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Original Article

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Intensive support does not improve positive-airway pressure use in spinal cord injury/disease: a randomized clinical trial

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Abstract

Study Objective: Treatment of sleep-disordered breathing (SDB) with positive airway pressure (PAP) therapy has unique clinical challenges in individuals living with spinal cord injuries and diseases (spinal cord injury [SCI]/D). Interventions focused on increasing PAP use have not been studied in this population. We aimed to evaluate the benefits of a program to increase PAP use among Veterans with SCI/D and SDB.

Methods: Randomized controlled trial comparing a behavioral Intervention ($n = 32$) and educational control ($n = 31$), both including one face-to-face and five telephone sessions over 3 months. The intervention included education about SDB and PAP, goal setting, troubleshooting, and motivational enhancement. The control arm included non-directive sleep education only.

Results: Primary outcomes were objective PAP use (nights ≥4 hours used within 90 days) and sleep quality (Pittsburgh Sleep Quality Index [PSQI] at 3 months). These did not differ between intervention and control (main outcome timepoint; mean difference 3.5 [–9.0, 15.9] nights/week for PAP use; $p = .578$; –1.1 [–2.8, 0.6] points for PSQI; $p = .219$). Secondary outcomes included fatigue, depression, function, and quality of life. Only fatigue improved significantly more in the intervention versus the control group ($p = .025$). Across groups, more PAP use was associated with larger improvements in sleep quality, insomnia, sleepiness, fatigue, and depression at some time points.

Conclusions: PAP use in Veterans with SCI/D and SDB is low, and a 3-month supportive/behavioral program did not show significant benefit compared to education alone. Overall, more PAP use was associated with improved symptoms suggesting more intensive support, such as in-home assistance, may be required to increase PAP use in these patients.

Clinical Trials Information: Title: "Treatment of Sleep Disordered Breathing in Patients with SCI." Registration number: NCT02830074. Website: https://clinicaltrials.gov/study/NCT02830074?cond=Sleep%20Apnea&term=badr&rank=5

Key words: adherence; positive-airway pressure therapy; sleep-disordered breathing; spinal cord injury

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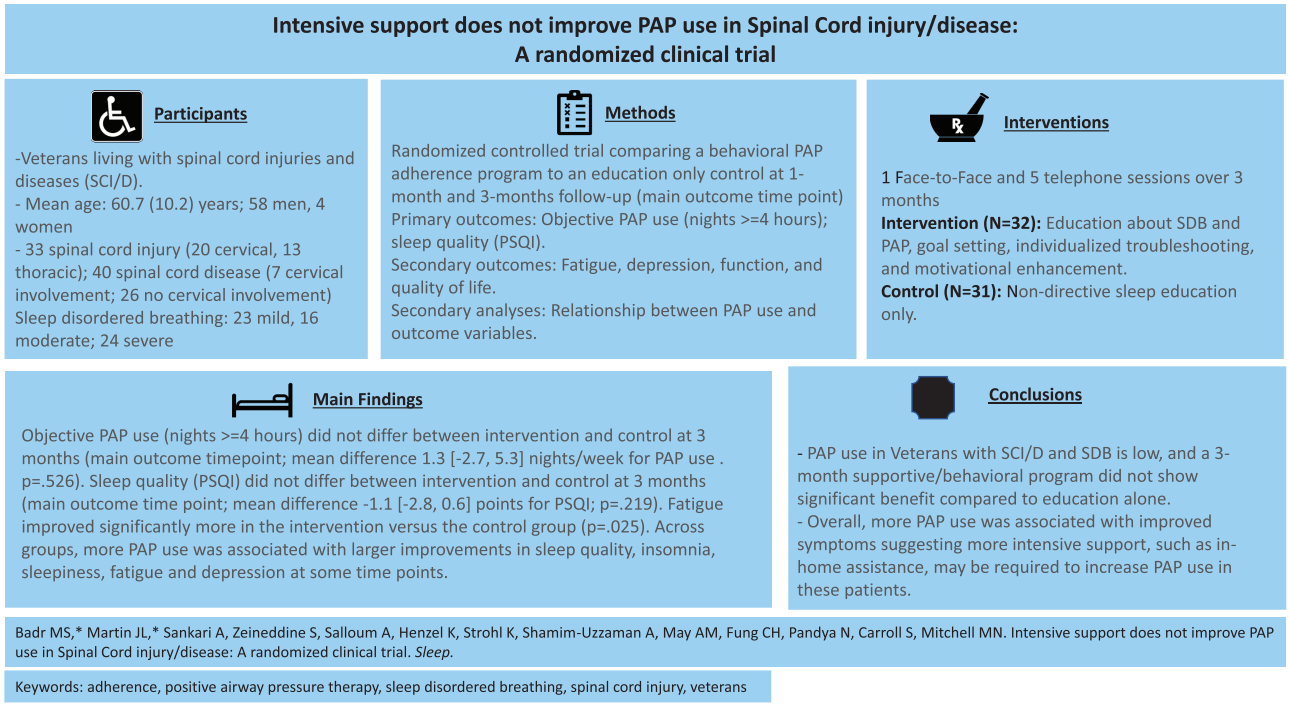
Graphical Abstract



Badr MS,* Martin JL,* Sankari A, Zeineddine S, Salloum A, Henzel K, Strohl K, Shamim-Uzzaman A, May AM, Fung CH, Pandya N, Carroll S, Mitchell MN. Intensive support does not improve PAP use in Spinal Cord injury/disease: A randomized clinical trial. *Sleep.*

Keywords: adherence, positive airway pressure therapy, sleep disordered breathing, spinal cord injury, veterans

Statement of Significance

Spinal cord injuries and diseases are associated with impairments in function, ability, participation, and health. Individuals with these conditions have high rates of sleep disorders, including sleep-disordered breathing; however, the use of first-line positive-airway pressure therapy is extremely challenging for these individuals. This study tested a novel, comprehensive program to increase use of positive airway pressure (PAP) therapy among Veterans with spinal cord injuries and diseases who had sleep-disordered breathing. We found that, even with intensive intervention, high levels of PAP use were not achieved relative to the usual-care control condition. Nonetheless, more use of PAP was associated with greater improvements in sleep and other symptoms over the first 90 days of use.

Introduction

Spinal cord injury and disease (SCI/D) are associated with impairments in function, abilities, participation, and health [1, 2]. Achieving health equity is a critical goal for the 17 000 individuals who experience acute traumatic spinal cord injury (SCI) every year; with persons identifying as black representing about a quarter of those injured every year [3]. Veterans living with SCI/D are part of a larger group of individuals who live with disabilities and the associated challenges of healthcare access. Thus, addressing and mitigating health disparity among individuals living with SCI will require development, refinement, and validation of targeted interventions to overcome the specific barriers experienced by our patients on the road to health equity [4].

Prevention of functional decline by optimizing treatment of comorbid conditions may lead to improved quality of life for individuals living with SCI/D, who have high needs for healthcare services [5, 6]. Medical advances have increased life expectancy for people with SCI/D; thereby, increasing the number of individuals with SCI/D who are also living with chronic conditions. In fact, one study reported that 56.7% of individuals with SCI/D were also overweight or obese [7].

Sleep disorders are common in Individuals living with SCI/D, with ensuing adverse health consequences [8]. Unfortunately, sleep disorders have not received adequate attention despite the compelling evidence that sleep disorders are frequent, severe, and associated with poor health in these individuals [9]. Underlying causes of poor sleep in SCI/D include depression, pain, bladder dysfunction, circadian misalignment, medication use, insomnia, and sleep-disordered breathing (SDB) [1]. In addition, poor sleep likely impairs mood and cognitive performance and may worsen pain in patients with SCI/D.

Individuals with SCI/D are three to four times more likely to have SDB than individuals in the general population [10, 11]. SDB is associated with significant adverse health consequences including poor quality of life and adverse cardiac consequences [9, 12, 13]. However, SDB has not received adequate attention in patients with SCI, likely due to the multitude of conditions that may adversely affect sleep [14].

Positive airway pressure (PAP) is the treatment of choice for SDB [15], resulting in improved metabolic function, and quality of life while ameliorating daytime sleepiness [16]. Unfortunately, adherence to PAP remains suboptimal in the general population requiring individualized and intensive education, monitoring, and support [17]. There is evidence that patients with SCI/D are even less adherent to PAP therapy [18], although there is no literature to inform PAP adherence interventions for patients with SCI/D [19].

The purpose of this study was to evaluate the effectiveness of a comprehensive program to improve PAP adherence for the treatment of SDB among individuals with SCI/D, called "BEST" (best practices, education, support, and treatment). The first aim was to test the efficacy of the BEST program, compared to a non-directive educational control program, in improving PAP use, defined as the percent of nights with >4 hours of use during the first 3 months of treatment (primary outcome). The second aim was to test the benefits of the BEST program for improving patient-reported sleep quality (primary outcome), physical functioning, quality of life, and respiratory functioning. We hypothesized that patients who received the BEST program would demonstrate more PAP use and show improvements in each of these domains from baseline to 3 and 6 months follow-up, relative to control.

Materials and Methods

Study design and participants

Using clinical and administrative data from three VA healthcare systems, we identified 988 individuals with an ICD-9 or ICD-10 code consistent with SCI/D. A medical record review was used to confirm documented SCI (at least 3 months post-injury) or spinal cord disease (at least 3 months post-diagnosis), and an IRB-approved recruitment letter was sent to 765 individuals, of whom 77 "opted out" of receiving a screening telephone call and 69 were not contacted because the study achieved its target sample size and it was not necessary to screen additional participants. In total, we attempted to contact 485 individuals by phone. Figure 1 (consort flow diagram) shows the outcomes for those screened by phone and the flow of participants through the study. A total of 145 individuals completed the study eligibility screening, 73 of whom were enrolled in the study. Ten were excluded and 63 (86%) were randomly assigned to intervention or control. Participants were randomized in two strata: cervical injury/involvement and thoracic or below. Randomization procedures followed CONSORT guidelines [20]. Participants and research staff assessing outcome measures were blinded to group assignment. Thirty-two individuals were randomized to receive the active treatment (BEST program), and 31 were randomized to receive the control intervention. The a priori sample size required was $N = 62$ randomized participants to address the main study hypotheses.

All study procedures were reviewed and approved by the Institutional Review Board at Wayne State University in Detroit, MI. During the study, a third site was added, and approval was obtained from the VA Northeast Ohio Healthcare System. A waiver of documentation of consent was obtained for screening, and written informed consent was obtained for participation (or witnessed verbal consent for those with limited upper extremity mobility). The clinical trial is registered at clincaltrials.gov (NCT02830074).

Procedures

A study physician prescribed PAP therapy, with or without oxygen, based on in-laboratory polysomnography (PSG) and PAP titration. This was followed by the completion of baseline assessment. Eligible participants were randomized (1:1, stratified by SCI/D level of injury/involvement) to the BEST program or a non-directive sleep education "control" condition (described below and in Table 1). For each strata, the statistician generated the randomization sequence using blocked randomization (block size = 2)

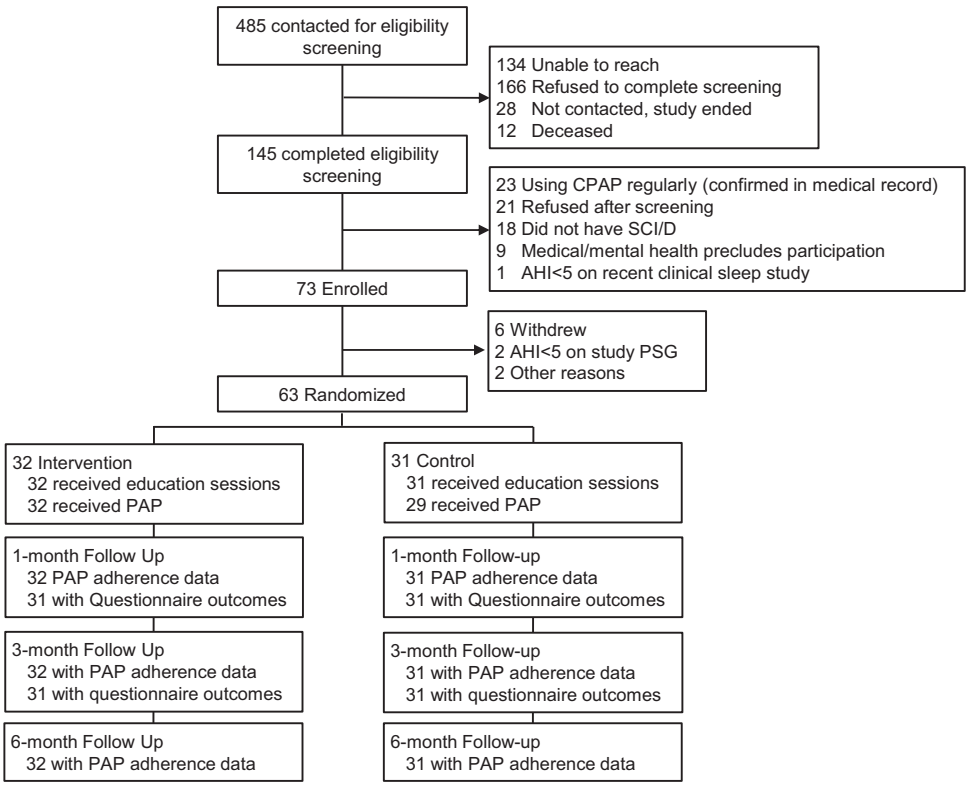


Figure 1. CONSORT diagram depicting participant flow through the study from screening through follow-up. AHI, apnea–hypopnea index; PAP, positive-airway pressure; SCI/D, Spinal cord injury or disease.

Table 1. Detailed Description and Comparability of Intervention and Control Conditions

Week	Session	Intervention session content	Control session content
1	Session 1: (PAP Titration)	Education: sleep apnea (including AHI severity and consequences), PAP titration study, PAP therapy-what to expect Behavioral components: establish plan for a regular sleep schedule, set PAP use goal for first week (encourage "behavioral experiment" to try PAP)	Education: sleep apnea definition, explanation of PAP therapy
2	Session 2	Review PAP use report; discuss/address challenges to use Education: sleep regulation (sleep drive and circadian rhythms), sleep stages, relationship between sleep apnea and sleep quality Behavioral components: learn/practice relaxation exercises to help with PAP adjustment Set weekly PAP use goal	Education: sleep stages and common sleep problems in SCI/D
3	Session 3	Review PAP use report, discuss/address challenges to use; discuss any benefits of treatment Education: benefits of long-term PAP use; discuss personal reasons for treating sleep apnea, Behavioral Components: adjust sleep schedule plan (if needed), learn/practice brief mindfulness exercises Set weekly PAP use goal	Education: sleep changes across the adult lifespan; how sleep impacts you during the day
4	Session 4	Review PAP use report, discuss/address challenges to use; discuss any benefits of treatment Education: Sleepiness and PAP use Behavioral Components: Implementing bedtime routine that includes PAP use; limiting non-sleep activities in bed, personal motivations for using PAP Set PAP use goal for the next month	Education: stress and sleep; relaxing activities that can help sleep
8	Session 5	Review PAP use report, discuss/address challenges to use; discuss any benefits of treatment Education: Sleep hygiene/healthy habits; plan for future obstacles to using PAP (travel, health events, etc.) Behavioral Components: sleep hygiene w/ personalized recommendations Set PAP use goal for the next month	Education: sleep hygiene components: sleep environment
12	Session 6	Review PAP use report, discuss/address challenges to use; discuss any benefits of treatment Education: Chronic disease patient self-management Behavioral Components: Reflect on challenges and benefits of PAP use; consider future goals for treatment of sleep apnea Set long-term PAP use goal	Education: sleep hygiene components: diet, exercise, and sleep

using Stata using the uniform() function From this sequence, two sets of envelopes containing group assignment were generated. The sealed envelopes were stored where the intervention and assessment staff did not have direct access. Once final eligibility was determined, the next envelope in the sequence for the appropriate block was opened to determine the intervention group to which the participant was assigned.

The Intervention and Control programs were provided by a trained health educator under the supervision of the study psychologist (JLM). Both programs included a total of six sessions over a 3-month period (Table 1). To facilitate blinding of assessment staff, the intervention and control structure were identical. Each session was guided by a handout (mailed to the participant approximately 1 week prior to each session) and the interventionist followed the content in order during the sessions. The first face-to-face session was conducted as soon after PAP titration as possible, followed by 3 weekly sessions, and 2 monthly sessions by telephone. Multiple steps were taken to ensure the fidelity of both the intervention and control conditions. Interventionists were carefully trained to avoid overlap between conditions and a checklist of topics was used to document completion of each component. Session checklists were reviewed weekly during consultation meetings between the study interventionists and the study psychologist.

The first aspect of the intervention program was to apply "best practices" models of care to the PAP therapy itself, starting with in-lab overnight PSG and an in-lab PAP titration study. PAP equipment was provided to the participants immediately whenever possible and the educational component was delivered weekly for the first month of PAP use. The program was based on one developed and used in prior research with older Veterans, many of whom had functional limitations [21], which includes information about sleep apnea, healthy sleep habits, patient decision-making, and motivational enhancement, while considering usability barriers known to impact the use of PAP [22]. Third, after the first month of use, we continued to provide ongoing support during the first 3 months of PAP therapy with monthly phone check-ins.

The first educational session was delivered when the participant received their PAP machine. This allowed discussion and strategies to address mobility/dexterity limitations that might affect acceptance and adherence to PAP. If the patient had a caregiver to assist with the equipment, the caregiver was also welcome to be present during this education session. One week after the PAP titration study, the patient was contacted by phone and additional support and troubleshooting were provided.

The educational component of the intervention included an adapted version of an OSA disease-specific intervention, which is based on the chronic disease management model using social cognitive theory and transtheoretical models of behavior change. Given the known relationship between poor sleep and PAP adherence, behavioral strategies to improve sleep (e.g. regular sleep

schedule, sleep hygiene, and understanding how stress can impact sleep) were also discussed during the intervention sessions (Table 1).

During each of the planned weekly phone calls, the interventionist reviewed the patient's PAP use information (by printing out and reviewing the detailed summary report from the EncoreAnyware platform) to assist with setting goals. During the first week after PAP initiation, the interventionist contacted the participant if the PAP machine was not set up and transmitted data to provide assistance. This was followed by 3 weekly telephone sessions, and then by 2 monthly sessions thereafter. The structure and content are described in Table 1.

The control program was identically structured but with different content. No additional patient education was provided when the participant received the PAP machine. Instead, general information about sleep in adults was provided. This accounted for the "extra" social contact associated with being in the study, but this type of information was not expected to change sleep quality or improve PAP acceptance or adherence.

At the same intervals as the intervention, a non-directive general sleep education program was delivered to individuals in the control program The interventionist did not provide individualized recommendations but provided general sleep education (Table 1). The interventionist reviewed EncoreAnywhere system to verify that the PAP machine was set up and transmitting data within 1 week of the PAP titration study, but Information on PAP adherence was not discussed during the sessions.

Study measures and outcomes

Outcome measures were assessed by blinded study staff members who were trained to administer study assessments. These were not changed during the trial. Questionnaires were completed in participant interview format. Standardized procedures were used for all objective measurements as described below. Methods and instruments were chosen to minimize participant impacts while maximizing reliability and validity. Whenever possible, we used measures that have been studied in patients with SCI/D.

PAP therapy adherence monitoring.

The main study outcome was adherence to PAP therapy, based on remote monitoring data collected by the PAP devices on nightly use of PAP therapy. The outcome variable used in our main analysis was the number of nights of PAP use over 4 hours per night during the first 90 days. As described in Supplementary Methods, we also considered additional measures of monthly PAP adherence, namely: nights of PAP use over 4 hours per night per 30-night period; the total number of nights used per 30-night period, the average number of hours used per 30-night period, and the average number of hours used on nights used per 30-night period.

When possible, data were obtained from the SD card in the machine after the 3-month follow-up period ended. In the event that the SD card data could not be obtained ($n = 68$ months of data out of 186 total months across participants), we used information stored in the EncoreAnywhere remote monitoring system. When no data were available from either source, we assumed nonuse for the period of time when data were not available.

Patient-reported outcome measures.

Patient-reported outcomes were collected in interview format to limit the negative impact of functional limitations on completeness of data. Participants completed the 18-item Pittsburgh Sleep Quality Index (PSQI; co-primary outcome) total score and the three-factor subscale scoring was used to assess this construct [23]. The three-factor scoring system has superior psychometric properties compared to the original seven-factor scoring system [24]. PSQI was considered the main sleep quality outcome measure (secondary outcome). PSQI scores range from 0 to 21 with higher scores indicating more sleep disturbance. The Craig Handicap Assessment and Reporting Technique (CHART) [25] is a 32-item questionnaire that measures the degree of handicap experienced by persons with SCI across six domains: orientation, physical independence, mobility, occupational functioning, social integration, and economic self-sufficiency. The test is designed to capture the degree of handicap in a community setting, by measuring the degree to which the respondent fulfills the roles typically expected from people without disabilities. Higher scores indicate greater ability in each area. Each domain has a maximum score of 100 (considered average performance of someone without disability). The total score is the sum of all domain scores. Quality of life was assessed with the WHOQOL-BREF [26, 27] a 26-item version of the WHOQOL-100, composed of four domains: physical health, psychological health, social relationships, and environment. It also includes one question on overall quality of life and one on general health. Importantly, items on this scale are not dependent on mobility, which is unlikely to change in patients with SCI/D as a result of improved sleep. The Patient Health Questionnaire-9 (PHQ-9) [28] is a nine-item depression module in the PHQ (a self-administered diagnostic instrument for common mental disorders) which is part of the primary care evaluation of mental disorders (PRIME-MD) suite of evaluation tools. Fatigue was assessed with the Flinders Fatigue Scale [29] a seven-item fatigue rating scale used to measure general symptoms of fatigue. Scores range from 0 to 31 with higher scores indicating more fatigue. Sleepiness was assessed with the eight-item Epworth Sleepiness Scale (ESS) [30], which inquired about the likelihood of falling asleep in different situations. Scores range from 0 to 24 with higher scores indicating more sleepiness.

Data analysis

The study design and data analysis followed the CONSORT criteria for randomized controlled trials. We followed intention-to-treat principles and continued to collect follow-up data from all randomized patients whether or not they completed the intervention program to which they were assigned. Over 98% (62 of the 63) of participants had complete data at each follow-up (Figure 1). We did not impute missing values; rather, we used mixed-effects models with Maximum Likelihood estimation. This method analyzes all non-missing observations at all time points. Power analysis and sample size determination are described in Supplementary Materials. There were no interim analyses and no stopping rules were established.

Summary statistics were computed for continuous variables and counts/percentages were computed for categorical variables for the overall sample, and for intervention (BEST) and control groups. Independent groups *t*-tests (continuous variables) and Fisher's Exact tests (categorical variables) were used to compare groups. Descriptive statistics were computed by treatment group and time.

PAP adherence (primary outcome), the number of nights of PAP use over 4 hours per night during the first 90 days, was analyzed using an independent groups *t*-test. The additional measures of monthly PAP adherence. Monthly PAP adherence was analyzed using a 2×6 factorial mixed-effects model with

a fixed intercept, with treatment group as a two-level between participants' factor and time as a six-level categorical repeated measures factor (i.e. month 1, 2 . . . 6). Three residual covariance structures were compared (autoregressive, unstructured, and exchangeable); the autoregressive had the lowest BIC and was used for analyses [31]. A priori contrasts comparing BEST versus control were performed for each month. Marginal mean by time and group was computed, along with the standard error and 95% confidence intervals (CI).

For remaining outcomes (including PSQI total score; co-primary outcome), 2 (BEST versus control) × 3 (baseline, 1-month, 3-month) factorial mixed-effects models were used. The impact of BEST (vs. control) was tested using two a priori interaction contrasts: interaction contrast 1—group by time (1-month vs. baseline), and interaction contrast 2—group by time (3-month vs. baseline). Marginal means by time and group were computed, along with the 95% CI.

Secondary data analyses.

We conducted a series of additional analyses (not pre-planned) to provide context to the findings of our main analyses described above. We did not conduct a priori power calculations for these analyses. First, given prior evidence that patient characteristics can be associated with PAP use, we used bivariate regression models to predict amount of PAP use in month three. PAP use was operationalized in the following four ways: (1) number of nights used, (2) number of nights used ≥4 hours, (3) average hours of usage on all nights, and (4) average hours of usage on nights PAP was used. Next, across intervention and control groups, we tested whether more PAP use was associated with greater improvements in clinical symptom measures. Bivariate regression models were used to assess the association between PAP use and improvement in sleepiness, fatigue, insomnia severity, sleep quality, and depressed mood, and the same four measures of PAP use were used as predictors. Bivariate models regressed each symptom improvement (from baseline to month-one follow-up) on each measure of PAP use in month one. This analysis was repeated using a different time frame, regressing symptom improvement (from baseline to 3-month follow-up) on each measure of PAP use (averaged across months 1, 2, and 3). We then tested the relationship between amount of PAP use and improvement in function and quality of life. Bivariate regression models were used to assess the association between PAP use in months 1 to 3 and improvement in function and quality of life (from baseline to 3-month follow-up). Function was operationalized using the six subscales of the CHART. Quality of life was operationalized using the four subscales of the WHOQOL-BREF (The World Health Organization Quality of Life Scale). Finally, to enhance the relevance of findings, for each of the first six months, we computed the proportion that met the criteria used by center for medicare services for determining PAP adherence. The definition used is 70% of nights over a 90-day window (i.e. 21 days/month) with at least 4 hours of usage.

Analyses were performed using Stata v17. Mixed-effects models were estimated using the mixed command; interaction contrasts were tested using the contrast command; marginal means were computed using the margins command. Significance tests used alpha = 0.05 and 95% CIs. See Supplementary Methods for a description of the a priori power calculations and secondary analyses.

Results

The enrollment period was from May 10, 2017, to April 17, 2019. Enrollment ended when the target randomized sample was reached. Figure 1 shows participant flow through the trial. Participant characteristics by intervention group are shown in Table 2. Supplementary Table S1 shows baseline study outcomes by treatment group. Descriptive statistics for each PAP outcome variable by month are contained in Supplementary Table S2. Descriptive statistics for other outcomes by time point are shown in Supplementary Table S3.

SDB and PAP therapy

The mean AHI for study participants was 30.3 events/hour (*SD* = 23.7; Range = 6.8–120.0 events/hour; see Table 2). Twenty-three participants (37%) had mild SDB (AHI > 5 and < 15 events/hour), 16 (25%) had moderate SDB (AHI≥15 and < 30 events/hour), and 24 (38%) had severe SDB (AHI≥30 events/hour). Based on PSG and clinical data, 55 participants were prescribed continuous PAP (CPAP) therapy, seven were prescribed bilevel PAP (BPAP) treatment, and one participant in the control arm did not pick up a machine (i.e. received no PAP therapy). Seven individuals required supplemental oxygen with PAP. No participants were switched from CPAP to BPAP.

Treatment completion/adherence

In the BEST intervention group, 31 (97%) participants completed all treatment sessions. In the control group, 29 (94%) completed all sessions. There was no significant difference in rates of completion between groups ($p = 0.533$).

Main outcome analyses

Effect of Intervention versus control on PAP adherence (primary outcome).

There was no significant difference, by treatment group, on PAP use (nights ≥4 hours used within 90 days, mean difference = 3.5 [−9.0, 15.9], $p = .578$), Supplementary Table S4.

In terms of monthly PAP use, there were no significant differences in the number of nights with > 4 hours of PAP use in the intervention versus control group in months 1 to 6 (p's > 0.343, Table 3). There were also no significant differences in the number of days used (without a minimum threshold), the average hours used per night, or the average hours used on nights of use (p's > .151; Table 3). The marginal means by time and group are shown for each of the four measures of PAP adherence in Supplementary Table S5. Figure 2 (panel A) shows the marginal means of days used PAP for ≥4 hours (left panel) and days used PAP (right panel) by time and treatment group. Supplementary Figures S1–S2 show the other two measures of PAP adherence by month and treatment group.

Effect of intervention versus control on sleep quality

There were no significant differences in PSQI total (co-primary outcome) or subscale scores, at 1- or 3-month follow-up (p's > 0.069, Supplementary Table S5). Figure 3 shows the marginal means of PSQI scores (with 95% CI) by intervention group and time.

Effect of intervention versus control on function and quality of life (secondary outcomes)

There were no differences in functioning as measured by the CHART (and subscale scores), Quality of Life as measured with

Table 2. Characteristics of Randomized Participants by Intervention Group

	Control (*n* = 31)	Intervention (*n* = 32)	Total (*n* = 64)
Gender			
Female	2 (6%)	3 (9%)	5 (8%)
Male	29 (94%)	29 (91%)	58 (92%)
Age	59.8 (10.4) [37–80]	61.6 (10.0) [35–73]	60.7 (10.2) [35–80]
Race/Ethnicity[1]	. (.)	. (.)	. (.)
White	16 (52%)	17 (53%)	33 (52%)
African-American/black	15 (48%)	14 (44%)	29 (46%)
Hispanic	1 (3%)	0 (0%)	1 (2%)
American Indian/Alaska Native	0 (0%)	1 (3%)	1 (2%)
Asian	0 (0%)	1 (3%)	1 (2%)
Other	0 (0%)	2 (6%)	2 (3%)
Multiple races	1 (3%)	2 (6%)	3 (5%)
Employment	. (.)	. (.)	. (.)
Employed for wages	2 (6%)	3 (9%)	5 (8%)
Retired	14 (45%)	21 (66%)	35 (56%)
Unable to work/unemployed	20 (65%)	11 (34%)	31 (49%)
Household income			
Up to $20 000	9 (29%)	6 (19%)	15 (24%)
$20 001–$50 000	11 (35%)	13 (41%)	24 (38%)
Over $50 000	10 (32%)	11 (34%)	21 (33%)
Don't know/declined to answer	1 (3%)	2 (6%)	3 (5%)
Education, years	13.5 (1.9) [11–18]	14.3 (2.2) [12–20]	13.9 (2.1) [11–20]
Marital Status			
Married/living as married	12 (39%)	16 (50%)	28 (44%)
Divorced/separated	12 (39%)	12 (38%)	24 (38%)
Widowed	2 (6%)	1 (3%)	3 (5%)
Single, never married	5 (16%)	3 (9%)	8 (13%)
Living Location			
Own home/apartment	26 (84%)	29 (91%)	55 (87%)
Home of a relative or friend	3 (10%)	3 (9%)	6 (10%)
Residential facility	2 (6%)	0 (0%)	2 (3%)
Spinal cord injury	17 (55%)	16 (50%)	33 (52%)
Cervical	10 (59%)	10 (63%)	20 (61%)
Thoracic	7 (41%)	6 (38%)	13 (39%)
Spinal cord disease	16 (52%)	17 (53%)	33 (52%)
Cervical involvement	3 (19%)	4 (24%)	7 (21%)
No cervical involvement	13 (81%)	13 (76%)	26 (79%)
Apnea–hypopnea index (AHI)	30.3 (24.9) [7–120]	30.2 (22.9) [7–82]	30.3 (23.7) [7–120]
AHI Categories			
Mild (AHI > 5, AHI < 15)	10 (32%)	13 (41%)	23 (37%)
Moderate (AHI ≥ 15, <30)	10 (32%)	6 (19%)	16 (25%)
Severe (AHI ≥ 30)	11 (35%)	13 (41%)	24 (38%)

Results shown (%) or Mean (SD) [Min–Max].
[1]Does not sum to 100% due to selection of multiple racial/ethnic groups by some participants.

Table 3. Contrasts Comparing BEST ($n = 32$) Versus Control ($n = 31$) at Each Month on PAP Usage Outcomes

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Nights used PAP 4 + hours	0.3 [−3.7, 4.3] $p = 0.893$	1.9 [−2.1, 5.9] $p = 0.343$	1.3 [−2.7, 5.3] $p = 0.526$	1.3 [−2.7, 5.2] $p = 0.538$	0.8 [−3.1, 4.8] $p = 0.677$	−0.6 [−4.6, 3.3] $p = 0.752$
Nights used PAP	3.0 [−1.8, 7.7] $p = 0.221$	2.4 [−2.3, 7.2] $p = 0.322$	2.2 [−2.5, 7.0] $p = 0.361$	0.8 [−4.0, 5.5] $p = 0.746$	0.2 [−4.5, 5.0] $p = 0.929$	0.0 [−4.7, 4.8] $p = 0.999$
Average hours of PAP use on all nights	0.1 [−0.8, 1.1] $p = 0.816$	0.5 [−0.5, 1.5] $p = 0.297$	0.3 [−0.7, 1.3] $p = 0.539$	0.3 [−0.7, 1.2] $p = 0.592$	0.1 [−0.8, 1.1] $p = 0.795$	−0.2 [−1.2, 0.8] $p = 0.672$
Average hours of PAP use on nights used	−0.2 [−1.4, 1.0] $p = 0.734$	0.9 [−0.3, 2.1] $p = 0.151$	0.7 [−0.5, 1.9] $p = 0.281$	0.3 [−0.9, 1.5] $p = 0.656$	0.3 [−0.9, 1.5] $p = 0.607$	0.2 [−1.0, 1.4] $p = 0.720$

*** $p < .001$, ** $p < .01$, * $p < .05$.
Results show contrast comparing BEST versus control at each Month with [95% CI] and p-value.

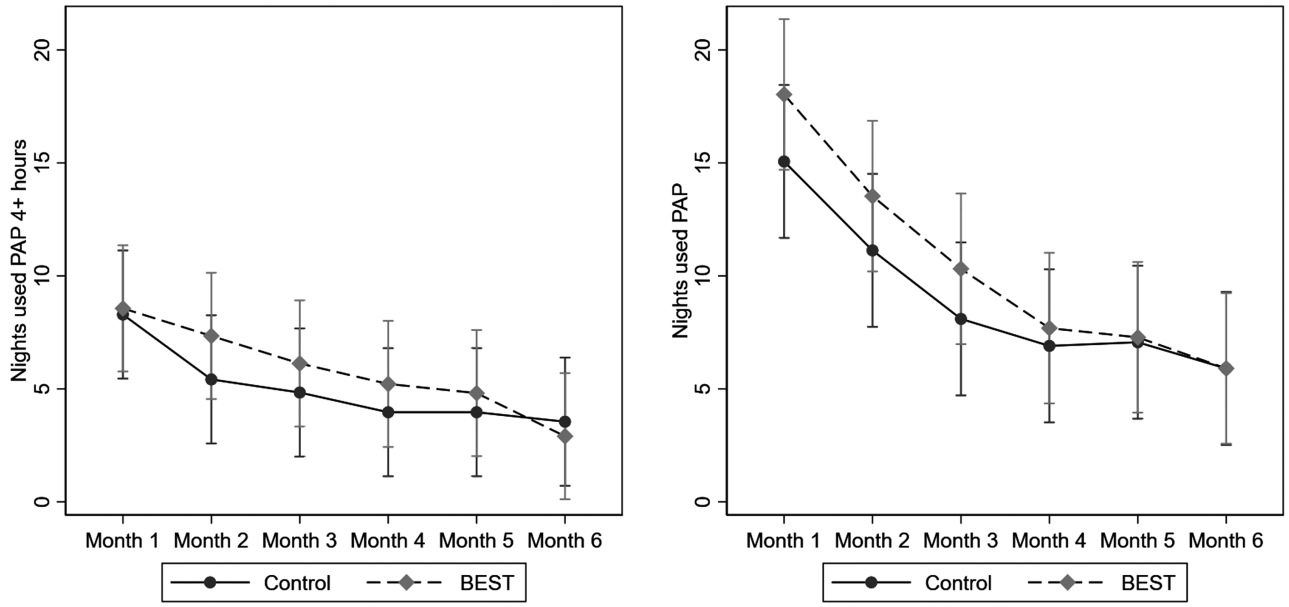


Figure 2. Monthly PAP use data for intervention (BEST) and control groups shown as marginal mean number of nights used out of 30 nights per month (primary outcome). There were no significant differences between groups at any time point. PAP, positive-airway pressure.

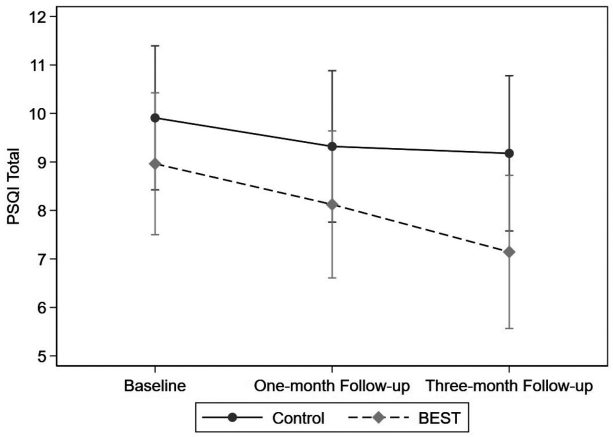


Figure 3. Marginal means of Pittsburgh Sleep Quality Index scores (with 95% CI) by intervention group and time.

the WHO-QOL-BREF (and subscale scores), and no differences in depression assessed with the PHQ-9, or Sleepiness assessed with the ESS (p's > 0.080, Table 4). Participants who received the BEST program had lower scores on the FSS at 3 months compared to controls ($p = 0.025$). Marginal means for the outcomes of sleep quality and quality of life are shown by treatment group and time in Supplementary Table S6.

Ancillary/secondary analyses

Baseline predictors of PAP use.

When data from both treatment groups were combined, none of the demographic or clinical baseline variables were associated with PAP use at the 3-month time point (Table 5).

PAP use and change in other outcomes.

Across treatment groups, all four PAP use variables were associated with a reduction in patient-reported insomnia symptoms (ISI) from baseline to 1-month follow-up. The number of nights with > 4 hours of use was associated with improved sleep quality (PSQI). higher mean hours of use on nights used were associated with a greater reduction in depression (PHQ-9) from baseline to 1-month follow-up (See upper portion of Table 6).

Focusing on outcome improvement from baseline to month 3, all four PAP use variables were associated with reduction fatigue (Flinders Fatigue Scale), while three PAP use variables were associated with reduced insomnia (ISI) and improved sleep quality (PSQI), and two were associated with reduced sleepiness (ESS)

Table 4. Interaction Contrasts on Sleep Quality and Quality of Life Outcomes

	One-month Follow-up[1]	Three-month follow-up[2]
	Contrast [95% CI]	Contrast [95% CI]
PSQI total	−0.3 [−1.9, 1.4] $p = 0.762$	−1.1 [−2.8, 0.6] $p = 0.219$
PSQI F1: sleep efficiency	0.7 [−0.4, 1.7] $p = 0.218$	0.3 [−0.8, 1.4] $p = 0.576$
PSQI F2: perceived sleep quality	−0.5 [−1.4, 0.4] $p = 0.308$	−0.8 [−1.7, 0.1] $p = 0.071$
PSQI F3: daily disturbanceS	−0.3 [−0.9, 0.3] $p = 0.259$	−0.5 [−1.1, 0.0] $p = 0.069$
CHART-phys	5.6 [−10.3,21.4] $p = 0.491$	0.1 [−13.5,13.7] $p = 0.988$
CHART-cognitive	3.6 [−5.7,12.9] $p = 0.449$	−3.4 [−13.4, 6.6] $p = 0.505$
CHART-mobility	0.2 [−6.3, 6.7] $p = 0.950$	1.0 [−5.9, 7.8] $p = 0.779$
CHART-occupation	8.7 [−4.7,22.0] $p = 0.204$	3.6 [−10.8,18.0] $p = 0.625$
CHART-social integration	−8.4 [−19.4, 2.6] $p = 0.134$	1.3 [−10.2,12.9] $p = 0.823$
CHART-economic	2.5 [−10.1,15.1] $p = 0.696$	5.0 [−5.0,15.0] $p = 0.325$
WHOQOL-physical	−0.9 [−7.9, 6.1] $p = 0.795$	3.2 [−5.1,11.5] $p = 0.453$
WHOQOL-psychological	2.7 [−4.3, 9.8] $p = 0.448$	4.2 [−1.9,10.2] $p = 0.176$
WHOQOL-social	5.6 [−4.6,15.8] $p = 0.280$	5.7 [−3.2,14.6] $p = 0.208$
WHOQOL-environment	2.2 [−4.1, 8.5] $p = 0.486$	0.2 [−5.9, 6.2] $p = 0.958$
Depressed mood (PHQ-9)	−0.1 [−2.6, 2.3] $p = 0.919$	−2.3 [−4.9, 0.3] $p = 0.080$
Fatigue (FFS)	−3.0 [−6.4, 0.5] $p = 0.093$	−4.6* [−8.6,−0.6] $p = 0.025$
Sleepiness (ESS)	1.1 [−0.7, 2.9] $p = 0.232$	−0.9 [−2.9, 1.2] $p = 0.415$

*** $p < .001$, ** $p < .01$, * $p < .05$.
PSQI, Pittsburgh Sleep Quality Index; CHART, Craig Handicap Assessment and Reporting Technique; WHOQOL, World Health Organization Quality-of-Life Scale; PHQ-9, Patient Health Questionnaire-9; FFS, = Flinders Fatigue Scale; ESS, Epworth Sleepiness Scale.
[1]Interaction contrast of BEST versus Control by One-month Follow-up versus baseline;
[2]Interaction contrast of BEST versus Control by 3-month follow-up versus baseline.

Table 5: Baseline predictors of PAP therapy use at month 3.

	Number of nights used[1]	Nights with > 4 hours use[1]	Mean hours of use on all nights[1]	Mean hours of use on nights used[1]
Apnea–Hypopnea Index (AHI)	0.07 (0.06)	0.02 (0.05)	0.01 (0.01)	0.01 (0.01)
Age at randomization	−0.01 (0.13)	−0.02 (0.10)	−0.01 (0.02)	0.00 (0.03)
Years of education	0.06 (0.64)	0.10 (0.52)	0.04 (0.12)	0.16 (0.16)
Epworth Sleepiness Scale (ESS) total score	−0.22 (0.25)	0.08 (0.21)	0.01 (0.05)	0.02 (0.07)
Flinders Fatigue Scale (FFS) total score	0.01 (0.17)	0.09 (0.14)	0.03 (0.03)	0.04 (0.04)
Insomnia Severity Index (ISI) total score	−0.25 (0.21)	−0.01 (0.17)	−0.01 (0.04)	0.02 (0.05)
Pittsburgh Sleep Quality Index (PSQI) total score	−0.39 (0.31)	−0.05 (0.26)	−0.03 (0.06)	−0.04 (0.08)
Patient Health Questionnaire-9 (PHQ-9) total score	−0.28 (0.23)	−0.14 (0.19)	−0.03 (0.04)	−0.02 (0.06)

*** $p < .001$, ** $p < .01$, * $p < .05$.
Results show coefficient with SE in parentheses.
[1]Month three.

and less depression (PHQ-9), see lower portion of Table 6. There were no significant relationships between PAP use and quality of life (WHO-QOL, Supplementary Table S7). The only significant relationship between PAP use and function (CHART) was for the number of nights used and the physical function subscale (Supplementary Table S8, coefficient = −0.26 (SE = 0.12), $p < .05$).

Number of participants using PAP at least 4 hours on at least 70% of nights.

Supplementary Figure S3 shows the proportion of participants who used PAP at least 4 hours on at least 70% of nights (that is, 21 of the 30 nights) for each month of the study across treatment groups.

Harms or adverse events

There were no significant adverse events during the trial, and treatment did not have to be discontinued due to side effects for any participants.

Discussion

Our study revealed no differences in key PAP use and clinical outcomes between the BEST intervention and control groups. Secondary analysis did not find that baseline characteristics predicted the use of PAP, regardless of group assignment. Nevertheless, we noted that more use of PAP was associated with improvements in insomnia symptoms and other clinical outcome variables.

Table 6. Month 1 PAP Usage Predicting Symptom Improvement: Baseline to 1 month; Baseline to 3 Months

	Symptom improvement: baseline to 1 month.				
	Sleepiness (ESS)[2]	**Fatigue (FFS)**[2]	**Insomnia severity (ISI)**[2]	**Sleep quality (PSQI)**[2]	**Depressed mood (PHQ-9)**[2]
Number of nights used[1]	−0.00 (0.05)	−0.16 (0.10)	−0.19** (0.07)	−0.05 (0.05)	−0.07 (0.07)
Nights with > 4 hours use[1]	−0.02 (0.05)	−0.18 (0.10)	−0.28*** (0.06)	−0.10* (0.05)	−0.10 (0.07)
Mean hours of use on all nights[1]	−0.12 (0.23)	−0.85 (0.43)	−1.20*** (0.28)	−0.32 (0.21)	−0.52 (0.31)
Mean hours of use on nights used[1]	−0.24 (0.20)	−0.76 (0.39)	−1.25*** (0.23)	−0.21 (0.19)	−0.61* (0.27)
	Symptom Improvement: Baseline to 3 months.				
	Sleepiness (ESS)[3]	**Fatigue (FFS)**[3]	**Insomnia Severity (ISI)**[3]	**Sleep Quality (PSQI)**[3]	**Depressed Mood (PHQ-9)**[3]
Number of nights used[1]	−0.01 (0.02)	−0.12** (0.04)	−0.03 (0.02)	−0.03 (0.02)	−0.04 (0.02)
Nights with > 4 hours use[1]	−0.04 (0.02)	−0.13** (0.04)	−0.06* (0.02)	−0.05** (0.02)	−0.05 (0.03)
Mean hours of use on all nights[1]	−0.57* (0.28)	−1.87*** (0.52)	−0.77* (0.31)	−0.61* (0.23)	−0.79* (0.34)
Mean hours of use on nights used[1]	−0.52* (0.22)	−1.29** (0.43)	−0.78** (0.24)	−0.45* (0.20)	−0.67* (0.28)

*** $p < .001$, ** $p < .01$, * $p < .05$.
Results show coefficient with SE in parentheses.
ESS, Epworth Sleepiness Scale; FFS, Flinders Fatigue Scale; ISI, Insomnia Severity Index; PSQI, Pittsburgh Sleep Quality Index; PHQ-9, Patient Health Questionnaire-9.
[1]Month one value.
[2]Symptom improvement computed as 1 month (post-treatment) score minus baseline score.
[3]Symptom improvement computed as Three-Month Follow-Up score minus Baseline score.

Effect of the BEST program on PAP adherence

Our findings suggest that PAP adherence in patients with SCI and SDB remains suboptimal despite combining best practices: in-person PAP setup in the sleep laboratory, education, and training, plus weekly telephone follow-up for the early weeks and months of use. A Cochrane review found that the implementation of supportive, educational, and behavioral interventions results in improved PAP use in adults with SDB [32]. Furthermore, Stanchina et al. found that four out of five patients receiving PAP in the lab with individualized instruction—as done in our study achieved a PAP adherence rate that meets the Centers for Medicare and Medicaid Services (CMS) standards (PAP of at least 4 hour/night for at least 70% of nights) [33]. Our findings also differ from published studies demonstrating that the use of telemedicine was associated with increased PAP adherence in the general population [34]. The significant difference in adherence corroborates studies demonstrating low adherence to PAP in people with SCI and SDB [9, 18, 35]. A key question is whether PAP use is "worth the effort" [35] a challenging balance of impacts versus perceived benefit in this population [35]. No difference emerged regardless of the specific PAP use variable tested and regardless of whether we looked at the first 90 days, or at 30-day intervals over the first 6 months of use.

Our study utilized a sleep coach to deliver an intervention focused on PAP adherence similar to the approach used by Alessi et al. in Veterans [21]. However, our intervention focused on PAP adherence only and did not address other sleep disorders, such as insomnia, which was noted in about a third of the randomized participants (22 participants had ISI > 14). In contrast, Alessi et al. deployed a PAP intervention and CBT-I simultaneously [21]. Overall, CBT-I prior to initiating PAP treatment improves PAP use and insomnia symptoms compared to initiating PAP without CBT-I [36]. However, untreated insomnia does not account for the suboptimal adherence as PAP use was low in participants free of insomnia symptoms as well.

We considered several explanations for the suboptimal PAP adherence among our participants, despite deploying a high-intensity intervention exceeding usual care. First, barriers to patient-reported usability were unlikely as all the randomized participants had accepted PAP use and attempted to use the device [22]. Second, individuals living with SCI/D experience substantial challenges that interrupt sleep, including spasticity, chronic pain, and periodic leg movements [14, 37, 38]. These challenges may downgrade the priority of PAP use among competing concerns. Third, specific PAP adherence issues include physical and relational dependence on a third party, increased daily care costs, and increased presence of medical devices in the daily environment [39]. Finally, individuals with cervical SCI experience additional difficulties including nasal congestion [40], and difficulty in adjusting or repositioning a PAP mask. Conversely, our findings and those of Graco et al. [35] are congruent in demonstrating that more use is associated with more benefits. Accordingly, people with SCI may need additional individualized support, addressing specific barriers that impede optimal use.

Methodological considerations

To the best of our knowledge, this is the first behavioral intervention RCT targeting PAP use in this population. A strength of the study was the development of a PAP adherence program for this understudied population, based on interventions proven effective in the general population. Conversely, several limitations may influence the interpretation and generalizability of our findings. Our study population consisted mostly of male veterans; the majority of whom were socioeconomically disadvantaged. The potential interaction between socioeconomic status and PAP adherence, as well as the potential impact of comorbid conditions and concurrent medications, cannot be determined from our findings. While we took multiple steps to align our study procedures with routine care, we did not offer alternative therapies, such as oral appliances or hypoglossal nerve stimulation. Generalizability may also be limited to veteran populations.

Another potential limitation is that our intervention was designed based on published literature and did not include direct input from end users, and hence it may have failed to address specific issues such as usability, impacts, and sleep quality. Future

studies should include active engagement of people with SCI in the design of the intervention to ensure that their unique needs are being addressed.

SCI and healthcare inequity

Individuals living with SCI/D face significant hurdles along the path of SDB management, including inadequate recognition among patients and providers, erroneous attribution of daytime symptoms, and limited access to sleep diagnostic and treatment services [9]. Overcoming these hurdles may require an overhaul of the continuum of care including equipping sleep centers with specialized beds for diagnostic testing, as well as patient-centered adjustment of PAP therapy. Such major changes in the care delivery model—upstream from the point of diagnosis—require evidence that patients living with SCI/D who have SDB are likely to accept, use, and derive benefit from PAP therapy.

Failure to address the unique healthcare needs of individuals with SCI is an example of healthcare inequity. Research addressing inequity in health care has rarely addressed disability as a determinant [41]. Individuals living with disabilities, especially those with limited mobility, experience healthcare inequity across the continuum of care. For example, rates of preventive care services, such as screening mammogram or PAP smear are lower in those with disabilities compared to the general population [42]. Management of SDB is another example of inequity.

A proposed approach: chronic care management model

While overall adherence was low, we noted that higher PAP use was associated with greater improvement in patient-reported symptoms and quality of life in those who used PAP; thus, supporting the benefit of PAP therapy in this population. Evidence in the literature suggests that collaborative chronic care models result in better outcomes in chronic medical conditions [43, 44]. Key requisites include work role redesign supporting continuous care, self-management support, clinician decision support, robust clinical information systems, incorporation of community resources; as well as leadership support [45]. The VA health System is uniquely positioned to provide comprehensive chronic care management for Veterans with SCI and sleep disorders and has developed similar models for other conditions [46].

While current standards of practice require remote monitoring of PAP use, individualized support is rarely implemented in real life [47]. We reasoned those individuals living with SCI would require additional individualized and intensive education, monitoring, and support. To this end, we developed an intervention that could be delivered by a health educator to allow for wide low-cost implementation in any sleep center. However, our findings do not support the adequacy of this approach. The positive relationship between PAP use and improvement in fatigue underscores the potential value of improving PAP use to improve overall health outcomes. Therefore, achieving health equity in this population, may require a more intensive and individualized intervention such as home visits, daily check-in, or direct involvement of partner/caregiver in the management plan. Such interventions could be evaluated using daily monitoring of PAP use combined with an ecological momentary assessment of daytime function [48]. Overall, improving the outcome of care may require that we reimagine the management of sleep disorders in this population from an episodic encounter to a chronic care model [49].

Supplementary Material

Supplementary material is available at *SLEEP* online.

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