/32) in

Figure 2—I-CAP study flow chart.



I-CAP = Improving CPAP Adherence Program, OSA = obstructive sleep apnea, PAP = positive airway pressure.

the control group and 71.4% retention (20/28) in the intervention group.

Primary outcomes

The unadjusted estimates of the mean daily use of PAP and the percentage of patients who were PAP-adherent are shown in Table 3 and Figure 3. The intervention group had a significant increase in mean daily use over the 3 study visits (changes from baseline–3 months and from 3–6 months; $P = .04$). This significant intervention effect resulted from changes occurring between 3 months and 6 months ($P = .02$), with patients in the intervention arm gaining approximately 1.16 hours in mean daily use (95% confidence interval, 0.22–2.09) between the 2 visits compared with patients in the control arm. The changes between baseline and 3 months in the 2 groups were not statistically significant ($P = .73$). There was no difference in PAP adherence (percentage of patients who used PAP for ≥ 4 hours/day for at least 70% of study days) between the 2 groups ($P = .63$).

The overall intervention effect in an age-adjusted model over the 3 time periods (changes from baseline–3 months and from 3–6 months) was significant at a 5% level ($P = .03$).

Table 1—Baseline characteristics of intervention and control arm patients.

Characteristic	Overall Cohort (n = 60)	Intervention Group (n = 28)	Control Group (n = 32)	*P* Value
Age (y)	53.5 ± 12.97	58 ± 11.75	50 ± 12.92	.01
Body mass index (kg/m^2)	37.6 ± 9.84	35.5 ± 7.2	39.4 ± 11.5	.13
Men	23 (38)	12 (43)	11 (34)	.60
Race				.20
White	49 (82)	25 (89)	24 (75)	
Black, Asian, American Indian, Native, Hispanic, and others	11(18)	3 (11)	8 (25)	
Hispanic or Latino	7 (12)	2 (7)	5 (16)	.43
Smoking history				> .99
Nonsmoker	26 (43)	16 (57)	18 (56)	
Smoker	34 (57)	12 (43)	14 (44)	
Married	47 (78)	21 (75)	26 (81)	.59
Room partner	57 (95)	27 (96)	30 (93)	> .99
Bed partner	55 (92)	25 (89)	30 (93)	.66
Living in the same household	55 (92)	26 (93)	29 (91)	> .99
Education level				
High school graduate or below	11 (19)	7 (26)	4 (13)	.31
Some college or above	48 (81)	20(74)	28 (87)	—
Health history				
Asthma	9 (15)	2 (7)	7 (22)	.15
Anxiety	12 (20)	7 (25)	5 (16)	.52
Cancer	5 (8)	2 ((7)	3 ((9)	> .99
Coronary heart disease	3 (5)	2(7)	1(3)	.60
Congestive heart failure	3 (5)	3 (11)	0 (0)	.10
Claustrophobia	2 (3)	1 (4)	1 (3)	> .99
Depression	16 (27)	8 (29)	8 (25)	.78
Hypertension	29 (48)	13 (46)	16 (50)	.80
High cholesterol	27 (45)	13(46)	14 (44)	> .99
Stroke	3 (5)	3 (11)	0 (0)	.10
COPD/emphysema	2 (3)	2 (7)	0 (0)	.21
Drink in last 30 d	35 (53)	16 (36)	19 (60)	> .99
PHQ-9 (score 0–27)	5.48 ± 5.1	5.96 ± 6.4	5.06 ± 3.9	.54
Baseline apnea-hypopnea index	26.0 ± 23.0	26.8 ± 25.0	25.5 ± 21.6	.83
Minimum SaO_2	78.6 ± 8.1	79.1 ± 7.1	78.1 ± 8.9	.64
Interval between receiving PAP and group visit (after excluding patients with group visit > 100 d)	30.6 (4–96 d)	37 (6–96 d)	22 (4–91 d)	.17

Values are presented as mean ± SD or n (column %) or median (range). COPD = chronic obstructive pulmonary disease, PAP = positive airway pressure, PHQ-9 = Patient Health Questionnaire-9, SaO_2 = oxygen saturation.

Table 2—Caregiver's relationship with the patient.

Relationship	Intervention (n)	Control (n)
Spouse	21	26
Significant other/partner	3	4
Son/daughter	2	1
Friend	1	—
Sister/mother	1	1
Total	28	32

This significant intervention effect adjusted for age resulted from changes occurring between 3 and 6 months (P = .008), with patients in the intervention arm gaining approximately 1.23 hours in mean daily use (95% confidence interval, 0.33–2.13) between the 2 visits compared with patients in the control arm. The adjusted changes between baseline and 3 months in the 2 groups were not statistically significant (P = .73).

Additional analyses were conducted to evaluate whether the intervention effects varied with age group (aged < 60 years and aged ≥ 60 years). Using 3-way interactions, we found no evidence to suggest that the (longitudinal) intervention effects varied with age group (P = .45).

Secondary analyses

ESS

The ESS scores improved in both the intervention and the control groups (Table 4). There was no preferential attrition (P = .21).

CPAP tactics survey

Analysis from the patient perspective: Among all of the 25 tactics studied, only item 7 ("Told me he or she was happy I was using CPAP") and item 15 ("Discussed using CPAP") had a significant change between the intervention and the control groups across time (Table 5). For item 24 ("Gave me space, showed patience in order to get me to use CPAP"), the percentage responding yes at 1 month was higher in the intervention group than in the control group (P = .04).

Analysis from the caregiver perspective: No significant differences in the 25 tactics were found either cross-sectionally at the 6-month follow-up or longitudinally across the 3 time points.

Pre- and postassessment survey

The results of the pre- and postassessment surveys showed that the patients assigned to the intervention arm had an improvement in their understanding of OSA (P = .04) and their understanding of the continuous use of CPAP for OSA (P < .01), compared to those in the control arm. Further analysis showed that patients in the intervention arm reported a marginal improvement in their understanding of the various effects of OSA on energy level and on cardiovascular diseases (P = .06), and they marginally reported that their comfort and satisfaction in making treatment decisions had improved compared to those in the control arm (P = .07).

COMRADE survey

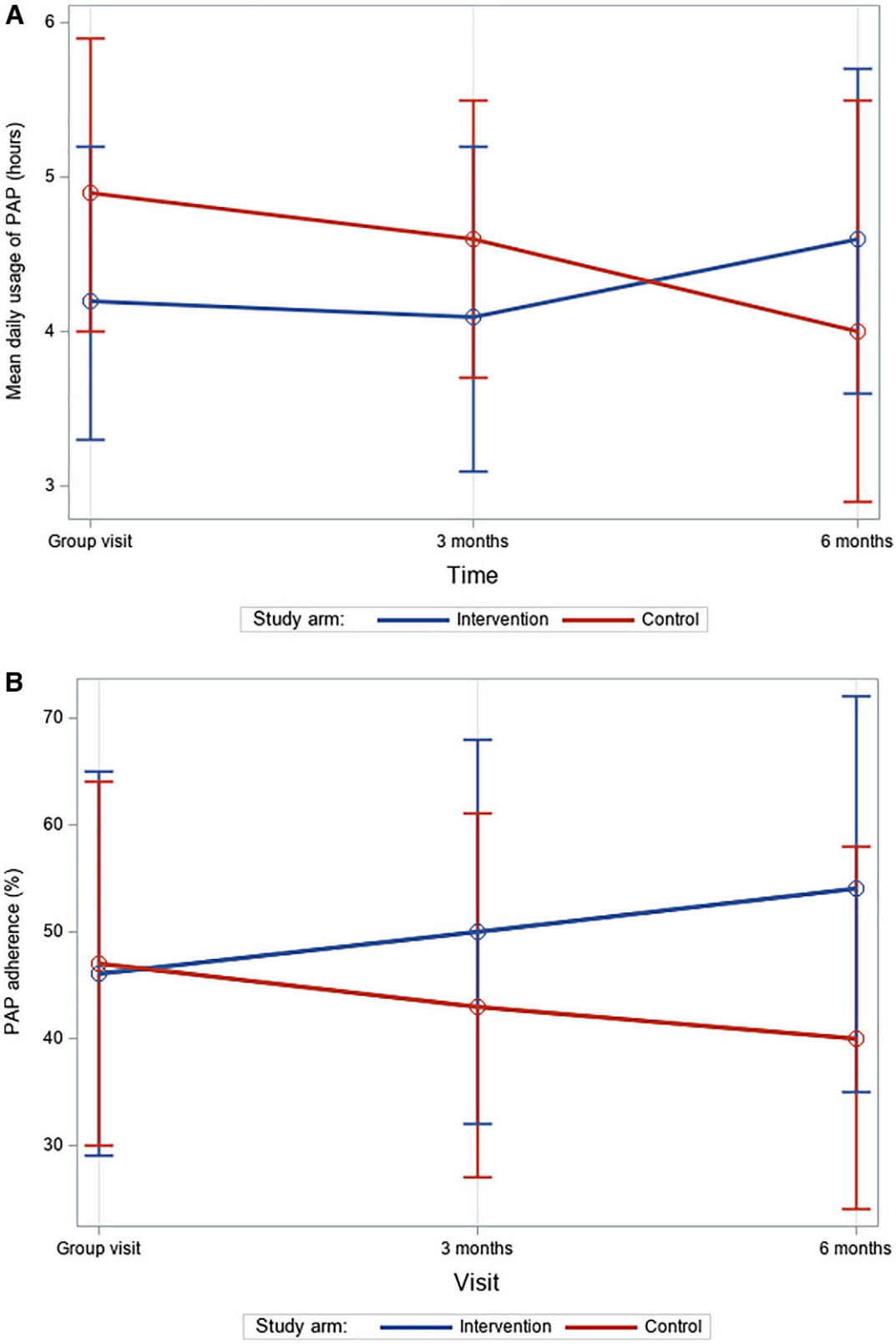
Item 7 ("I know the advantages of treatment or not having treatment"), item 8 ("I know the disadvantages of treatment or not having treatment"), item 10 ("The doctor gave me a chance to be involved in the decisions during the consultation"), and item 11 ("Overall I am satisfied with the information I was given") were found to be associated with the intervention (item 7 and item 8, odds ratio = 3.65, P = .02; item 10, odds ratio = 3.25, P = .04).

Table 3—Time course of primary endpoints.

Adherence	Intervention Arm			Control Arm			*P* Value: Time × Group Interaction (Overall Longitudinal Effect)	
	Baseline	3 Months	6 Months	Baseline	3 Months	6 Months	Unadjusted	Age-Adjusted
Mean daily use,[a] h/d (95% CI)	4.2 (3.3–5.2)	4.1 (3.1–5.2)	4.6 (3.6–5.7)	4.9 (4.0–5.9)	4.6 (3.7–5.5)	4.0 (2.9–5.0)	.043	.03
PAP adherence,[b] % (95% CI)	46 (28–65)	50 (32–68)	54 (35–72)	47 (30–64)	43 (27–61)	40 (24–58)	.59	.46

[a]Mean daily use = the number of hours of PAP use with mask on divided by the total number of study days. [b]PAP adherence = PAP use for ≥ 4 hours/day for at least 70% of study days. CI = confidence interval, PAP = positive airway pressure.

Figure 3—PAP usage and adherence.



Averages and confidence intervals of mean daily PAP usage **(A)** and proportion of PAP adherence **(B)** generated from unadjusted longitudinal analysis. PAP = positive airway pressure.

Table 4—Time course, ESS.

ESS Scores	Intervention Arm			Control Arm			*P* Value: Time × Group Interaction (Overall Longitudinal Effect)
	Baseline	3 Months	6 Months	Baseline	3 Months	6 Months	
Mean ± SE	9.1 ± 0.9	6.6 ± 0.95	6.0 ± 0.7	10.2 ± 0.9	6.5 ± 0.8	4.8 ± 0.7	.11

ESS = Epworth Sleepiness Scale, SE = standard error.

DISCUSSION

In this RCT, the use of PAP declined at 6 months in the control group but was retained in the intervention group. These findings of the I-CAP study indicate that engagement of caregivers could improve and sustain improvement in PAP adherence in patients with OSA.

Our study was based on a patient-centered interaction with engagement of the caregiver through each step of learning to develop a shared mental model.[29] Using qualitative analyses, several studies have highlighted both the patients' and partners' perspectives and experiences with OSA and have identified barriers and facilitators of PAP treatment.[28,29,38] Our findings are similar to the study by Batool-Anwar et al[23] showing that spousal involvement is an important determinant of PAP adherence in men, especially in the first 6 months. However, our study focused on engaging the caregiver, whether it was a spouse, parent, sibling, or significant other. Similarly, Luyster et al[30] showed that the implementation of couple-centered interventions may improve PAP adherence. Their study showed an improvement in PAP use at 1 month only, with PAP use declining back to 1-week values at 3 months. In contrast to the work of Luyster et al,[30] our study involved a larger sample size and patients were followed for 6 months. We found an improvement in the hours of PAP use at 6 months in the intervention group vs the control group, whose hours of PAP use declined.

The findings of our study are consistent with prior evidence that early CPAP use is predictive of long-term adherence.[39] The device abandonment rates in our study are somewhat similar to those in other RCTs of behavioral intervention. For example, in a large RCT of motivational enhancement to improve PAP adherence in patients with OSA,[14] CPAP adherence data were not available for 16.5% of educational group participants at 6 months, whereas only 6.5% of motivational enhancement therapy group participants (tailored intervention and personalized feedback using patient-centered counseling) did not have CPAP adherence data available. Telemedicine education and telemonitoring can also promote CPAP adherence[40] and could be used in future studies.

Another novel aspect of our study is that we used a broad definition of *caregiver,* including not just spouses or partners. The "pair" of patient-housemate jointly participated in robust patient-centered intervention. In addition, we included a peer coach who shared her experience with PAP therapy adherence.

Studies have found a variable effect of age on PAP adherence, with some studies noting higher rates of PAP adherence with increasing age in univariate analysis[41–43] and multivariate analysis,[23,27,44] whereas the association with age disappeared when multivariate analysis was conducted with the adjustment of other confounders.[45] In our study, we found that age was an important factor in affecting the outcome from baseline–3 months, but not from 3–6 months, in both groups.

The significant findings of the CPAP tactics survey, which measures the perceptions of caregiver involvement, revealed that caregivers were more involved in encouraging the index participants to use their PAP. We also found that the intervention arm patients had more improvement in their understanding of OSA and use of CPAP for OSA compared to those in the control arm. Furthermore, the study revealed improved shared decision-making skills and overall satisfaction in patients in the intervention arm. These findings suggest that caregivers have an important role to play in providing a socially supportive environment and that the impact of caregiver engagement goes beyond the conventional interventions in keeping patients motivated and adhering to treatment in the long term.

Limitations and future research

There are several limitations in our study. First, the trial has a small sample size and lacks generalizability because only patients from private practices were recruited. Second, despite the plan to have a group visit within 2 weeks of receiving the PAP machine, the interval in the scheduling of the group visits varied and was longer for both groups because of challenges in having 2 or more couples (patient and caregiver) scheduled together. This issue may be reduced in large-scale studies in which participants and their caregivers may have options to choose from multiple classes available per week. Nonetheless, we did not find any statistically significant difference in the interval between the intervention and control arms. Third, the CPAP tactics surveys were completed by the patient and caregiver at 1, 3, and 6 months and are subject to recall bias. Fourth, our pilot study did not look at measures of functional improvement such as the Functional Outcomes of Sleep Questionnaire, measures of health-related quality of life such as the 12-Item

Table 5—Time course of CPAP tactics.

CPAP Tactics	Intervention Arm			Control Arm			*P* Value: Time × Group Interaction (Overall Longitudinal Effect)
	Baseline	3 Months	6 Months	Baseline	3 Months	6 Months	
Item 7 ("Told me he or she was happy I was using CPAP")	60 (38–79)	73 (50–88)	59 (35–79)	81 (60–92)	33 (14–58)	46 (25–68)	.01
Item 15 ("Discussed using CPAP")	37 (19–59)	69 (46–85)	52 (28–76)	81 (60–92)	62 (38–81)	33 (15–57)	.0008

Values are % (95% confidence interval). CPAP = continuous positive airway pressure.

Short-Form Health Survey, or self-efficacy measures such as the Self-Efficacy Measure for Sleep Apnea, which would have been useful to show PAP adherence improvement that was statistically significant and clinically important. Finally, although this is the first RCT to include a support person other than the spouse or significant other, the number of housemates who were not bed partners was small.

Large-scale studies are needed to further explore the impact of specific strategies that could be used by the social support person to influence PAP adherence positively. Future studies may explore the combination of social support with timed telemedicine, automated feedback, or self-directed software support and integration of PAP devices into the electronic medical record[46] for timely intervention and improved outcomes.

CONCLUSIONS

Our findings support the hypothesis that the patient-centered intervention shows promise and that caregiver strategies that are based on collaboration and mutual respect are perceived as encouraging by patients with OSA. Interventions to increase caregiver engagement in OSA may improve PAP adherence. More studies are needed to determine the effectiveness and the cost-effectiveness of caregiver engagement in improving PAP usage.

ABBREVIATIONS

COMRADE, Combined Outcome Measure for Risk Communication and Treatment Decision-Making Effectiveness
CPAP, continuous positive airway pressure
ESS, Epworth Sleepiness Scale
I-CAP, Improving CPAP Adherence Program
OSA, obstructive sleep apnea
PAP, positive airway pressure
RCT, randomized controlled trial

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