Monitoring and Peer Support to Improve Treatment Adherence and Outcomes in Patients with Overlap Chronic Obstructive Pulmonary Disease and Sleep Apnea via a Large PCORnet Collaboration (O₂VERLAP)

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Study & Project Aims

PCORI related Aims and Background… This project aims to (1) bring together 5 PPRNs, 1 CDRN and 1 patient-led, patient- governed organization to help build PCORnet's "patient infrastructure," and (2) to provide answers to an important research question that serves patients who have at least two pulmonary medical conditions, chronic obstructive pulmonary disease (COPD) and obstructive sleep apnea (OSA), known as Overlap Syndrome (OS).

Patients with OS have a worse prognosis compared with patients with only COPD or OSA. Positive airway pressure (PAP) use is associated with improved walking capacity and longer survival in COPD patients who are hypercapnic, and that higher levels of PAP adherence are associated with better outcomes. However, of the 80% of patients who accept PAP therapy, most patients fall into a partial use pattern of 3-5 hours per night. Adherence with long-term oxygen use has a parallel story - it is beneficial the more it is used but adherence is less than optimal, ranging from 45% to 70%.

The O₂VERLAP study is developing a patient centered online platform called 360Sleep that will seek to improve patient adherence to O₂ and PAP therapies.

Figure 1.0. 360Sleep: Online, proactive care, interventional platform with customized patient curriculum

- Tailored, planned curriculum
- Access to adherence monitoring
- Scheduled peer and professional support
- Access to support as needed

O₂VERLAP study specific aims…

Aim 1… Use focus groups will be conducted to determine barriers to O₂ and CPAP use in the overlap syndrome population. This information will help guide protocol development for the intervention.

Aim 2… Compare the effectiveness of a proactive care (web-based peer coaching education and support intervention) versus reactive care on improving adherence to nocturnal oxygen and positive airway pressure (PAP) therapies in patients with OS.

Aim 3… Create best practices for PCORnet collaborations and emerging research methodologies.

Benefits to PCORnet Commons…

- Documenting best practices for governance structures for a multi-network study including multiple PPRNs /CDRN
- Creating and operationalizing methods of cross recruitment for specific clinical trials and individual networks.
- Piloting the creation of peer lead educational and coaching content as part of the intervention.
- Engaging and training patients in the research process
- Developing models for patient engagement through robust social media networks.
- Engaging DMEs and other providers who provide oxygen, PAP and other medical services.
- Testing of large-scale crowdsourcing platform (Sleeptember.org) to collect data from many patient communities.

Methods

Recruitment…will rely on the engagement of 5 PPRNS, 1 CDRN and multiple scientific advisors within the PCORnet family to successfully recruit 330 participants with Overlap Syndrome.

The O₂VERLAP protocol is being shaped by information collected during patient centered focus groups made up primarily of overlap syndrome patients. The goal of the focus groups is to gain information on patient reported adherence barriers in O₂ and CPAP use. The information collected will then help guide the protocol outcome measures to evaluate the efficacy of the 360Sleep intervention.

PCORnet Collaborators…PRIDEnet PPRN, ABOUT PPRN, Health eHeart PPRN, PI connect PPRN and pSCANNER CDRN.

Research Team	CDRN		PPRNs					HME		
COPD Foundation	ASAA	pSCANNER	Health eHeart	About	PIConnect	PRIDEnet	The VGM Group	CMB Solutions	Total	
1,750	2,500	17396*	2,000	500	500	1,000	12,000	5,500	43,146**	

Figure 2.0. Estimate of OS population using PCORnet partner data

* Note that the pSCANNER total only include the University of California health system campuses, and does NOT include the other pSCANNER partners; the data was not available at the time this application was submitted.
** Note that because of conservative estimates, including only including a portion of the pSCANNER health care systems, the total number may be an underestimate of the total number of patients diagnosed with both COPD and OSA.

Research Objectives

Significance…The overlap syndrome (OS) patient population is poorly studied. This project will to contribute tools to support improved outcomes in the OS patient population, to demonstrate effective collaboration among the PCORnet infrastructure and to contribute a significant number of tools to the PCORnet commons, including guidelines for PCORnet best practices.

Study Design

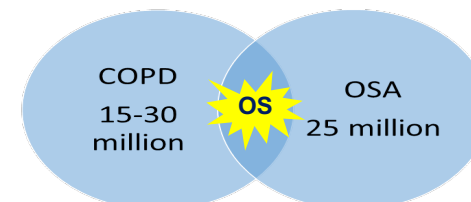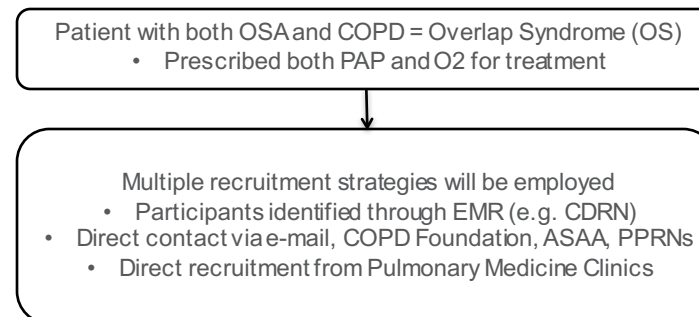**Patient population**

COPD 15-30 million — OS — OSA 25 million

Fig. 3.0 Graph representative of overlap population

330 overlap syndrome patients will be randomized 1:1 ratio to either a proactive or reactive care arm

Recruitment

Patient with both OSA and COPD = Overlap Syndrome (OS)
- Prescribed both PAP and O2 for treatment

Multiple recruitment strategies will be employed
- Participants identified through EMR (e.g. CDRN)
- Direct contact via e-mail, COPD Foundation, ASAA, PPRNs
- Direct recruitment from Pulmonary Medicine Clinics

Patients review study information online and then navigate to the patient portal where they can…
- Register to the patient portal
- Sign the eConsent form
- Participants are then randomized to RC or PC arm

Randomization

Arms 1 & 2

Reactive Care (RC)
- Web-based access to data
- Reactive web-based support

Proactive Care (PC)
- Web-based access to data
- Proactive web-based support

Study timeline

Assessments at baseline, 6 weeks & 12 weeks

Hypotheses

- *Hypothesis 1:* CPAP adherence in 6 weeks will be improved in the proactive care group compared to the reactive care group.
- *Hypothesis 2:* The improvement in the sleep quality, symptoms and patient-centered outcomes in 6 weeks and 12 weeks will be larger in the proactive care group compared to the reactive group.

CONTACT INFORMATION
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COPD FOUNDATION

pcori

pcornet℠ The National Patient-Centered Clinical Research Network