

Official Study Title:

Intimate Partner Violence and Fatherhood Intervention in Residential Substance Abuse Treatment

NCT Number: NCT02979262

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Data analysis Plan

Because the variables of interest involved a mix of continuous, count, dichotomous, and multinomial variables, generalized linear modeling techniques were used to test for between group differences in the demographic and clinical characteristics of the participants, the process outcomes, and the secondary outcomes only measured once or twice at the end of treatment or the end of the 3-month period of follow-up. Similarly, generalized estimating equations (GEE), the repeated-measures extension of generalized linear modeling, was used to test for between group differences in baseline values, within-group change over time, and between-group differences in the rate of change for primary and secondary outcomes measured two to five times from randomization through the 3-month period of follow-up. When there were only two measurements, time was dummy coded to represent the first and second measurements. When there were three or more measurements, time was coded as a continuous variable representing weeks from randomization. Consistent with the CONSORT recommendations, process, primary, secondary, and end-point outcomes were analyzed for both the intention-to-treat and per-protocol samples.

Across statistical analyses, dummy coding was used to represent facility and treatment assignment; and preliminary analysis of descriptive statistics, graphical representation, and goodness of fit statistics were used to determine the appropriate response distribution and link function for use in the final analysis of each dependent variable. When it was not fixed at 1.0, the deviance/df statistic was used to determine the dispersion parameter. Given the limited sample size and the potential costs of a Type II error in this type of pilot study, statistics with p values less than .10 were considered statistically significant. Despite this, there was a focus on the consistency of findings across variables and intention-to-treat versus per-protocol samples.