A BEHAVIORAL INTERVENTION WITH FOSTER FAMILIES

NCT Number: In progress of registering

Date of Original Document: October 25, 2021

STATISTICAL ANALYSIS PLAN

Plan for Data Management/Analysis

Randomization: The central hypothesis will be tested using a randomized controlled trial (RCT) design. The intent of the RCT design is to measure the effectiveness of the intervention and decrease bias through randomization (Montori & Guyatt, 2001). Because severity of disability may affect stress levels in the home, partial stratified randomization for disability severity will be employed. Stratified randomization creates balance between the control and intervention groups. Furthermore, stratification between each group allows for disaggregation of data (Friedman et al., 2015). If the highest-needs children are overrepresented in either the control or intervention groups, inferences could be incorrectly skewed. Families will complete an adapted Autism Behavior Checklist (ABC) before randomization, designed to screen for developmental and behavioral problems in children. The ABC was developed to provide a valid behavior checklist to measure level of behavioral concerns in children with disabilities (Krug, 1980) and has demonstrated intra-rater reliability of $r = 0.87$. Families with will be stratified to ensure equal disability severity among groups. The two study groups will include 1) the control group with no intervention and 2) families receiving the intervention. Families will fill out the prescreening tool, be randomly assigned to a group, and receive the survey tools. The same surveys will be collected after the intervention for comparison among groups. Families not assigned to the intervention will be offered the option to receive the intervention after the initial study has concluded. Families participating in the salivary cortisol collection will be randomly chosen form the intervention group.

Statistical analysis will be blinded through use of an independent statistician. STATA statistical software will be used to calculate descriptive statistics, t-tests, correlations, and

regressions to examine prediction and address the study aims. Consistent with the aims of the study, the primary outcome is to determine the feasibility and effect of the intervention on family hardiness and relationship development, with a secondary outcome of stress levels measured via cortisol levels. We hypothesize that the intervention will improve family hardiness measures and sibling relationships, and that salivary cortisol collection of families participating in the collection of saliva will be feasible within this population. The primary investigator examine potential mediation analysis and multi-level modeling to identify relationships of the concepts and individual characteristics nested within families.

References

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Krug, D. A. (1980). Behavior checklist for identifying severely handicapped individuals with high levels of autistic behavior. *Journal of child psychology and psychiatry*, *21*(3), 221-229. https://doi.org/10.1111/j.1469-7610.1980.tb01797.x

Montori, V. M., & Guyatt, G. H. (2001). Intention-to-treat principle. *Canadian Medical Association Journal (CMAJ)*, *165*(10), 1339-1341.