Trials

STUDY PROTOCOL

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Caregivers on point: a randomized treatment–control prevention trial for foster and kinship caregivers to reduce behavior challenges among children in foster care

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Abstract

Background Children in foster care who are newly placed with licensed or kinship caregivers are often vulnerable to increased behavior problems associated with trauma and social disruptions. When those issues are not addressed, children are susceptible to placement disruptions that exacerbate behavior problems. Few preventive interventions are available for foster and kinship caregivers, and none are designed to be delivered at the time of a child's placement into the home. This study aims to examine the impact of the Chicago Parent Program adapted and customized for foster and kinship caregivers (CPP-FC), locally branded as Caregivers on Point, on caregiver stress, parenting confidence and strategies, children's behaviors, and placement stability.

Methods Caregivers ($N=300$) are being recruited from a specialized foster care clinic that sees children and caregivers within five business days of a new placement. Upon completing baseline surveys and behavioral observation, caregiver-child dyads are randomized to receive CPP-FC ($n=150$) or usual care ($n=150$). Those in the treatment condition will complete 11 weekly sessions addressing child behavior management and caregiving approaches. A booster session will occur one month after the weekly sessions conclude. A mid-point assessment and behavioral observation will be collected four months after the baseline assessment for all participants, coinciding with the completion of the CPP-FC programming. At 6 months post-baseline, an end-of-study assessment will be collected. Administrative data will be extracted from the child welfare record to determine placement stability for the 12 months following enrolment. The primary outcome of interest is child behavior, indicated by changes in caregiver reports and objective ratings of behavior from observations, where raters are blinded to the treatment arm and timing of data collection. Secondary outcomes include placement stability and changes in caregiver stress and confidence in managing children's behavior.

Discussion If found to be effective, CPP-FC would be helpful for families involved with child welfare. It could be delivered by child welfare agencies, licensing and kinship navigator agencies, and foster care clinics and may be eligible for government reimbursement as a preventive intervention for children in foster care.

Trial registration This study was prospectively registered with ClinicalTrials.gov, NCT06170047.

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Keywords Foster care, Kinship care, Child welfare, Parenting program, Child behavior problems, Prevention

Administrative information

Title {1}	**Caregivers on Point: A randomized treatment–control prevention trial for foster and kinship caregivers to reduce behavior challenges among children in foster care**
Trial registration {2a and 2b}	This study was prospectively registered with ClinicalTrials.gov, NCT06170047
Protocol version {3}	Protocol 2023–0760, version 1. 12/14/2024
Funding {4}	Eunice Kennedy Shriver National Institute on Child Health and Human Development, National Institutes of Health, R01HD105727
Author details {5a}	Sarah J. Beal, Cynthia Zion, Constance A. Mara, Meera A. Patel, Lisa M. Vaughn, Mary V. Greiner, and Robert T. Ammerman: Cincinnati Children's Hospital Medical Center/University of Cincinnati College of Medicine Amie F. Bettencourt: Johns Hopkins University Susan M. Breitenstein: The Ohio State University
Name and contact information for the trial sponsor {5b}	Layla Esposito, Program Director, National Institutes of Health esposito@mail.nih.gov
Role of sponsor {5c}	This study is completed independent of input from the study sponsor/funder, the National Institutes of Health. The protocol authors are solely responsible for the study design, collection, analysis, interpretation, and dissemination. The National Institutes of Health has no authority or input over these activities

Introduction

Background and rationale {6a}

More than 430,000 children are in child welfare protective custody and out-of-home care (i.e., foster care) in the United States [1]. Children in foster care are disproportionately from low-income families [2, 3], and children of color are overrepresented in the foster care system [4]. More than half of children enter foster care from urban settings [5]. Therefore, children in foster care face multiple systemic social challenges and barriers that impact their development and well-being. The incidence of trauma among children in foster care is high, with 76% of children in foster care reporting exposure to childhood adversity and other traumatic events as compared to 33% of children in the United States general population [6]. These traumatic experiences are associated with increased psychosocial needs, including more internalizing and externalizing behavior problems in children [7, 8]. The primary goal of the foster care system is to ensure child safety and support family preservation [9]; child safety is addressed when intervention is needed, primarily by placing children in out-of-home care with temporary caregivers (i.e., licensed non-relative foster caregivers, kinship caregivers), with caseworker's monitoring and oversight [10]. However, foster and kinship caregivers report being inadequately prepared to meet children's psychosocial and physical needs [11].

Child maltreatment (i.e., physical, emotional, or sexual abuse or neglect [12]) and other early childhood adversities [6] contribute to young children entering foster care and to the potential for increased behavior problems in young children (i.e., non-compliance, withdrawal, aggression, inhibition, attention-seeking, hyperactivity) [7, 13–15]. Separation from parents and other characteristics of foster care (e.g., disruptions in school and community settings when children move between caregivers) further exacerbate these challenges [2]. Among youth in foster care, behavior problems (e.g., increased aggression, more frequent tantrums, oppositional and withdrawn behaviors) are associated with a higher likelihood of placement changes [16–20]. Caregiver training for licensure is 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 [21]. Unfortunately, foster caregiver training often focuses on rules and regulations [22] and lacks evidence-based culturally relevant strategies and programming for foster caregivers that proactively prepare them to manage common child behavior problems [22, 23]. Additionally, this programming is largely unavailable to kinship caregivers who do not seek to become licensed.

The Chicago Parent Program (CPP) is an evidence-based preventive intervention designed for racially and ethnically diverse parents raising young children in under-resourced communities and fills an essential gap in preventive interventions because it can be delivered by trained group leaders from a variety of educational backgrounds (only a high school diploma or GED is required) and in a variety of settings, including healthcare. The CPP

was developed in collaboration with parents of young children residing in Chicago and designed to be delivered during 12 face-to-face group sessions with parents and two trained group leaders. Parents of young children learn parenting skills through group discussions, brief 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 and practice of key parenting concepts. The CPP has demonstrated effectiveness in reducing behavior problems for young children ($N > 500$, primarily African American and Latino youth), with the effect of CPP on reductions in child behavior outcomes 12 months after intervention ranging between $d = -$ [24] 0.43 and -0.46 [25]. The CPP model has been delivered in a variety of settings, including five healthcare systems in the Northeast and Midwest United States. Asynchronous web-based delivery of CPP (ezParent) [26] and synchronous online adaptations [24] have been successfully delivered to parents. The curriculum and outcomes impacted by the CPP are particularly relevant for young children in foster care, where challenges related to disrupted routines and inconsistent parenting practices contribute to poorer self-regulation [27] and increased emotional and behavior problems [28, 29]. Thus, the CPP is ideally suited to meet the need for prevention-focused caregiver training to prevent and reduce behavior problems among children in foster care. However, the CPP has not been evaluated for use with foster and kinship caregivers of children in out-of-home care.

Prior to this study, a cohort of five foster and kinship caregivers completed the CPP and provided their feedback on the program and its applicability to their experiences [30]. Caregivers reported that several aspects of the CPP were applicable to their experiences (e.g., child-centered time, logical commands, ignoring behavior). However, some aspects of the program did not generalize to their experiences (e.g., use of physical discipline, incorporating families of origin, establishing new routines and traditions), and they expressed a strong desire to receive training from group leaders with exposure to foster and kinship care. The CPP was, therefore, customized to the unique needs of children placed with foster caregivers following the 7-step method outlined by Card et al. [31] for adapting effective programs for new contexts. A caregiver advisory board of four licensed foster caregivers and three kinship caregivers were recruited to work with the study team to review the CPP content and provide feedback as materials were tailored for the foster care setting. The advisory board and study team reviewed study materials and identified areas of CPP that need tailoring for the foster care context. The CPP content and group leader materials were enhanced to address identified needs, and two group leaders were trained to deliver the CPP with tailoring to foster and kinship caregivers. A pilot of the CPP-FC was conducted with 18 licensed foster and kinship caregivers (67% retention, treatment $n = 12$). Three cohorts of foster caregivers (5–6 families per cohort) were recruited to complete CPP-FC in synchronous online sessions. The same two group leaders trained in the CPP and the CPP-FC delivered the 11 weekly and 1-month booster sessions. Caregivers participated in pre- and post-assessments and completed a qualitative interview following the 11th session. The purpose of the pilot was to ensure that tailored materials were acceptable to foster and kinship families, that the order of materials being delivered was logical and sound, that caregiver engagement with materials was high, and that group leaders found it feasible to deliver.

Objectives {7}

A parallel, two-group, 1:1 randomized controlled trial of $N = 300$ caregiver-youth dyads will be conducted through a study called "Caregivers on Point," comparing the CPP adapted for foster and kinship caregivers (CPP-FC) of young children (ages 2–8 years) versus a usual care control. Quantitative and qualitative data will be collected from foster and kinship caregivers and through observations of caregivers and youth. The findings from this study will demonstrate whether CPP-FC is effective in reducing behavior problems in children ages 2–8 and whether that contributes to reduced caregiver stress, increased caregiver confidence, increased positive parenting behavior, and longer lengths of time that children remain with foster and kinship caregivers, preventing unnecessary moves from one caregiver to another and improving child wellbeing. This will be accomplished by testing the following aims and hypotheses:

Aim 1: To assess the impact of CPP-FC on caregiver stress, confidence, and behavioral strategies in managing child behavior. Hypothesis 1: Caregivers receiving CPP-FC will report significantly lower levels of caregiver stress, significantly higher confidence, and more effective strategies in managing child behavior compared to the control group at the mid-point and 6-month assessments.

Aim 2: To assess the impact of CPP-FC on child behavior. Hypothesis 2: CPP-FC will be associated with improved behavior (e.g., decreased aggression, increased compliance), measured via observation at the mid-point assessment and through caregiver report at the mid-point and 6-month follow-up assessments. Hypothesis 3: CPP-FC will be associated with fewer placement changes due to child behavior problems at 1-year post-enrolment.

Aim 3: To explore if demographic characteristics, including caregiver gender, age, race, kinship/foster

caregiver status, demographic characteristics of children placed in the home, household composition, and child maltreatment and placement history impact response to treatment as assessed by caregiver report, behavior observations, and placement stability outcomes.

Trial design {8}

This is a parallel two-group 1:1 randomized controlled superiority trial to establish the positive impact of The Chicago Parenting Program for Foster and Kinship Care above usual care in reducing children's behavior problems, reducing caregiver stress, increasing caregiver confidence, and supporting placement stability for young people ages 2–8 in foster and kinship homes.

Methods: participants, interventions, and outcomes

Study setting {9}

Participant recruitment for Caregivers on Point will occur at the Cincinnati Children's Hospital Medical Center's Comprehensive Health Evaluations for Cincinnati's Kids (CHECK) Foster Care Center. The CHECK Center provides state-mandated healthcare visits to children newly entering foster and kinship care or experiencing a placement change for the region surrounding the medical center. Per state requirements, healthcare visits must occur within five business days of a new placement, ensuring that eligible families in the region will be invited to enroll in this study within one week of a new placement. The CHECK Center operates at two locations approximately 30 travel minutes apart. One clinic is in an urban neighborhood with a nearby highway, a bus line, and adequate parking for patients and families. The second is in a suburban business region. Research study staff are physically on-site at both locations during usual clinic operating hours (Monday–Friday, 8 am–5 pm) to meet with families as they arrive for their healthcare visit and introduce the study.

Caregivers on Point recruitment will take place in cycles, and each recruitment cycle will span 6 to 8 weeks. Depending on clinic volume, it is anticipated that 20 to 30 participants (10–15 per condition) will be enrolled during each cycle. After enrolment, a baseline assessment will be conducted, including surveys completed by the caregiver and a behavioral observation of the caregiver-youth dyad. Surveys will be administered via a secure web-based platform. behavioral observations will occur in the caregiver's home and be recorded by research staff using Microsoft Teams. Caregivers facing technology barriers will receive a data-enabled tablet to complete behavioral observations and the CPP-FC when necessary. Following completion of the baseline assessment surveys, caregivers will be randomized to receive either the CPP-FC ($n=150$) or usual care ($n=150$).

Treatment

The CPP-FC is delivered synchronously via 12 2-h sessions in a group format delivered online by two trained group leaders over 15 weeks (11 concurrent weeks, one 1-month booster). Participants receiving the CPP-FC will complete weekly assessments and practice assignments. Surveys and practice assignments will be completed on an electronic device using REDCap. In the event a caregiver expresses that electronic submission is a barrier, alternative strategies to submit practice assignments will be coordinated, such as secure e-mail or paper submissions. At the mid-point assessment, a subset of caregivers assigned to the CPP-FC treatment arm will be asked to participate in a qualitative interview assessing their experiences with the CPP-FC. Caregivers who attended at least one CPP-FC session will be asked to participate in the interview. The interview will be video recorded and later transcribed for analysis.

Usual care

Participants in the control condition will receive usual care, which does not include specialized training. Surveys will assess whether caregivers complete other community-based training or interventions to support the children in their care.

Regardless of random assignment, caregivers will complete a mid-point and 6-month follow-up assessment. Assessments will be conducted remotely using a web-based platform, REDCap, for survey completion and Microsoft Teams for behavioral observations. The mid-point assessment consists of surveys completed by the caregiver and a caregiver-youth behavioral observation. The 6-month follow-up assessment consists of surveys. Completion of baseline, mid-point, and 6-month follow-up assessment measures are estimated to take approximately 30–40 min. At each assessment timepoint and 12 months post-enrolment, data will be collected from child welfare administrative and electronic health records.

Eligibility criteria {10}

Adult caregivers

Inclusion criteria for adult caregivers participating in this study include (a) being a licensed foster or kinship caregiver, (b) being in good standing with the foster care network or public children's services agency, (c) English-speaking (adapted intervention materials are currently only available in English), and (d) having a child who is eligible for study inclusion.

Exclusion criteria include (a) the potentially eligible child being placed in the home more than 45 days before enrolment or being moved out of the placement prior to the start of the intervention, (b) the potentially eligible child having previously been enrolled with another caregiver, (c) the caregiver having previously been enrolled with another child, and (d) the caregiver is unable to commit to completing all study activities. Caregivers who meet initial enrolment criteria and subsequently become ineligible before the initiation of the intervention period will be eligible for re-enrolment with a new eligible child.

Children

Eligibility criteria for children participating in this study include (a) being in foster or kinship care between the ages of 2 and 8, inclusive, and (b) being in the custody of a children's services agency that has agreed to have children in their custody participate in the study.

Exclusion criteria include (a) having previously been enrolled with another caregiver who met intent to treat criteria, (b) being placed with a caregiver who is ineligible for enrolment, (c) being placed with a caregiver who cannot commit to completing all study activities, and (d) receiving a request from a guardian ad litem, court-appointed special advocate, or caseworker that the child not participate. Ineligible children who become eligible for enrolment with a new caregiver will be re-assessed for eligibility.

Who will take informed consent? {26a}

Adult caregivers

Informed consent will be conducted by a clinical research coordinator (CRC) trained in the International Conference on Harmonization-Good Clinical Practice and human subjects research. Caregivers will provide written informed consent either electronically using REDCap or via paper-and-pen. During the consent form review with caregivers, adequate time will be allocated for the adult caregiver to review the study procedures. The CRC will solicit questions from the caregiver and assess their understanding of the research. The CRC will emphasize that (1) participation is voluntary, (2) the caregiver can change their mind and withdraw from the study at any time, and (3) refusal to participate in the study will in no way affect their involvement in and receipt of services from the medical center. Caregivers agreeing to participate will receive a copy of the fully executed consent form with signatures from both the caregiver and research staff.

Children

The county child welfare agency holding temporary or permanent custody of the child will provide consent for children's participation in foster or kinship care. Cincinnati Children's Hospital has established a memorandum of understanding (MOU) with the counties in the region, allowing for the inclusion of youth in foster care in minimal-risk research studies. Specifically, this MOU establishes that studies recruiting foster youth will first be reviewed and conditionally approved by the Cincinnati Children's Institutional Review Board (IRB). When conditional approval is granted, study materials are provided to the county child welfare agency for review and approval. A committee of caseworkers, the director of child protective services, and the prosecutor's office review study materials and determine approval. Once approval is documented, the study is approved by the Cincinnati Children's IRB, with consent provided by the county child welfare agency.

Once a caregiver has consented to participation, research staff will notify professionals associated with the child's case (i.e., the caseworker, guardian ad litem, and court-appointed special advocate) of the study and the caregiver's intent to enroll as well as the county's approval of the study and provision of consent for child participation. Those individuals will be provided with instructions for opting the child out of participation. If a request to opt out is received after study procedures have been initiated, the child and caregiver will be unenrolled, and no additional data will be collected from that caregiver or child. Caregivers who are unenrolled due to an opt-out request will be eligible for re-enrolment with a different placement. Due to the age of children being enrolled (2–8 years old), assent from children will not be collected.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

No additional provision for participant data use, or biological specimen collection was included in the consent procedures.

Interventions

Explanation for the choice of comparators {6b}

Per usual care, participants assigned to the usual care (comparator) condition will receive services from the county, CHECK Center, and community agencies. Caregivers receive training and support from their county and/or licensing agency. When behaviors emerge, the caseworker refers children to community services, and support from behavioral health specialists is available when caregivers request it.

This study follows the pragmatic model for comparator selection in health-related behavioral trials recommended by an NIH-convened expert panel [32]. The panel identified that the question about whether an

intervention (in our case, the CPP-FC) works better than a clinically relevant alternative (in our case, community-based foster and kinship caregiver training) is best answered when treatment as usual or standard of care is used in the comparison sample. Importantly, and as highlighted by others [33], the aims of this clinical trial are pragmatic rather than explanatory. The objective is not to isolate the components of the CPP-FC that make it a more effective intervention. Instead, because this is the first study of the CPP-FC, the logical first step is to demonstrate a difference in the CPP-FC compared to the broader population of foster and kinship caregivers who receive usual foster and kinship care training. Caregivers in the region where the study occurs must complete 20 h of ongoing training per year to maintain licensure. The CPP-FC fulfills that training requirement. Caregivers in the usual care condition can choose from any community-offered training program to meet their 20-h training requirements. The use of a usual care comparator allows us to evaluate the CPP-FC versus the training caregivers typically receive from the county and/or licensing agency.

Consistent with best-practice guidance [34], details will be gathered about the content, timing, and context of training received by caregivers in the control condition while they are enrolled in the study so that we can monitor and clearly describe the treatment as usual for this sample and any variability across caregivers that occurs.

Intervention description {11a}

The CPP-FC is a caregiver-directed prevention program to strengthen parenting skills and confidence in foster and kinship caregivers and prevent or reduce behavior problems in children 2–8 years old. The CPP-FC uses the CPP [35], including its logic model and format of group leader training, discussion questions, vignettes, role plays, and practice assignments. The CPP-FC was tailored to specifically meet the unique needs of children ages 2–8 who are placed with foster and kinship caregivers. The intervention consists of 12 2-h sessions delivered online by two trained group leaders over 15 weeks (11 concurrent weeks, one 1-month booster) in a group-based format. Foster and kinship caregivers of young children are systematically taught parenting skills using group discussions, videotaped vignettes of real families, structured role plays, and weekly practice assignments. Sessions focus on building positive relationships with children (e.g., child-centered time, family routines and traditions, praise and encouragement), child behavior management skills (e.g., setting clear expectations, following through with consequences, effective discipline strategies), stress management, and problem-solving skills. Participants assigned to the CPP-FC will receive 24 h of training in addition to the services typically offered by the county, CHECK Center, and community agencies.

We expect that some caregivers will not complete all sessions. Each weekly group session is offered on two different days and times during the week, and caregivers can choose to attend the session that best fits their schedule each week. Caregivers unable to participate in either online group session will be offered access to a video recording of the session and a one-on-one make-up session with the group leader to recap the material covered. The research record will document participants' utilization of the video recording and engagement in the one-on-one sessions.

Criteria for discontinuing or modifying allocated interventions {11b}

At the time of initial consent, adult caregivers will be informed of their right to withdraw from this study at any time and of the procedures for doing so. When a participant withdraws prior to completing the study, the research staff will make reasonable attempts to obtain a reason for withdrawal, and this will be documented in the participant research record. Unless requested in writing, the participant data collected up until the point of withdrawal will be retained.

Caregivers who withdraw prior to the initiation of the intervention will be eligible for re-enrolment with a new child who meets enrollment criteria. A caregiver's withdrawal from the study will result in the child's withdrawal. If youth are withdrawn because of a caregiver withdrawal prior to the initiation of the intervention period, that child will be eligible for re-enrolment if they are placed with a new caregiver.

Any randomized caregiver who expresses the inability to complete study activities, is lost to follow-up prior to the initiation of the intervention period, or is lost to follow-up prior to completing the baseline behavioral observation will be unenrolled. Caregivers who are unenrolled prior to week one of the intervention period will be eligible for re-enrolment with a new placement. A caregiver's unenrollment from the study will result in the unenrollment of the child. If youth are unenrolled as a result of caregiver unenrollment prior to initiation of the intervention period, that child will be eligible for re-enrolment if they are placed with a new caregiver. All incidents of unenrollment will be documented, and the reason for unenrollment will be detailed. Data collected up to the point of unenrollment will not be used in the final analysis.

Intervention allocation cannot be manipulated or changed during the study period. No enrolled participant in the treatment arm can be reassigned to the control

condition, and no enrolled participant in the control arm can be reassigned to the treatment arm.

Strategies to improve adherence to interventions {11c}

Fidelity to the CPP-FC program components and group leader competency will be assessed by independent raters using Fidelity Checklists [36] developed for the CPP and adapted for the CPP-FC. All intervention sessions will be audio and video recorded. Trained independent fidelity raters will review a random selection of 20% of audio recordings. Group leaders will receive written detailed feedback and numeric ratings addressing fidelity to the program components. Remedial training for group leaders will be provided if fidelity drops below 80%. These activities will ensure that the intervention is delivered consistently.

Caregiver adherence to the intervention will be monitored throughout the study. The research staff will proactively send email and text reminders about upcoming CPP-FC sessions. Meal delivery on the day of the first session, study-branded materials, and other caregiver and child comfort and play items will be provided to encourage participation in the intervention and promote adherence. The CPP-FC sessions will be offered at two different times and days of the week, with flexibility so that caregivers with schedule conflicts can choose to attend the session each week that is most convenient for them. An incentive for attending CPP-FC sessions will be offered to promote participation further. If caregivers miss a session, group leaders are trained to reach out to the participant to communicate our desire to have them continue attending sessions and provide access to the material (via recorded sessions) they have missed. Group leaders are also available to discuss material with caregivers.

To promote adherence to the core principles taught in the CPP-FC, caregivers are assigned weekly practice assignments that include checklists of activities to encourage using the skills taught in each session with the children in their homes over the week between sessions. Caregivers will receive reminder texts and emails to complete practice activities, and practice assignments are collected at the start of each weekly CPP-FC session and reviewed by the group leaders. Incentives will be offered for completed practice assignments to promote adherence to that component of the program.

We recognize that some caregivers assigned to the treatment condition may have scheduling difficulties that prevent them from participating in the CPP-FC. Prior to the initiation of the intervention, caregivers expressing an inability to attend intervention sessions scheduled within their recruitment cycle will be offered the subsequent recruitment cycle intervention schedule, where classes are offered on different days and times. Caregivers expressing inability to attend either cycle's intervention schedule will be unenrolled from the study.

Relevant concomitant care permitted or prohibited during the trial {11d}

There are no restrictions on care interventions accessed by participants enrolled in the trial. Additional care received by study participants will be captured as part of assessments at the mid-point and the end of the study.

Provisions for post-trial care {30}

This is a minimal-risk intervention, and no post-trial care or harm-reduction intervention is required.

Outcomes {12}

The primary outcome is child behavior, assessed using the Strengths and Difficulties Questionnaire [37] 6 months after enrolment (end of study) and the Dyadic Parent–Child Interaction Coding System (DPICS) [38] assessed 4 months after enrolment (midpoint).

The secondary outcomes are (a) caregiver stress at end of study (6 months) as measured by the Perceived Stress Scale [39] and Parental Stress Scale [40], (b) caregiver confidence at end of study (6 months) as measured by the Child Adjustment and Parent Efficacy Scale and the Parenting Sense of Competence Scale [41], (c) parenting behaviors at midpoint (4 months) as measured by the Parenting Behaviours and Dimensions Questionnaire [42] and the DPICS [38], and (d) placement stability at 12 months as measured by placement duration (up to 12 months).

Analyses of child behavior outcomes will examine change from baseline to mid-point and end-of-study assessments. For continuous variables (e.g., from The Strengths and Difficulties Questionnaire), mean differences in the treatment and control arms will be compared, controlling for baseline. For behavioral observations (count outcome), a change in the count of observed positive and negative behaviors from baseline to mid-point assessment will be examined, testing for group differences in counts.

Analyses of caregiver outcomes will examine changes from baseline to mid-point and end-of-study assessments. For continuous variables (e.g., from the Perceived Stress Scale, Parental Stress Scale, Child Adjustment and Parental Efficacy Scale), mean differences in the treatment and control arms will be compared, controlling for baseline. For behavioral observations (count outcome from DPICS), a change in the count of observed positive and negative behaviors

from baseline to mid-point assessment will be examined, testing for group differences in counts.

Analyses of placement change outcomes will examine the duration of placement (in weeks) for those in the treatment vs. control condition over the 12 months following enrolment in the study as well as the proportion of dyads in each condition that experience a placement change. Follow-up analyses will examine the proportion of placement changes in each arm due to child behavior problems vs. for other reasons (e.g., reunification with parents, adoption by caregivers).

All analyses will assume intent-to-treat and will be conducted in Stata version 18 with robust maximum likelihood estimation.

The study will also evaluate participant engagement and acceptability of the CPP-FC. Participant engagement will be assessed using attendance rates, completion of weekly practice assignments, and evaluation of the group experience using the Group Environment Scale [43]. The acceptability of the intervention will be measured through weekly satisfaction surveys. In addition, group leaders will provide ratings adapted from the CPP to assess caregiver engagement in each group session, and an independent fidelity coder will rate the level of caregiver engagement overall using similar items from the CPP [36].

Participant timeline {13}

Table 1 details a schedule of events. Eligibility screening and enrolment will occur within three days of a CHECK

Table 1 Participant timeline and order of trial events

Timepoint	Study period					
	Enrolment	Allocation	Post allocation		Close out	
	$-t_1$ (baseline) −8 to 0 weeks[a]	0	t_1–t_{12} (intervention) 1–16 weeks	t_{13} (midpoint) 17 weeks	t_{14} (end of study) 26 weeks	t_{15} 52 weeks
Enrolment						
Eligibility screen	X					
Recruitment	X					
Informed consent	X					
Allocation		X				
Intervention session scheduling (CPP-FC only)		X				
Intervention						
CPP-FC			X			
Usual care			X			
Assessments—CPP-FC and usual care						
Demographics	X					
Child Adjustment and Parent Efficacy Scale	X			X	X	
The Parenting Behaviours and Dimensions Questionnaire	X			X	X	
Strengths and Difficulties Questionnaire	X			X	X	
Parenting Sense of Competence Scale	X			X	X	
Parental Stress Scale	X			X	X	
Perceived Stress Scale	X			X	X	
Caregiver-child observation	X			X		
Child health and administrative record review (EHR and placement changes)	X			X	X	X
Intervention assessments—CPP-FC only						
Weekly Satisfaction Questionnaire			X			
Practice assignments			X			
Photos of outside of session implementation			X			
End of program satisfaction evaluation			X			
Group Environment Scale			X			
Qualitative interview				X		

[a] Up to 8 weeks between consent and start of intervention to allow a cohort of participant recruitment for group sessions

Center visit. Following enrolment, the baseline assessment will occur within 8 weeks of enrolment and prior to treatment initiation. The mid-point assessment will occur after delivery of the last CPP-FC session (session 12) for treatment and control conditions, which will be within 26 weeks of enrolment. The end-of-study assessment will occur approximately 7–11 weeks following the mid-point assessment and within 35 weeks of enrolment.

Sample size {14}

Previous research on the CPP found moderate effect size differences between treatment and control groups on reductions in child behavior outcomes, the primary outcome of this study, ranging between $d = -0.43$ and -0.46 [25]. A power analysis conducted via Monte Carlo simulation in Mplus 8.5 with $N = 5000$ replications indicated ≥ 80% power to detect the smallest group difference observed in previous research ($d = -0.43$) at our mid-point assessment with a total sample size of $N = 300$ ($n = 150$ per group) assuming 20% attrition at the mid-point assessment.

Recruitment {15}

The CHECK Foster Care Center provides care for over 1050 children under the age of 9 annually; approximately 400 of these are for children who would be eligible for this study or approximately eight children per week. On average, children in our region remain stable in placement for 9 months, with lengths of time in foster care lasting 12 months on average. Our goal will be to recruit four families weekly (2 in CPP-FC, 2 in usual care) over 30 months.

Research staff will review upcoming CHECK Center schedules daily and conduct an electronic medical record review to evaluate inclusion and exclusion criteria for caregivers and children on the schedule. Each caregiver-youth dyad screened will be assigned a unique screening identification number. Potentially eligible caregivers will be recruited from the CHECK Foster Care Center at CCHMC during their child's mandated healthcare examinations. 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 recruit and retain families in research studies. Clinical research staff trained in human subjects' research and experienced with recruiting foster and kinship caregivers will approach caregivers in the waiting room, where the study procedures will be described. Research staff will conduct a fully informed consent procedure for caregivers interested in participating. Caregivers will be asked to complete baseline survey assessments electronically using REDCap. An electronic device will be provided to the caregiver, or a link will be sent to the caregiver's device to complete the baseline survey assessment at the clinic, based on caregiver preference. If the caregiver requests additional time or if a fully informed consent procedure is not feasible during the visit, research staff will arrange a time to contact the caregiver by phone or Microsoft Teams to complete informed consent. Caregivers will be provided with a study flyer containing brief details on the study and contact information for the research staff should they have questions. Caregivers' contact information, including telephone number and email address, and their most preferred method of contact (text, phone call, email) will be obtained. Caregivers will be sent a reminder email, phone call, and text message ahead of the scheduled appointment. Caregivers from the same household as enrolled participants who are assigned to the CPP-FC treatment condition will be invited to join sessions with the enrolled participant but will not be enrolled nor complete study-related surveys.

Upon caregiver enrolment, the child eligible for participation will also be enrolled. On the day of enrolment, the CRC will initiate an email notifying the child's caseworker, guardian ad litem, and court-appointed special advocate about the child's participation in the study, with instructions for how those personnel can notify the study team to request that the child be unenrolled.

Assignment of interventions: allocation

Sequence generation {16a}

Block sequential randomizations will be generated using the "blockrand" [44] function in R [45] by clinic day and stratified by clinic location, such that all caregivers presenting to a clinic on a specific day will be randomized to the same intervention group. A block randomization strategy will be applied over a predefined 6 to 8-week recruitment period, such that an equal number of days will be assigned to treatment or control conditions at each site during the 6- to 8-week recruitment period based on clinic operation schedule. The statistician will conduct randomization before the recruitment cycles begin. In the event of a clinic closure, the randomization sequences will not be modified. To minimize bias, study personnel designated to recruit participants will not be made aware of the random assignment until the day of their scheduled shift. The REDCap Randomization database will generate an email alert notification to all actively recruiting coordinators. The statistician will be responsible for generating sequences, and the program manager will be responsible for uploading randomization sequences in REDCap. Randomization sequences will not be available to other study team members.

Concealment mechanism {16b}

The study statistician and senior study manager will maintain the randomization schedule. The investigators, clinical care scheduling and delivery teams, and study coordinators will be blinded to the randomization schedule.

Each morning, the study coordinator assigned to recruitment in the clinic for that day will receive an email initiated by REDCap notifying them of the condition assignment for participants recruited at that site for that day. Study coordinators are trained not to disclose treatment assignments to enrolled caregivers until baseline assessments are completed.

Caregivers will be blinded to assignment when their visits are scheduled at the CHECK Center, at the time of enrolment, and until baseline assessment completion. When caregivers complete baseline assessments in the clinic, the study coordinator will confirm baseline study completion and reveal treatment assignment, along with confirmation of times for the CPP-FC sessions when the participant is assigned to the treatment arm. This will allow study coordinators to work with caregivers in the treatment arm if scheduling conflicts prevent them from participating in one or more CPP-FC training sessions and unenroll the participants if scheduling conflicts cannot be resolved.

For caregivers who do not complete baseline assessments in the clinic, the caregiver will remain blinded to assignment until the assessments are complete. At the time of completion, a study coordinator will call the study participant to reveal the assignment and confirm any scheduling conflicts as needed. After baseline assessments are complete, all caregivers will also receive confirmation regarding treatment assignments via email, phone call, and text message.

Behavioral assessments will be coded by independent coders trained and reliable in the use of DPICS. They will be blinded to both treatment conditions and to whether the observation occurs at baseline or at the midpoint assessment.

Implementation {16c}

The study statistician and senior study manager will maintain the randomization schedule. The study coordinators responsible for participant enrolment will not be involved in creating the allocation sequence or assigning participants to intervention. Participant assignments will occur at random based on clinic location and day, and clinic scheduling will occur without awareness or insight into the allocation schedule.

Assignment of interventions: blinding

Who will be blinded {17a}

To protect against bias, the principal investigator, co-investigators, clinical research coordinators, clinical staff, and study participants are blinded to the allocation schedule. The PI, Co-Is, and clinical staff will remain blinded throughout the enrolment process, and trial participants will remain blinded until baseline assessments are complete. The PI, Co-Is, and clinical staff will remain blinded after trial participants are made aware of the treatment assignment. The trained coders for behavioral observations will also remain blinded to treatment condition throughout the study. Study staff interacting with study participants will be aware of the treatment arm to facilitate their retention and adherence to the intervention. All REDCap data fields, including those reflecting condition assignment, will be restricted to prevent study staff from editing or manipulating values once the study participant or behavioral observation coder enters them. The statistician completing data analysis will receive de-identified data containing a variable indicating treatment assignment but will not have access to identifying information revealing the identities of enrolled participants in either the treatment or control conditions.

Procedure for unblinding if needed {17b}

There are two instances where unblinding is permitted with Caregivers on Point. In both instances, only selected co-investigators can be unblinded to ensure the integrity of the study is maintained. Of note, the PI and statistician will remain blinded to the specific assignment of any specific caregiver at all times. The selected co-investigators designated to be unblinded when necessary will not have access to REDCap or the randomization procedures and will, therefore, not have the opportunity to manipulate treatment assignment or data collected for the study.

Instance 1: Concern about potential conflict of roles for participants randomized to the CPP-FC

Foster and kinship caregivers enrolled in Caregivers on Point and assigned to receive the CPP-FC may have existing personal or professional relationships with other caregivers enrolled and assigned to receive the CPP-FC. This is unavoidable. While some of those existing relationships will not be known to the group leaders prior to the initiation of groups, others may be identified at the time of assignment or throughout data collection and leading up to the first session. For example, a clinician who is also a foster or kinship caregiver may be enrolled in the study and be assigned to the CPP-FC with the caregivers of one of their patients, or a caseworker who is also a foster or kinship caregiver may be enrolled in the study and assigned to the CPP-FC with the caregivers of a child on their caseload.

When a potential conflict of roles is identified, the study staff working with the caregiver who has the potential role conflict will contact a designated Co-I

with expertise in medical ethics and a history of managing similar role conflicts in clinical settings to discuss the conflict and strategies to minimize the potential for the conflict to negatively impact the experience of that caregiver or other caregivers with the intervention (the CPP-FC).

Instance 2: Concern about mental or behavioral health for participants in caregivers on point

When a concern about mental or behavioral health for a caregiver or the child in a caregiver's home emerges, the study staff working with the caregiver will notify a Co-I with training as a clinical psychologist about that concern, who can work with the study staff to determine the level of support needed and provide additional action steps as necessary. Action steps recommended by the Co-I will align with the resources outlined in the Human Subjects Protection plan for the study. They may include referring the caregiver to clinical services if mental or behavioral concerns are related to the child in the home or referral to adult community-based mental health providers if concerns are related to the caregiver.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Caregivers and youth will participate in three direct contact assessments to establish a change in outcomes at the end of the intervention and the end of the study. The baseline assessment will occur within 8 weeks of enrolment and prior to CPP-FC session 1. The mid-point assessment will occur immediately following the delivery of the last CPP-FC session (session 12). The 6-month follow-up will occur approximately 7–11 weeks following the mid-point assessment. Caregiver-report measures will be completed by caregivers using REDCap. We estimate that caregivers will need 30–40 min to complete baseline, mid-point, and 6-month follow-up assessment surveys. Caregivers will be offered the choice of completing survey measures at the CHECK Center or home through a web-based option and both methods will utilize REDCap. To promote data quality, survey data is supplemented by a behavioral observation conducted at baseline and mid-point (4 months after baseline, corresponding to end of intervention). The caregiver-child behavioral observation will utilize Microsoft Teams or, if preferred by the caregiver, will be conducted in the clinic, whichever is most convenient.

Group leaders trained in the CPP and CPP-FC will be used for intervention delivery, and one certified group leader must be present at all intervention sessions. Caregivers randomized to CPP-FC will be asked to complete surveys following each session to assess satisfaction with the session, relevance of the material, and the group environment. They will also be asked to complete weekly practice assignments. Surveys and practice assignments will be completed on an electronic device using REDCap. In the event a caregiver expresses that electronic submission is a barrier, alternative strategies to submit practice assignments, such as secure e-mail or paper submissions, will be coordinated. Attendance data will also be retained and used as another indicator of engagement. Finally, fidelity coding of CPP-FC sessions will occur for a random 10% of intervention sessions to ensure that there is consistency in content delivered to caregivers.

At the mid-point assessment, a subset of caregivers assigned to the CPP-FC treatment arm will be asked to participate in a qualitative interview assessing their experiences with the CPP-FC. Caregivers who attended at least one CPP-FC session will be asked to participate in the interview, which will be conducted via Microsoft Teams. The interview will be video recorded and later transcribed for analysis. Electronic video recordings will be stored behind multiple electronic barriers on a protected CCHMC network drive that can only be accessed by authorized personnel. The estimated time to complete the interview is 45–60 min. 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. We anticipate most interviews will not run longer than 60 min; however, if an interview exceeds a 60-min duration, an additional qualitative interview session will be conducted. Verbal consent will be obtained at the start of the follow-up interview session.

Child behavior, the primary outcome, is measured using the Strengths and Difficulties Questionnaire [37] assessed at baseline, midpoint, and end of study to allow for an estimation of change in child behavior in the intervention vs. control group. The Strengths and Difficulties Questionnaire is a 25-item questionnaire. Items are rated on a 3-point scale and responses range from 0 ("Not true") to 2 ("Certainly true"). Items are summed to yield a total score and 5 subscales: Emotional Problems, Conduct Problems, Hyperactivity, Peer Problems, and Prosocial. Higher scores in each subscale and the total score indicate more child behavior problems. Internal consistency for the parent report measure is acceptable, with Cronbach's $\alpha = 0.76$ for the total score and a range between 0.49 and 0.69 for subscales in a recent meta-analysis [46]. To provide additional, objective ratings of child behavior changes, the Dyadic Parent–Child Interaction Coding System (DPICS) [38] observational coding scheme, measured at baseline and midpoint, is also being used. While caregivers are blinded to treatment assignment, a study coordinator trained and supervised by a

certified trainer in DPICS is completing the behavioral observation task with families, which includes 5 min of play time between the caregiver and target child enrolled in the study, followed by 5 min of observation after the caregiver asks the child to clean up from their play time together. The same tasks are observed at the mid-point. Observations are recorded and transcribed. A separate, independent group of coders blinded to treatment assignment who are also supervised by a certified trainer in DPICS is reviewing the recorded sessions to code for compliance behaviors, noncompliance behaviors, negative talk, whining, or yelling from the child. DPICS has high convergence with caregiver report of children's behaviors ($r = -0.31$, $p < 0.01$ for child compliance scores on DPICS and parent-reported behavior problems) [47].

Two data sources are used for indicators of each of the caregiver-reported secondary outcomes for this study to increase rigor. Those are (a) the Perceived Stress Scale [39] (14 items assessing stressful life circumstances on a 5-point scale from 0 ("Never") to 4 ("very often"), where a higher total score indicates more stress; Cronbach's $\alpha = 0.85$) and Parental Stress Scale [40] (18 items rated on a 5-point scale, where higher scores indicate higher parental stress; Cronbach's $\alpha = 0.84$), (b) the Child Adjustment and Parent Efficacy Scale (19 items with responses on a 10-point scale from 1 ("Certain I can't do it") to 10 ("Certain I can do it"), where higher scores for the sum across items indicates higher self-efficacy; Cronbach's $\alpha = 0.90$) and the Parenting Sense of Competence Scale [41] (17 items on a 6-point scale from 1 ("Strongly disagree") to 6 ("Strongly agree") such that higher scores indicate higher levels parental self-efficacy; Cronbach's $\alpha = 0.75$), and (c) the Parenting Behaviours and Dimensions Questionnaire [42] (33 items that measure emotional and disciplinary aspects of parenting using a 6-point scale from 1 ("Never") to 6 ("Always"), where higher scores indicate higher functioning; Cronbach's $\alpha = 0.83$ for emotional warmth, 0.66 for anxious intrusiveness) and parenting behaviors (e.g., labeled and unlabeled praise, direct and indirect commands) coded consistent with the instructions above using the DPICS [38].

Finally, an objective assessment of placement stability at 12 months is being collected from the child welfare record, to determine if the intervention aids in keeping children with caregivers for longer periods of time prior to reunification or adoption.

Plans to promote participant retention and complete follow-up {18b}

Due to the age range of youth enrolled, retention efforts are targeted at caregivers. Group leaders will use the existing strategies developed by the CPP (e.g., emailed calendar appointments for each session, reminder phone calls, texts, and emails) to promote participation in the CPP-FC. Attendance will be taken at each session to monitor caregiver engagement in the CPP-FC. Additionally, all licensed caregivers are eligible to receive $10 per hour in compensation for completing training through the agency licensing them as foster caregivers; completion certificates for each session will be provided for each caregiver in attendance to support caregivers in receiving those benefits. Weekly practice assignments and survey data collection addressing satisfaction with materials will be administered immediately following the session to ensure complete data collection. Additionally, caregivers will provide their contact information and two additional people we could contact to connect with them and support the delivery of retention strategies.

All participants will be emailed a link to complete data collection (or mailed surveys if technology access is limited). Follow-up emails, text messages, and phone calls will occur to remind participants to complete surveys. Participants will receive study-branded t-shirts and other materials to assist with retention throughout the 6 months they are enrolled. A quarterly study-branded newsletter will also be mailed to participants with information about community resources, encouraging stories, content appropriate for caregivers of children ages 2–8 (e.g., tips on safe sleep, picky eating, and environmental safety), and information for contacting study staff. Caregivers and youth will receive holiday and birthday cards from the study team and a personalized thank you card after each study visit. Caregivers will also provide consent for us to maintain contact with or relocate caregivers who are lost to follow-up. We will also use the shared healthcare and child protective services database to maintain up-to-date contact information for caregivers enrolled in the study.

Caregivers who are identified as having technology barriers to participation in either the behavioral observation or the intervention will receive materials on loan from the study team to support their continued participation in the study, including portable hot spots to support access to the Internet, portable devices to support Teams access (tablets), a webcam, and headphones with a microphone if needed. Caregivers can self-identify that they need access to these materials, or the study team will provide materials if observations indicate materials will be useful. To ensure the return of materials when study activities requiring technology access are complete, caregivers will receive bonus payments ($50) for the return of hot spots, tablets, and webcams. Additional retention bonus payments ($10) will be used to incentivize scheduling study visits or session attendance for difficult-to-schedule households.

Data management {19}

This minimal risk randomized control trial involves the administration of a behavioral intervention known to be effective and without risk for other populations of caregivers and children and therefore poses minimal risk to participants. The study team will follow data management practices, including using REDCap for secure data storage, that adheres to the protocol approved by the institutional review board at Cincinnati Children's Hospital Medical Center (CCHMC) in compliance with existing regulations and policies for the conduct of minimal risk research.

Confidentiality {27}

We will use the following procedures to protect the confidentiality of research data. Study data will be collected and managed using the REDCap data management system. The REDCap system is a secure, web-based application designed specifically around HIPAA-Security guidelines with built-in features to address confidentiality and compliance requirements. REDCap can only be accessed by authorized personnel. Users are given individual user IDs and passwords, and their access is restricted on a role-specific basis. Participants will be assigned a unique study identifier to be used in REDCap, on paper forms and electronic files. A master key linking identifying participant information and study ID will be maintained in REDCap. REDCap supports advanced de-identification options that will be deployed when exporting data. Data export permissions will be restricted to the principal investigator and data managers. Electronic files, videos, audio recordings, and paper records will be stored behind multiple electronic and physical barriers that can only be accessed by authorized personnel.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

No biological specimens are being collected or stored for future use as part of this study.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Quantitative analysis

Descriptive statistics will be computed for each variable. The comparability of the CPP-FC and usual care groups on baseline demographic and clinical variables will be assessed using chi-square tests for categorical variables and *t*-tests for continuous variables. All analyses will assume intent-to-treat and will be conducted in Stata version 18 [48] with robust maximum likelihood estimation.

Our primary hypothesis examines group differences (CPP-FC versus usual care) in caregiver stress and confidence in managing child behavior at the mid-point and end of the study (i.e., our primary endpoints). Regression-based analysis of covariance (ANCOVA) models (one for each outcome) will be used to test the primary hypothesis that the CCP-FC group will demonstrate significantly lower caregiver stress scores and significantly higher confidence in managing child behavior compared to the usual care group after controlling for baseline scores and current placement length of stay. The statistical precision of the effects will be presented as 95% confidence intervals. Standard errors will be adjusted to account for clustering within treatment group cohorts. Additional demographic or clinical covariates may be added to this model should we observe group differences at baseline on these variables or these variables are associated with missing data on the outcomes. Overall group trajectories across all time points will also be compared using longitudinal mixed effects models with an unstructured covariance matrix. A significant group-by-time interaction would indicate that the trajectory of the outcomes differed by intervention group (CPP-FC versus usual care).

To explore the effects of caregiver gender, age, race, kinship/licensed caregiver status, demographic concordance with foster children placed in the home, and household composition, we will conduct subgroup analyses to determine whether the response to treatment varied by any of these demographic characteristics by including a group X covariate interaction in the ANCOVA models described above.

The same analytical approach will be used to evaluate group differences in caregiver-reported aggression and compliance at the mid-point and end of study assessments and the overall longitudinal trajectories with continuous outcome measures reported by caregivers. Additionally, given that the data collected from the behavior observations are counts, we will conduct a negative binomial regression analysis of number of behaviors observed at the mid-point assessment as the outcome and group (CPP-FC versus usual care) as our primary predictor. These models will covary for baseline observed number of behaviors. Additional demographic or clinical covariates may be added to this model should we observe group differences at baseline on these variables or these variables are associated with missing data on the outcomes.

Finally, placement change (1 = yes, 0 = no) will be the outcome in a logistic regression model. The primary predictor will be "group" (CPP-FC versus control), with child and caregiver age, race, and gender entered as covariates. Potential moderators of the effect of group on placement change will be assessed via interaction terms added to

this model (e.g., maltreatment status X group, number of previous placements X group). Due to the use of administrative data collection for this outcome, all outcome data for this analysis will be complete.

Qualitative analysis

Using a hybrid of inductive and deductive analyses [49–51], semi-structured interviews will be coded and analyzed. This process will be informed by Braun and Clarke's described multi-step process for thematic analysis [52]: familiarization with the data, generating initial codes, searching for themes, reviewing themes, and defining and naming themes. Qualitative analysis will include three phases: inductive coding, deductive mapping, and theme generation.

Inductive coding procedures will involve team members reading two interviews and sharing preliminary codes they see in the data. These preliminary codes will be organized into an official codebook, with the remaining interviews coded and reviewed by pairs of team members. These pairs will meet to discuss any code discrepancies. Discrepancies will be resolved through discussion and consensus agreement. The entire team will meet intermittently as transcripts are coded to ensure the team can address any conceptual issues that emerge during analysis. The codebook will be adjusted to accommodate new codes as needed.

Following this inductive process, the team will also apply a deductive mapping approach with the same interview transcripts to map caregiver descriptions of their experiences with the CPP-FC onto the logic model for the CPP [35]. This will allow us to examine how fully caregivers perceived the CPP-FC aligned with the CPP's intended goals. Members of the coding team will develop a codebook based on the CPP logic model to be used when coding transcripts. The team will explore and discuss these categories to capture what the interviews communicate about the CPP-FC adaptation of the CPP.

Analysis will conclude with a final theme generation, where codes are distilled into categories, and patterns within categories are identified to create themes. Each theme will be described and labeled using participant responses to reflect underlying meanings, including quotations to illustrate themes in the voices of the caregivers who participated.

Interim analyses {21b}

No interim analyses or stopping guidelines are planned for this study because treatment outcomes cannot be reasonably assessed prior to approximately 6 months following randomization.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Adjusted and subgroup analyses are planned, as detailed in other sections of this manuscript.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Participants will be analyzed as randomized in the primary aims assessment, and all participants randomized to a treatment group will be included in the analysis, regardless of their adherence to interventions. Sensitivity analyses will be conducted to determine whether participants who received less than the full "dose" of the intervention varied significantly from those who received the full intervention per protocol within each group on the primary outcomes, where the dose will be calculated as the number of intervention sessions attended. Should we observe a significant variation in intervention response due to dose, we will adjust for this dosing imbalance through direct covariate control.

Data that remain missing despite our retention efforts will be accommodated in our analyses via maximum likelihood estimation, and their impact will be evaluated through sensitivity analyses. The models we propose can be estimated without bias under the missing at random (MAR) assumption [53] and provide valid analysis as long as auxiliary covariates associated with missingness (if any) are included in the analysis model. To determine which covariates are associated with the missing data, we will create binary indicators of whether an observation was missing (=1) or not (=0) on each of the outcome variables at our primary endpoint. If a covariate is correlated with the missingness at $r > 0.4$ and relatively uncorrelated ($r < 0.2$) with the original response variable, it will be included in the analysis as an auxiliary correlate [54].

Plans to give access to the complete protocol, participant-level data, and statistical code {31c}

The full protocol will be available upon request to and approval by the PI, and access to participant-level data will be granted with approved data use and transfer agreements. All code used for data management, variable creation, and record selection will be archived with the final limited dataset, along with a complete study codebook that describes each variable in the dataset. Those documentation and metadata will be made available automatically for those who receive the dataset.

Analytic code and output will be archived with each set of analyses as papers are disseminated and made available upon request and through the publisher when possible.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

This study is being accomplished by an interdisciplinary team of 1 physician, 1 nurse scientist, 3 clinical psychologists, one of whom has experience as a clinical trialist, one developmental psychologist, one quantitative methodologist, one qualitative methodologist, three interventionists with training in social work ($n=2$) and early childhood education ($n=1$), one clinical supervisor, and one study coordinator. A team located at the study institution meets twice weekly to review study progress toward recruitment and retention goals. Those meetings involve the primary investigator, the clinical supervisor, and the interventionists and study coordinator involved in recruitment and intervention delivery. Interventionists and the study coordinator review clinical schedules daily to identify potentially eligible participants to recruit, and approach those individuals to confirm eligibility during their clinic visits. Eligible patients have the opportunity to consent to study participation and are provided with survey links to complete study activities. At that time, participants are assigned by their unique study identification number to the study coordinator (control) or interventionists (treatment) for follow-up. Performance of study staff toward successful completion of study activities is monitored by the clinical supervisor and the primary investigator, to ensure that there is no variation in retention between staff and that recruitment efforts are successful. The clinical supervisor also completes regular audits of the data to ensure quality and meets quarterly with the quantitative methodologist to confirm randomization tables for treatment assignment. This study has no trial steering committee or stakeholder and public involvement group.

Composition of the data monitoring committee, its role and reporting structure {21a}

This study has no data monitoring committee because the intervention is less than minimal risk.

Adverse event reporting and harms {22}

Given the nature of the study, we do not expect to have adverse events. However, we are prepared to handle these appropriately should they occur. Possible risks to study participants include psychological distress resulting from participating in the treatment group or completing survey measures, identification of child maltreatment, and loss of data or confidentiality. The study procedures are implemented by CRCs and the CPP-FC group leaders trained in human subjects research. The CRCs and group leaders will bring adverse events volunteered by participants or observed by group leaders or study staff to the attention of investigators. The PI will be notified immediately of an adverse event. Events will be blinded from the study condition and characterized as follows: *Severity*: Mild, Moderate, Severe, or Live threatening or disabling; *Relatedness*: Definite unrelated, possibly related, probably related, or definitely related; *Action:* None, Psychological support, medical intervention, Participation discontinued, Other; *Expectedness*: Expected or Unexpected; and *Outcome*: Resolved, recovered with minor sequelae, Recovered with major sequelae, Condition worsening, Patient Death. Separately, the patient's enrolment status as a result of the adverse event will be noted. All adverse events will be monitored by the PI and co-investigators weekly and will be reported to the IRB consistent with CCHMC research policies. Any risks associated with trauma, acute psychiatric concerns, suicide, or potential for child maltreatment will be addressed by the study team, and when appropriate participants will receive assistance with identifying psychological counseling services appropriate for their symptoms.

Frequency and plans for auditing trial conduct {23}

The investigator team is responsible for auditing the trial. This will be accomplished through regular meetings with the study team, ongoing recruitment monitoring, data collection and retention activities, and semi-annual data audits. Unanticipated problems and protocol deviations that occur during the study will be documented and reported to the IRB consistent with CCHMC research policies. The PI and study staff will review all data on an ongoing basis for completeness and accuracy. Missing data will not be considered a protocol deviation.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

Protocol amendments will be submitted to the institutional IRB where the study occurs. When deemed necessary, changes will be emailed to the children's services directors of counties where recruitment occurs. When recommended by the institutional IRB, changes will be communicated to study participants via a reconsent process.

Dissemination plans {31a}

Consistent with open science practices and with the directive of clinicaltrials.gov to include a data sharing plan in submissions, we will have the following data sharing policy: we will share with other investigators (1) all individual participant data after deidentification and (2) study management documents (protocol, statistical

analysis plan, consent form, analytic code, data dictionary). Those requesting data will be required to submit a proposal to the PI. The investigative team will review this for methodological soundness and scientific merit. Proposals approved by the PI will be shared with the legal department at Cincinnati Children's Hospital Medical Center and prosecuting attorneys and directors of children's services at Hamilton, Butler, and Montgomery counties for approval. Once all parties approve, the outside investigator will establish a data use agreement before data is shared. This plan is consistent with guidelines developed by the International Committee of Medical Journal Editors [55] and established memoranda of understanding between Cincinnati Children's and children's services agencies for research involving children in foster and kinship care.

Discussion

Since the launch of the study in February 2024, we have had one practical issue and two operational issues involved in performing the study. The practical issue is that the intervention, which involves 12 sessions delivered over 16 weeks, spans major holidays and other events that can disrupt session attendance. To address this practical challenge, our study team has flexed the duration of recruitment so that stretches of time for longer holidays (e.g., December 24–January 1) occur during natural breaks in the CPP-FC sessions or groups start after the January 1 holiday. The operational issues we faced are (1) the senior coordinator resigned for another job opportunity and was replaced by another senior coordinator with similar expertise, and (2) in spite of randomization with balanced days of recruitment at our clinical sites for treatment and control conditions, we observed that 40% of participants were assigned to treatment and 60% were assigned to usual care for the first four cohorts. After the fifth cohort, randomization tables were updated and these patterns are being monitored with each cohort moving forward to address these concerns.

Trial status

Version 1 – 12/14/2023.

Recruitment began February 2, 2024, and should be completed by February 23, 2026.

Abbreviations

CPP	Chicago Parent Program
CPP-FC	Chicago Parent Program for Foster Care
CCHMC	Cincinnati Children's Hospital Medical Center
CHECK	Comprehensive Health Evaluations for Cincinnati's Kids Center
HCJFS	Hamilton County Job and Family Services
BCCS	Butler County Children Services
MCCS	Montgomery County Children Services

Acknowledgements

We thank Julie Dougherty, Ro Gigger, Nathan Lutz, Houley Sall, Katie Fox, and Kellie Jo Reynolds for their contributions to this study.

Authors' contributions {31b}

SJB is the primary investigator; she conceived the study and led the proposal and protocol development. CZ, MP, RTA, MVG, SMB, and AFB contributed to the study design and to the development of the proposal. CM is the lead trial methodologist. All authors read and approved the final manuscript.

Authors' information (optional)

The authors have no additional information to disclose.

Funding {4}

The Eunice Kennedy Shriver National Institute on Child Health and Human Development, National Institutes of Health, Award Number R01HD105727, funds this study. Study data were collected and managed using REDCap electronic data capture tools hosted at Cincinnati Children's Hospital Medical Center with support from NCATS (UL1TR001425). REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for data integration and interoperability with external sources.

Availability of data and materials {29}

SJB will maintain access to the final trial dataset, which will be provided upon request and approval of a data transfer agreement between Cincinnati Children's Hospital and the institution/individual requesting data access.

Declarations

Ethics approval and consent to participate {24}

The Institutional Review Board at Cincinnati Children's Hospital Medical Center has approved this study. Written, informed consent to participate will be obtained from all adult participants and the children's services agencies who hold custody of children represented in the data.

Consent for publication {32}

The investigators are willing to provide a model consent form used in this trial upon request. The materials included for this publication do not include images, videos, or likenesses of individuals, and therefore, no consent for publication is required.

Competing interests {28}

The authors declare that they have no competing interests.

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Received: 16 May 2024 Accepted: 1 October 2024
Published online: 10 October 2024

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