A BEHAVIORAL INTERVENTION WITH FOSTER FAMILIES

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STUDY PROTOCOL

Purpose and Aims

The purpose of this study is to test the effects of an easily accessible intervention that is unique for including both caregivers and children living in the home. Three aims will be conducted to: (1) establish the feasibility of the technology-based, family-centered intervention; (2) explore in a preliminary manner the effects of the intervention on stress and relational quality outcomes among family member participants; and (3) explore feasibility and preliminary efficacy of the intervention on diurnal salivary cortisol levels within the foster family population.

Design

This study will use a randomized controlled trial design. Randomization will be used to assign participants into the experimental or control group. Blinding of the two groups to participants will not be done. However, the team will blind the statistical analysis to group with the use of a statistician. Families assigned to the control will have the opportunity to participate in the intervention post- data collection and analysis and outside of the research protocol. The intervention was created in partnership and adapted from the Connected Family Series (CFS) by psychologists at the Karyn Purvis Institute of Childhood Development (KPICD). Adaptation is needed as the original intervention was geared toward adoptive families and excluded foster families. This process is currently occurring, but has not been completed. The intervention also needed content specific to fostering children with special needs. Stress and relational quality outcomes among members will be measured using the concepts of family hardiness, preparedness, and relationship development through a self-report questionnaire which include the Family Hardiness Index, the Integrating Foster Children subscale from the Casey Foster Applicant Inventory, and the Sibling Inventory of Behavior respectively.

Study Timeline

The study will span 6 months to 1 year; 1 month for recruitment and collection of baseline data, 2 months for the intervention, 3 months for post intervention data collection and 3 months for data analysis in 2022. Data will be gathered during the spring and summer of 2022 with the weight-listed control group able to participate in the intervention after data collection of the initial trial period. Dissemination of results is expected by 2023.

Sample

The study proposed here will follow rigorous guidelines to recruit and screen participants, in order to aid in the study's reproducibility and appropriate application (Friedman et al., 2015). The defined study population is foster families with both permanent and foster children in the home. Inclusion criteria for the study includes the following: 1) licensed foster families, 2) must have at least 1 permanent child (biological or adopted) living in the home before the foster or newly adopted child entered the home, 3) at least one foster or foster-to-adopt child placed in the home, 4) all participants other than the foster or foster-to-adopt child must have English as their primary language or be proficient in English. Families will be recruited through professional organizations such as the Karyn Purvis Institute of Childhood Development (KPICD), the Utah Foster Care Foundation – an organization responsible for the prelicensure training and continuing education of foster parents in the state of Utah, as well as a foster parent support group social media platforms (letter of support on file with Dr. Gephart). Eligibility criteria ensures that sibling interactions and how they affect placement stability will be captured.

Sample Size Justification

The total sample size for the study (N=130) of families was estimated for 80% power for t-test and ANOVAS, $\alpha<.05$ using G*Power software. Although the exact effect size of the intervention is unknown, we used results from the randomized control trial by Schoemaker et al.

(2020) in which a video intervention to improve parenting among foster families was used and their effect size of 0.34 for differences of the intervention on parenting sensitivity measures using the adapted Ainsworth scales for sensitivity and non-interference. Consistent with Shoemaker et al., a similar sample size was found to be sufficient to detect significant results for the original Connected Family Series. Collection of salivary cortisol to achieve exploratory aim 3 will be done with a smaller sample size of 40, consistent with previous similar feasibility studies for hypothalamic–pituitary–adrenal (HPA)-axis function (Pace et al., 2021).

Participant Recruitment

Once a family is recruited, they will be connected (within 1 week) with a study team member and screened for inclusion and exclusion criteria via zoom. If appropriate, the family will be enrolled in the study. Information will be given about the study and informed consent will be collected. An independent statistical team will ensure stratified random assignment to study groups.

Human Subjects Protection

Foster families, including parents, biological children, and foster children in the home (age 6 to 18), recruited through a licensing agency (Foster Care Foundation) will take part in an educational training and support network designed to help participants to prepare and thrive while caring for children in the foster care system. Subjects will come in contact with a Trust-Based Relational Intervention (TBRI) trainer and therapist virtually on-line (K. B. Purvis et al., 2013). TBRI education is the current standard for foster parent training for families accepting level III placements. The pediatric population is needed because both the caregivers and the children in the home have an impact on the stability of the placement.

A special and vulnerable population (children) will be involved in order to conduct research that is intended to impact to improve participant lives and by extension, more vulnerable children (i.e., those in foster care) with current great need relative to risks that are comparably minimal. Online platforms, particularly those that are intended to facilitate effective parenting of children with special needs, hold promise for strengthening current training programs (Kaasbøll et al., 2019). Including children is likely to increase the success of parental trainings. Without studying the family as a whole, we lose the family-centered potential to improve long-term outcomes for foster children. We also are likely to improve the functioning and mental health of the children who participate in the training/intervention. The proposed research uses a stratified randomization design for children with severe behavioral and developmental disabilities, to ensure that the research is reproducible. The control group (receiving no intervention) will be given the opportunity to participant in the intervention after the initial trial.

Potential Risks

Participants will not be put at financial or physical risk during any phase of the proposed research. Psychological and social risks will be addressed through the use of confidential psychological support and referral to treatment or therapy as needed. Because all participants will be licensed foster families, cost of therapy will be covered under the current program already available to foster families. Participants will continue to receive the standard of care or support available in addition to the intervention. Due to the sensitive information that may arise during the study, legal risks and obligations will be monitored by a data and safety monitoring board, compromised of individuals not directly tied to the study (see below). A report will be given by the PI on a monthly basis to the board. A case worker positioned within the governing

agency will be available via cell phone 24/7 to the PI. If a researcher or therapist encounters a situation that may appear to be a safety or legal risk, they will have 24 hours to notify the PI and caseworker.

Adequacy of Protection Against Risks

Recruitment and Informed Consent

Families will be recruited through social media platforms. The study coordinator will screen interested families. For participants who fit the inclusion criteria, the study coordinator will explain the study and expectations and provide the paperwork for informed consent. Signed consent forms will be locked in a cabinet in the Office of Nursing Research at the University of Arizona.

Protection Against Risk

The identity of participants will remain anonymous and confidential. The following safeguards will be put in place: a) unique identification numbers will be used for computerized data entry, b) data will not be released except in aggregate form, c) agency and names or other identifying variables will be absent from written communication or presentations.

Potential Benefits of the Proposed Research to Humans Subject and Others

The average participant will have a 50% chance of being randomized into the intervention group, but all participants will have the opportunity to eventually participate in the intervention if they so choose. The intervention is aimed at improving family relationships and will provide additional community resources. Foster children will benefit from having foster parents and siblings that better understand how to connect and develop positive relationships with children who may have a background of trauma.

Importance of the Knowledge to be Gained

Findings from this trial will be used to improve the placement stability and health of over 600,000 children in the foster care system every year. Results are expected to help improve the resilience of foster families through education and preparation.

Data and Safety Monitoring

The PI will be responsible for reviewing the feedback from the modules. Each week, a review meeting will be held with the PI and the trained therapist to review any concerns or needs of the participants. The Institutional Review Board (IRB) at the University of Arizona will be used for approval and oversight of the trial. The independent safety auditor will conduct reviews of patient responses and reaction to the intervention. A Data and Safety Monitoring Board (DSMB) will oversee coordination and risks across the different settings. This committee will consist of 4 individuals (the PI, the KPICD licensed therapist, and two dissertation committee members), who will meet on a quarterly basis to review and address any perceived or potential risks as the study progresses.

ClinicalTrials.gov Requirements

This study does not include trials of drugs or biologics nor does it include a trial for a device. However, it will be registered at clinicaltrials.gov.

Instrumentation

Sources of Materials

Research material will be obtained in the form of online surveys and point-of-care saliva collection. Surveys and saliva will be collected before the intervention (T1) and after the intervention (T2). Additional collection at 1-month post intervention (T3) will occur. Surveys include the Sibling Inventory of Behavior (SIB), the Family Hardiness Index (FHI), and a modified version of the Casey Foster Applicant Inventory-Applicant Version. Data gathered will

be coded using a unique identifier for each participant. The name and identifying number will be locked separately from the data with access only available to the primary investigator. Saliva specimens will be collected by the participants with only the identifying number on the tube.

Pre-Intervention Assessment

Participants screened and deemed to fit inclusion and not exclusion criteria will fill out a demographic survey and intent to offer permanency. Families will also be asked their willingness to participate in salivary cortisol collection. Caregivers will complete the three-pronged battery of assessments containing a total of 52 questions with an expected time to complete of 15 to 20 minutes for all questionnaires, which will be formatted into one questionnaire for participants. The three questionnaires include the Family Hardiness Index, the Sibling Inventory of Behavior, and the Modified Casey Applicant Inventory.

Hardiness - Family Hardiness Index (FHI)

Measurements for family hardiness will be done using the Family Hardiness Index (FHI). The FHI instrument is a 20-item Likert-type scale with a 4-point response scale ranging from false to true about the family situation (McCubbin et al., 1987). Higher scores indicate higher family hardiness. Validity and reliability have been established through positive correlations with family function measures, with an Cronbach's alpha coefficient of .82 with test-retest reliability of .86 (McCubin et al., 1996). Studies have employed the FHI to accurately indicate a hardiness levels within foster families and those raising children with special needs (Hendrix & Ford, 2003; Roberts et al., 2017). See Appendix D: Family Hardiness Index.

Relationship Development - Sibling Inventory of Behavior (SIB)

The Sibling Inventory of Behavior (SIB) was developed to assess sibling relationships between a typically developing sibling and a child with a disability using a 28-item questionnaire (Schaefer, 1981) and will be used here to assess relationship development. The measure assesses four aspects of sibling relationships: kindness (nine items), avoidance (six items), involvement (seven items), and empathy (six items). Validity of the SIB scales was demonstrated using correlational and observational data with Cronbach alphas ranging from .64 to .81 for each item, indicating that these items are closely related and thus internally consistent (Volling & Blandon, 2003). See Appendix E: Sibling Inventory of Behavior.

Family Preparedness - Modified Casey Foster Applicant Inventory

A modified version of the Casey Foster Applicant Inventory-Applicant Version will be used to assess family preparedness, which is a psychometric self-report tool used to assess the potential readiness and ability to foster parent successfully (Buehler et al., 2006). Data from previous studies involving foster parents have shown internal consistency and reliability (ranging from 0.64 to 0.96) (Orme et al., 2007). The *Integrating Foster Children* subscale includes ability to integrate a foster child into a foster family with birth or adopted children (Orme et al., 2006). Questions are based on a Likert scale from 1 (strongly disagree) to 4 (strongly agree). Example statements include, “My children want to have a foster brother or sister” and “My children are able to deal with a foster child with serious problems.” See Appendix F: Casey Foster Applicant Inventory Questionnaire.

Exploratory Objective Biological Measure of Stress – Salivary Cortisol

To measure the exploratory aim for objectively measuring an indicator of family stress and HPA axis function, the psychobiological maker of diurnal salivary cortisol will be tested. Concentration of cortisol in saliva over the course of the day is normally high in the morning,

peaks 30-60 minutes after wakening (cortisol awakening response/CAR), and is low at night, indicating healthy hypothalamic-pituitary adrenal (HPA) axis function (Adam et al., 2017). Relative disruptions in diurnal cortisol rhythm (e.g., high bedtime levels, a flatter diurnal slope from waking to bedtime, high overall concentration across the day) have been associated with self-reported stress, as well as other aspects of psychological well-being (e.g., depression)(Adam et al., 2017; Juarez Garcia et al., 2016). This study will employ the same methods and analysis as employed by Pace et al. (2021) and was done with permission.

Salivary Cortisol

Collection of saliva will include two family members: the primary caregiver and the permanent sibling that is closest in age to the foster child. If two permanent children are the same age difference away from the foster child, the permanent sibling with who the foster child interacts with most will be selected. Consent and assent forms will be signed by parent and child. Saliva will be gathered for three consecutive days before the intervention (days 1, 2, and 3) and after the intervention (days 31, 32, and 33); each sampling day, participants will provide a waking, 30 min after waking, and bedtime sample. A two-week window for saliva collection will be allowed depending on when the participating family completes the intervention. Participants passively drool through a straw into a 2mL polypropylene tube and labeled each tube with the time and date. Participants will be instructed not to eat, drink, or brush their teeth 30 minutes before each sample, and to keep completed samples in the refrigerator throughout the study period. Participants will ship saliva samples to the lab and samples will be then stored at -20°C. Saliva samples will be batch assayed in duplicate according to manufacturer instructions for cortisol concentrations using an enzyme immunoassay (EIA) kit (Salimetrics, State College, PA). Inter- and intra-assay coefficients of variability in previous studies by the Pace research team

were 8.16% and 7.74%, respectively. In line with prior work (Zeiders et al., 2014), the following cortisol parameters will be assessed: waking level (Sample 1), bedtime level (Sample 3), the CAR (the difference between Sample 2 – Sample 1), the diurnal slope (the difference between Sample 3 - Sample 1), and the area under the curve (AUC) to assess total cortisol output across the day. AUC will be calculated using the trapezoidal method.