

Current Clinical Trials

Pragmatic Trial of Behavioral Interventions for Insomnia in Hypertensive Patients: Hush Trial

Dan Buysse, MD

This pragmatic, patient-centered, randomized controlled trial will compare two cognitive behavioral interventions for insomnia in patients with comorbid hypertension relative to online education in primary care. Recruitment will be conducted using alerts in the EpicCare EHR triggered by patient characteristics (hypertension; hypnotic medications or insomnia diagnosis/problem).

The primary outcome will be self-reported sleep at three months. Other outcomes include domains of symptoms, health, and patient/provider satisfaction obtained by self-report, and blood pressure control by home blood pressure monitoring.

For more information consult HUSH in the UPMC electronic health record or call 412-246-6445.

The Effect of Treatment of OSA on Diabetes Self-Management and Glycemic Control: DOTT Trial

Eileen Chasens, RN, PhD

Our goal is to improve understanding of the effect of OSA on diabetes self-management and to determine the efficacy of CPAP treatment in improving diabetes outcomes in adults treated with CPAP compared to those on sham-CPAP. We will enroll 210 adults (50 percent female; 40 percent minority) with T2DM and moderate-to-severe OSA (apnea + hypopnea index > 15) who have suboptimal glycemic control (A1C \geq 7.0 percent) for a double blind, randomized, placebo-controlled trial to determine if diabetes self-management outcomes and glycemic control are better in subjects with OSA who are treated with CPAP and receive diabetes education and counseling compared to control subjects who are on sham-CPAP and receive diabetes education.

We will compare the effectiveness of the intervention after six weeks and 12 weeks on measures of glycemic control, retention of information taught during the diabetes education sessions,

lifestyle behaviors required for optimal diabetes control, reported monitoring of self-management activities, physical activity, and diabetes-related distress. We will explore whether the average nighttime use (adherence) of CPAP, sleep quality, daytime sleepiness, mood, and vigilance mediate the effect of CPAP treatment on glycemic control and diabetes self-management outcomes. We will also explore if adherence to CPAP is associated with outcome measures of glycemic control and lifestyle behaviors in the entire sample after 24 weeks of therapeutic CPAP. This study uses objective measures to measure CPAP adherence, physical activity, vigilance, and glycemic control. After 12 weeks, subjects who were originally on sham-CPAP will be crossed over to active treatment.

For more information call 412-624-9380.

Sleep Disorder Breathing, Obesity, and Pregnancy Study: SOAP Trial

Francesca Facco, MD

Our central hypothesis is that SDB is an effect modifier that increases maternal cardiovascular risk and placental hypoxic injury in obese pregnant women, and that CPAP treatment during pregnancy will result in an improved cardiovascular risk and placental profile. To test this hypothesis we will identify a cohort of obese women both with and without SDB. We will examine SDB's impact on maternal vascular stiffness (uterine artery Doppler), angiogenesis (pregnancy specific angiogenic factors e.g., sFLT-1) and metabolism (insulin resistance) across pregnancy (Aim 1). We will perform a randomized controlled trial of autotitrating-CPAP versus sham-CPAP in pregnancy to examine the impact of CPAP treatment during pregnancy on cardiovascular risk (Aim 2) and we will explore the interplay between SDB, CPAP and evidence of maternal vascular disease and chronic fetal hypoxia by evaluating the placental profile of obese women with and without SDB (Aim 3).

For more information call 412-641-5406.