Informational Meetings for Planning and Coordinating Treatment (IMPACT)

NCT number: NCT04330833

Document Date: 7/17/26

Statistical Analysis Plan for the IMPACT Study

Analyses were performed in SAS (version 9.4; SAS Institute Inc., Cary, NC, USA) and R Statistical Software (version 4.4.1; R Foundation for Statistical Computing, Vienna, Austria). Cronbach's alpha's were calculated for all multiple-items scales. The alpha level was set at 0.05 for all statistical tests. The protocol indicated that Holm's method would be used to adjust the alpha levels for tests of subscale-based secondary outcomes. This was not done due to lack of significance at the alpha = 0.05 level.

A clustered Wilcoxon rank sum test was run to compare days in hospice between Program A and Program B clustered by Practice. Subjects never enrolled in hospice were counted as 0 days.

The use of high intensity medical interventions at EOL, modeled as yes or no, was tested with generalized estimating equations (GEE) accounting for within practice correlation. The protocol indicated generalized linear mixed models would be used but due to data sparseness, a more robust analytic approach was used.

For each longitudinal survey outcome, a joint model was fit linking a linear mixed effects model and an exponential survival model. This is because the pattern-mixture model approach specified in the protocol was not sufficient to handle the complexity of the missing data pattern observed in this study. The joint model approach accounts for informative dropout due to death while on-study. Intervention group, caregiver gender, child gender, tumor type, nurse credentials, previous palliative care training, and practice size were included as covariates in both the mixed effects and survival models. The current predicted value of the outcome was also included as a predictor in the survival model. In the mixed effects model, the interaction term between time and intervention group was included to assess whether the changes in outcome per 3 months (slopes) differed by intervention group. One outcome per family was used at each timepoint. In cases of only one participating parent, or cases where one parent completed five or more additional visits compared to the second parent, that parent's responses were used. Otherwise, for families with multiple participating parents, the contributing parent was chosen at random to reduce bias. First time relapsed and baseline (T1) outcomes were not included as covariates as originally stated in the protocol. First time relapsed was not included because it was noted that outcomes were not different between first-time relapsed vs not and it was also not a modifier of the intervention effect. Baseline outcomes were not included as covariates due to the change in modeling technique used for scale-based outcomes noted above. The key explanatory variable was the change in outcome per 3 months, so baseline was treated as an outcome in the models instead.