

# **Ostomy Telehealth for Cancer Survivors**

University of Pennsylvania

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**Statistical Analysis Plan**

## Statistical Analysis Plan

**General.** Aim 1 will be analyzed with linear mixed models for repeated measures. Aim 2 will utilize a variety of sources and methods to enumerate the intervention program and ostomy-related family resources in each study arm.

**Aim 1:** Using our enhanced telehealth techniques, determine if **patient activation**, self-efficacy, ostomy-related knowledge, and HRQOL will be improved and sustained over time in the online interactive communication Ostomy Self-Management Telehealth program (OSMT) curriculum compared to a UC group.

Under an intent-to-treat approach, change in outcomes will be evaluated longitudinally with linear mixed models, testing the effect of study arm adjusted for potential confounders. Such models evaluate both associations and rates of change, accounting for within-subject correlation. The Primary Outcome will be PAM. Secondary Outcomes include SE, COH-QOL-CRC scales, and Ostomy Knowledge. Post hoc contrasts will evaluate effect of training (baseline to post) and whether effect is sustained after training (6 month post to follow-up). Standard multivariable modeling procedures will be used to select or eliminate potential confounding variables, starting with candidate variables that are biologically plausible or found to be associated with endpoint change scores (baseline vs. follow-up) in bivariate analyses with a p-value of less than 0.20. Potential candidate covariates and confounders include (but are not limited to) CG participation in training sessions, depression (HADS), time since surgery, ostomy type, age, sex, stage, anticipated permanence of ostomy, and pre- or post-surgical radiation or chemotherapy. We will explore potential interaction for plausible effect modifiers, such as gender, or having a CG.

The COH QOL-CRC assesses ostomy burden and care abilities, including time taken to perform daily ostomy care, comfort with ostomy care, comfort with diet, adjustment of diet for ostomy, appetite, clothing and other problems with ostomy placement. We will also measure clinically related outcomes, including medical attention for problems with bowel, bladder, or ostomy. Changes in these responses will be compared between treatment groups with linear mixed models, chi-square tests or t-tests, as appropriate.

Descriptive statistics will be presented on attendance at training sessions. We will describe and contrast quantity and type of ostomy-care help (professional and lay) sought outside of the training sessions, including calls for support from study Peer Ostomates. Self-reported Peer Ostomate call frequency and duration will be corroborated with a call log maintained by the Peer Ostomate. We will evaluate hypothesized association between OSMT attendance level and outcomes using linear mixed models that have a weighted attendance score as an independent variable. Alternative attendance scores will be tested that give weight to ostomy-care help outside of training sessions.