Health Coaching to Improve Self-Management in Thoracic Transplant Candidates
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ANALYSIS PLAN: **Sample size**: This is a pilot and feasibility study. However, to inform our enrollment we have made the following calculations. **Change in SMAS-30.** A sample size of 25 in each group will have 80% power to detect an effect size of 0.81 using a two-group t-test with a 0.05 two-sided significance level, where effect size is the end of study difference in means between the two groups relative to the SD of the end of study measures, after adjusting for baseline and other factors. From the literature, we estimate an unadjusted end of study SD for SMAS-30 of 8.5. Whereas we do expect our intervention to impact SMAS-30, it is our clinical impression that without intervention, patients tend to exhibit similar patterns over time. Therefore, we expect the between-person variability in SMAS-30 to be at least as large as the variability in assessing SMAS-30 for the same person at different time points. If these two sources of variability were the same then they would both have a SD of 6.0, in particular the end of study SD for SMAS-30 would be 6.0 or less. With this SD, we would have power to detect a difference of 0.81x6.0=4.9. Thus, this pilot study is reasonably powered. Allowing for a 20% withdrawal rate (primarily due to transplantation during intervention), we will aim for a sample size of 30 per arm. **Analysis plan:** Demographic characteristics will be summarized by mean, median, SD and range (continuous variables) and counts and percents (categorical variables). Our primary variable will be end of study SMAS-30 (adjusting for baseline), which we will analyze using analysis of covariance (ANCOVA), estimating between group differences. Subgroup analysis will be performed by sex, ethnicity, and race as feasible. A similar procedure to that described above will be employed to impute data if necessary. Missing data and end of study SDs for SMAS-30, adjusting for baseline, will guide analysis and power calculations for future R01 studies. Secondary Outcomes will examine between group differences of changes in gait speed, activity levels, body composition, weights, and RISC-10, PANAS, MUIS, FDI, SMAQ, and KCCQ or CRQ measures to inform future R01 planning. A two–tailed $p< 0.05$ will be considered statistically significant.