Testing a consumer wearables program to promote use of positive airway pressure therapy in patients with obstructive sleep apnea: protocol for a pilot randomized controlled trial

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Abstract

Background: Although positive airway pressure (PAP) therapy is considered first-line treatment for obstructive sleep apnea (OSA), non-adherence is common. Numerous factors influence PAP use, including a belief that the therapy is important and effective. In theory, providing information to patients about their blood oxygen levels during sleep, which may be low when PAP is not used, juxtaposed to information about their PAP use may influence a patient's beliefs about therapy and increase PAP use. With the advent of wearable devices' blood oxygen saturation monitoring capability (and the existing routine availability of PAP use data transmitted via modem to clinical dashboards), there is an opportunity to provide this combination of information to patients.

Objective: The Chronic care management with wearable devices in patients prescribed Positive Airway Pressure therapy (mPAP) study is a pilot randomized waitlist-controlled trial testing the feasibility, acceptability, and preliminary efficacy of a program that augments current PAP therapy data with consumer-grade wearable device to promote self-management of PAP therapy for OSA.

Methods: Single-blinded randomized controlled trial. We will randomize 50 individuals with a history of OSA who receive care from a Department of Veterans Affairs medical center in the Los Angeles area and are nonadherent to prescribed PAP therapy to Immediate intervention or Waitlist control. During a 28-day intervention, the participants will wear a study-provided consumer wearable device and complete a weekly survey about their OSA symptoms. A report that summarizes consumer wearable-provided oxygen saturation values, PAP use derived from modem data, and patient-reported OSA symptoms will be prepared weekly and shared with the patient. Immediate intervention group will begin intervention immediately after randomization (T1). Assessments will occur at week 5 (T3; one-week post-treatment for Immediate intervention group and repeat baseline for Waitlist control group) and week 11 (T5; follow-up for Immediate intervention group and one-week post-treatment for Waitlist control group). The primary outcome will be the change in 7-day PAP adherence (average minutes/night) from T1 to T3. The primary analysis will be a comparison of the primary outcome between the Immediate intervention and the Waitlist control groups (intention-to-treat design), using a two-sample t-test on change scores (unadjusted).

Results: Recruitment began in October 2023. Data analysis is expected to begin in September 2024 when all follow-ups are complete, and a manuscript summarizing trial results will be submitted following completion of data analysis.

Conclusions: Findings from the study may provide additional insights on how patients with OSA might use patient-generated health data collected by consumer wearables to inform self-management of OSA, and possibly increase their use of PAP therapy.
Clinical Trial: ClinicalTrials.gov NCT06039865

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ABSTRACT (420 of 450 words)

Background: Although positive airway pressure (PAP) therapy is considered first-line treatment for obstructive sleep apnea (OSA), non-adherence is common. Numerous factors influence PAP use, including a belief that the therapy is important and effective. In theory, providing information to patients about their blood oxygen levels during sleep, which may be low when PAP is not used, juxtaposed to information about their PAP use may influence a patient's beliefs about therapy and increase PAP use. With the advent of wearable devices' blood oxygen saturation monitoring capability (and the existing routine availability of PAP use data transmitted via modem to clinical dashboards), there is an opportunity to provide this combination of information to patients.

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Trial Registration: ClinicalTrials.gov NCT06039865

BACKGROUND

Obstructive sleep apnea (OSA) is prevalent and affects more Veterans who obtain care in Veterans Health Administration facilities than any other sleep disorder (20%).[1] Characterized by repetitive blockage in the airway during sleep that causes breathing to stop or get very shallow and that may cause transient hypoxemia, OSA disrupts sleep and contributes to symptoms of excessive daytime sleepiness, decreased quality of life, and increased risk of health conditions such as depression, cardiovascular disease, erectile dysfunction, and dementia.[1] OSA is also associated with work disability[2] and increased risk of motor vehicle crashes.[1]

OSA is a chronic disease that requires long-term management.[3] Positive airway pressure (PAP) devices, which deliver air under pressure into the airway to stent the airways open, are considered the gold standard treatment for OSA. Success of this treatment is quantified by hourly and nightly adherence plus changes to symptoms (e.g., daytime sleepiness) and reduction in the number of times per hour airflow ceases or is reduced, as well as improvement in sleep-related oxygen levels.[4, 5] Adherence to treatment can improve sleep quality, reduce the risk of OSA-related co-morbidities, and improve quality of life.[6] However, low PAP adherence is a significant issue.[7]

Among a number of important factors that influence whether a patient uses prescribed therapy is the belief that the therapy is important and effective.[2] Through clinical experience and a prior project that have focused on patients' decision-making about their OSA and treatment, we found that providing information to patients about their blood oxygen levels (e.g., lowest blood oxygen level) during sleep is very powerful as a tool for engaging them in their OSA management. With the advent of wearable devices' blood oxygen saturation monitoring capability, there is both an opportunity and an impending need to optimize the manner in which this information is used in patients' daily lives and in

routine sleep clinic care so that the information enhances patients' experience with care.

The Health Beliefs Model provides a framework for incorporating wearable data (specifically oxygen data) in a PAP therapy program.[8] The model suggests that the desire to get well if already ill (e.g., improve OSA) and the belief that a specific health action will cure illness, together, influence health behavior (e.g., use PAP for OSA), and the patient's course of action often depends upon the patient's perceptions of the benefits and barriers related to that health behavior (e.g., PAP use). The perceptions influencing PAP use may include: 1) perceived susceptibility—if levels of oxygen saturation collected during sleep are intermittently low; 2) perceived severity—if oxygen levels are lower than normal values; 3) perceived benefits—if oxygen levels during sleep are different on days PAP used versus not used. Cues to action (e.g., PAP use) may be feedback showing wearable oxygen data combined with PAP usage and patient-reported outcomes.

Newer models of wearables (e.g., Fitbit) are providing blood oxygen saturation (SpO2) measurements.[9] Although these wearables are not intended for medical purposes such as diagnosing OSA, they are currently used by patients for self-monitoring oxygen levels, which can reach low levels in some patients when off PAP therapy. Theoretically, patients who use their PAP therapy inconsistently may have patterns in consumer wearable data that correlate with PAP usage. Given the high prevalence of OSA and the growing use of wearables, inevitably a subset of patients with OSA will use wearables for self-monitoring their oxygen levels during sleep and will present to their sleep clinicians with questions about their wearable oxygen levels. A conundrum is how best to incorporate the vast amount of sleep data from consumer technology into the chronic care management of patients with sleep disorders such as OSA.

Although the PAP devices include airflow sensors that can provide physiologic data feedback,{,#29} additional feedback about oxygen levels may influence behavior. The

proposed research study will incorporate the use of a wearable collecting SpO2 data during sleep and provide a weekly report that will not only depict the physiological consequences of non-adherence as a timely behavioral reinforcement strategy, but also day-to-day relationships of adherence and possible barriers (e.g., lower adherence on nights of greater pain). In conjunction with PAP device data and patient-reported outcomes (e.g., daytime sleepiness, alertness), the wearable data represents an opportunity to augment current strategies for increasing use of PAP therapy. The goal of the project is to assess the impact and acceptability of augmenting current PAP therapy data with consumer-grade wearable device data to promote self-management of PAP therapy for OSA. To isolate the impact of the augmentation by the wearable device, the comparator intervention is receiving current PAP therapy data while on a wait-list to add the wearable device data.

STUDY AIMS AND HYPOTHESES

Specific Aim 1: To measure the effect of the consumer-grade wearable-augmented program on PAP use. *Primary Hypothesis*: Compared to participants in the Waitlist control group, participants in the Immediate intervention group will have greater improvement in PAP adherence (change in average minutes per night from baseline [T1] to Post [T3]). *Secondary Hypothesis*: PAP adherence (average minutes per night) from delayed baseline [T4] to delayed Post [T5]) will improve among participants in the Waitlist control group after receiving the delayed wearable intervention. *Exploratory hypotheses*: The effect of the program will be maintained at T5 for the Immediate intervention group.

Specific Aim 2: To assess the acceptability of the program.

METHODS

Study Design

This study is a randomized parallel two-group waitlist-controlled trial with 1:1 allocation evaluating the efficacy of a consumer wearable-augmented self-monitoring program on PAP adherence compared to a standard self-monitoring program on PAP adherence among patients with OSA prescribed PAP therapy. In addition, following the primary endpoint, the control group will crossover to the intervention condition and be compared to their time in the control condition (i.e., single-group nonrandomized crossover design). The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 statement was used to report standard protocol items for clinical trials.{,#34;,#10}(see Additional file 1)

Study Site

The study will be conducted at Veterans Affairs Greater Los Angeles Healthcare System (VAGLAHS) in Los Angeles, California.

Participants: Inclusion/Exclusion Criteria

Inclusion criteria: Aged ≥ 21 years, prescribed PAP therapy from the sleep center for > 1 week, have an active profile in our Center's ResMed AirView or Respironics Care Orchestrator accounts for > 1 week, willing to continue using current PAP device for 28 days continuously, non-adherent to PAP therapy (i.e., not using their PAP for at least four hours a night for 70% of nights),{,#33} and have a smartphone compatible with the wearable app.

Exclusion criteria: heart failure, chronic lung disease, home oxygen use, dementia, active substance use disorder, unstable medical or psychiatric illness, concurrent participation in another clinical trial that would interfere with study procedures, planned non-use of PAP therapy (e.g., waiting for replacement of

recalled PAP device), planned surgery or hospitalization during study period that would limit PAP use, planned extensive travel during study period, and history of repeated non-attendance at clinic visits.

Procedures

Recruitment and Screening

Recruitment strategies will include: 1) mailing letters to patients with active modem accounts; 2) posting flyers/posters in the clinic areas and enclosing flyers with PAP equipment distributed to patients; and 3) notifying sleep center staff about the study. Participants will undergo an initial telephone screen to assess for eligibility and to collect demographic data (age, gender, race, ethnicity). Research staff will perform a brief medical chart review to verify eligibility and OSA history (diagnosis date, severity [apnea-hypopnea index], PAP settings [fixed versus auto]). We will verify the patient has a PAP modem profile on the clinic's AirView or Care Orchestrator account. The research team will meet weekly to review eligibility requirements for each individual after completing baseline assessment and one-night oximetry to determine whether the individual is eligible for randomization in the clinical trial.

We increased the number of letters mailed each week to patients meeting inclusion criteria to help us achieve adequate participant enrollment to reach target sample size. Another strategy employed was to present this study to the Greater Los Angeles Veteran Engagement Team (GLA VET) [CIN 13-417] in December 2023 for feedback on our recruitment strategy. The GLA VET is composed of a diverse team of local Veterans whose mission is to partner as active stakeholders with the Greater Los Angeles research community and impart Veteran-based knowledge and perspectives on research and other improvement efforts. Some of their suggestions include posting flyers in additional locations with more foot traffic.

Assessments

Baseline assessment: Participants in both arms will undergo a baseline assessment (T1 for Immediate intervention group; T3 for Waitlist control group), where current 7-day and 30-day PAP adherence will be collected from modem data. One-night oximetry using a United States Food and Drug Administration-approved wrist-worn pulse oximeter (Nonin, Plymouth, Minnesota) will be conducted. Other measures such as determinants of PAP compliance, sleep disturbance, sleep quality, daytime function, comorbidities, and health literacy will be collected through an electronic survey using the Qualtrics™ platform. A baseline assessment appointment with a research team member will be conducted, where the research team member will review the survey and administer any items that were unintentionally left incomplete.

Follow-up assessment: The Immediate intervention group will undergo post-treatment assessment at T3 and follow-up assessment at T5. The Waitlist control group will complete the post-treatment assessment at T5. Participants will also undergo an intervention program evaluation upon completion of the intervention (either T3 or T5, depending upon group assignment). At T3 and T5, 7-day and 30-day PAP adherence data will be abstracted from modem data, regardless of whether participants wear the watch or view the reports.

Randomization

Eligible participants will be randomized to one of the two study arms: an Immediate intervention and Waitlist control, using a 1:1 ratio. Randomization will be performed using a random permuted block design with varying block size. Opaque sequentially numbered envelopes were prepared by a researcher who was not involved in any part of our study, thus implementing the random allocation sequence which randomized each successive

eligible participant.

Blinding

The primary and secondary outcomes at follow-up (i.e., T3 - week 5 and T5 - week 11) will be assessed by research team members who are blinded to study arm assignment. The portion of the assessment covering program evaluation will be administered by an unblinded team member. Participants will not specifically be informed that they are in the Immediate versus Waitlist group; rather, they will be informed of the expected date of beginning the program.

Intervention

Immediate Intervention: Consumer-grade Wearable-Augmented PAP Adherence Intervention Program: Immediately following randomization (Day 0), each eligible participant assigned to the Immediate intervention group will be given on Day 1 a consumer-grade wearable registering minute-by-minute SpO_2 data (Fitbit Charge 5™) and instructions on use. They will be asked to wear the wearable nightly, even if not using treatment device. Participants will be oriented to using their wearable for the self-monitoring program, including a feature that includes viewing their own personal reports on demand (described below). Participants who are not available for an in-person visit will be sent the device and scheduled for a telehealth visit with the research team. Participants will share data with project team via a third-party platform (Fitabase; San Diego, CA) and will be sent a weekly survey about OSA-related symptoms. The weekly survey about each 7-day period will be sent the morning of day 7, 14, 21, and 28. An automated reminder will be sent after 12 hours if the participant has not completed the survey. We will track the percentage of surveys completed as part of monitoring adherence to intervention protocols.

Data shared by participants will be used to generate customized reports that emphasize the amount of time participant had SpO2 values in the various oxygen range categories (e.g., minutes spent >92% SpO2), PAP use modem data, and responses from the participant about their OSA-related symptoms. The juxtaposition of these three different types of information (SpO2, PAP use, and symptoms) is intended to help participants identify patterns of association between PAP use and objective (SpO2) and subjective (symptoms) data. Within 1 to 2 days of the first report delivery (or scheduled for delivery) to the participant, the participant will meet with a member of the research team, who will review the report and the meaning of the information presented using a structured session guide. The participants will continue to complete an OSA-related symptoms survey weekly until Day 28 so that weekly customized reports can be delivered to the participant (also using the Qualtrics™ platform). The report is presented as an embedded image in the Qualtrics™ survey that participants can view and download.

The allocated intervention may be modified or discontinued at the participant's request or by the study team in cases where the intervention (i.e., charts) causes severe anxiety or distress or PAP treatment causes harms (e.g., dermatitis that is persistent despite changing interfaces). Permitted concomitant care and interventions include those recommended and provided by the participant's provider within the sleep center (e.g., mask fitting, psychoeducation, PAP desensitization).

Waitlist control: Participants assigned to Waitlist control will receive usual care from the sleep center, which is comprised of clinic visit every 6 to 12 months on average, with access to durable medical equipment such as PAP interfaces on an as-needed basis. Each device can be paired with a self-monitoring app by the manufacturer so that patients can monitor adherence (e.g., myAir, DreamMapper), and patients also receive feedback about

their PAP use on the device display. These participants will receive instructions on the wearable at timepoint T4 and be offered the same intervention as the immediate group until T5 (28 days).

Program Evaluation

We will conduct a semi-structured interview with participants at the completion of the program to obtain feedback from participants about the program and to elucidate opportunities to improve the trial design. Research staff with experience conducting program evaluation interviews will conduct these interviews using a semi-structured interview guide with questions like, “What did you think about the reports?” or “What did you think about using a Fitbit to collect pulse oximetry data while you slept?” The staff will ask the participants how many of the reports they viewed, for how long, and if they had any technical difficulties opening or viewing them. Those who choose not to view any reports will still be interviewed for their impressions of the process and concept. We will record and transcribe interviews for analysis.

Participant Incentives

Participants will be offered a $25 incentive for participating in the T1 and T5 assessments (total $50). The wearable device will be given to the participant and may be kept after study completion (no sharing of Fitbit data after the intervention period).

Participant timeline

Participants are enrolled on a rolling basis. After baseline assessment (T1), participants are randomized into either Immediate intervention or Waitlist control. Immediate intervention participant starts immediately (T2) and are in the program for 28 days. Seven

days later, at T3, Immediate intervention participants undergo post-treatment assessment and Waitlist control participants complete delayed baseline assessment. After 7 days, at T4, Waitlist control participants start the intervention for 28 days. Seven days later, at T5, Waitlist control participants undergo post-treatment assessment and Immediate intervention participants complete follow-up assessment.

Privacy and Informed Consent Procedures

A Health Insurance Portability and Accountability Act (HIPAA) waiver will be requested for the chart review. Patients who are eligible based on preliminary telephone screening will be invited to participate in an informed consent appointment where the risks and benefits of the study will be presented. After written informed consent (either paper or electronic) is obtained, participants will undergo a baseline assessment.

Measures

Sample characteristics

Participants will be asked to provide demographic characteristics, such as age, gender, race/ethnicity, marital status, and education level. We will also abstract from the medical record OSA history (severity, PAP settings). Comorbidities will be summarized by the Self-Administered Comorbidity questionnaire (convergent validity with Charlson Comorbidity index r=.55).[11] Participants' overnight oxygen desaturation based on clinical overnight oximetry will be summarized (time spent at various oxygen saturation ranges).

Primary outcome measure

The primary outcome measure will be the change in PAP adherence (average minutes/night over a 7-day period) from T1 to T3. PAP adherence, defined as usage of the

device for at least 4 hours per night on 70% of nights during a consecutive 30-day period, {,#33} is measured continuously and is recorded by the participant's PAP machine and transmitted to the participant's PAP account (e.g., Airview™, Care Orchestrator™) through a cellular modem that is embedded in the device.[12] PAP devices can distinguish between periods when the mask is on versus off the face (by detecting flow).

Secondary outcome measures

Additional PAP adherence metrics will be abstracted from the participant's PAP modem report: % days used ≥ 4 hours, # days used out of 7 days, and average residual AHI on therapy.

Participant acceptability will be assessed.[13] We will review the data and evaluate the proportion of nights participants used the wearable overall and while on treatment to ascertain feasibility and acceptability of using a wearable to collect SpO2 data. We will further assess intervention feasibility, acceptability, and appropriate with items developed by Weiner et. al.{,#13} The post-program survey will be followed by an interview with patients about their experience using the wearable with treatment, including opinions about the wearable program and intention to continue using the wearable.

Other measures

Sleep disturbance and sleep-related impairment will be measured by the 8-item Patient-Reported Outcomes Measurement Information System (PROMIS™) Sleep Disturbance (SD) and 8-item Sleep-Related Impairment (SRI).[14] Scores are presented as *t* scores, with average of 50 and SD of 10. Scores > 60 are considered elevated. Internal consistency has previously been very high (Cronbach α >.94).[15]

Hypersomnolence will be assessed with the 8-item Epworth Sleepiness Scale.[16]

Score ranges from 0 to 24 (internal consistency Cronbach α=.82).[17]

Determinants of PAP compliance subscales chosen from constructs of social cognitive theory (self-efficacy [5 items], knowledge [12 items], and transtheoretical model (decision balance [11 items], and stages of change [1 item]), will measure factors that are commonly associated with PAP use (subscale Cronbach α's=.66-.93).[18]

Graph literacy will be evaluated using a 4-item Short Graph Literacy Scale[19] that presents data in the form of a chart and queries the respondent's comprehension, with the number of correct answers out of 4 indicating graph literacy. Scores >2 are considered above-average. (Convergent validity r=.90 with Long Graph Literacy Scale and r=.44 with a detailed query of comprehension.)

The impact of OSA on biopsychosocial aspects (e.g., mood/psychosocial outcomes) will be assessed using the STAMP (Symptoms, Tiredness, Alertness, Mood, and Psychosocial) questionnaire.[20] It is a 12-item questionnaire that is scored on a 6-point scale (internal consistency Cronbach α=.91).

Statistical Analysis

An intention-to-treat approach will be used. Demographic and clinical characteristics, as well as all outcome measures at baseline, will be summarized using descriptive statistics by study arm to assess baseline comparability. If the distribution of the continuous variable is skewed, an appropriate variable transformation will be made before the comparison. Multiple imputation will be implemented to account for missing data, using software for regression models developed by Shafer.{,#30;,#31;,#32}

Changes in sleep-related outcome measures will be analyzed to assess the "success" (effect) of the wearable intervention. The primary sleep-related outcome is change in average minutes per night of PAP usage from T1 to T3. Our primary hypothesis

is that the proposed intervention program will improve PAP adherence among participants who receive the program immediately compared to a Waitlist control group. The primary analysis will be a comparison of mean change in PAP usage between Immediate intervention and Waitlist control using a two-sample t-test (unadjusted). Next, we will construct an ANCOVA regression model that includes baseline PAP adherence score, study arm (intervention vs. control), demographic characteristics (e.g., age), and pre-selected clinical characteristics (e.g., Determinants of PAP compliance score, OSA severity, and PAP setting) to examine whether the effect of the wearable intervention on PAP adherence, where the change score is the primary outcome, is significant. Since this is a single site pilot, we have no plans to conduct any interim analyses that would be used to determine termination of trial.

Secondary analyses will be implemented to compare the secondary outcomes, e.g., % of days used $\geq$ 4 hours out of 28 days, % of days used out of 28 days, between study arms using generalized linear mixed-effects models (GLMMs) with appropriate link functions (e.g., logit for binary, log for count). Each regression model will include the fixed-effects of interest (study arm, time, and a two-way study arm-by-time interaction term) and participant-level random effects to account for dependency of repeated observation within participants. Similar to the primary analysis, adjusted analyses of secondary outcomes with pre-selected factors will be performed. In addition, a GLMM will be used to compare change scores before and after the wearable intervention within the Waitlist control group to estimate whether the difference in change scores before and after is significant (secondary hypothesis). This analysis will include the PAP adherence measurements from T1 to T5 for all the Waitlist control participants. A similar modeling approach will be utilized to evaluate whether the effect of the 28-day wearable intervention is maintained at the end of study (exploratory analysis).

Participant acceptability will be measured/analyzed to assess acceptability. We will summarize acceptability measures (frequency, mean, etc.). For interview data, we will summarize interview content thematically using VA-approved qualitative data analysis software (e.g. Atlas.ti) and identify ways to improve the protocol for a future full-scale trial.

Power and sample size considerations

A sample size of 25 participants per study arm will provide at least 80% power to detect a standardized effect size (Cohen's d) of 0.72 using a two-group test with a 0.05 two-sided significance when comparing mean changes in primary outcome between study arms. We anticipate a relatively larger effect size since the study timepoint is in a shorter timeframe post-treatment. The effect size estimated from this pilot study will be used to plan a future full-scale, multi-year trial.

Data management

Electronic data will be stored behind a VA firewall on a secure research server, with access limited to the research team. Paper charts will be secured in locked filing cabinets in locked research offices with access limited to the research team. PAP modem reports will be downloaded and data extracted and converted to data files using an automated process. Random files (10%) will be manually extracted and these manually extracted data will be compared to the automated process. Data will be cleaned over the course of the study. All personal information about potential and enrolled participants will only be accessible to study team members before, during, and after the trial to protect confidentiality. We will retain and dispose of records in compliance with VA Record Control Schedules.{,#33}

Monitoring and Auditing

A data and safety monitoring board (DSMB) will not be needed for this study because our study is a single-site clinical trial involving the use of PAP machines that is considered standard of care for patients with OSA. We will be pairing the use of PAP machines with a consumer-grade wearable device, but using both together should pose minimal risk to the patient since none of the data collected will be used for diagnosing purposes. We will conduct a check-in visit with patients to ask about their experience with the program, which will include questions about adverse events related to study participation. We will follow VA reporting requirements to our institutional review board for adverse events and serious adverse events.

VA GLA Compliance conducts monthly audits to ensure compliance with procedures for informed consent. This process is independent from investigators.

Ethics Approval

The study procedures were reviewed and approved by the VA Greater Los Angeles Institutional Review Board and University of California, Los Angeles, and the full trial was registered through ClinicalTrials.gov with identifier: NCT06039865. Any modifications to the protocol related to deviation of study aim, study design, patient populations, or study procedures will not be implemented until the formal amendment to the protocol is approved by the IRB.

RESULTS

Institutional review board's approval was granted in July 2023. The research team has finalized the standard operating procedures for each part of the clinical trial. Recruitment and enrollment have begun at the time of manuscript submission. Results will be disseminated through conferences and peer-reviewed journals in the sleep, digital

health, and health services fields.

DISCUSSION

The proposed protocol will examine the impact and acceptability of augmenting current PAP therapy data with consumer-grade wearable device to promote self-management of PAP therapy for OSA. Utilizing SpO_2 data collected by a consumer-grade wearable represents an opportunity to support self-management of OSA to increase use of PAP therapy and promote dialogue between patients and their sleep clinicians about OSA treatment. The proposed pilot trial will provide important information regarding the acceptability of the consumer-wearable intervention.

Underuse of PAP therapy is common among patients with OSA. Improving adherence to PAP therapy remains a formidable task, and new approaches that can be used alone or in combination with existing programs to improve adherence are needed. The growing use of consumer wearables provides a new opportunity to increase and optimize use of PAP therapy. Including a consumer-grade wearable device to collect pulse oximetry data nightly and discussing the data presented in a customized report with a clinician as part of the patient's OSA therapy represents a new approach. The self-monitoring program provides participants the support they might need between clinic visits, agency to manage their own treatment, and self-awareness. The intervention was designed to maximize accessibility by incorporating virtual modalities such as e-surveys and video visits to allow participants who live further away from the sleep clinic to participate in the study, thus ensuring access to care and tools for these patients who may experience greater barriers to attending follow-up visits.

Limitations

There may be data limitations to using pulse oximetry data collected by a consumer-grade wearable device. We may encounter instances where there are missing data from

part of the night when a participant was asleep, which could be due to the position of the wearable while sleeping. Anticipating this issue, we have established a procedure to notify the participant that no data had been collected for the previous night and to remind them to wear the device on their non-dominant wrist. Also, we do make it clear that the report will be based on available data only, which is adequate for the purposes of self-monitoring. There may also be situations where the device fails to sync and does not transmit to the third-party platform for the research team to download. For these instances, we will send an email reminder after 24 hours of not having synced their device.

Some participants may have difficulty understanding and applying information from the charts.[21] To increase the utility of the weekly report displaying nightly oxygen saturation data and patient reported outcomes on sleep quality, mood, and functioning, our study will include a check-in video visit at day 7 to orient the participant to the weekly report, which may promote participant engagement.[22] We will explore the effect of these sessions as well as participant experience with the intervention with semi-structured interviews conducted at the end of the research study.

Some studies have suggested that knowing there will be a delay in receiving the intervention may influence a participant's behavior such that it is no longer an accurate portrayal of their natural behavior while awaiting treatment.[23] Some participants may in fact put less effort in their current treatment, potentially exacerbating their symptoms. This could result in an inflated estimated effect of the intervention if Waitlist control participants improve "significantly" once in treatment. However, our trial's wait time is brief (6 weeks), which is not very different from other delays they have encountered in receiving sleep equipment given recent device recalls.[24] We will not use the term "waitlist," which may carry negative connotations, for participants who will start the intervention after an initial waiting period.

Lastly, we may encounter a selection bias due to participants who may not be comfortable with video visits or using a wearable device declining participation. This is a common issue with trials involving technology.

Possible Implications

Findings from the study may provide additional insights on how patients with OSA might use patient-generated health data collected by consumer wearables to inform self-management of OSA, and possibly increase their use of PAP therapy. Studies have shown data visualizations may be associated with positive effects on decision-making due to the decreased cognitive and intellectual burden of interpreting data.[25, 26] When patients are provided with meaningful data, in the form of oxygen saturation and their symptoms, and they are able to identify patterns and relationships between these datapoints, this may help increase patient awareness of their condition and lead to better decision-making about their treatment.[27] We will be examining the utility of the curated data visualizations delivered weekly to further our understanding of how to deploy this type of intervention to improve use of PAP therapy and promote patient engagement in their own care.

Promoting engagement with one's own care is vital to management of OSA. Our study will examine the effect of providing support to patients with OSA with a self-monitoring program between clinic visits. The intervention will provide patients with curated data visualizations and will also assist patients with interpreting these weekly reports. Findings from examining the acceptability and efficacy of augmenting current PAP therapy with wearable oxygen data will enable us to optimize implementation of patient-generated health data as an enhancer of daily living and routine clinic care. Findings will contribute additional knowledge regarding the implementation of interventions aimed at increasing OSA self-management practices.

Registration number

The trial was registered through ClinicalTrials.gov with identifier: NCT06039865

Ethics declarations

This study was approved by the Veterans Affairs Greater Los Angeles Health Care System (VAGLA) IRB on July 13, 2023 and University of California, Los Angeles IRB on July 25, 2023. Written, informed consent to participate will be obtained from all participants.

Trial status

The original protocol was approved July 2023. Amendments were approved by VAGLA IRB in October 2023 and in March 2024. Recruitment began in October 2023 and recruitment should be completed by July 2024.

July 2023: Original

September 2023, Amendment 01, approved October 2023: Primary reason for amendment: Protocol updates included addition of non-adherence to PAP therapy (percent PAP use ≥4 hours/night is <70% of the nights) as inclusion criteria; changed collection of 3 nights oximetry at baseline assessment to 1 night of oximetry if no prior overnight oximetry results available; added PROMIS Sleep Disturbance Short Form and Sleep Related Impairment Short Form and removed Pittsburg Sleep Quality Index and Insomnia Severity Index (ISI) as baseline assessment instruments; clarified that STAMP, PROMIS Sleep Disturbance Short Form, Sleep related Impairment Short Form, Determinants of nasal CPAP compliance would be asked at T3 and T5, and that Acceptability of Intervention Measures, Intervention Appropriateness Measures and Feasibility of Intervention Measures would be collected from participants after they complete the intervention program.

February 2024 amendment 02, approved March 2024: Protocol updated by adding VA DocuSign as a method of obtaining written consent during VA telehealth consent visit.

Competing interests

The authors declare there are no competing interests.

Availability of data and materials

Requests for access to the final dataset can be made to Constance Fung, MD, MSHS and requests must be approved by the VA. Requests must carry a methodologically sound proposal for use of the data.

Dissemination Policy

Results will be disseminated through conferences and peer-reviewed journals in the sleep, digital health, and health services fields.

Organizational structure and responsibilities

All co-investigators (CHF, SSM, GIA, MRZ) will meet regularly and will take responsibility for monitoring recruitment and randomization and standard operating procedures. The conduct of the study is led by CHF with a team including study coordinator and research assistants, who are responsible for identifying potential recruits, obtaining consent, reporting adverse events, finalizing standard operating procedures, and all day-to-day study activities. The principal investigator, CHF, is responsible for all communication including with the sponsor, IRB, R&D Committee, ClinicalTrials.gov. Listed authors will have met the International Committee of Medical Journal Editors (ICMJE) criteria for authorship.

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REFERENCES

1. Young T, Peppard PE, Gottlieb DJ: Epidemiology of obstructive sleep apnea: a population health perspective. *Am J Respir Crit Care Med* 2002, 165(9):1217-1239. PMID: 11991871
2. Omachi TA, Claman DM, Blanc PD, Eisner MD: Obstructive sleep apnea: a risk factor for work disability. *Sleep* 2009, 32(6):791-798. PMID: 19544756
3. Epstein LJ, Kristo D, Strollo PJ, Jr., Friedman N, Malhotra A, Patil SP, Ramar K, Rogers R, Schwab RJ, Weaver EM *et al*: Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med* 2009, 5(3):263-276. PMID: 19960649
4. Centers for Medicare & Medicaid Services. Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea. 2023.
5. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea. 2021.
6. Timkova V, Nagyova I, Reijneveld SA, Tkacova R, van Dijk JP, Bultmann U: Quality of life of obstructive sleep apnoea patients receiving continuous positive airway pressure treatment: A systematic review and meta-analysis. *Heart Lung* 2020, 49(1):10-24. PMID: 31668362
7. Sawyer AM, Gooneratne NS, Marcus CL, Ofer D, Richards KC, Weaver TE: A systematic review of CPAP adherence across age groups: clinical and empiric insights for developing CPAP adherence interventions. *Sleep Med Rev* 2011, 15(6):343-356. PMID: 21652236
8. Becker M: The Health Belief Model and Sick Role Behavior. *Health Education Monographs* 1974, 2(4):409-419.
9. Rafl J, Bachman TE, Rafl-Huttova V, Walzel S, Rozanek M: Commercial smartwatch with pulse oximeter detects short-time hypoxemia as well as standard medical-grade device: Validation study. *Digit Health* 2022, 8:20552076221132127. PMID: 36249475
10. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gotzsche PC, Krleza-Jeric K, Hrobjartsson A, Mann H, Dickersin K, Berlin JA *et al*: SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013, 158(3):200-207. PMID: 23295957
11. Selim AJ, Fincke G, Ren XS, Lee A, Rogers WH, Miller DR, Skinner KM, Linzer M, Kazis LE: Comorbidity assessments based on patient report: results from the Veterans Health Study. *J Ambul Care Manage* 2004, 27(3):281-295. PMID: 15287217
12. Weaver TE, Maislin G, Dinges DF, Bloxham T, George CF, Greenberg H, Kader G, Mahowald M, Younger J, Pack AI: Relationship between hours of CPAP use and achieving normal levels of sleepiness and daily functioning. *Sleep* 2007, 30(6):711-719. PMID: 17580592
13. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, Boynton MH, Halko H: Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci* 2017, 12(1):108. PMID: 28851459
14. Yu L, Buysse DJ, Germain A, Moul DE, Stover A, Dodds NE, Johnston KL, Pilkonis PA: Development of short forms from the PROMIS sleep disturbance and Sleep-Related Impairment item banks. *Behav Sleep Med* 2011, 10(1):6-24. PMID: 22250775
15. Jones J, Nielson SA, Trout J, Swenson M, Reiley J, Tanner J, Bowers D, Kay DB: A Validation Study of PROMIS Sleep Disturbance (PROMIS-SD) and Sleep Related Impairment (PROMIS-SRI) Item Banks in Individuals with Idiopathic Parkinson's Disease and Matched Controls. *J Parkinsons Dis* 2021, 11(2):877-883. PMID: 33579874
16. Johns MW: A new method for measuring daytime sleepiness: the Epworth sleepiness scale.

Sleep 1991, 14(6):540-545. PMID: 1798888
17. Goncalves MT, Malafaia S, Moutinho Dos Santos J, Roth T, Marques DR: Epworth sleepiness scale: A meta-analytic study on the internal consistency. *Sleep Med* 2023, 109:261-269. PMID: 37487279
18. Stepnowsky CJ, Jr., Marler MR, Ancoli-Israel S: Determinants of nasal CPAP compliance. *Sleep Med* 2002, 3(3):239-247. PMID: 14592213
19. Okan Y, Janssen E, Galesic M, Waters EA: Using the Short Graph Literacy Scale to Predict Precursors of Health Behavior Change. *Med Decis Making* 2019, 39(3):183-195. PMID: 30845893
20. Mehta N, Mandavia R, Patel A, Zhang H, Liu ZW, Kotecha B, Veer V: Patient-reported outcome measure for obstructive sleep apnea: Symptoms, Tiredness, Alertness, Mood and Psychosocial questionnaire: Preliminary results. *J Sleep Res* 2020, 29(2):e12960. PMID: 31860161
21. Grossman LV, Feiner SK, Mitchell EG, Masterson Creber RM: Leveraging Patient-Reported Outcomes Using Data Visualization. *Appl Clin Inform* 2018, 9(3):565-575. PMID: 30068012
22. Coşkun A KA: Data sensemaking in self-tracking: Towards a new generation of self-tracking tools. . *International Journal of Human–Computer Interaction* 2022, 26:1-22.
23. Mohr DC, Spring B, Freedland KE, Beckner V, Arean P, Hollon SD, Ockene J, Kaplan R: The selection and design of control conditions for randomized controlled trials of psychological interventions. *Psychother Psychosom* 2009, 78(5):275-284. PMID: 19602916
24. Owens RL, Wilson KC, Gurubhagavatula I, Mehra R: Philips Respironics Recall of Positive Airway Pressure and Noninvasive Ventilation Devices: A Brief Statement to Inform Response Efforts and Identify Key Steps Forward. *Am J Respir Crit Care Med* 2021, 204(8):887-890. PMID: 34461022
25. Liang Z PB, Liu W, Nagata Y, Bailey J, Kulik L, Li Y.: SleepExplorer: a visualization tool to make sense of correlations between personal sleep data and contextual factors. *Personal and Ubiquitous Computing* 2016, 20:985-1000.
26. Park S, Bekemeier B, Flaxman A, Schultz M: Impact of data visualization on decision-making and its implications for public health practice: a systematic literature review. *Inform Health Soc Care* 2022, 47(2):175-193. PMID: 34582297
27. Ravichandran R SS, Patel SN, Kientz JA, Pina LR: Making sense of sleep sensors: How sleep sensing technologies support and undermine sleep health. In: *InProceedings of the 2017 CHI conference on human factors in computing systems.* 2017: 6864-6875.

Supplementary Files

CONSORT (or other) checklists

SPIRIT Checklist.
URL: http://asset.jmir.pub/assets/db9b370017fcf0291fffe9ebd089a7c2.pdf