Chronic Care Management With Wearable Devices in Patients Prescribed Positive Airway Pressure Therapy (mPAP) Trial

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Study Title: Augmenting obstructive sleep apnea chronic care management with consumer wearable devices in patients prescribed positive airway pressure therapy

Overview:

The proposed randomized controlled trial will test the efficacy of a consumer wearable-augmented positive airway pressure (PAP) adherence program in a total of 50 participants (25 per group). This program uses minute-level pulse oximetry data from consumer wearables (e.g., Fitbit) to generate customized weekly reports for patients that contain feedback about their oxygen levels during sleep, juxtaposing patients' PAP adherence data and their self-reported symptoms (e.g., daytime sleepiness) with their pulse oximetry data. Changes in PAP adherence data will be compared between the intervention and waitlist control groups in the primary analysis. Given the growing interest in self-monitoring with consumer wearables, there is an urgent need for sleep centers to incorporate consumer wearable data into the chronic disease management of sleep disorders. Our project is at the forefront of consumer wearable research, leveraging the recent capabilities of consumer wearables to provide minute-to-minute pulse oximetry data during sleep, to uncover new ways to promote PAP usage among patients with OSA.

Background/Significance:

Consumer wearables can promote disease self-management in patients with obstructive sleep apnea (OSA): An increasing number of patients in sleep centers use consumer-grade wearable devices ("wearables") such as Fitbit® to self-monitor and improve their health. Patients purchase wearables and are eager to share their health data with their sleep clinicians, who may have varying levels of trust in the data and time to digest the data. 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. The proposed health outcomes research project aims to begin addressing this issue, by developing a pilot program for incorporating data from wearables into the chronic care management of adults with OSA. For this project, we focus on patients with OSA who are treated with positive airway pressure (PAP) therapy—a group that currently has access to PAP device self-management apps and whose PAP data are routinely reviewed by sleep clinicians.

Newer models of wearables such as Fitbit Sense™ and Apple Watch® are providing oxygen measurements.[1] 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 nadirs in some patients when off PAP therapy. 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. Patients with OSA who use PAP therapy and are self-monitoring oxygen levels represent an opportunity for sleep centers to support self-management of OSA to increase use of PAP therapy and promote dialogue between patients and their sleep clinicians about OSA treatment. For example, patients who use their PAP therapy inconsistently may have patterns in consumer wearable data that correlate with PAP usage. 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.

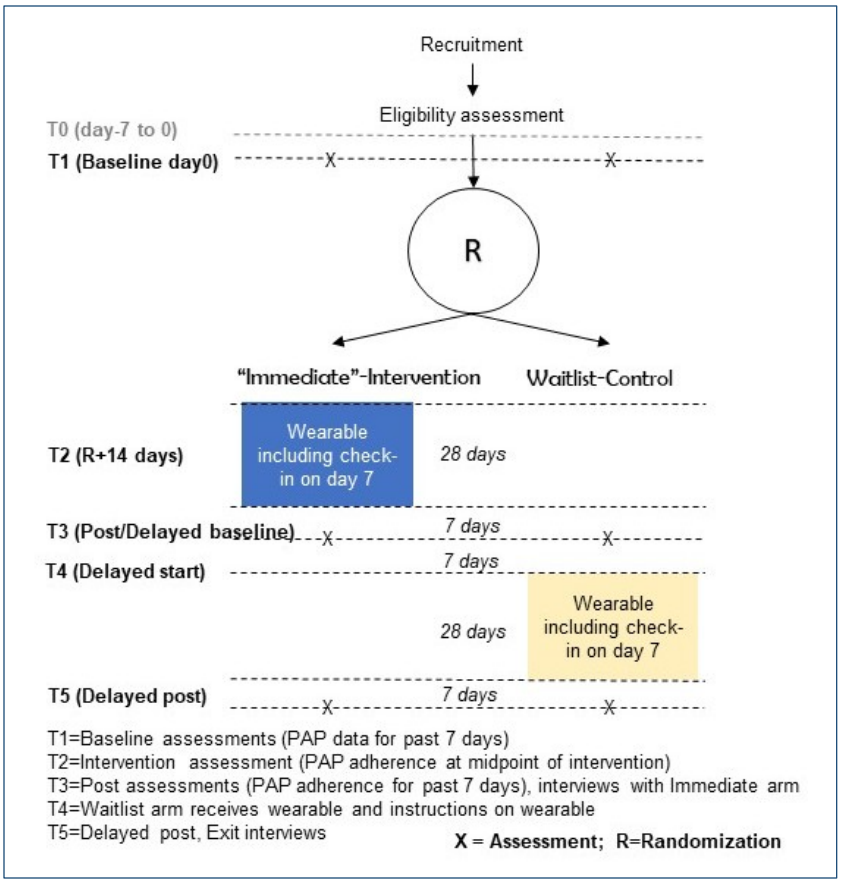
The Health Beliefs Model provides a framework for incorporating wearable data (specifically oxygen data) in a PAP therapy program.[2] The model suggests that the desire to get well if already ill (e.g., improve OSA) and the belief that a specific health action will cure illness, together, influence health 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) Perceive 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.

The goal of the project is to assess the impact and acceptability of augmenting current PAP therapy data with consumer-grade wearable device to promote self-management of PAP therapy for OSA. The specific aims are:

Specific Aim 1: To measure the effect of the consumer-grade wearable-augmented program on PAP use.

- *Primary Hypothesis*: Participants in the immediate wearable group will have greater improvement in PAP adherence (change in average minutes per night from baseline [T1] to Post [T3]) than participants in a waitlist-control group. (Figure 1)
- *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.

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



Approach:

Overview and Site: The proposed randomized, waitlist-control trial aims to assess the effects of a consumer-grade wearable intervention on PAP adherence. The proposed research project will be conducted at VA Greater Los Angeles, which receives more than 6,000 sleep consults per year. We will obtain approval from our local institutional review board.

Environment: The University of California, Los Angeles (UCLA) David Geffen School of Medicine (DGSOM) and Department of Veterans Affairs Greater Los Angeles Healthcare System (VAGLAHS) have missions to deliver exceptional health care. UCLA and VAGLAHS provide rich environments and infrastructure to support the proposed research. The DGSOM Department of Medicine (DOM) includes a division that is based at the VAGLAHS. VAGLAHS houses an American Academy of Sleep Medicine (AASM)-accredited sleep lab. VAGLAHS has outpatient sleep clinics at three campuses, in-lab sleep studies (6 beds), home-based sleep testing, and durable medical equipment (e.g., positive airway pressure devices). VAGLAHS sleep center provides consultation and expertise related to treatment monitoring as well as advice on implementation of sleep research findings. VAGLAHS also houses the Geriatric Research Education and Clinical Center (GRECC), which includes a group of behavioral and clinical sleep researchers.

Recruitment, screening, eligibility: We will recruit patients with OSA with the following **inclusion criteria**: aged >= 21 years, prescribed PAP therapy from the sleep center for $\geq$ 1 week, have an active profile in our Center's ResMed AirView or Respironics Care Orchestrator accounts for $\geq$ 1 week, willing to continue using current PAP device for 28 days continuously, non-adherent to PAP therapy (percent PAP use >= 4 hours/night is < 70% of the nights) and have a smartphone compatible with the wearable app; and do not have the following **exclusion criteria**: heart failure, chronic lung disease, use home oxygen, dementia, active substance use disorder, unstable medical or psychiatric illness, planned non-use of PAP therapy (e.g., waiting for replacement of recalled PAP device), planned surgery or hospitalization during study period, planned extensive travel during study period, history of repeated non-attendance at clinic visits.
Recruitment strategies will include mailed letters to patients with active modem accounts, flyers/posters in the clinic areas and with PAP equipment distribution, and in clinic recruitment. We have used similar strategies for prior studies (e.g., K23AG045937, R01AG057929) with success. Participants will be offered a $25 incentive for participating in the baseline and T5 assessments. The wearable device will be given to the participant and may be kept after study completion.

Participants will undergo an initial telephone screen to assess for eligibility and to collect demographic data (age, gender, race, ethnicity). A brief medical chart review will be performed to verify eligibility and OSA history (diagnosis date, severity [apnea-hypopnea index], PAP settings [fixed versus auto]). Verification of a PAP modem profile will be performed by checking the clinic's AirView or Care Orchestrator account.

Patients who are eligible based on preliminary telephone screening will be invited to participate in an informed consent appointment (VA telehealth or in-person), where the risks and benefits of the study will be presented. After written informed consent is obtained (through ink paper signature or through VA-provided e-consent platform [DocuSign]), participants will undergo a baseline assessment. DocuSign forms ("envelopes") are provided by the VA's Office of Information and Technology (OIT), Development, Security, and Operations (DevSecOps) Infrastructure Operations (IO). A fully executed digital copy of the Informed Consent and HIPAA Authorization forms will be available through the DocuSign portal, or the study team can mail or e-mail the participant a copy of all signed documents. Potential participants also will be informed before the consent visit that they can be provided sample Informed Consent and HIPAA Authorization forms (paper or watermarked unfillable PDF) to provide them with sufficient time to consider participation and discuss participation with family members, should they so desire.

Baseline assessments, Randomization, Intervention and Follow-up Assessments:

Primary baseline assessment (T1): Participants in both arms will undergo a baseline assessment, where current 7-day PAP adherence (average use [minutes/night], % days used $\geq$ 4 hours, # days used out of 28 days, average residual AHI on therapy) will be collected (PAP data "Day -7 to Day 0) from modem data. 1-night oximetry will be conducted (if no prior overnight oximetry results available). Other measures will be collected through Qualtrics™: "Determinants of PAP compliance" subscales (including attitudes and knowledge about PAP),[3] PROMIS Sleep Disturbance Short Form and Sleep Related Impairment Short Form, daytime function (Epworth Sleepiness Scale[5], STAMP[8]), comorbidities, and health literacy.[7]

Treatment allocation: The study will use a waitlist-control design. Participants who are eligible will be randomly assigned to receiving the intervention immediately versus 5 weeks later.

Intervention

Consumer-grade Wearable-Augmented PAP Adherence Intervention Program:

- Immediately following baseline assessment on Day 0, each eligible participant assigned to the Immediate Intervention group will be given a consumer-grade wearable registering minute-by-minute SpO_2 data (e.g., Fitbit Sense™) and instructions on use in a face-to-face visit. Patients 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.
- On Day 7: One week after the initial wearable session, the intervention team will contact the participant to check-in on the wearable use and personal reports access, using a structured interview guide.
- Day 0 through Day 28: Participants will share data with project team via the institution-approved data sharing platform. Within the VA, the SyncMyHealth/Share My Health Data app is one method, which is similar to apps in non-VA settings such as Epic's MyChart App that enable patients to share their patient-generated health data by syncing the MyChart app with Fitbit® and Apple HealthKit®. Weekly, participants will complete the STAMP,[8] a 12-item questionnaire that assesses the impact of OSA on biopsychosocial aspects, by a Qualtrics™ link delivered weekly through email (Day 0, Day 7, Day 14, Day 28). The processing of minute-level sleep SpO2 data that we are currently using in a quality improvement project will be used to construct reports with information such as 1) amount of time SpO_2 data was available, 2) SpO_2 summary, and 3) SpO_2 distribution showing # of minutes/% time SpO_2 was at a certain range.
- Patient Reports: Data shared by patients will be used to generate reports that emphasize the biometric and patient-reported outcomes associated with PAP therapy use. Oxygen levels from the wearable will be juxtaposed to PAP modem use data and reported daytime sleepiness and OSA-related quality of life.

Intervention assessment (T2): We will also extract PAP adherence day on Day 14 of the intervention period for use for secondary analyses.

Post-treatment assessment for both groups/Delayed baseline for waitlist-control (T3): Participants in both groups will undergo a research post-assessment to assess: 1) *Sleep-related outcomes*: PAP therapy adherence data (average use [minutes/night], % days used ≥ 4 hours, # days used out of 7 days) will be abstracted from the PAP modem account (Airview™, Care Orchestrator™). Sleep-related symptoms (Epworth Sleepiness Scale, STAMP, PROMIS Sleep Disturbance Short Form and Sleep Related Impairment Short Form, Determinants of nasal CPAP compliance questionnaire) will be repeated through a Qualtrics™ Survey (or by telephone/in-person if Qualtrics™ survey unanswered). This assessment will also serve as the delayed baseline for the waitlist-control group.
2) *Participant acceptability will also be assessed in the immediate intervention group*: % of days used the wearable overall and while on treatment, acceptability,[9] # of days with unavailable/not recorded measurement or unusable wearable data. A semi-structured interview assessing acceptability of the intervention program (including Acceptability of Intervention Measures, Intervention Appropriateness Measures, and Feasibility of Intervention Measures) will also be conducted by the research team, including participant's experience with using wearable with treatment.

Waitlist-Control (T4): 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 equivalent such as PAP interfaces on an as needed basis. They will receive instructions on the wearable at timepoint T4 and will use their wearable for 28 days.

Delayed Post for Waitlist-Control group/*Exit interview (T5)*: PAP adherence data similar to post-treatment T3 will be collected. Sleep-related symptoms (Epworth Sleepiness Scale, STAMP, PROMIS Sleep Disturbance Short Form and Sleep Related Impairment Short Form, Determinants of nasal CPAP compliance questionnaire) will be repeated through a Qualtrics™ Survey (or by telephone/in-person if Qualtrics™ survey unanswered). Participants in both groups will be interviewed to obtain feedback on the study, including opinions about the wearable program and intention to continue using the wearable. Participants in the Waitlist-Control group will also be asked the Acceptability of Intervention Measures, Intervention Appropriateness Measures, and Feasibility of Intervention Measures. This information will be added to the interview data collected from the "Immediate" group at Post assessment about the program.

Data collection and security: PAP modem data will be downloaded and stored in a secure research folder at VA Greater Los Angeles behind the VA's firewall. Data from wearables will be shared by participants through VA's Share My Health Data app or Fitabase™ software. Patient-reported outcomes will be collected via VA Qualtrics™. We will use Audacity® software to record and transcribe interviews.

Evaluation and Statistical Plan:
An intention-to-treat approach will be used. Descriptive statistics and frequencies for demographic and clinical characteristics and all outcome measures at baseline will be summarized and compared 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.

Changes in sleep-related outcomes will be measured and analyzed to assess the "success" (effect) of the wearable intervention: 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 PAP change in average minutes per night of PAP usage from T1 to T3 between the intervention study arms (Immediate Intervention versus Waitlist-Control) from T1 to T3, using an intention-to-treat design. Using a paired two-sample t-test on change scores for our primary analysis(unadjusted), we will compare PAP adherence (average use [minutes/night] over 28-day period) between groups (Immediate Intervention versus Waitlist-Control) from baseline to post assessment (T1 to T3). 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.

Secondary analyses will be implemented to compare the secondary outcomes, e.g., % of days used ≥ 4 hours, the proportion 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 following fixed-effects: study arm (intervention vs. control), time (all available time points), and a two-way study arm-by-time interaction term. Each model also includes participant-level random effects to account for 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 with identity link function 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).

Sample size and Power calculations: Sample size and power calculations are provided for the primary outcome, change in average minutes per night of PAP use over the 28-day period within participant from baseline to post-intervention assessments. The primary objective is to compare the mean change scores from baseline between study arms. A sample size of 25 participants per group (total n=50) will provide at least 80% power to detect an effect size 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. A prior study evaluating a behavioral intervention for improving PAP adherence in older patients with comorbid OSA and insomnia reported an effect size of 0.59 at 3 months follow up.[10] Because our study's end point is 1-week post-treatment, we anticipate a slightly larger effect size. The estimates from this study will be used to plan a future full scale, multi-year trial.

Participant acceptability will be measured/analyzed to assess "success" (acceptability): We will summarize acceptability measures[9] (frequency, mean, etc.). For interview data, we will summarize interview content thematically (Dedoose software) and identify ways to improve the protocol for a future full-scale trial.

Progress reports and results: We will provide quarterly reports and a final evaluation to the ResMed Foundation as well as an expenditure report.

Expected results, use of results, and dissemination:
Underuse of PAP therapy is common among patients with OSA. Wearables are an innovative method of augmenting existing tools and educational programs designed to increase and optimize use of PAP therapy. This project will inform sleep clinicians about the efficacy of augmenting current PAP therapy with wearable oxygen data. The trial will be registered and reported in clinicaltrials.gov and results disseminated in a peer-reviewed journal and an abstract will be submitted to professional meetings (e.g., Associated Professional Sleep Societies Annual Meeting).

Timetable

Q1	Q2	Q3	Q4
Obtain IRB approval Procure wearables Begin recruitment ResMed Foundation report	Recruitment, Intervention, Evaluation, Data entry and cleaning ResMed Foundation report	Recruitment, Intervention, Evaluation, Data entry and cleaning ResMed Foundation report	Complete data analyses, report, dissemination, and grant writing ResMed Foundation report

Key individuals involved in the study and brief summary of qualifications

Expertise	Name, Role	Experience
Grant planning & execution, sleep medicine	Constance Fung, MD, MSHS, Associate Professor of Medicine at UCLA. Principal Investigator	Current PI NIA R01AG057929 and R01AG057929-03S1 (wearables for cognitive assessment). Past PI on shared decision making OSA project. Staff physician at VA Greater LA (VAGLA) Sleep Center
Sleep center operations	Michelle Zeidler, MD, MS, Director of VAGLA Sleep Center and Professor of Medicine at UCLA. Co-Investigator	Supervises & operates VAGLA Sleep Center. Completing VA Office of Connected Care (VA OCC) project examining tele-vs face-to-face diagnostic sleep test setup
Implementation science	Selene Mak, PhD, MPH, Core Investigator at VAGLA CSHIIP. Co-Investigator	MPI on VA OCC project evaluating integration of wearables into VAGLA sleep center. Completed evaluation of Project Resilience, VHA Innovation Ecosystem's Fitbit distribution program. Works on quality improvement project involving wearables in health coaching
Wearable devices for self-management	Garrett Ash, PhD, Associate Research Scientist, Yale School of Medicine & VA Connecticut PRIME COIN. Co-Investigator	MPI on VA OCC project evaluating integration of wearables into VAGLA sleep center. Implements interventions that integrate wearables to promote behavioral skills for people with chronic diseases

Statistical	Li-Jung Liang, PhD, Biostatistician at UCLA and VAGLA	Biostatistician for recent trial testing patient decision aid for OSA (K23AG045937; PI: Fung)
Project coordination, intervention	Claudia Perdomo, Staff Research Associate II. Project Coordinator	Current project coordinator, recruiter on two research projects that use sleep wearables. Previously delivered intervention for sleep apnea decision aid trial to participants
Recruitment, data entry	Sara Ghadimi, Staff Research Associate I. Research Assistant	Research assistant who successfully recruited and conducted assessments for ongoing sleep clinical trial. Also refined procedures manual for pilot study that used smartphones for cognitive assessment

Long-term strategies for funding beyond this grant period: We plan to submit a research grant (e.g., NIH R01 or VA Merit) to study the effect of the wearable program in a large sample of patients with OSA, including those who use a variety of therapies (PAP therapy and non-PAP therapy), to estimate the effects of the program on a variety of healthcare outcomes such as adherence to OSA therapy, cardiovascular (e.g., blood pressure), and patient-reported outcomes (e.g., excessive daytime sleepiness).

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