STATISTICAL ANALYSIS PLAN

March 26, 2019

NCT# 02772432

Development of a Resiliency Training Program for Parents of Children With Specific

Learning Disabilities

Randomization

We asked participants for their daytime or evening time preferences prior to randomizing them to the intervention or control from November 2016 to September 2017, balancing for group size. Participants were randomized using a random plan generator, with 1:1 randomization.

Statistical Analyses

To assess study feasibility, we assessed enrollment, intervention session attendance (>6) and retention at time 2 (75% response; intervention group: end of treatment; wait-list control: 3-month post-enrollment) and time 3 (intervention group: 3-months post end-of treatment; wait-list control: end of treatment). Study completers and non-completers at time 2 were compared on baseline demographic characteristics using independent samples t-tests for continuous variables and Chi-square tests or Fisher's exact tests for categorical variables. To assess study acceptability, we reviewed participant self-report survey feedback (e.g., satisfaction with the number and length of intervention sessions, comfort level with group sessions, continued RR practice) and open-ended qualitative program feedback. To explore preliminary efficacy of the intervention to improve our proposed psychosocial outcomes, we first characterized the two randomized groups (intervention group and wait-list control) by baseline demographic factors and reviewed baseline psychosocial data for univariate distributions. We then used all available data to test between-group (intervention group versus wait-list control) differences in change scores from time 1 to time 2 (intervention group: end of treatment; wait-list control: 3-month post-enrollment) using independent samples t-tests. Using the intent-to-treat principle, we replicated the analysis using multiple imputation⁶⁶ (five imputed datasets) to address missingness at time 2.

We followed our main preliminary efficacy analyses with a series of paired samples t-tests using all available data, to further characterize results. First, we evaluated changes in scores from time 1 to time 2 within each randomized group. To further explore intervention efficacy, we evaluated the combined change from pre- to post-intervention across intervention group condition participants (using time 1 to time 2 data) and wait-list control participants (using time 2 to time 3 data). Finally, we explored potential maintenance of intervention benefits by evaluating change in scores from time 2 to time 3 within the intervention group only. Additionally, to support a future larger scale trial, including identification of a potential moderator of intervention effects, we explored whether greater parenting stress at baseline was associated with greater changes in our proposed psychosocial outcomes among participants (before treatment and end of treatment) using Pearson correlations.

Running head: A VIRTUAL INTERVENTION PROMOTING RESILIENCY FOR PARENTS OF CHILDREN WITH LAD Analyses were conducted using IBM SPSS version 23.

Running head: A VIRTUAL INTERVENTION PROMOTING RESILIENCY FOR PARENTS OF CHILDREN WITH LAD