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Tailoring the Chicago Parent Program for the Foster Care Setting

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Study Protocol

PROTOCOL TITLE:

Adapting Chicago Parent Program for the Foster Care Setting

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REVISION HISTORY

Revision #	Version Date	Summary of Changes
1	November 22, 2022	A sixth visit for the Foster Care Advisory Board group has been added, and the compensation structure has been updated. Foster Care Advisory Board members will receive up to $250 for attending all six meetings.
2	April 10, 2023	Adjusting age for eligibility criteria from 2-5 years to 2-8 years. Adding more specific detail as to what caregiver-report measures will be completed during the CPP-FC pilot.
3	May 30, 2023	We are requesting a waiver for collecting participant Social Security Numbers and W9s. Over 30% of the potentially eligible participants we have recruited have declined participation due to not wanting to provide their Social Security Number or complete a W9 form. Because the compensation for this phase of the study is not more than $100, we feel that a waiver is warranted.
4	July 21, 2023	Due to successful recruitment for our pilot phase, we are adding a third pilot cohort. We enrolled n = 5 participants into our first pilot cohort, and n = 11 into our second pilot cohort, of which n = 5-6 will instead participate in the third pilot cohort.
5	September 7, 2023	We are requesting to add $5 compensation per session for participant attendance. We also added clarifying language for compensation and completion of homework, as well as including more than one caregiver in the same household in qualitative interviews.
6	October 4, 2023	In the event that an end-of-program qualitative interview runs beyond 60 minutes, and not all parties are able to continue the interview at that time, we will schedule a time with the participant to complete the remainder of the interview. We will reimburse participants an additional $10 if the interview lasts longer than 60 minutes, whether it occurs in one

		or two sessions. We anticipate most interviews will not run longer than 60 minutes.

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1.0 Study Summary

Study Title	Adapting Chicago Parent Program for the Foster Care Setting
Study Design	This study involves administration of an evidence-based prevention program to prevent and reduce behavior problems in children (Chicago Parent Program; CPP). CPP content will be delivered to foster and kinship caregivers who are members of a Foster Caregiver Advisory Board. The Foster Caregiver Advisory Board will provide feedback and guide the development of CPP adapted for foster care (CPP-FC) in collaboration with the research team. Adapted content will be delivered to three cohorts of foster caregivers virtually in 11 synchronous weekly sessions and 1 booster session with two trained facilitators. Facilitators use video vignettes, handouts, and role play during sessions to support content delivery and engage parents in material. We will adapt CPP by creating additional handouts, discussion questions, and topics that contextualize CPP material to foster care, to meet the needs and social norms of foster caregivers. Adaptations will not modify the core components of CPP known to impact caregiver and child outcomes. Data for this study will come from multiple sources, including caregiver participant report, and review of existing electronic databases at CCHMC.
Primary Objective	The primary aim of this study is to deliver and adapt Chicago Parent Program for the foster care setting and pilot adapted content in three cohorts of foster caregivers.
Secondary Objective(s)	The secondary objective of this study is to gather preliminary data for a later clinical trial of CPP that has been adapted for the foster care setting (CPP-FC).
Research Intervention(s)/ Investigational Agent(s)	The Chicago Parent Program adapted for foster care (CPP-FC)
IND/IDE #	None
Study Population	Adults who are either licensed foster caregivers or kinship caregivers to children in foster care.
Sample Size	Foster Care Advisory Board, N = 6; CPP-FC Pilot, N = 12-16
Study Duration for individual participants	Approximately 32 weeks
Study Specific Abbreviations/ Definitions	Chicago Parent Program (CPP) Parents on Point (PoP)

2.0 Objectives

2.1 Purpose and objectives

The purpose of this study is to adapt the content of Chicago Parent Program (CPP) for the foster care setting (CPP-FC) in collaboration with a foster caregiver advisory board, and to pilot the adapted CPP-FC content with three cohorts of foster caregivers. Participants will be caregivers to a child in foster care between the ages of 2 and 8 years.

The Chicago Parent Program (CPP) is an evidence-based 12-session program designed for families raising young children in low-income settings. CPP was designed with an advisory council of African American and Latinx low-income parents and has since demonstrated significant and sustained improvements in consistent discipline, parenting self-efficacy, and child behavior problems 1 year following training in randomized studies with more than 500 minority parent-child dyads. CPP utilizes best practices for retention and engagement of hard-to-reach populations including employing trainers from a variety of backgrounds, featuring diverse individuals in video vignettes, using interactive training methods (role play, group discussion) and a focus on real world application (practice assignments). If available to foster caregivers, CPP could prevent or reduce behavior problems in foster youth, increase self-efficacy and consistent discipline with caregivers, and prevent unnecessary placement changes. Further, CPP can be delivered synchronously using virtual platforms, which addresses barriers faced by foster caregivers (i.e., competing activities, childcare and transportation challenges). However, tailoring of the existing program is necessary. Unlike custodial parents, relationships between foster caregivers and children must be established, and the foster care setting introduces additional challenges (e.g., maltreatment histories in children, lack of shared family routines). It is unknown whether those differences create barriers that foster and kinship families perceive as limitations to accessing and utilizing CPP.

2.2 Study aims

The primary aim of this study is to adapt CPP to meet the unique needs of children ages 2-8 years who are placed with foster and kinship caregivers, and pilot delivery coordinated with mandated healthcare visits. CPP will be adapted (e.g., additional content regarding trauma and child maltreatment, modified discussion of vignettes, additional role-play targeting specific foster care scenarios) while maintaining core elements integral to the program. The ensure validity, generalizability, and relevance a stakeholder adaptation team of 6 caregivers has been established to guide development of adapted content.

3.0 Background

3.1 Gaps in current knowledge

CPP components address gaps in foster caregiver training to prevent child behavior problems through proactive management. Unfortunately, few existing evidence-based prevention programs are available to foster caregivers. A meta-analysis of foster caregiver and adoptive parent training programs and their effectiveness in modifying child behavior problems identified 29 studies of programs developed or adapted for US foster caregivers.[1] Of those, two group-based caregiver training programs were found to be effective for foster children ages 2-5: Treatment Foster Care Oregon (TFCO) and Parent-Child Interactive Therapy (PCIT).[2,3] Both programs require rigorous implementation resources (e.g., a child welfare system trained and maintaining fidelity to implement TFCO; clinicians that accept Medicaid who are trained in PCIT) that can be challenging to maintain, limiting reach and impact in preventing behavior problems among young children and thus reducing placement disruptions. Leveraging programs that can be administered more feasibly (like CPP) may allow resources for PCIT and similar programs to be available for children with more intense needs. CPP fills an important gap by making a prevention program with evidence of effectiveness available to diverse caregivers in a variety of settings, including healthcare. This is particularly relevant for young children in foster care, where challenges related to disrupted routines and inconsistent parenting practices contribute to poorer self-regulation and increased behavior problems.[4–6] Thus, CPP is ideally suited to meet the need for prevention-focused caregiver training to prevent and reduce behavior problems in foster youth.

3.2 Relevant preliminary data and relevant prior experience

Effectiveness of CPP in prevention/reduction of behavior problems among at-risk youth. CPP was developed in collaboration with parents of young children (2-5 years of age) residing in Chicago and designed to be delivered during 12 synchronous in-person sessions with groups of parents and two trained facilitators. Parents of young children learn

parenting skills through group discussions, videotaped vignettes of real families managing behavior in real situations, structured role plays, and weekly practice assignments. Video vignettes and structured role plays are used to facilitate discussions around key parenting concepts. CPP has demonstrated effectiveness in reducing behavior problems for children ages 2-5 (N > 500, primarily African American and Latinx youth), with the effect of CPP on reductions in child behavior outcomes 12 months after intervention ranging between d = -0.43 and -0.46.[7,8] The CPP model has been delivered in a variety of settings, including 5 healthcare systems in the Northeast and Midwest United States. Asynchronous virtual adaptations of CPP (ezParent)[9] and synchronous virtual adaptations including for our pilot study have been successfully delivered to parents for the past 18 months. Our comparison of virtual and in-person delivery of CPP identified higher percentages of parents completing 6 or more sessions with virtual CPP (47%) vs in-person CPP (36%) and no differences in key outcomes of interest (i.e., caregiver self-efficacy, stress; disruptive child behaviors; ps > .15).

CPP with foster caregivers. We recruited 5 caregivers (100% African American, 60% female) through the CHECK Center (2 licensed, 3 kinship) to participate in CPP virtually beginning in May 2021. Caregivers completed between 9 and 11 sessions (higher than the average of 6.7-7.5 published elsewhere) and all 5 graduated.[8,10] Increases in confidence in managing challenging behaviors were reported by all 5 caregivers. Median confidence on a 10-point scale was 7 in week 1 and 9 on week 11; all caregivers reported feeling "a little more (40%)" or "much more (60%)" confident in managing children's behaviors at the end of the program, and all caregivers reported improvements in their child's behaviors by the end of the program ("At this point, I feel that my child's behavior is: better [40%]" or "much better [60%]"). All five caregivers reported that the behavior concerns that motivated them to engage in CPP were "much better" at the end of the program. Caregivers also reported that CPP was more effective than other trainings they had received. Caregivers reported that it was "not at all hard [60%]" or "a little hard [40%]" to attend session and complete practice assignments each week.

3.3 Significance

The foster care system is complex. More than 430,000 children are in child welfare protective custody (i.e., foster care) in the United States. [11] One in five foster youth (~86,000) are between the ages of 2 and 5 years. Children in foster care are disproportionately from low-income families,[12,13] minority children are over-represented in the foster care system,[14] and more than half of children enter foster care from urban settings.[12,13,15] The primary goal of the foster care system is to ensure child safety and support family preservation; child safety is addressed primarily by placing children with foster caregivers (i.e., licensed non-relative caregivers, kinship caregivers), with caseworker monitoring and oversight.[16,17] However, foster caregivers report being inadequately prepared to meet children's psychosocial and physical needs.[18]

Children in foster care have significant behavior problems. Child maltreatment (i.e., physical, emotional, or sexual abuse or neglect; and other early childhood adversities contribute to young children entering foster care and to potential for increased behavior problems in young children (i.e., non-compliance, withdrawal, aggression, inhibition, attention-seeking, hyperactivity; separation from parents and other characteristics of foster care further exacerbate these challenges.[12,19–24] Among foster youth, behavior problems are associated with a higher likelihood of caregivers requesting that children move to another home (i.e., placement changes).[25–28] Caregiver trainings for licensure are expected to alter child behaviors by raising caregiver awareness of the potential histories of children in foster care and their influence on behavior, as well as preparing caregivers to establish healthy patterns of interaction with youth through behavioral modeling, socialization, reinforcement, and sensitive responding to child behavior.[29] Unfortunately, foster caregiver training often focuses on rules and regulations, and lacks evidence-based strategies and programming for foster caregivers that proactively prepare them to manage common child behavior problems.[1,30]

The Chicago Parent Program offers a unique opportunity for early intervention and prevention. The Chicago Parent Program (CPP) is an evidence-based, parent-directed prevention program to strengthen parenting skills and confidence and prevent or reduce behavior problems in children 2-8 years old. CPP is grounded in the Coercive Process Theory and Social Learning Theory and this is reflected in the model's format, content, and delivery.[30–32] Sessions focus on building positive relationships with children (e.g., child-centered time, family routines and traditions, praise and encouragement), child behavior management skills (setting clear expectations, following through with consequences, effective discipline strategies), stress management, and problem-solving skills. CPP was developed in collaboration with an advisory board of African American and Latinx parents raising young children in low-income neighborhoods.[7,8] CPP is designed to be

culturally and contextually relevant and engaging for parents and caregivers from diverse backgrounds, particularly to the needs of African American and Latinx families. This is a noteworthy feature that is absent from other parenting support approaches.[3] The primary goals of CPP are to improve parent-child relationships, increase consistency in parenting behavior, reduce use of harsh discipline, promote parent confidence and skills in managing behaviors, expand the social support network for parents through the group meetings, and prevent and reduce children's behavior problems as a result.[33] This is accomplished in 12 two-hour group sessions facilitated by two trained group leaders who use multiple parent education strategies. The egalitarian group structure and use of group facilitators from the same community as participants (as opposed to interventionists identified as "experts") provides a safe and supportive space in which to discuss challenging issues related to parenting. Leveraging theories regarding small groups and behavior change and robust evidence linking video vignettes to promote content acceptability, CPP is offered in a group format of 10-15 parents.[33–36] The group format encourages parents to connect with each other, and form relationships that may continue outside of the group. Content delivery methods include (1) brief video vignettes of parents and children engaged in real-life challenging situations at home and in public settings (e.g., grocery stores, laundromats, etc.); (2) discussion questions tied to the vignettes that are designed to highlight key principles and strategies relevant to the session topic; (3) role play and group activities designed to help parents try out new skills and receive feedback and support; (4) list making activities intended to help parents clarify their goals and values relevant to the session topic; (5) weekly handouts summarizing key messages from each session; and (6) weekly practice assignments designed to help parents apply the new skills with their children. After each session, parents receive a "practice assignment" designed to help parents practice the new skill with their child during the week. Practice assignments are reviewed at the beginning of each session and preparation for practice is discussed at the end of each session. Parents submit a practice checklist noting which and how much of the assignment they were able to complete.

CPP has demonstrated impacts on parents and children.[7,8] Across two RCTs with 504 families, CPP led to significant improvements in parenting self-efficacy (d = .37), parents' use of effective discipline strategies (d = .29), parents' use of commands (d = -.38) and reductions in child behavior problems (d = -.43) when caregivers completed at least 50% of CPP sessions.[8] Effects are maintained one year post-intervention.[7]

Adapting CPP for the foster care context is needed. In tailoring CPP to foster caregivers (CPP-FC), several critical differences from typical family settings must be considered. First, foster caregivers are frequently unfamiliar with the children placed with them, and establishing new shared routines, house rules, expectations, and social norms are often required. This is not always an explicit process, and caregivers do not receive standardized training in establishing positive relationships with new foster youth.[37] This leads to inconsistent knowledge and training among foster caregivers of young children and variable practices when placements begin. It is not until problems emerge that referral to evidence-based interventions might occur. Addressing these foster care specific issues and contexts is critical for prevention programs to be successful. Customized tailoring of CPP is also important for engagement and retention purposes. Providing vignettes, role plays, and applications of CPP concepts that reflect foster care can be done without altering the critical elements that make CPP effective.

4.0 Procedures Involved

4.1 Study design

This study involves the adaptation and administration of an evidence-based prevention program to prevent and reduce behavior problems in children, Chicago Parent Program (CPP). CPP is being adapted for a population with unique needs (foster care; CPP-FC). Participants are adult caregivers to a child in foster care aged 2-8 years. Caregivers are being recruited into one of two groups: a foster caregiver advisory board (N = 6) and participants in the CPP-FC pilot (N = 12-16).

CPP uses 12 sessions to deliver content. Topics include concepts such as the value of child-centered time; family routines and traditions; use of praise and encouragement; use of rewards for challenging behavior; limit setting; following through on commands; use of behavior management strategies such as ignoring, distraction, and time-out; managing stress; and problem-solving. Facilitators use video vignettes, handouts, and role-play during the sessions to support content delivery and engage parents in the material. This study team will ask foster caregiver participants to provide additional feedback regarding the application of CPP content to the foster care setting via weekly questionnaires and an exit interview.

Data for this study will come from multiple sources including caregiver report and review of existing electronic databases at CCHMC (i.e., Epic and IDENTITY), and all data will be entered into REDCap.

4.2 Study procedures

CPP Adaptation Procedures. An established Caregiver Advisory Board of 3 licensed foster caregivers and 3 kinship caregivers will work with the study team to review all CPP content and provide feedback as materials are being adapted for the foster care setting. We will use the seven-step method outlined by Card et al., 2011 for adapting effective programs for new contexts. Those steps include (1) selecting CPP as a suitable and effective program; (2) Gathering original program materials, including all training materials and content; (3) Reviewing the logic model; (4) Identifying CPP core components and best practice characteristics; (5) Identifying and categorizing mismatches between the original model and materials in the new context; (6) Adapting the original program model; and (7) Adapting the original program material. Steps 1 – 4 of this model have already been completed, and those materials will be reviewed by the study team and caregiver advisory board at the outset of the study. The PI and caregiver advisory board will collaborate to complete step 5, where each caregiver and the PI will individually identify mismatches in material/the logic model and the foster care context. The group will come together to discuss and classify each mismatch identified. The PI and advisory board will then collaborate to develop adaptations to the program material. Those adaptations will be brought to the study team for full review and discussion. Adaptations will not be made if there are concerns that they will undermine the key components of CPP. Disagreements between stakeholders will be resolved through iterative discussions and final decisions will be made by the study team. Once modifications are agreed upon by all parties, the PI and study coordinator will collaborate to fully develop adapted content and the CPP-FC manual. Modifications will be developed in a collaborative co-design process, which the study team has prior experience completing [39,40]. Advisory board members will meet with the research team 6 times over the course of 24 months, and the duration of these meetings will vary depending on the amount of group discussion taking place. Advisory board members will be compensated for their participation in these activities. Adapted materials will be used to train CPP-FC facilitators, who will have also completed CPP training.

CPP-FC Pilot Procedures. Once CPP-FC is prepared, three cohorts of foster caregivers (6-8 families per cohort) will be recruited to complete CPP-FC in synchronous virtual sessions. Recruitment strategies will maximize inclusion of African American and Latinx families. Two facilitators trained in CPP and CPP-FC who are familiar with the child welfare system will deliver the 12 sessions. When possible, trained facilitators who have experience as caseworkers, kinship or licensed caregivers, or other child welfare experience will be used. The purpose of this pilot phase is to ensure that adapted materials are acceptable to foster families, that the order of materials being delivered is logical and sound, that caregiver engagement with materials is high, and that facilitators find it feasible to deliver. At baseline, after each session, and at the end of CPP-FC, participating caregivers will complete surveys assessing their satisfaction with the program, their stress and confidence in managing behavior problems, and the behaviors of children in their homes (see 4.3 Study measures).

4.3 Study measures

Adaptation of CPP for the foster care context. As steps 1 – 4 of the model outlined by Card et al., 2011 have been completed, the adaptation procedures at the outset of this study will begin with step 5 where the research team and caregiver advisory board will review materials gathered during previous steps. The research team and caregiver advisory board will individually review these materials and will produce a descriptive list of mismatches between the original CPP content and the foster care context. Researchers and advisory board members will have group discussions on each identified mismatch and will classify mismatches as a) concerns about the applicability due to caregiver characteristics (e.g., cultural beliefs, norms, values, or language and terminology; b) concerns about the applicability due to context, including social factors, policy-related factors, and other logistical concerns; or c) ignorable concerns. In step 6, the research team and caregiver advisory board will adapt CPP for the foster care context (CPP-FC). During adaptation, researchers and advisory board members will produce lists of program goals and objectives, and then make decisions on whether these goals and objectives align with the foster care context. Researchers and advisory board members will also produce lists of possible additions to program content that are necessary to achieve goals and objectives of CPP-FC. Potential areas for adaptation identified by results of a previous study where 5 foster or kinship caregivers participated in CPP (CCHMC IRB # 2021-0294) are listed in Table 1.

Table 1. Summary of possible adaptations to CPP, with caregiver feedback justifying changes provided in blue font under example changes

Domain of Modification for CPP-FC	Example Change
Incorporating trauma-informed concepts	1. References to families of origin, placement, caseworker as part of discussion questions 2. Considering maltreatment and trauma as drivers of misbehavior "Just, it doesn't have to be a whole entire session, but maybe every now and again adding a footnote for those people who are in kinship care and understand that there's a transition period that they would have to go through. And how, sometimes with foster care you're dealing with children who have experienced trauma. And so that trauma, it's going to be magnified."
Adapted discussion questions for vignettes and role play scenarios, expanded handouts	1. Add discussion questions about limit-setting and child discipline in the context of foster care (e.g., physical discipline is not permitted) 2. Expand handouts to include common concerns about time-out and address trauma and maltreatment 3. Include caseworker, parent as other individuals giving children praise "We saw bigger outbursts when he wasn't getting his way, right? We have children, we couldn't discipline him the same way that we normally, you know, did our children, so [CPP] helped us to figure out new techniques."
Add role play scenarios, additional discussion topics	1. Identifying and teaching routines to better integrate the child into existing caregiver routines 2. Considering the child's perspective on routines and adjust routines as appropriate 3. Getting to know your child outside of child-centered time 4. Managing behaviors and conflict around supervised and unsupervised visitation with parents "[Some CPP discussions were] kind of confusing because, you know, we don't always know our kids but we're learning and we're needing help, you know, for kids that we don't know."

Members of the caregiver advisory board will also assist the researchers with reviewing and identifying themes in the semi-structured interviews conducted with CPP-FC pilot participants at the end of the study.

CPP-FC baseline measures. After providing informed consent, participants in the CPP-FC pilot will complete self-report surveys including demographics such as age, race and ethnicity, gender, education, household structure and income, and the caregiver type (i.e., licensed foster caregiver vs. kinship), as well as assessments of caregiver stress, caregiver confidence, and child behavior.[41–45] Child demographics including age, race and ethnicity, gender, education, child welfare history (e.g., placement history), and receipt of services (i.e., developmental, medical, and behavioral health service utilization) will be collected from existing electronic databases (i.e., Epic and IDENTITY), as well as caregiver report when appropriate.

Caregiver-report measures administered at baseline and end of program include the Perceived Stress Scale[46], Child Adjustment and Parent Efficacy Scale (CAPES)[47], Parenting Sense of Competence Scale[43], Eyberg Child Behavior Inventory[42], Strengths and Difficulties Questionnaire[44], and the Parental Stress Scale[48].

CPP-FC end of session measures. At the end of each CPP-FC session, caregiver participants will complete surveys on satisfaction with session material, as well as weekly homework assignments.[33] Following sessions 4, 8, and 12, participants will also complete the Group Environment Scale.[49]

CPP-FC end of program measures. At the end of the CPP-FC program, caregiver participants will complete surveys assessing program satisfaction, caregiver stress, caregiver confidence, child behavior, and receipt of child developmental, medical, and behavioral health services. In the event that the child has changed placements during the study, the caregiver will continue to participate and give feedback on program content but will not report on child behavior at this follow-up. Caregiver participants and any additional caregivers residing in the same home who attended one or more CPP-FC sessions

will also complete a semi-structured interview approximately 45 minutes in length, facilitated by the research team and report on strengths and difficulties of CPP-FC, impact of CPP-FC, and feedback on how to further adapt and improve CPP-FC content.

5.0 Data and Specimen Banking

All study data will be stored on secure, password-protected servers at CCHMC. These will include local network drives at CCHMC, as well as HIPAA-compliant electronic file storage via OneDrive and REDCap. Data will be stored indefinitely and will be available for future research after the present research objectives of this project have been met and will require additional IRB approval. Only approved study staff who have completed all required training will have access to the data.

6.0 Study Timelines

This study is expected to take place over the next 24 months. Months 1-9 will be spent recruiting members of the foster caregiver advisory board and adapting CPP materials. Month 9-15 will be spent recruiting and delivering CPP-FC content to participants. Months 16-24 will be spent collecting follow-up data from CPP-FC pilot participants, and further adapting CPP-FC as needed.

7.0 Inclusion and Exclusion Criteria

Inclusion criteria for participation on the foster caregiver advisory board are a) being either a licensed foster caregiver or a kinship caregiver; and b) must be willing to commit to participation for 24 months.

Inclusion criteria for participation in the pilot study are a) being a licensed foster caregiver or a kinship caregiver, and b) having a child in foster care between the ages of 2-8 years placed in their home no more than 45 days before enrollment.

8.0 Vulnerable Populations

This study will recruit caregivers to a child in foster care age 2-8 years. Caregivers will be ages 18 and older. All participants will participate voluntarily, recruited from the CHECK foster care clinic. The study represents two potentially vulnerable populations – female caregivers of reproductive age and foster children cared for by the study participants. Based on our prior studies, we expect that most caregivers participating in this study will be women and some of those women will be of reproductive age. We do not anticipate any negative impact of participation in this study on pregnant or postpartum women who may be enrolled.

The foster children being cared for by caregivers are also protected, both as a result of their status as children and their involvement in child protective services. These children have already experienced maltreatment and are known to be at elevated risk for victimization. At thetime of enrollment, caregivers of children in foster care will already have been identified by the local child protection services agency (CPS) as being suitable and with capacity to meet the child's needs. As such, this study will not be evaluating the appropriateness of the caregiver.

CPS, the court, and, when appropriate, the licensing agency for the foster caregiver will continue to provide oversight and supervision of the child and his/her placement with the foster caregiver. This minimal risk study is not expected to increase risk of maltreatment or elevate therisk of harm for this vulnerable population. It is possible, however, that study staff will identify risks and concerns; these concerns are being managed by the study team.

9.0 Number of Subjects

We will recruit 6 foster caregivers (N = 3 licensed foster parents; N = 3 kinship caregivers) to serve on the Foster Caregiver Advisory Board and assist with CPP-FC adaptation. For the CPP-FC pilot, we will recruit 12-16 foster and kinship caregivers of a child in foster care age 2-8 years old.

10.0 Recruitment Methods

Caregiver Advisory Board. Caregivers will be recruited from the existing CHECK Foster Care Center Advisory Board where licensed (N = 3), and kinship (N = 3) providers participate alongside other caregivers. Additionally, the CHECK Center maintains a listserv for caregivers, and if we do not recruit a sufficient number of caregivers from the existing advisory

board, caregivers from the listserv will also be notified and invited to apply to partner with the study team on this advisory board. We will also notify existing licensing agencies and kinship support programs in the community about the study and will invite nominations for members of the advisory board from those resources. Caregivers will commit to participate for a minimum of 24 months on the advisory board, with a stipend to support their involvement. Replacement members will be recruited in the same manner, if needed. When initially contacted, caregivers will complete brief demographics form, including race, ethnicity, and duration as a foster or kinship caregiver in order to ensure a representative sample from the foster care population.

The CPP-FC Pilot. Caregivers will be recruited from the CHECK Foster Care Clinic at CCHMC during their foster child's mandated healthcare examinations. In the state of Ohio, all children in foster care are required to have comprehensive health examinations at the time of entry into foster care, and with each placement change. Clinical research staff are embedded into the clinic to recruit for research studies and have access to a shared health and child welfare administrative database to use for recruiting and retaining families in research studies. Clinical research staff who are trained in human subjects research and experienced with recruiting foster caregivers will approach families in the waiting room, and the study procedures will be described. Caregivers who agree to participate in the study will complete eConsent procedures with clinical research staff during the visit and will be asked to complete baseline survey assessments electronically using REDCap. Caregivers from the same household as enrolled participants who participate in qualitative interviews will provide verbal consent to interviews and recordings at the start of the qualitative interview. Additional qualitative interview sessions may be added as needed, if interviews run longer than 60 minutes, with verbal consent captured at the start of each follow up interview session. We anticipate most interviews will not run longer than 60 minutes.

11.0 Withdrawal of Subjects

Under no circumstances are we expecting participants to be withdrawn from the research without their consent. Participants are free to withdraw at any time. Participants may fail to complete a survey or attend a session and not intend to withdraw from the study. We will continue to call and invite them to complete surveys and attend sessions even if they miss a previous survey or session or are otherwise non-communicative. A phone communication or email notification that they wish to withdraw from the study will be sufficient and necessary to cease communication from study staff.

12.0 Risks to Subjects

Underlying concerns with caregivers. While engaging with the study, caregivers may express behaviors or concerns indicative of child maltreatment, or study staff may observe interactions between caregivers and children that suggest an investigation is warranted. Resources available to caregivers to address any underlying concerns will be incorporated into the information sheet, and facilitators will remind caregivers about resources as they participate in the study.

Underlying concerns with foster children. The children being cared for by participants of this study also have existing histories of trauma, experiences with maltreatment, and may develop acute psychiatric concerns during the course of the study. While CPP does not explicitly assess or address children's psychiatric concerns, caregivers may disclose concerns that require additional resources, treatment, or immediate action and intervention (in the case of acute psychiatric issues). Additionally, while engaging with the study, caregivers may express behaviors or concerns indicative of child maltreatment, or study staff may observe interactions between caregivers and children that suggest an investigation is warranted. None of these risks are directly caused by the study; however, by the nature of the study design, these risks may be detected. Resources available to caregivers to address any underlying concerns associated with foster children will be incorporated into the information sheet, and facilitators will remind caregivers about resources as they participate in the study.

Risk of loss of privacy or confidentiality. There is also the risk of possible loss of privacy of data or loss of confidentiality as a result of participating in this study. These risks are inherent in all research. While HIPAA-compliant health technology will be used to collect participant data, there is a risk of loss of privacy of data and a risk of loss of confidentiality associated with health technology use. Every effort will be made to ensure that all participant information will be kept confidential and secure.

13.0 Potential Benefits to Subjects

There is a potential for direct benefit to the participants in the form of potentially improved child-parent relationships, reduced child mental, emotional, and behavior problems, reduced caregiver stress, and increased caregiver self-efficacy. Their participation may also benefit others as this study will provide preliminary data for a foster care-specific prevention program. These likely benefits outweigh the unlikely risks present in this study, consistent with the IRB's classification of this study research involving minimal risk.

14.0 Data Management and Confidentiality

14.1 Data analysis plan

Descriptive statistics (frequencies, percentages, means, medians, distributions, or responses) will be gathered and qualitative feedback about sessions (e.g., likes and dislikes, suggestions for additional topics, activities, or discussions) will be summarized. As the focus of this pilot is descriptive, no inferential statistics will be conducted.

Coding of qualitative written feedback and transcripts from semi-structured interviews at the end of the pilot CPP-FC (N = 12-16 caregiver interviews) will be completed by the PI, a trained research coordinator, and members of the caregiver advisory board, in collaboration with the Cincinnati Children's Hospital Qualitative Methods Analysis Center (QMAC). A thematic coding manual will be created to organize all caregiver comments in an iterative manner, with two transcripts reviewed by each coder to generate themes and structure, which will be applied when subsequent transcripts are coded. All coders will then code the same set of three transcripts to establish reliability. Additional codes will be added as needed, with revisions to the coding manual to ensure consistency across all coders. Weekly meetings to discuss coding will occur until all transcripts have been coded by 2 coders. Discrepancies will be resolved through discussion with a third coder, with the goal of extracting themes that will direct the study team toward opportunity to improve and further adapt CPP-FC. Proposed changes will be brought to the full study team and caregiver advisory board for approval before further modifications are made.

14.2 Data processing

Data de-identification. All data will be de-identified with the use of unique assigned study identifier codes. These codes will only be used on study measures for data entry and analysis. No other identifying information such as address, date of birth, phone numbers, or social security numbers will be entered on measures. With oversight from the study PI, study coordinators will maintain a password-protected REDCap database to link study identifiers to participants. This database will be housed on the CCHMC network. Only trained study staff involved in the research and under the direct supervision of the PI will have access to this database.

REDCap. Data entered by the participant into REDCap will be housed securely on the CCHMC network. CCHMC employs industry-standard system builds for security, anti-virus and anti-malware products, and IDS/IPS products on the systems and networks. Additionally, CCHMC utilized firewall and network traffic monitoring and inspection. Data will be stored and accessed in accordance with HCFA's Internet Security Policy and HIPAA.

The database created to store participant data will be located on a secured CCHMC server and will be password protected. Only coded, de-identified information will be entered into the database using randomly generated identification numbers. No co-investigators will receive identified data, and all analyses will be conducted using de-identified data. Codebooks to re-identify data and link existing data with new data collected will be stored separately from the data and will only be available to the PI and lead research coordinator on the study team. Additionally, only study coordinators will have data-entry access.

15.0 Provisions to Secure Data

The PI and research personnel will complete compliance and human subjects training, and all study procedures will be approved by the IRB at CCHMC. Research staff are aware of the highly sensitive nature of the data collected during this protocol (i.e., maltreatment and trauma history), data securities are in place to ensure data are protected. Data will be stored on a secure server at CCHMC that will be password protected and only available to the study team. Only study coordinators will have data entry access, the PI will monitor research personnel closely to ensure compliance with data

storage practices. To further protect participant privacy, data will be de-identified prior to analysis and no identified data will be stored with de-identified participant responses.

16.0 Provisions to Protect the Privacy Interests of Subjects

During this study, participant self-report data will be collected. All data are for research purposes only, and data will be kept in strict confidence. No identified information will be shared with anyone outside of the study team. To protect data, all data, will be identified with a unique study identification number that is not derived from any identifying information (e.g., name, date of birth, address, etc.).

In the highly unlikely event that there is a breach in security, the protocol used by CCHMC when there are violations in health information privacy will be used. This protocol aligns with the requirements laid out by the Department of Health and Human Services. Specifically, in the event that there is a security breach, the participant whose data was breached will be notified and information about the extent of the breach will be described. The Secretary of Health and Human Services (HHS) will also be notified. HHS records indicate that CCHMC has not had a health information privacy breach since HHS began reporting breaches publicly in 2009.

17.0 Economic Burden to Subjects

There is no economic burden associated with participation in this study.

18.0 Compensation for Participation

Foster caregiver advisory board members will receive up to $250 for participating in all 6 meetings. Members will receive $35 for attending meeting 1, $45 for attending meetings 2, 3, 4, and 5, and $35 for attending meeting 6. Members will receive compensation in the form of a Clincard.

Participants in the CPP-FC pilot will receive up to $155 for completing all study tasks. Participants will be paid $10 for completing baseline surveys, $5 for each session attended (sessions 1-11 only), $5 for completing homework and weekly surveys (sessions 1-11 only) after each weekly CPP-FC session, $15 for completing end of program follow-up surveys, and $20 for completing the end of program semi-structured interview. If the end-of-program interview runs beyond 60 minutes, we will pay participants an additional $10 (making the total possible compensation in this case $165), but we expect most interviews will not last longer than 60 minutes. These will be paid per household if more than one caregiver in the home participates. Participants will receive compensation in the form of a Clincard. Foster caregivers may also be able to receive ongoing training hours through their licensing agency, if eligible. We are requesting a waiver for collecting participant social security numbers and W9s. As of May 24, 2023, over 30% of the potentially eligible participants we have recruited have declined participation due to not wanting to provide their social security number or complete a W9 form. Because the compensation for this phase of the study is not more than $200, and the impact on recruitment thus far has been substantial, we feel that a waiver is warranted and is consistent with the memorandum of understanding regarding waivers for collecting SSNs for foster youth research participants.

19.0 Consent Process

Adult caregiver participants in this study will provide documented informed consent electronically via REDCap's eConsent module within 1 week of initial recruitment, before any pilot data are collected. For households with more than one caregiver participating in qualitative interviews, verbal consent for participation and recording of the qualitative interview will be collected at the start of the interview. Because there will be no direct interaction with the foster children of adult participants, and the burden of obtaining consent from the legal guardian of the child (i.e., the county caseworker) would make the research infeasible (as evidenced by CCHMC IRB# 2012-0005), we are requesting a waiver of informed consent and a HIPAA waiver so that we may collect necessary health and child welfare information for the foster children from electronic databases at CCHMC (i.e., Epic and IDENTITY).

20.0 Setting

These study procedures will be conducted in-person at the CHECK Foster Care Clinic at CCHMC, and virtually via HIPAA-compliant Microsoft Teams.

21.0 Resources Available

Resources available to the research team include a secure, HIPAA-compliant electronic data collection platform (i.e., REDCap), a secure, HIPAA-compliant teleconferencing platform (i.e., Microsoft Teams), the CCHMC electronic health records system (i.e., Epic), and a shared health and child welfare administrative database (i.e., IDENTITY).

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