

ID: SPH-2018-26507

NCT03343093

November 13, 2023

Title: Restore: Improving Sexual Outcomes of Gay and Bisexual Prostate Cancer Survivors

Statistical Analysis Plan

Data Analysis Plan (NCT03343093)

The purpose of Hypothesis 3.1 is to test whether structured rehabilitation (intervention) will yield statistically significantly better QoL, sexual and urinary outcomes than routine care (control) over 24 months. The data to be analyzed will comprise of 9 measurement occasions (1 baseline measurement, 7 quarterly measurements and 1 final measurement). The primary outcomes are: (1) sexual function measured by overall SF and EPIC sexual function and bother scores, and (2) urinary function measured by overall UI and EPIC urinary function and bother scores. We will use a mixed-effects model for repeated measures data to investigate the difference in the overall improvement trajectory between the intervention group vs. the control group over 24 months of the study on the primary outcome variables. If we find the statistical evidence to support our hypothesis, we will run an additional secondary analysis where we will compare different facets/components of the intervention. That is, we will investigate the main effects, along with the interaction effects among the different components of the intervention. To test for Hypothesis 3.2, we will incorporate treatment type, demographics, and health status as moderator variables into the statistical framework of mixed-effects models. We will evaluate Hypothesis 3.3 to test whether the effects of intervention are greater in newly treated men (<2 years since prostate cancer treatment) vs. men 2+ years, post-treatment. We will analyze this hypothesis by using the grouping variable (early vs. long term) in the mixed-effects model to study the difference in the improvement trajectory of the two levels of this grouping variable. To evaluate Hypothesis 3.4 we will assess if the overall slope coefficient for the men 2+ years post-treatment obtained from the mixed-effects model is statistically significant. The analysis of Hypothesis 3.5 would include the dependent variable of Climacturia, measured by single items from the GSFS scale, and the intervention components of pelvic floor exercises and PDE5-I drugs are the predictors/independent variables. We will test if pelvic floor exercises and PDE5-I drugs can predict improvement in Climacturia over time by using a mixed-effects model.

Power Estimation. We expect 80% power to detect the statistically significantly differences between the intervention group and the control group. The power calculation was based on standardized effect size = 0.35, total number of observations per participant during the course of the study, $M = 9$, total number of participants, $N = 450$, assumed within-subject variability, $\sigma^2 = 0.50$, assumed between-subject variability, $\tau^2 = 0.20$ and a linear change over time.