Caregiver Speaks Data Analysis Plan

January 5, 2019

NCT04103580

Data Analysis

Statistical Assumptions

We will routinely test assumptions of linearity, independence and homoskedasticity by calculating and plotting residuals and Cook's distance for all models. Where data are missing, we will substitute the mode for categorical data and the median for continuous data, given that <0.5% of data were missing for any measure in our preliminary trial. If the proportion of missing data is higher, we will use multiple imputation. In the analysis for H1a, we will use the final measure provided by caregiver before patient death, and for H1b we will use the final measure during bereavement. Because the sample size is relatively large, we expect that known and unknown confounders will be distributed evenly among the two groups. We acknowledge that this study is not powered to detect small interaction effects. Additional confounders will only be introduced as covariates if we find evidence of imbalance between groups at baseline.

We will test whether randomization created balanced groups by comparing baseline measures and demographic characteristics, using chi-square or t-test analysis for categorical or continuous variables, respectively. Variables that differ significantly between groups will be included in regression models as potential confounders. To compare outcomes for our hypotheses, we will use the last available measure post-baseline and prior to death or the end of the study and last measure during bereavement. This is a last-observation analysis. Carpenter and Kenward argue that, in such analyses, time to this event should be taken into account. Therefore, we will include time from study enrollment to the last observation as a covariate. We will report estimates with 95% confidence intervals. To draw inferences from our study to the likely benefit to an equivalent population where the intervention under trial is a model of service delivery, all analyses of outcomes will be by intention-to-treat. The intention-to-treat analysis, consistent with the objectives of a pragmatic trial, will minimize the influence of "informative missingness" of the data and preserve groups' comparability.

Statistical Analysis

H1a: Family caregivers receiving the Caregiver Speaks intervention will report lower levels of depression and anxiety compared to those in the control group during active caregiving.
H1b: Family caregivers receiving the intervention will report lower levels of depression and anxiety compared to those in the control group during bereavement.
H2: Bereaved family caregivers receiving the intervention will report lower levels of grief intensity compared to those in the control group.

We will examine differences between longitudinal profiles of the two study groups for each of the outcomes (PHQ-9, GAD-7, social support, & grief intensity). We will use mixed (hierarchical) models with repeated outcome measures nested within participants (see model below). This will allow us to draw inferences about how our outcome measures (PHQ-9, GAD-7 & grief intensity) change over time (slope) between the two study groups. Mixed models are able to accommodate differing numbers of measurements at varying time intervals for participants. Additionally, we will examine how social support mediates our outcomes of interest (depression, anxiety, and grief intensity). As described above, we will also include covariates where indicated.

Last post-baseline measure = $\beta_0 + \beta_1$[study group] + β_2[baseline measure] + β_3[time since enrollment]

Qualitative Data Analysis

We will enter all photos, qualitative Facebook data, and transcribed interviews into qualitative coding software (Dedoose) for triangulation (use of multiple data sources to ensure a rich and robust dataset[110,111] and thematic analysis).[112] Drs. Rolbiecki, Teti, and Washington will lead qualitative data analysis. We will begin by developing initial codes based on our preliminary work. We will reduce the qualitative data, and condense the data into overarching themes. We will assure trustworthiness of the data.