Cover Page

Study Protocol

Official title of the study: Intervention to Improve Outcomes for Foster Children Reunited with Their Birth Families

Brief title: Families Together: Intervention for Reunified Families

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Research Plan and Methodology

All procedures were reviewed and approved by the Washington State Institutional Review Board (WSIRB; study number D-110816-Y17.18). A Data Safety and Monitoring Board (DSMB), an external, independent oversight board, monitored the study's conduct to assess ongoing feasibility, data integrity, and safety. The research team selected DSMB members who had expertise and no conflicts of interest. The three participants had individual expertise in clinical trials/methods/research in child welfare systems [ME], clinical content area/collaborative research with parent support programs [LR], and clinical trials/methods/biostatistical issues [JR]. During the enrollment and intervention phases, meetings occurred annually. [The group agreed not to meet during 2020 and 2021 when the study temporarily stopped research activities due to COVID-19.]

Study Design

This study was a randomized controlled trial. The effects of the intervention were tested in a two-arm trial comparing Promoting First Relationships (PFR; Arm 1) with the Resource and Referral (R&R) control condition (Arm 2). Assessments were completed at Time 1 (baseline, before randomization), immediately after the intervention (Time 2), and 6-month follow-up (Time 3).

Recruitment and Study Procedures

Eligibility and recruitment. Between December 2017 and May 2023, the *Families Together* project enrolled parent-child dyads into the study. Parents were eligible if they had an open case in "Trial Return Home" status through a participating Department of Children, Youth, and Families (DCYF) office in the greater Seattle, Washington area; were age 18 or older; were conversant in English; had access to a telephone; had a minimum of temporary housing; and had not previously received PFR. At enrollment, children were between 1 and 5 years of age and recently reunified with a birth parent after a foster care placement.

Study recruitment was conducted in collaboration with the Washington State Department of Children, Youth, and Families (DCYF). A DCYF--study liaison received bi-monthly lists of potentially eligible families from a DCYF data manager. The liaison mailed opt-out recruitment letters to 1,082 potentially eligible families, briefly describing the study. A study recruiter attempted to contact the 882 families that did not opt out to explain the study and conduct additional screening. Of these families, 168 could not be reached, and 287 were determined ineligible. Of the eligible families (*N*=427), 264 were interested in the study. For each of these families, a DCYF social worker was contacted to obtain consent for the child to participate (100% of contacted social workers signed the consent form). A research visitor then scheduled to meet in the family's home to obtain written consent from the parent and conduct the first research visit. The enrolled dyad included one identified parent and one identified child in the family who were followed throughout the study. Enrolled parents agreed to randomization (PFR or R&R) and three in-home research visits (T1: baseline, T2: post-intervention, and T3: 6 months post-intervention). For families who did not complete the intervention, post-intervention and 6-month post-intervention assessments were scheduled based on the dates they would have completed the interventions if they had kept their appointments. The project compensated participants $75 after each research visit. The research visitor was not informed of the randomization group of enrolled families, and reminded the parent at each follow-up research visit not to share with them what group they were in.

Randomization. Randomization to condition occurred after the baseline interview. The project director initiated the computerized randomization program, based on the minimization method: parent-child dyads were stratified based on parent's race, parent's Hispanic ethnicity, child's age (1–2 years, 3–5 years), and geographic region, then subsequently randomized within strata into the PFR intervention or control condition. The algorithm conditioned the probability of assignment on prior allocations to

generate roughly balanced numbers in the intervention and control conditions, while avoiding predetermined assignments that could be anticipated by research staff.

COVID-19 impact. By February 2020, we had enrolled 168 families into the project. Due to stay-at-home orders related to the COVID-19 pandemic in the spring of 2020, the project received approval from the WSIRB and the funding agency to pause intervention and recruitment activities. Families who were in the intervention phase at the onset of the pandemic were dropped from the research study because stay-at-home orders prevented completion of the home-based intervention for those randomized to PFR (n=11; of those, 5 had not started PFR). To maintain balance, those randomized to the control group during that period were also dropped (n=13). Families who had completed the treatment phase and were due for follow-up assessments had research visits by telephone but were unable to complete the video-recorded activities. Thus, 7 participants at T2 and 37 participants at T3 are missing the observational assessments. In August 2021, the study resumed enrolling participants and conducting in-home visits, and by May 2023, another 96 families were enrolled, yielding a final retained longitudinal sample of 240 parent-child dyads (264 – 24 dropped due to COVID-19 = 240).

Interventions

Promoting First Relationships (PFR) (Kelly, et al., 2003, 2008, 2016, 2025) aims to train service providers to use an attachment theory-based intervention program that is strengths-based. The PFR program designed specifically for birth families being reunited with their child consists of a 12-week intervention that is delivered in the home (or in rare cases, an alternate location). Each week has a theme for discussion, an activity which includes videotaping or viewing and reflecting on a videotaped session, and time for "joining." Joining is described as checking in with the parent, listening to their concerns, and establishing a positive, supportive relationship. Each session includes at least two handouts, one with the content area covered that day and one titled "Thoughts for the Week" which

asks parents to think about a topic discussed during the session and apply it to their relationship with their child. The provider videotapes playtime between parent and child five times and alternates every other week with watching the video with the parent, called Reflective Observation. When the parent and provider watch the previous session of playtime on video, they reflect on what the needs are of both the parent and the child; the provider helps the parent "enter the mind" of the child to develop greater empathy and understanding of the child's needs and feelings. The provider also helps the parent identify her own feelings and needs around parenting. In addition to training providers to deliver the intervention to parents, PFR also teaches providers five consultation strategies that are strengths-based methods for conveying information (such as child development expectations) and enhancing parents' self-efficacy in parenting. The consultation strategies include: Joining, Positive Feedback, Instructive Feedback, and Reflective Questions and Comments, and Instruction with Handouts. It is argued that these core strategies, which enhance parents' sense of security and competency, are the heart of the PFR program.

For this study, we adapted the PFR model to be sensitive and relevant to the family's reunification process. The standard 10-week program was expanded to 12 weeks to include two additional parent-only sessions: (1) session 1 to build rapport, discuss reunification challenges, and set boundaries for discussing sensitive topics when the child was present and (2) session 4 to support the parent in reflecting on the parent's own childhood experiences and how those experiences relate to the parent's caregiving. All other sessions followed the standard PFR model, involving both parent and child.

Providers deliver the following weekly content to families:

Week	Theme-Discussion/Handouts	Activity and Handout (HO)	Thoughts for the Week
1.	Introduction to PFR and Social and Emotional Health	Elements of a Healthy Relationship Video	Healthy relationships
2.	Attachment Behaviors, Social & Emotional Needs of Children	Videotape Play Session & Developing Trust HO	Attachment behaviors

3.	How We Can Meet Social and Emotional Needs	Reflective Observation and Calming Myself HO	Social and emotional needs
4.	Repair In Relationships, When Things Go Wrong	Repair & Staying Connected during Difficult Moments HO	Staying connected
5.	Learning the Non-Verbal Language of Young Children	Videotape Play Session, Baby Cues and Teach/Play HO	Nonverbal communication
6.	Understanding Challenging Behaviors	Reflective Observation and Challenging Behavior HO	Social and emotional needs
7.	Separations and Transitions	Videotape Play Session, & Separations and Transitions	Separations & transitions
8.	Calming Myself, Calming my Child	Reflective Observation & Calming HO	Calming steps
9.	Encouraging Cooperation	Videotaped play session & Balanced Parenting and Cooperation	Setting limits & offering choices
10.	Behaviors, Feelings and Needs	Reflective Observation & Understanding Behavior	Behaviors, feelings, needs
11.	Focus on Consolidating Gains	Videotape Play Session	Choose two things to focus on
12.	Closing	Reflective Observation	Certificate of completion

All providers of PFR were from the community and had been previously trained and certified to deliver PFR, unrelated to the study. Providers had various degrees of experience providing the program directly to families. The providers were required to either have an active certification or update their certification by demonstrating fidelity with a practice family prior to seeing a study family. Approximately five providers were employed by the study at any given time. Due to staff turnover during the COVID-19 pandemic, 16 different PFR providers served study families throughout the study. All providers were female. Of the 16 PFR providers, 4 had bachelor's degrees and 12 had master's degrees.

Provider fidelity to the PFR model was continuously monitored. Providers videotaped themselves providing reflective video feedback with each family at the sixth PFR visit. These fidelity

videos were then reviewed and coded by an expert PFR trainer, who rated the delivery quality on a 1- to 5-point scale (with higher scores indicating greater fidelity). If a provider received a rating of less than 4, she received additional mentoring until fidelity to PFR was reestablished. The provider continued to serve study families on her caseload; however, she did not receive any new cases until fidelity was reestablished. Of the 121 cases randomized to PFR, 77 had 6 or more sessions and should have had a fidelity video. However, 7 were not completed, and 4 could not be coded due to technical problems. Of the 66 submitted videotapes, the average delivery quality score was 4.64 (*SD*=0.54), and 97% passed.

The **Resource and Referral (R&R)** program was delivered by one of three providers via phone, text, postal mail, and email. All providers were female; one had a master's degree, and two had bachelor's degrees.

A needs assessment was conducted during an initial phone call, after which the provider compiled a personalized resource and referral list, which was emailed or mailed to the parent. Three additional check-in calls, texts, or emails occurred over the subsequent months to offer additional resources if requested.

Outcome Measures

Child Welfare Services removals were identified from placement records obtained from DCYF that covered allegations, removals, and placements prior to enrollment and up to two years post-intervention, with complete coverage of 18 months after study enrollment for all families. These records were used to assess CWS r*emovals* in the 1.5 years subsequent to enrollment.

Parental sensitivity was measured observationally at each research visit using the Nursing Child Assessment Teaching Scale (NCATS; Barnard, 1994). The NCATS was designed for use with children aged 3 years and under; here, we adapted the NCATS for use with older children up to age 6 years by allowing for more complex teaching tasks and minor word changes for 22 of 50 items to be more appropriate for

preschool-aged children (e.g., the infant item, “Caregiver positions child so that it is possible for them to have eye- to-eye contact...” was modified to “Caregiver assumes a position that facilitates eye-to-eye contact with the child...”). Parents were presented with a list of activities and instructed to select the first task their child could not yet do (e.g., stack blocks, string beads, draw a shape, print his/her name) and to attempt to teach it to their child. The research visitor provided a standard set of manipulatives and video-recorded the teaching interactions. A single coder, masked to the intervention condition and trained in reliability with a certified NCATS instructor, coded all tapes. For reliability checking, 18.8% of the videos were also coded by one of two expert trainers. Overall inter-rater agreement was 86.7%. Videotapes were scored on 50 dichotomous (0 = no, 1 = yes) items measuring sensitivity to cues; response to distress; social, emotional, and cognitive growth fostering; and contingency between mother and child. The sum of items yields a total parenting sensitivity score. Thirty-seven items were used for this study; we did not use the Response to Distress subscale and two other items deemed not appropriate for older children. Thus, sensitivity scores could range from 0 to 37, with higher scores indicating greater sensitivity. Cronbach’s α in the study sample ranged from .57 to .62 across the three time points.

Parenting knowledge of child development was measured by the Raising a Child (RAC) Scale, adapted from the Raising a Baby Scale (RAB; Kelly & Korfmacher, 2008), a measure of caregivers’ knowledge of children’s social-emotional needs and developmentally appropriate expectations. The adaptation included changing the language from “babies” and “toddlers” to “children” to be more relevant to the sample. Two items that only applied to babies were also removed (“Parents spoil babies by picking them up when they cry,” “Talking to babies only really becomes important when they are old enough to start using some of their own words”), for a total of 14 items that parents rate on a 4-point scale (*strongly agree* to *strongly disagree).* The RAB evidences construct validity in other studies of PFR and has shown treatment effects in CWS-involved populations (Oxford, Spieker, et al., 2016; Spieker et

al., 2012). Cronbach's *α*s ranged from .61 to .63 across the three time points. The scale was summed, and scores could range from 14 to 56, with higher scores indicating greater parental knowledge.

Child externalizing problem behavior and ***child internalizing problem behavior*** were assessed via parent report using the Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2000). The CBCL is a 99-item clinical tool appropriate for children 1.5 to 5 years old that measures social, emotional, and behavioral problems in young children. Parents rate their child on a three-point response (0 = *not true* to 2 = *very true or often true*). The externalizing domain has 24 items, and the internalizing domain has 36 items; raw scores were used in analysis; higher scores indicate more problem behavior. Across the three time points, Cronbach's *α*s ranged from .90 to .91 for externalizing and .86 to .88 for internalizing.

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