Evaluation of a “Fast Track” Respiratory Therapy Clinic for Patients with Suspected Severe Sleep-Disordered Breathing

STATISTICAL ANALYSIS PLAN

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Statistical Analysis

This study will use a modified intention to treat analysis, in which results will be analyzed for patients who are randomized and have treatment adherence data three months after initiating PAP therapy.

Paired t tests will be used to compare clinical outcomes from baseline to 3 months and one year and unpaired t tests will be used to compare time to treatment initiation and measures of patient demand. Multiple logistic regression will be used to identify predictors of study outcomes using variables identified as predictive on univariate regression. Outcomes will be transformed into binary variables based on clinically relevant cut-offs.

The economic analysis will be performed using the perspective of a publicly funded healthcare system. An estimate of mean utility scores based on the HUI questionnaire will be calculated and the average quality-adjusted life- year (QALY) will be calculated for each study arm. Using bootstrapping, we will compare the difference in mean costs and QALYs between the study arms to generate an incremental cost-effectiveness ratio for an ACP-led clinic compared to traditional physician-led care. Sensitivity analyses will be performed to evaluate the effect of changes in physician fees, RT salaries, diagnostic testing costs and treatment costs.

All study outcomes will be analyzed in different subgroups to clarify the impact of ACP-led care for patients with different patient flow pathways or clinical treatments. Pre-specified subgroups include:

- Patients who undergo PSG vs. patients who do not undergo PSG
- Patients treated with bilevel PAP vs. patients treated with CPAP
- Patients who are treated with oxygen vs. patients treated without oxygen

Sample Size

The study is powered to assess the non-inferiority of ACP-led care compared to usual care by sleep physicians. A non-inferiority margin of -1 hour of PAP adherence was determined by consensus of the investigators and has been used in previous studies comparing different models of care for SDB. One hundred thirty eight patients (69 in each arm) will be required to achieve 90% power with a type I error of 0.05, using this non-inferiority margin and a standard deviation of 2 hours of nightly CPAP use. The standard deviation used in the sample size calculation was based upon the results of two previous studies. To account for withdrawals and loss to follow-up (approximately 15% at the FMC Sleep Centre), recruitment will continue until three-month adherence data is available for 150 patients.

Reference: Ip-Buting A, Kelly J, Santana MJ, Penz ED, Flemons WW, Tsai WH, et al. Evaluation of an alternative care provider clinic for severe sleep-disordered breathing: a study protocol for a randomised controlled trial. BMJ Open. 2017 Mar;7(3):e014012.