PROTOCOL TITLE:
A PILOT STUDY TO DETERMINE THE FEASIBILITY OF A COUPLES' ORIENTED INTERVENTION TO PROMOTE CPAP ADHERENCE AMONG AFRICAN AMERICAN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA

PRINCIPAL INVESTIGATOR:

J. Daryl Thornton, MD, MPH
Center for Reducing Health Disparities
Department of Internal Medicine
216-778-3732
dthornton@metrohealth.org

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1.0 Study Summary

Study Title	A PILOT STUDY TO DETERMINE THE FEASIBILITY OF A COUPLES' ORIENTED INTERVENTION TO PROMOTE CPAP ADHERENCE AMONG AFRICAN AMERICAN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA
Study Design	Randomized Controlled Trial
Primary Objective	Mean CPAP adherence at 90 days
Secondary Objective(s)	Mean CPAP adherence at 30 days Change in mean CPAP adherence at 90 days (compared to baseline) Self-efficacy to use CPAP Patient and bed partner quality of life Patient and bed partner quality of sleep
Research Intervention(s)/ Investigational Agent(s)	Peer motivators Behavioral couple therapy Telemonitoring and feedback
IND/IDE #	N/A
Study Population	African American patients with OSA and bed partner
Sample Size	20 patients and 20 bed partners
Study Duration for individual participants	90 days
Study Specific Abbreviations/ Definitions	OSA Obstructive Sleep Apnea CPAP Continuous Positive Airway Pressure

2.0 Background and Objectives

Obstructive sleep apnea (OSA), which affects 26% of adults over age 30 in the US[1] and over 900 million people worldwide[2], is a disorder of sleep that results from intermittent complete or partial airway collapse and leads to episodes of apnea, hypopnea, and arousal from sleep.[3,4] Without treatment, OSA is associated with both immediate and long term adverse health outcomes, including motor vehicle accidents, hypertension,[5] and coronary artery disease.[6] African Americans are more likely to develop OSA and its complications despite presenting with similar symptoms.[7–9] Continuous positive airway pressure (CPAP) is efficacious in treating moderate to severe OSA[10–12] and in preventing many of its complications. However, CPAP adherence is low among African Americans.

In our prior work, we found that untreated OSA can also adversely affect the sleep and daytime functioning of bed partners by preventing them from having continuous, restful sleep.[13,14] Partners' sleep loss often results in frustration, exhaustion, interference with work, and a strained relationship. In contrast, OSA treatment improves bed partner sleep quality and may improve intimate relationships.[15] Perceived partner support is associated with more CPAP use.[14] Few studies, however, have examined the efficacy of bed partner interventions in improving OSA outcomes.

We propose to pilot test a couple-oriented intervention in a randomized controlled trial of 20 African American patients diagnosed with moderate to severe OSA and their partners. Half of the patients will receive optimal **usual care currently implemented at MetroHealth**, consisting of sleep therapist-initiated standardized education about OSA, sleep hygiene, and CPAP use; personalized mask fittings; and follow-up at 1 week to troubleshoot problems with CPAP utilization. Participants will follow up with their sleep providers per usual. The remaining patients and their bed partners will receive a **couple-oriented intervention** consisting of guideline-recommended best practices for improving CPAP adherence consisting of sleep therapist-initiated **standardized education for couples** about OSA, sleep hygiene, and CPAP use; personalized mask fittings; and follow-up at 1 week to troubleshoot problems with CPAP utilization. Couples will participate in two couple-oriented support groups led by an African American patient with long standing OSA treated with CPAP and their partner. Patients and partners will receive tailored text messages encouraging adherence. In addition, **couples will receive** five 60-minute **virtual cognitive behavioral couple therapy** sessions with a health psychologist trained in behavioral sleep medicine that will focus on enhancing **couples' knowledge** of CPAP, **patients' self-efficacy** to use CPAP, **couple's relationship dynamics**, and **partners' skill and self-efficacy** in assisting the patient with CPAP adherence.

Primary Aim 1: To determine the impact of a couple-oriented intervention on CPAP adherence.

Hypothesis: Compared to usual care patients, patients who receive the couple-oriented intervention will use CPAP for more hours per night over 90 days (primary outcome).

Primary Aim 2: To determine the impact of a couples-oriented intervention on quality of sleep, functional status, and quality of life of OSA patients and their partners.

Hypothesis: Compared to usual care couples, couples who receive the couple-oriented intervention will have a higher quality of sleep, functional status, and quality of life at 90 days (secondary outcomes).

3.0 Background

3.01 Many Americans have obstructive sleep apnea (OSA).

Obstructive sleep apnea (OSA) affects 13% of adult men and 6% of adult women in the US.[1] OSA occurs when the upper airway intermittently narrows or completely closes during sleep, resulting in complete or near cessation of breathing for at least 10 seconds at a time.[16] Oscillations in oxygen saturation are common and may fall dangerously low. Snoring may be loud and disruptive to others. These respiratory events cease when the patient partially arouses. Partial arousals almost never cause the person to wake completely, but significantly decrease the likelihood of obtaining continuous sleep. As a result, OSA is often first recognized by bed partners who encourage the patient to seek medical care.[17]

3.02 OSA is a cause of significant morbidity and mortality.

Untreated OSA is associated with motor vehicle accidents and occupational injuries.[18,19] Over time, the cardiovascular system may become affected leading to the development of hypertension,[5] coronary artery disease,[6,20] atrial fibrillation,[21] and sudden cardiac death.[22] OSA is also associated with the development of ischemic stroke.[23] The all-cause mortality hazard ratio for untreated OSA compared to no OSA is 3.8 (95% CI 1.6 – 9) after adjustment for age, sex, body mass index (BMI), and other factors.[24]

3.02 African Americans are at increased risk of being adversely affected by OSA.

Meta-analyses have found African Americans to have worse subjective and objective sleep and to be at increased risk of developing OSA compared to whites.[25,26] Studies have found a higher severity of OSA among African Americans compared to whites as well as an increase in OSA-related complications. For example, in the Multi-Ethnic Study of Atherosclerosis (MESA), African Americans with an increased risk of OSA had a higher prevalence of inflammatory mediators and cardiovascular risk factors compared to other racial and ethnic groups.[27,28]

3.03 Continuous Positive Airway Pressure (CPAP) treats moderate and severe OSA.

CPAP effectively treats OSA by providing a pneumatic splint preventing airway collapse during sleep.[10–12] It is associated with improvements in quality of life,[29–32] and reductions in morbidity.[33–37] By reversing snoring and sleep disruption, CPAP also improves sleep quality among bed partners.[29,38] There is no threshold duration of use for optimal benefit from CPAP suggesting a linear improvement in outcomes with use. While use for more than 4 hours/night improves sleepiness and is considered the gold standard duration,[39] more than 5 hours/night of use improves blood pressure[40] and lowers the risk for weight gain.[41] More than 6 hours/night of use improves memory and daily functioning.[42]

3.04 CPAP adherence is low, particularly among African Americans.

Only about 50% of patients with OSA use CPAP for more than 4 hours per night.[42] African Americans and patients of lower socioeconomic position have lower adherence compared to whites and patients of high socioeconomic position even when adjusting for its cost.[43–45] Patient adherence soon after CPAP initiation is associated with long-term adherence.[46] There are differences in symptom recognition, risk perception, and outcome expectations between patients who adhere to CPAP and those who do not.[47]

3.05 Individual interventions to improve CPAP adherence have had modest results.

Multiple studies have examined the impact of different interventions on CPAP adherence with negative or moderately positive results.[48–55] A recent systematic review categorized the

interventions to determine which had the greatest impact on CPAP adherence.[56] Troubleshooting interventions increased CPAP usage by approximately 40 minutes/night, and educational interventions increased CPAP usage by about 50 minutes/night. Behavioral therapy interventions had the largest effect with an increase of 1.31 hours/night. However, the quality of the evidence was rated as low. Guidelines encourage use of **multifaceted interventions that combine educational interventions at CPAP initiation with troubleshooting and behavioral interventions during the initial period of accommodating to CPAP** to maximize adherence.[57] In addition, telemonitoring is recommended for early identification and intervention among those who are non-adherent. There have been few studies that tested interventions among African American patients to specifically address sleep health disparities.[58,59]

2.07 Bed partners may be an integral component of OSA adherence.
Randomized trials demonstrate CPAP therapy improves sleepiness and quality of life not only in patients, but also their bed partners.[60,61] Thus, a couple-based intervention may improve both the patient's OSA and the adverse effects of OSA on the bed partner.[62] A qualitative study of 20 couples by our group identified several facilitators of CPAP use, including couples working together to use CPAP, perceived benefit of CPAP to both partners, patients motivated to use CPAP for the benefit of partners, and partner support to encourage CPAP use.[63] Barriers to use included bothersome equipment causing disruptions in sleep and bedtime routine, interruptions to intimacy, and concern about a change in body image while wearing CPAP. Sawyer identified daily interactions with the partner providing support, assistance with troubleshooting, and observing positive response to CPAP in the patient as positive influences on patients' commitments to CPAP.[47]

2.08 Cognitive behavioral couple therapy (CBCT) may improve OSA adherence.
Cognitive behavioral couple therapy (CBCT) integrates behavioral couple and cognitive therapy to improve communication, problem-solving, and relationship quality among couples.[64] CBCT focuses on the role of dysfunctional attitudes and attributions on each partner's cognitions, behaviors, and emotional responses. Specifically, CBCT assists couples by restructuring cognitions that bring in relational distress through unrealistic expectations, irrational beliefs, and dysfunctional assumptions. Effectiveness studies of CBCT showed improved relationship satisfaction, communication, and problem-solving skills among couples.[65] Studies using the CBCT approach with patients suffering from PTSD, OCD, vestibulodynia, and cancer, found positive improvement in couples' relationships and relationship satisfaction.[64,66,67]

CBCT has been used previously among OSA patients. In Australia, CBCT was associated with a 2.9-hour improvement in CPAP adherence.[48] Because cognitive behavioral therapy is the gold standard for insomnia management, the expertise delivering this treatment already exists in most sleep medicine clinics. It should therefore not be difficult for providers to implement CBCT into their OSA management.

2.09 Preliminary work: African American patients with OSA and their partners are receptive to remote intervention
We conducted Zoom interviews with 15 African American patients with OSA and their 15 partners to determine their unique needs regarding OSA management and to determine their willingness to receive the intervention remotely. Couples were excited about having a remotely administered couples-oriented intervention to improve OSA management. One patient commented, "It's really helpful if the person knows you're saving your spouse's life. So yeah, I

think they should be involved." Another stated, "She encourages me, and she's another reason why I wear my CPAP." Couples also suggested that African American couples with experience in dealing with OSA and CPAP interact with newly diagnosed patients and their partners to help them understand what to expect and how to address problems that arise. One patient stated, "When you first start using the machine, it's going to be uncomfortable." Another said, "Just hearing about the issues… Just even talking like 'Hey, this is normal'." These findings were used to develop our couple-oriented intervention for African Americans.

2.10 Innovative features of proposed trial

Previous studies of CPAP adherence have had little or no involvement of bed partners, short follow up durations, small sample sizes, and single interventions. Furthermore, African American participation has been extremely limited. There are several unique features that distinguish this project from prior work. First, we will recruit African American participants using a similar approach to that used to successfully recruit participants in our prior work. Second, we will incorporate bed partners into the intervention. Third, our intervention is built on feedback received from African American patients and their bed partners. Fourth, African American couples with personal experience with OSA will serve as peer motivators. The use of peer motivators looks promising.[68,69] Fifth, rather than testing single interventions, we propose a multi-modality intervention that combines education, troubleshooting, peer motivators, continuous telemonitoring, and remote feedback of CPAP use, each of which in isolation have been suggested to modestly improve CPAP adherence.

4.0 Study Endpoints

Primary Endpoint:	Mean CPAP adherence over 90 days
Secondary Endpoints:	Mean CPAP adherence over 30 days Patient and Bedpartner quality of sleep at 90 days Patient and Bedpartner functional status at 90 days Patient and Bedpartner quality of life at 90 days

5.0 Study Intervention/Investigational Agent

5.01 Usual care arm

Patients in the usual care arm will receive standard of care in the management of OSA. Patients will receive care from their sleep provider per usual. MyChart, the patient portal of the electronic health record, will be used to send patients a link to user-friendly OSA patient education programs (Emmi; Emmi Solutions LLC.).[53] Within 1 week of being diagnosed with OSA and enrolled in the study, sleep technologists will meet in person with patients and provide them with their auto-titrating CPAP machine; train them on its use, upkeep, and troubleshooting; and perform personalized mask fittings. Patients will be informed that their CPAP adherence will be monitored. Every morning, CPAP adherence data will be uploaded to RedCap. Patients with CPAP technical difficulties will be encouraged to contact the sleep technologist for assistance. Patients will attend a 90-minute virtual webinar and question-answer session on hypertension management, cancer screening, or weight management at 1 and 3 months led by African American physicians with expertise in each topic.

5.01a Virtual sleep logs as ecological momentary assessments. Patients will be asked whether they would prefer to receive communications via telephone, email, text message, or a

combination. During the first 6 months of the study, patients and bed partners will receive up to 4 interactive text messages/week in the morning inquiring about the quality of their sleep, their sleep-wake patterns, symptoms attributable to OSA, perceptions regarding OSA and CPAP, what time they went to sleep, when they woke up for the final time, how they rated the quality of their sleep, and any additional comments they may have.[70,71]

5.02 Couple-oriented intervention arm

5.02a Peer-Motivator Couples. Patients in the couple-oriented intervention arm will also receive usual care. However, the health-related virtual webinars at 1 and 3 months will be replaced by OSA virtual support groups led by an African American patient with long-standing OSA and their bed partner. Peer-motivator couples will be trained and certified as competent prior to interacting with study participants. They will share their experiences with managing OSA including coping strategies to maximize CPAP adherence.

5.02b Telemonitoring. Physiologic and adherence data from patients' CPAP machines will be uploaded into RedCap and used to automatically trigger messages of encouragement to patients and partners. For the first three days following receipt of CPAP, patients and bed partners will each receive text messages regarding CPAP use for the previous night. Similar messages will be received after the first study week with 3 nights of consecutive use (or lack of use). No more than 4 messages will be sent per week to prevent respondent fatigue. Example messages include:

Trigger	Patient Message	Bed Partner Message
CPAP use < 4 hours per night in any of the first 3 nights of the study	*Did you have any difficulty using CPAP last night? What changes can you make to increase your use tonight?*	*Did your partner had trouble using CPAP last night? How can you help them use it tonight?*
CPAP use > 4 hours per night in any of the first 3 nights of the study	*Congratulations on wearing your CPAP last night. Let's see if you can do it again tonight!*	*Your partner was able to wear their CPAP tonight. How can you help them to use it again tonight?*
CPAP use < 4 hour per night for 3 consecutive nights (first occurrence)	*It takes some time to get use to CPAP. However, regular use can improve your sleepiness and your wellbeing. Can you try again tonight?*	*Your partner has not reached their CPAP goal for the last 3 nights. What are some ways to help them use it tonight?*
CPAP use > 4 hours per night for 3 consecutive nights (first occurrence)	*Way to reach your sleep goal 3 nights in a row!* *Can you do it again tonight?*	*Your partner has reached their CPAP goal 3 nights in a row! Can you encourage them again tonight?*

5.02c Cognitive Behavioral Couple Therapy (CBCT). A psychologist will facilitate two virtual 60-minute CBCT sessions. Virtual psychotherapy for couples is both efficacious and feasible.[72] The therapy process will be based on the principles of psychology and chronic illness, the reciprocal association between the couple's functioning and the issues related to OSA.[73] These sessions will consist of four main components: problem-solving training, communication training, cognitive restructuring, and functional structuring of the couple's relationship. Dr. Burger will have a not-guiding stance towards a preconceived thought but will facilitate open exploration and problem solving.

Each session will begin with review of assigned tasks from the prior session. Couples and therapist will review the digital sleep logs and CPAP adherence data. They will then problem-solve ways to improve CPAP adherence. Dr. Burger will use guided discovery with Socratic questioning to facilitate couples' exploration of automatic thoughts, emotions, assumptions, and beliefs. Behavioral experiments will be used to help couples test the validity of their cognitions and beliefs and to promote awareness of the way they perceive and react to events and to each other. Couples will be encouraged to continue the experiments in their daily lives outside of the sessions. Sessions will conclude with assigned homework to be completed by the couple prior to the subsequent session. Prior to ending the session, couples will be asked to comment on whether they received the help they needed for that day and whether they felt fully understood. The final session will have discussion of the positive effects resulting from having OSA (benefit finding), a review of the progress made in therapy, and the challenges that lie ahead.

SESSION	SESSION GOALS
1[74]	-Introduction to cognitive behavioral couples' therapy -Review of goals of therapy -Collaborative setting of agenda by therapist and couple -Discuss baseline digital sleep log data -Review recommendations for optimal sleep hygiene -Review tasks to be completed for next session (continue sleep log completion and review sleep hygiene recommendations)
2	-Conceptualize OSA as a multidimensional problem -Identify cognitive, emotional, reciprocal influences, and environmental factors affecting couples' functioning -Discuss cognitive distortions and communication -Improve adaptive coping through improving self-efficacy and working with cognitive distortions such as maximization and castrophizing -Benefit finding -Relapse prevention -Consolidate skills

6.0 Procedures Involved

This is a pilot randomized controlled trial involving 20 African American patients with OSA and their bed partners. Patients will be identified within 48 hours of a new diagnosis of moderate to severe OSA and planned prescription of CPAP by their providers. Patients will be randomized to a usual care arm or a couple-oriented intervention arm and complete the tasks below. All patients will receive auto-titrating CPAP machines equipped with cellular modems upon enrollment into the study. Every morning the machines will use cellular communications to upload physiologic data (CPAP adherence, applied CPAP pressure, mask leak, and residual respiratory events) to RedCap. Ecological momentary assessments (EMA) in the form of morning text message will allow patients and partners to report their sleep quality and CPAP experiences in the mornings over the first 6 weeks of enrollment.[75] Shortly after waking, patients and their bed partners will receive automated interactive text messages up to 4 times per week asking them about their sleep duration, quality, and experiences with CPAP from the prior night. Their responses will be uploaded directly into RedCap for comparison to nightly CPAP machine usage reports. Couples in the intervention arm will receive automated text messages when their CPAP usage drops below designated thresholds or when there is substantial improvement in CPAP adherence.[53] Mosio text messaging software will be used to automatically send and receive text messages between study participants and RedCap.

STUDY TASKS	USUAL CARE ARM	COUPLE-ORIENTED INTERVENTION ARM
Care from sleep providers	- Order CPAP - Counsel patient about OSA diagnosis	- Order CPAP - Counsel patient about OSA diagnosis
Care from study sleep technologists	- Standardized review of sleep study, auto-CPAP instruction and troubleshooting, and mask-fitting with patient - Standardized phone call with patient 1 week later to answer questions and address any problems that arose - Meet with patient as needed to troubleshoot problems	- Standardized review of sleep study, auto-CPAP instruction and troubleshooting, and mask-fitting with patient **and partner** - Standardized phone call with patient **and partner** 1 week later to answer questions and address any problems that arose - Meet with patient **and partner** as needed to troubleshoot problems
Care from experienced African American patient with OSA and bed partner (peer motivators)	- Two health talks moderated by African American health care providers	- Two support group sessions for African American patients **and their partners** to assist with OSA and CPAP
Automated telehealth care	Not applicable	- Daily review of CPAP adherence data - Contact patient **and partner** when any of the following is present: no data uploaded from CPAP machine in > 72 hours, mask leak > 40L/min > 30% of night, < 4hr of use for 3 consecutive nights, machine measured AHI > 10events/hr, & 90% of pressure > 16cmH_2O.[50] - Contact patient **and partner** when CPAP use exceeded 4hr for 3 consecutive nights.[53]

We expect about 55% of the participants will be women, 94% will be African American non-Hispanic, and 6% will be African American and Hispanic.

Patient demographic and medical characteristics (e.g., comorbid conditions) will be obtained directly from EpicCare. Socioeconomic status will be assessed by asking patients about their education, occupation, and income. Patient and bed partner relationship quality will be assessed using the 4-item version of the Dyadic Adjustment Scale (DAS-4), one of the most widely used measures of couple satisfaction in research and clinical practice.[76] The 6-item Zarit Burden Interview for Dementia Caregivers is one of the most widely used measures of caregiver burden.[77] OSA severity will be assessed using the apnea-hypopnea index, the time spent with oxyhemoglobin saturation < 90%, and the lowest value of oxyhemoglobin saturation each retrieved from the polysomnogram report.[78] All participants will be given an autotitrating CPAP machine that can be monitored remotely. The device will upload objective adherence data to RedCap each morning following use. **Adherence is the average nightly use of CPAP from baseline to designated follow-up times (30 days, 90 days).**

Instruments to measure OSA knowledge and beliefs, depression, sleepiness, quality of sleep, quality of life, self-efficacy to use CPAP, and degree of bed partner involvement in CPAP adherence will be completed by all study participants at **baseline, 30 days, and 90 days**. These instruments have demonstrated reliability and validity and have been used in previous

studies of OSA and CPAP adherence. Depression, a potential factor confounding the relationship between the presence of sleep apnea and CPAP adherence, will be assessed using the 9 item Patient Health Questionnaire (PHQ-9).[79] It performs well among diverse patient populations.[80] The 8-item Epworth Sleepiness Scale (ESS) measures the propensity to fall asleep in eight unique situations.[81] Scores on the ESS are positively associated with OSA severity,[82] and they improve with CPAP treatment. The 8-item short version of PROMIS Sleep Disturbance Index will be used to assess self-reported perceptions of sleep quality, sleep depth, and sleep restoration. It has greater measurement precision than the ESS and the Pittsburgh Sleep Quality Index.[83] The impact of sleepiness on functional status will be assessed using the 10-item Functional Outcomes of Sleep Questionnaire (FOSQ-10). Quality of life will be assessed with the 12-item Medical Outcome Survey Short Form (SF-12).[84] Sleep-related quality of life will be assessed using the Calgary Sleep Apnea Quality of Life Index (SAQLI). Self-efficacy, or confidence in one's ability to use CPAP when faced with difficulties, will be assessed using the Self Efficacy Measure in Sleep Apnea (SEMSA).

DATA ELEMENT	SOURCE
- Patient and bed partner demographic and clinical characteristics: age, gender, race, ethnicity, socioeconomic status, comorbidities, sedative and psychoactive medications	- Electronic health record and questionnaire
- Bed partner involvement	- Patient and bed partner texts about sleep quality
- Bed partner burden	- Zarit Burden Interview (6-item)
- Patient and bed partner relationship quality	- 4-Item Dyadic Adjustment Scale (DAS-4)
- OSA severity (apnea-hypopnea index, duration of oxygen hemoglobin saturation < 90%, oxygen hemoglobin saturation nadir)	- Sleep study reports from electronic health record
- CPAP settings and proper interface	- CPAP machine download
- CPAP adherence	- CPAP machine daily download
- Depression	- Patient Health Questionnaire 9-item Depression Scale (PHQ-9)
- Excessive daytime sleepiness	- Epworth Sleepiness Scale (ESS)
- Sleep quality	- PROMIS Sleep Disturbance Index (PSQI)
- Impact of sleepiness on functional status	- Functional Outcomes of Sleep Questionnaire short version (FOSQ-10)
- General quality of life	- SF-12 questionnaire
- Sleep apnea-related quality of life	- Calgary Sleep Apnea Quality of Life Index
- Self-efficacy to use CPAP	- Self-Efficacy Measure in Sleep Apnea (SEMSA)

7.0 Data and Specimen Banking

Not Applicable.

8.0 Sharing of Results with Subjects

Results from the study will be shared through the publication of findings in research journals and via presentation at scientific meetings. Results will be directly shared with participants upon inquiry.

9.0 Study Timelines

Participants will be enrolled from April 1, 2022 to December 31, 2022. Participants will participate in the study for 90 days. The estimated date for primary analysis to be completed will be March 1, 2023.

10.0 Inclusion and Exclusion Criteria

We will focus on eligible patients with moderate or severe OSA as CPAP is first-line therapy for this population. Because of their similar performance, sleep studies will be performed in patients' homes[85,86] or in the sleep centers of The MetroHealth System and will be interpreted by registered polysomnographic technologists using standard criteria.[87] Split night studies will be eligible for inclusion. We will focus on adults as the causes and treatments for OSA are often different in children. To maximize the chances that patients will continue to have the same bed partner throughout the duration of the study, we will only include couples who have been bed partners for at least 6 months. We will focus on English-proficient patients as study interventions have been tailored for English-proficient patients and their bed partners and there are relatively few Spanish-speaking patients in our area. We will exclude patients with conditions that may interfere with their participation or alter their management of OSA. We will also exclude patients who have more complex forms of sleep-disordered breathing requiring other forms of positive airway pressure.

SCREENING INCLUSION CRITERIA	EXCLUSION CRITERIA
-Moderate or severe OSA (Apnea hypopnea index ≥ 15 events/hour) -Age ≥ 18 years -Bed partner for ≥ last 6 months who is willing to participate -English proficient	-Terminal illness -Mentally incompetent -Unstable housing -Need for other forms of positive airway pressure (BPAP or VPAP)

11.0 Vulnerable Populations

This study will not enroll vulnerable populations.

12.0 Local Number of Subjects

This study will enroll 20 African American patients of MetroHealth with OSA and their bed partners.

13.0 Recruitment Methods

Prior to enrollment of the first subject, sealed envelopes containing participant computer-randomized study arm assignment will be created. To assure balanced but unpredictable assignments of participants we will use permuted block randomization, stratified by study site.[88,89] Study flyers will be distributed to sleep providers to distribute to eligible patients who can contact study staff for enrollment. Research assistants will obtain automated digital reports from EpicCare of patients who have received an at-home or in-lab diagnostic sleep study over the previous 48 hours and an order for initiation of CPAP. They will review EpicCare to verify eligibility (see Table above). Study staff will mail a study brochure and consent form to patients. Those who do not respond within 72 hours will receive a phone call to confirm patient and bed partner eligibility and to explain the study in detail. Upon obtaining verbal confirmation, staff will arrange a date and time to meet with patients and their bed partners in person to obtain written consent and to administer baseline study instruments. After completion of these initial tasks, staff will open envelopes to determine subject study arm assignment. Only the sleep technologist, the research assistants who enroll the patients and the participants will be aware of study arm assignments. Participants will receive Clincard payments within 1 week of completion of study tasks. Participants will receive $50 for completion of the baseline, 30-day, and 90-day instruments ($150 total / participant paid by ClinCard). Participants will also be reimbursed for public transportation or parking.

14.0 Withdrawal of Subjects

Participants will not be withdrawn from the research without their consent. Participants who withdraw from the study will be able to keep their CPAP machine and will continue to receive care at MetroHealth per usual. Their data collected up to the time of withdrawal from the study will continue to be used according to intention to treat methodology.

15.0 Risks to Subjects

Potential risks to participants are (a) discomfort with sleep technologist interactions and (b) breaches of confidentiality. Precautions to minimize these risks are described below. The only alternative is to no participate in the study. However, patients may refuse to interact with study staff, decline to follow their advice, or withdraw from the study at any time.

All interactions with subjects will occur within the MetroHealth System where they receive care. As a result, all the usual approaches to maintain privacy and confidentiality in the health care setting will be observed. We will immediately notify the patients' primary care provider if they are suicidal at any time during the trial so that urgent evaluation and treatment can be arranged.

To protect against beaches of confidentiality, all study-related data to be secured on the password- and firewall-protected servers of The MetroHealth System. These servers are continuously backed up. No participant identifying data will be released or reported publicly.

The project manager and research assistants will have password-protected laptops with encrypted storage to enter study data into RedCap, the secure web-based database manager residing on the servers of The MetroHealth System. No data will reside directly on the laptops, but instated will be backed up to the secure, private servers of The MetroHealth System. These servers are protected by MetroHealth's firewall. Mosio will use HIPAA compliant procedures to securely send and receive data between study participants and RedCap.

16.0 Potential Benefits to Subjects

The risks of the proposed study are minimal as discussed above. Our proposed intervention is designed to improve CPAP adherence among patients with moderate and severe OSA. This approach may lead not only to improved sleep quality for patients and their bed partners, but increased functional status, and increased quality of life.

Participants will receive a CPAP machine and supplies that they keep upon conclusion of the study. They will also receive access to CPAP machine and equipment management.

17.0 Data Management and Confidentiality

Our study database will be stored in RedCap (https://www.project-redcap.org),[90] a secure, open-source software application regularly utilized by Dr. Thornton's research teams. RedCap runs on the MetroHealth server and therefore is HIPAA compliant, provides user-specific data access, and facilitates removal of participant identifying data prior to exporting. It also facilitates double data entry with real-time data validation and data integrity checks. Patient data will be entered directly into the RedCap. Study data will be held for 7 years following study completion. Paper records will be stored in locked filing cabinets within the Center for Reducing Health Disparities (Rammelkamp R209). Mosio will use HIPAA compliant procedures to securely send and receive data between study participants and RedCap.

Because this is a pilot study, a power calculation is not provided.

We will begin our analysis by computing descriptive statistics and using graphical representations to examine all predictor and outcome variables. For each study patient, the primary outcome will be CPAP adherence at 90 days as determined by the mean daily CPAP usage (the total number of hours of CPAP use divided by the number of days observed for the

individual). An intention to treat analytic approach will compare mean daily CPAP usage between intervention and control patients as randomized. Linear mixed effects models using random effects will be used to adjust for clustering of patients within sleep provider. Covariates (fixed effects) will include indicator variables for BMI, AHI, gender, and treatment.[89] The model assumption that the overall CPAP usage outcome is normally distributed will be tested using the Shapiro-Wilk test. If a significant departure from normality is obtained (and a suitable transformation, such as log, is not found) an alternative approach will be to use a generalized linear (e.g., Poisson regression) model for the overall adherence (CPAP usage rate). A Wald test (with robust estimate of standard error) will be used to test for an intervention effect and a corresponding 95% confidence interval for the intervention effect will be computed. If substantial variability in follow-up times are found (e.g., due to dropout and/or missed visits), a weighting approach (using weights proportional to the number of days observed for each individual in conjunction with the selected model) can be used.

We will perform primary and secondary analyses like those for Aim 1. However, the outcome variables for Aim 2 analyses will be scales and subscales related to quality of sleep (Epworth Sleepiness Scale, PROMIS Sleep Disturbance Index), functional status (Functional Outcomes of Sleep Questionnaire short version), and quality of life (SF-12, Calgary Sleep Apnea Quality of Life Index) for both patients and their bed partners. If these outcome variables are not normally distributed, we will use proportional odds with random effects by study site and sleep provider to test differences in these ordinal data between arms.[91]

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

We propose several methods to ensure safety and to monitor our intervention. First, our intervention is theoretically sound and based on our prior work and that of others. Second, the principal investigator will meet weekly with other study personnel to trouble-shoot any potential areas of concern regarding the safety of the study protocol. Third, all study staff will undergo rigorous training. Fourth, the principal investigator will closely monitor study staff through a combination of regular meetings, monitoring of data collection, and direct observation. Fifth, project data will be reviewed quarterly by the entire study team.

Any indications of potential threats to patient safety or a pattern of refusal by patients to participate in specific study tasks will be responded to immediately by a careful review conducted by the study team. When appropriate, the patient's physician, reporting to the Institutional Review Board of The MetroHealth System, and adjustment to the study protocol will occur. Although risks to subjects is considered minimal, any adverse events will be reported to the Institutional Review Board of The MetroHealth System and the National Institutes of Health.

19.0 Provisions to Protect the Privacy Interests of Subjects

All study-related data to be secured on the password- and firewall-protected servers of The MetroHealth System. These servers are continuously backed up. No participant identifying data will be released or reported publicly.

The project manager and research assistants will have password-protected laptops with encrypted storage to enter study data into RedCap, the secure web-based database manager residing on the servers of The MetroHealth System. No data will reside directly on the laptops, but instated will be backed up to the secure, private servers of The MetroHealth System. These servers are protected by each institution's firewall.

20.0 Compensation for Research-Related Injury

This is a minimal risk study. No compensation will be provided in the event of research related injury. Patients will receive care from The MetroHealth System per usual.

21.0 Economic Burden to Subjects

Participants receive study compensation and are reimbursed for parking and transportation costs to complete study instruments. No additional economic burden is anticipated.

22.0 Consent Process

Each day, research assistants will review electronic health record-generated reports of patients who received a diagnostic sleep study over the previous 48 hours and a prescription for CPAP from their provider. Assistants will review the electronic health record of each patient to confirm eligibility. They will then mail a study brochure and consent form to patients. Those patients that do not respond by 72 hours will be contacted to confirm that both the patient and bed partner are eligible and to explain the study in greater detail. After obtaining verbal confirmation, the staff will schedule a date and time to meet with patients and their bed partners at MetroHealth to fully explain the study, address any questions that patients and partners may have, obtain written consent, and administer baseline study instruments using the IRBs standard operating procedures. Following completion of these tasks, staff will open premade sealed envelopes to determine subject study arm assignment.

23.0 Process to Document Consent in Writing

The IRB's standard operating procedures will be used to document written consent and to obtain HIPAA Authorization.

24.0 Setting

This study takes place virtually among patients of the MetroHealth System. Study interventions will be administered online while study instruments will be completed in person at The MetroHealth System (within the Population Health Research Institute or Clinical Research Unit).

25.0 Resources Available

The study will be conducted from the research space of the Center for Reducing Health Disparities. The Center has all the necessary resources to successfully conduct this project. Dr. Thornton and his research team have received funding from NIH to provide sufficient time to complete the project. All members of the team have been involved in the design of the study protocol and are aware of their duties to carry out research procedures.

The MetroHealth System has ample number of patients from which to recruit.

	Sleep Providers	Eligible Patients	Mean Age ± SD	Percent Female	Percent African American	Percent Married	Mean AHI ± SD
The MetroHealth System	7	1,453	48 ± 14	59%	40%	36%	27 ± 27

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