Quantitative Analyses Plan

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2.9.1. Quantitative analyses

The RCT will enroll at least 120 providers who are expected to complete treatment with at least 3 child TF-CBT cases over the course of the project. This strategy results in a nested data structure in which cases (i) are nested within providers (j), which are nested within sites (k). Hypotheses will be tested within a multilevel modeling framework (MLM) that accounts for several issues including: (1) dependency in outcomes due to the nesting; (2) multiple outcome distributions; (3) linear, non-linear, and/or piece-specific change patterns; (4) variable measurement points; and (5) missing observations. First, site-level variation will be evaluated to determine if there is systematic variability attributed to provider location. If there is evidence for significant between-site variability, then site will be added as additional level of analysis. However, if the amount of between-site variability is negligible, then the effects of site can be ignored. The benefit of removing site as an additional level is the increased power it affords to detect the primary effects of interest. The aims of the study do not include hypotheses for effects at the level of site. Separate models will be used for each variable described below. All subsequent models will be constructed according to the guidelines of Singer and Willett with respect to including fixed and random effects. Statistical significance will be determined with false discovery rate based on the number of tests conducted to account for multiple testing. To determine if provider fidelity is affected by overall SPARK use, a 2-level MLM (level-1 child; level-2 provider) will be used. Fidelity will be measured by the TF-CBT TPOCS-S. Providers' overall use of the toolkit will be calculated per child participant and averaged across toolkit content. Fidelity scores will be calculated per child participant such that each provider will have three ratings. An aggregate fidelity score will determine if there are differences across conditions (SPARK + TF-CBT vs. standard TF-CBT) while accounting for the nesting of providers. A similar approach will be used to evaluate the effect of SPARK use on child engagement. Response to the intervention will be evaluated with a piecewise longitudinal MLM that contains an additional level corresponding to time. Level-1 will correspond to time, level-2 to child, and level-3 to provider. The primary outcome will be scores on the CATS, CAT-Caregiver, CES-DC, and BPM. A piecewise model allows for separate change trajectories to be estimated for distinct periods of time. Patients are expected to show more rapid change during treatment than during follow-up (roughly corresponding to 9- and 12-month post-baseline period). Group comparisons will be made at level-3. Of interest is the cross-level interaction between rate of change during treatment and the condition to which the provider was assigned. Cross-level interactions between the rate of change during follow-up also will be examined. An enhancement mediation design will be used to determine if provider fidelity and child engagement are the mechanisms by which SPARK reduces symptomatology. Enhancement designs evaluate mediation by experimentally manipulating a variable that enhances the effect of the mediator when direct experimental control of the mediator is not possible. These mechanistic hypotheses will be tested with established guidelines for multilevel mediation. Significance is determined by a product of coefficients test with asymmetric bootstrapped standard errors and 95% confidence intervals for the product. This requires estimation of two paths: the effect of SPARK on engagement and fidelity (a-paths); and the effect of engagement and fidelity on outcomes, controlling for the effect of SPARK (b-paths). A Monte Carlo method is used to create a 95% confidence interval to test for the mediated effect as this effect does not assume a normal distribution. Provider fidelity and child engagement will be evaluated in separate models. The mediation hypothesis will first be evaluated using all time points. If supported, follow-up analyses in which mechanism measures

obtained from the first half of treatment will evaluate change in symptomatology in the second half of treatment. Combined, the proposed mediation model will provide important evidence to support, or reject, therapist fidelity and child engagement as potential mediators of the effect of SPARK on child outcomes.