Clinicianless Training in Autism Treatment: An Adaptive Online Parent Education Program

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STATISTICAL PLAN

Pilot studies in clinical translational research are designed to assess key feasibility characteristics of a planned research methodology prior to embarking on a larger study (Moore, Carter, Nietert, & Stewart; 2011; Thabane et al, 2010; Van Teijlingen & Hundley, 2001). Such studies serve as a "trial run" of procedures to ensure that potential problems are identified and necessary modifications are made in order to maximize the likelihood of a successful follow-up investigation. The current pilot study of the PRT app clinical trial will evaluate several critical aspects of clinical translational trial feasibility across participant factor, treatment protocol, and outcome domains. All efforts were undertaken to inform the design of a future large-scale randomized controlled trial. This statistical plan facilitates this aim:

Multilevel Modeling. To analyze the between and within group repeated measurement data obtained in this project, multilevel models will be employed. For the repeated measure/ longitudinal data, variance components models (with no predictors) will be specified, to estimate the total between- and within-person variance of the outcome data for each of the dependent variables. Next, random intercept models will be specified, with a dummy variable for condition as a predictor. The shape of within-person growth over the course of intervention will be visually inspected; nonlinear trajectories may be modeled with polynomials (e.g., both a linear and quadratic effect of time) or dummy variables, as appropriate (Singer, Willett, & Willett, 2003). These models will be used to provide descriptive characterizations of average trajectories of change over time and the heterogeneity in these trajectories across participants (in terms of the mean and variance of the change over time), and to determine if any longitudinal improvements observed in fidelity and observational data uniquely associated with the two PRT apps. Additionally, these models will be used to explore the extent to which heterogeneity in growth trajectories may be attributed to demographic or study variables such as age or total app usage time, and the relationship between parent PRT fidelity mastery and corresponding child outcomes on coded social behaviors and standardized assessment measures. Effect sizes for growth modeling will also be employed following procedures outlined by Feingold (2009). Analyses will be conducted using the software program R, using packages such as lmer.