Official Title: Vascular Impairment in Type II Diabetes Mellitus with Co-morbid Obstructive Sleep Apnea
ClinicalTrials.gov ID (NCT number: NCT01629862
Statistical Analysis Plan Date: 01/05/2018

For the cross-sectional analysis of those with diabetes, sleep apnea, both, or neither, we will first use analysis of covariance to determine whether there is any interactive effect of sleep apnea and diabetes on our primary outcome (flow mediated dilation) as well as the three secondary outcomes (nitroglycerin-induced dilation, acetylcholine-induced skin blood flow, and sodium nitroprusside-induced skin blood flow) after controlling for age, sex, and body mass index (BMI). If a significant interaction is identified, the main effects of diabetes, sleep apnea, and their interaction will be reported using multivariable linear regression adjusting for age, sex, and BMI. If the interactive effect of sleep apnea and diabetes is not significant (α=0.05), we will ignore any interaction and examine the additive effects of diabetes and sleep apnea on each outcome using multivariable linear regression adjusting for age, sex, and BMI. Using post-hoc contrasts, we will then further test for differences between those having both diabetes and sleep apnea alone versus those with diabetes alone and those with sleep apnea alone. All tertiary outcomes will be assessed in a similar fashion.

For the randomized clinical trial analysis, the primary outcome is percent change in flow mediated dilation (post-treatment minus pre-treatment divided by pre-treatment) with percent change in nitroglycerin induced dilation, acetylcholine induced skin blood flow and sodium nitroprusside induced skin blood flow as secondary outcomes. The primary analysis will be based on the use of unpaired t-tests to compare each outcome in those randomized to CPAP versus sham-CPAP using an intention to treat principle and α =0.05. All tertiary outcomes will be assessed in a similar fashion. If significant differences (α =0.05) are identified in key covariates (age, sex, BMI) between those randomized to CPAP and sham CPAP, secondary analyses will adjust for those covariates that significantly differ.

For all analyses, we will also report effect sizes with 95% confidence intervals to establish the size of our effects of interest.