# Implementation of Home-Based Palliative Care in Limited Resource Settings

Statistical Analysis Plan

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# Statistical Analysis Plan:

**Sample Size.** For this pilot study, we will recruit 45 patients in the intervention and control groups (n=90). As advocated by Leon, pilot studies "serve to check availability of eligible and willing subjects using the recruitment methods proposed, test feasibility of the treatment and measurement protocols, train researchers in study tasks, and set up data collection, checking, storage, and retrieval capabilities." Leon also noted that pilots are deficient in estimating effect size with sufficient accuracy for future study design. Thus, we will monitor the multiple process measures and obtain estimated variability of primary outcome measures. For a total sample of 90 participants, 95% CI estimates of between groups difference in change scores of palliative needs, pain, QOL and cancer symptom burden for the 2 groups can be estimated with precision ranging from ±1.0 to ±2.1 for standard deviations of difference scores ranging from 2.5-5.0 SD units.

**Analysis Plan:** Outcome measures as described in Results were collected to evaluate study aims. Data will be analyzed in SAS. All measures will be evaluated overall and by patient age, gender and cancer type and by CHW caseload. For aim 1, implementation mesures will be reported as means, standard deviations, medians, range, frequencies and proportions as appropriate. When appropriate, outcomes will be compared between intervention and control groups using t-tests and chi-square tests (or equivalent nonparametric tests) as appropriate. For primary analyses for aim 2 the intent-to-treat (ITT) sample will be used comprising all randomized patients. Descriptive statistics will be calculated for all variables. For continuous variables we will report means, standard deviation, medians and ranges. We will compare between group differences for continuous variables using either t-test for variables that are normally distributed or can be log-transformed or a Wilcoxon rank sum test for variables if normality cannot be approximated. For categorical variables, we will report frequencies, percentages and compare between group values with Chi Square or Fisher exact test. 95% CIs will be reported. In exploratory analysis to obtain variance estimates of effectiveness outcomes and the covariance structure of the longitudinal scores, generalized linear mixed models (GLMM) will be used to compare the two groups (intervention vs. control group) with intervention group as the primary independent variable and pain as the dependent variable. GLMM can account for clustering of measurements within CHW and within patients as well as accommodate missing data. Group (intervention vs. control group) will be a fixed effect; demographics (age, sex, distance from TMC cancer center); and clinical (time since diagnosis, cancer type, baseline pain) variables will be adjusted for, along with a CHW variable accounting for cluster effects among patients by CHW. We will estimate the difference (via 95% CI) in average slopes between intervention and control groups and evaluate linearity of trajectories as input to inform a future trial. Further, dropout rate will be examined. If over 10% of data are missing, we will adjust data collection intervals in a future trial.