Data Analysis Plan

Patient-surrogate dyads will be the primary unit of analysis; all analyses will be intent to treat with all available data from all participants. The preliminary analysis will include summarizing variables with standard descriptive statistics and graphical displays or frequency tables. Distributional assumptions will be assessed and the data will be transformed as necessary. Clinic characteristics (e.g., rural-urban status) will be compared using χ^2 tests for categorical variables and t-tests for continuous variables. We will compare SPIRIT and usual care participants on baseline characteristics (e.g., age, race/ethnicity) to explore possible between-group differences using generalized estimating equation (GEE) methods, accounting for the observed correlation within the same cluster.[105,106] In our previous work SPIRIT has no effect on patient mortality[20]; however, we will compare survival time between SPIRIT and usual care using Cox proportional hazards models, adjusted for cluster effects. If imbalanced, we will consider adjustment for the group difference.

Handling Missing Data During Analyses: Although we expect minimal missing data given the short-term follow-up, we will investigate missing data with pattern analysis for data missing completely at random, missing at random or missing not at random, and use maximum likelihood or multiple imputation appropriate for each type to impute missing values. We will also conduct sensitivity analyses to encompass different scenarios of assumptions and evaluate consistency or discrepancy among them.

SPIRIT effectiveness on the preparedness outcomes: Dyad congruence and the composite outcome (binary variables) will be analyzed by fitting a generalized mixed effects model for each, where the binary outcome is modeled in terms of a logit link[105] with both a random intercept and random slope to control for variation within and between subjects and clusters. For patient DCS and surrogate DMC scores, we will replace the logit link by the identity link with an additional error term. These models will allow us to examine whether SPIRIT was superior to usual care in the primary outcomes at 2 weeks and whether the effect of SPIRIT varies by cluster size. The analysis will be adjusted for potential covariates, such as race/ethnicity, and rural-urban status, in the model, including interaction between treatment and race/ethnicity.

SPIRIT effectiveness on surrogates' post-bereavement psychological distress: We will use the same approach as in Aim 1 to compare anxiety, depression, and post-traumatic distress symptoms in SPIRIT vs usual care among surrogates of patients who die during the initial implementation and 9-month follow-up (See Figure 2).

SPIRIT effectiveness on end-of-life treatment intensity: Among patients who die during the initial SPIRIT implementation and 9-month follow-up, percentages of patients hospitalized, having ICU admission, having intensive procedures and length of hospital stay in the final month of life will be summarized using descriptive statistics, 95% CIs, and graphical displays. The exploratory examination of SPIRIT's effectiveness on improving these outcomes, we will use the same analytic approach as in the Aims above.