

COVER LETTER

**Title: Cardio-pulmonary Rehabilitation and
Sleep Quality**

NCT Number: NCT04668599

Document Date: 05/10/2020

STATISTICAL ANALYSIS PLAN

Statistical Analysis Plan Data will be analyzed using SPSS and STATA. The primary outcome measure will be the change in individual Pittsburgh sleep quality index scores at the beginning, end and after 3-months of cardiac and pulmonary rehabilitation. Secondary outcome measures will include changes in the hospital anxiety and depression scale, insomnia severity index, COPD assessment test, Epworth sleepiness scale, short form survey36, insomnia severity index at the beginning, end and after 3-months of cardiac and pulmonary rehabilitation. A paired-sample Student t-test will be used to compare means before and after the CP-R. Pearson's product co-efficient (r) will be used to analyze association between changes in Pittsburgh sleep quality index, hospital anxiety and depression scale, COPD assessment test, Epworth sleepiness scale, Short form health survey-36 at the beginning, in the CP-R cohort. We are planning a study of a continuous response variable from matched pairs of study subjects. Prior data indicate that the difference in the response of matched pairs is normally distributed with standard deviation 4.6. If the true difference in the mean response of matched pairs is 3, we will need to study 27 pairs of subjects to be able to reject the null hypothesis that this response difference is zero with probability (power) 0.9 (90%). The Type I error probability associated with this test of this null hypothesis is 0.05.