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Randomized Controlled Trial of the Promoting First Relationships® Preventive Intervention for Primary Caregivers and Toddlers in an American Indian Community

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Abstract

Preventive intervention programs that address parenting practices and children's developmental needs early in life have led to positive changes in caregiving behavior and children's developmental outcomes. However, little is known about the efficacy of such programs among American Indian families. This study tested the efficacy of the strengths-based Promoting First Relationships® (PFR) program in American Indian families living on a rural reservation. Participants were 34 toddlers (10-30 months old) and their primary caregivers. Families were randomized to an Immediate ($n = 17$) or Waitlist ($n = 17$) group after a home visit for baseline data collection, which included assessment of observed caregiver-child interactions, caregiver perceptions, and child behavior. After randomization, we delivered the PFR intervention in 10 visits to the Immediate group, with some adaptations based on focus groups with community

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members and staff input. We analyzed follow-up assessments by implementing multiple regression analyses, controlling for baseline scores and using multiple imputation to handle missing data. Results supported our primary hypotheses: the Immediate group, compared with Waitlist, had significantly higher scores on the quality ($p = .011$, $d = 1.02$) and contingent responsiveness ($p = .013$, $d = 1.21$) of caregiver-child interactions, as well as on caregiver knowledge of toddlers' social and emotional needs and level of developmentally appropriate expectations ($p = .000$, $d = 0.58$). Caregiver stress and caregivers' reports of child behavior did not differ significantly. Our results hold promise for additional PFR research in other Native communities.

Keywords

American Indians; home visiting; Promoting First Relationships; caregiver-child interaction; randomized controlled trial

American Indian (AI) children are at elevated risk of experiencing poverty, parental mental health disorders, household exposure to substance use, domestic violence, maltreatment, and other traumas, all of which increase their risk of developing mental and physical health issues and substance use problems in adolescence and adulthood (Brockie, Heinzelmann, & Gill, 2013; Sarche & Spicer, 2008; Whitesell et al., 2009). AI children are thus a vulnerable group, deserving of intensive, culturally sensitive efforts to develop and disseminate preventive interventions designed to meet their unique needs in their own tribal communities.

Although AIs have been resilient in the face of attempts to terminate their tribes (Dunbar-Ortiz, 2014) and eradicate their cultures, the resulting negative impact on physical and mental health has been profound (Stanley, Swaim, Kaholokula, Kelly, Belcourt & Allen, 2017). AI health disparities have persisted, and for some factors are even increasing (Sequist, 2017). Thus, given their own challenges, AI parents may struggle to provide an environment for their children that optimizes growth and development, even though children are highly valued and considered an important part of AI communities (Bigfoot & Funderburk, 2011). For example, AI parents who experienced childhood maltreatment themselves may have less than optimal parenting skills (Duran et al., 2004; Libby et al., 2008). Moreover, parental mental health issues, parental stress, and poverty in AI families are associated with lower levels of social-emotional competence and more behavior problems in AI children (Frankel et al., 2014, Sarche, Croy, Big Crow, Mitchell, & Spicer, 2009). Although prior studies have highlighted specific parent-child and family issues and their impact on children's development, it is equally important to consider the effects of historical factors, especially historical trauma and cultural oppression (Brave Heart, 1999; Rothe et al., 2006). The bitter legacy of historical trauma includes past governmental policies that forcibly removed AI children from their families and placed them in boarding schools that punished expression of Native culture. The resultant traumatization and separation from their primary caregiver, as well as the loss of parenting skills (Kawamoto, 2001), parenting models, and cultural values (Morrissette, 1994), likely contribute to current burdens of substance use and domestic violence in AI populations (Rothe et al., 2006). Efforts to implement programs that support AI parents and their capacity to support their

children must overcome these endemic barriers, as well as community resistance to outside interference born of longstanding mistrust of the Federal government.

In randomized controlled trials, preventive interventions focusing on parenting practices and children's developmental needs early in life have yielded measurable changes in caregiving behavior and child developmental outcomes (Rayce, Rasmussen, Klest, Patras, & Pontoppidan, 2017; Sweet & Appelbaum, 2004) while fostering resilience in the face of challenging life circumstances (Luthar & Eisenberg, 2017). Yet very few of those trials have included AI or Alaska Native (AN) families, and even fewer have conducted scientifically rigorous evaluations (Macvean, Shlonsky, Mildon, & Devine, 2017; but see Barlow et al., 2015).

Theoretical Foundation: Attachment Theory

Early preventive intervention programs for parents and children vary in focus and in underlying principles and assumptions. For the present study, the primary theoretical framework was Bowlby's attachment theory, which stresses that the child's attachment to the primary caregiver can keep the child safe, secure, and protected while providing a secure base for exploration (Bowlby, 1969/1982). Attachment theory is useful in understanding the experiences and reactions of infants and children exposed to stress, adverse events, and trauma. One of its key tenets is that caregiver sensitivity and responsiveness to the child are critical in developing a secure (versus insecure) attachment that becomes a protective (versus risk) factor for subsequent adaptive (versus maladaptive) child outcomes (see Cassidy, Jones, & Shaver, 2013).

Predictors of attachment security.

Meta-analyses have shown that parental sensitivity strongly predicts infant attachment security (Bakermans-Kranenburg, van IJzendoorn, & Juffer, 2003; De Wolff & van IJzendoorn, 1997). Secure attachment develops out of the parent's ability to "take the child's perspective" or understand the child's social and emotional needs (Grienemberger, Kelly, & Slade, 2005). Interventions like the one in the present study build on caregivers' ability to understand and respond to children's needs, thereby promoting attachment security (van den Boom, 1995). Caregivers less able to provide a safe, secure, and nurturing environment for their children because of their own issues are less likely to be sensitive to their children's needs, resulting in insecure attachment. This negative outcome is more common in demographic groups that have experienced child maltreatment, substance dependency, poverty, adolescent parenting, and parental depression than in groups that have not (van IJzendoorn, Schuengel, & Bakermans-Kranenburg, 1999). Therefore, increasing parental sensitivity to, and understanding of children's social-emotional needs is an important intervention goal.

Promoting First Relationships®

Given our theoretical framework, we selected the Promoting First Relationships® intervention (PFR; Kelly, Zuckerman, Sandoval, & Buehlman, 2008) for the current study. PFR is a theoretically driven, relationship-based intervention strategy grounded in

attachment theory. It promotes trusting and secure caregiver-child relationships and healthy child development, and is delivered in a relatively brief home visiting program structured in 10 sessions. The program's brevity is a strength, as a meta-analysis of more than 70 preventive intervention research studies demonstrated that brief interventions (16 sessions or fewer) that focus solely on parental sensitivity are most effective in improving parental behavior and child attachment security in families at all levels of risk (Bakermans-Kranenburg et al., 2003). PFR offers additional strengths, as it 1) is well-grounded in developmental research; 2) focuses on strengthening families and positive aspects of the caregiver-child relationship, rather than targeting deficits; 3) is easily implemented in communities by a wide range of service providers; and 4) permits sensitive responses to the needs of individual children. We believed that PFR would align well with the cultural beliefs and practices of our tribal partner, and we worked to adapt the program in ways that would enhance its acceptability and feasibility in the community while retaining the core elements of the PFR intervention.

Several previous quasi-experimental studies of PFR have demonstrated positive results in at-risk populations, including infants and toddlers in foster care, Early Head Start, low-income families, and homeless families. Specifically, mothers who received PFR in these studies became more socially and emotionally responsive and more stimulating in their interactions. Children whose caregivers received PFR also improved in their social competence, behaviors, and interactions with their parents (see Kelly, 2012). Two previous randomized controlled trials of PFR have been conducted. The first, which focused on children in foster care, demonstrated that PFR (compared with a control treatment) improved caregivers' observed sensitivity and understanding of toddlers' social and emotional needs, as well as children's sleep problems and hormonal response to stress (Nelson & Spieker, 2013; Spieker, Oxford, Kelly, Nelson, & Fleming, 2012); but did not alter caregivers' perceptions about their children's behavior or their own parenting stress. PFR also increased the likelihood of stable, uninterrupted foster care and eventual adoption (Spieker, Oxford, & Fleming, 2014). In the second trial, which enrolled families referred to child protective services, caregivers who received PFR (compared with a control treatment) exhibited greater parenting sensitivity, fewer affective communication errors, and greater understanding of toddlers' social and emotional needs; but neither their perceptions of parenting stress nor their children's behavior changed. Their children were 2.5 times less likely to be placed in foster care during the year following the intervention (Oxford, Spieker, Lohr, & Fleming, 2016).

Current Study

In the current study, we tested the efficacy of PFR in improving the quality of caregiver-child interaction between AI toddlers and their primary caregivers. We did so by conducting a randomized controlled trial to compare an intervention group that immediately received PFR with a waitlist control group. This trial was conducted in collaboration with a rural AI tribe on a reservation in the Northwest region (as defined by the Indian Health Service) of the United States. Together, we adapted aspects of the PFR intervention so that they aligned more closely with the tribe's cultural practices and preferences. We then hired and trained Native members of the tribal community who lived on the reservation to assist in

implementing the study: a PFR Provider to deliver the PFR intervention and a Research Visitor to collect assessment data.

We evaluated the efficacy of the PFR intervention by comparing baseline and follow-up assessment data for caregivers and children in the Immediate group versus the Waitlist group. We hypothesized that following the PFR intervention (or the waiting period) and after accounting for baseline scores, the Immediate group, compared with the Waitlist group, would have significantly higher-quality caregiver-child interaction (our primary outcome measure) and greater contingent responsiveness to one another (hereafter referred to as “contingency”); 2) caregivers in the Immediate group would have greater knowledge and more appropriate expectations of their children’s social and emotional needs, and would experience less parenting stress; and 3) their children would exhibit less problematic social-emotional behaviors.

Method

Participants

The participants were 34 primary caregivers living on or near the reservation with their toddlers aged 10-30 months, who were identified by their caregivers as AI/AN. We enrolled primarily biological mothers, but we use the term “caregiver” because the primary caregiver could have been another relative. In fact, two primary caregivers were fathers. We present the study flow of participant recruitment, random assignment, and completion in Figure 1.

Eligibility and recruitment.—We recruited most participants from the tribal health clinic, but we also posted flyers in the community, publicized the study on Facebook, and provided information to Head Start teachers. Our Research Visitor telephoned community members who expressed interest, provided detailed information on the study, determined eligibility, and then scheduled a home visit to obtain informed consent and collect baseline data.

To be eligible for the study, families had to have at least one parent or guardian who 1) was at least 18 years old; 2) spoke English; 3) was the primary caregiver for an AI/AN child aged 10-30 months; 4) had telephone access; 5) was not in a treatment facility or shelter; 6) was not hospitalized or imprisoned; 7) was willing to have researchers come to their home; and 8) lived on or near the reservation. If the household included multiple children in the target age range, we selected the child with whom the caregiver wished to work for the present study. Participating caregivers received \$50 for each data collection visit they completed, for a maximum of \$100. They did not receive payment for intervention visits.

Table 1 presents the demographic characteristics of the sample by study group. Of the total sample, 73% of the primary caregivers identified as AI/AN, 15% as white, and 12% as mixed. All were living on the reservation, all of the non-Native caregivers had AI/AN partners or spouses, and all had an AI/AN child between 10 and 30 months old. The sample was similar to the population (82% AI/AN) of the primary town from which the sample was recruited, $\chi^2(2, N = 34) = 1.82, p = .18$. At baseline, no statistically significant ($p < .05$) differences appeared between the Immediate and the Waitlist groups on any variables.

However, more of the caregivers in the Immediate group were white ($p = .053$); consequently, we controlled for race in the substantive analyses.

Promoting First Relationships Intervention

PFR supports caregivers in becoming more aware of, and responsive to their children's age-appropriate behaviors and needs. The full program comprises 10 hour-long sessions in the caregiver's home, but takes 14 weeks on average to complete (Oxford et al., 2016). PFR providers are trained to use five "consultation strategies" labeled Joining, Positive Feedback, Instructive Feedback, Reflective Questions and Comments, and Instruction with Handouts. These strategies create trust and rapport between the PFR provider and the caregiver; provide opportunities for the caregiver to reflect on their needs as a parent and their child's social and emotional needs; and promote authentic and non-judgmental interaction between the PFR Provider and caregiver. Consultation strategies focus on positive qualities that enhance caregivers' sense of security and competency, as well as our primary aim of increasing caregiver sensitivity and the quality of caregiver-child interaction. Every session has specific goals and deliverables, with a checklist to ensure complete, successful administration.

Each session has a broad structure, including check-in, reflection on the previous week's content, a discussion topic for the current week, video recording or observation, and handouts (14 total illustrations and charts). A central part of the program is that in alternate weeks, part of the visit is dedicated to either recording a play session between caregiver and child or observing and reflecting on a video of such a session, for a total of five opportunities for video reflection. While viewing the videos, the caregiver is invited to reflect on the child's behaviors, feelings, and needs, as well as his or her own behaviors, feelings, and needs. These sessions, which are a key element of the intervention, also offer an opportunity for the PFR Provider to give positive instructive feedback on actions the caregiver takes to support the child's development and social and emotional needs. The PFR Provider is also trained to use reflective questions during the video feedback sessions. These questions support the caregiver's reflective capacity, but they are not directive. In other words, PFR Providers do not tell caregivers *how* to parent, rather, they encourage the caregiver to reflect on their own, and their child's underlying needs and behaviors. In this way, PFR is personalized to support the caregiver and child and their relationship and is a strengths- and relationship-based approach to service.

As a standard part of the intervention model in the present study, a PFR consultant engaged in weekly reflective practice with the PFR Provider to offer guidance about intervention elements and to support her in working with vulnerable families.

PFR adaptations for the study community.—We adapted the PFR intervention for AI families by using community-based research principles and qualitative approaches (see Oxford, Booth-LaForce et al., 2019 for details). In accordance with recent debates about cultural adaptation versus intervention fidelity (Mejia, Leijten, Lachman, & Parra-Cardona, 2017), we adapted only those aspects of PFR that could increase cultural relevance while maintaining PFR's core principles and components.

We began by conducting two focus groups that included tribal elders, healthcare and agency staff, and child and family service providers. We presented information about the PFR intervention to enable participants to evaluate its underlying philosophy and its acceptability in the community. Their perceptions were positive, primarily because PFR's emphasis on parenting strengths and relationships aligns with local cultural values. The resulting adaptations included creating a unique name for the study, commissioning an appropriate study logo by a Native artist, lengthening each home visit to include more time for conversation and "checking in" activities, providing a small gift for the child at each research visit, and adding one handout about caregiver-child transitions and separations.

Training, certification, and fidelity.—We trained the PFR Provider, who was a tribal member living on the reservation, by using an established PFR distance-learning model (see <http://www.pfrprogram.org/training/>) that included expanded background content (see Oxford, Booth-LaForce et al., 2019). After initial certification, the PFR Provider submitted one video recording of an intervention session per family to enable a PFR master trainer to monitor ongoing fidelity (see Oxford et al., 2018), by rating the PFR Provider's quality and completeness of intervention delivery on a 5-point scale ($M = 4.21$, $SD = 0.70$ in the present study).

Dosage.—Nine of the 17 caregivers in the Immediate group completed all 10 PFR visits. In addition, four completed some of the visits (3, 5, 7 and 7) and another four dropped out of the study after the baseline assessment but before the first PFR visit. Reasons for partial completion and attrition included the following: three participants became too busy because of family responsibilities, new jobs, or other obligations; one participant experienced difficult life circumstances, such as domestic violence or homelessness; and four did not respond to repeated attempts to make contact. Three of the 17 caregivers In the Waitlist group dropped out of the study between the baseline and follow-up assessments. One dropped out because of relapse into alcohol or drug dependence and two because of becoming too busy with family responsibilities, new jobs, or other obligations.

Acceptability and satisfaction.—An unfamiliar staff member telephoned each caregiver after completion of the PFR intervention to evaluate their experience. Each caregiver who completed the intervention ($n = 9$) responded to a series of items on a 4-point scale (1 = strongly agree, 2 = agree, 3 = disagree, 4 = strongly disagree). All caregivers agreed or strongly agreed that they were satisfied with the PFR program ($M = 1.50$, $SD = 0.54$), and all agreed or strongly agreed that they would recommend PFR to other caregivers ($M = 1.38$, $SD = 0.52$).

Procedures

The Research Visitor, who was blinded to study group assignment, conducted one home visit before randomization to collect baseline data and a second visit a few months later to collect follow-up data. Each research visit lasted about 90 minutes (30 minutes for questionnaires, 20 minutes for video recording of caregiver-child interaction, and 40 minutes for interviewing). The Research Visitor read aloud the survey instruments, which were written at a 7th grade level, so that caregiver literacy was not a barrier. At each visit, the Research

Visitor video-recorded caregiver-child interactions during a teaching task. From a list ordered by developmental level (e.g., taking the lid off a small container, stacking blocks), the caregiver was asked to select the first activity that the child could not perform and to try to teach the child how to do so.

After baseline data collection, the university researchers used an algorithm to randomize participants, blocking on male or female caregiver, in equal numbers to the Immediate group and the Waitlist group. Families in both groups completed their follow-up assessment after the intervention period concluded. In the Immediate group, the median time between baseline and follow-up assessments was 15 weeks ($M = 18.00$, $SD = 5.29$). In the Waitlist group, the median time between assessments was 17 weeks ($M = 19.14$, $SD = 9.45$). Families in the Waitlist group then had the opportunity to receive the PFR intervention.

Measures

Caregiver-child interaction.—Our primary outcome measure was the total score for Caregiver/Child Interaction on the *Nursing Child Assessment Teaching Scale* (NCATS; Oxford & Findlay, 2013), coded on the basis of video recordings of the teaching task. We chose NCATS because 1) it has excellent psychometric properties and extensive literature on its predictive validity relative to social-emotional and cognitive outcomes in children (Oxford & Findlay, 2013); 2) it is sensitive to intervention effects (Bakermans-Kranenburg et al., 2003), including PFR (Oxford et al., 2016; Spieker et al., 2012); and 3) it has been implemented successfully with AI (Seideman, 1992) and indigenous Canadian (Letourneau, Hungler, & Fisher, 2005) families.

A certified NCATS coder viewed the video recordings and scored them for caregiver sensitivity, stimulation of the child, and emotional responsiveness. The coder was blind to treatment group and time of assessment (baseline versus follow-up) and reviewed the videos in a randomized order provided by the investigators. The coder evaluated the caregiver's verbal and non-verbal support and the child's clarity of cues and response to the caregiver by responding to 73 yes/no items. "Yes" scores were summed to calculate the Caregiver/Child Interaction total score. Additionally, 32 of the 73 items on the NCATS refer to the contingent responsiveness of the caregiver to the child, or vice versa. We summed the "yes" scores on the contingency items to yield a score for Caregiver/Child Contingency.

Caregiver measures.—We assessed caregivers' understanding of their children by using the *Raising a Baby* scale (Kelly & Korfmacher, 2008). This 16-item scale measures caregivers' knowledge of the social-emotional needs of infants and toddlers as well as caregivers' level of developmentally appropriate expectations of their children. Caregivers rate the items on a 4-point scale (from strongly agree to strongly disagree), with higher scores indicating more parental knowledge. Internal consistency of the scale (Cronbach's α) was .64 at baseline and .70 at follow-up.

We measured parental stress associated with the perception of having a difficult child or a dysfunctional parent-child relationship by using the 36-item short-form *Parenting Stress Index* (Abidin, 1990). Caregivers rate their stress levels on a 4-point scale (from strongly

agree to strongly disagree), with higher scores indicating less total stress. Internal consistency of the scale was .91 at baseline and .93 at follow-up.

Child behavior measures.—We assessed children’s social-emotional competences by using the 125-item *Infant-Toddler Social Emotional Assessment* (ITSEA) (Briggs-Gowan & Carter, 1998), a comprehensive caregiver-report measure. Caregivers rated each item on a 3-point scale (1 = not true/rarely, 2 = somewhat true/sometimes, 3 = very true/often). We focused on ITSEA continuous scores for the domains of Internalizing ($\alpha = .70$ at baseline and .88 at follow-up), Externalizing ($\alpha = .73$ and .76), and Competence ($\alpha = .87$ and .93).

Analytic Strategy

Table 2 presents descriptive statistics by study group for all study variables at baseline and follow-up. We used *t*-tests to compare groups at baseline, finding no significant differences on any variables except the ITSEA Competence score. For this measure, the Immediate group had higher baseline scores than did the Waitlist group ($p = .034$). We used multiple regression models to assess differences between the Immediate and Waitlist groups in caregiver-child interaction, caregiver measures, and child measures at the follow-up assessment, adjusting for caregiver race, time elapsed between assessments and the baseline score on the given measure. This approach gives an unbiased assessment of treatment effects in a randomized design (Van Breukelen, 2006). To address missing data we employed multiple imputation, which has shown exceptional performance compared with other, more common methods when the assumption of “missing at random” can be safely satisfied (Enders, 2010). Multiple imputation is desirable for small sample sizes, and it produces unbiased parameter estimates with standard errors that adjust appropriately for additional variability in the data due to the imputation process. We conducted these analyses in SPSS (version 24) and STATA (version 14), using “intent-to-treat” models.

Results

Table 3 presents the results of multiple regression analyses for all measures, adjusted for caregiver race, baseline scores, and time elapsed between baseline and follow-up assessments. Analyses with default listwise deletion yielded similar results but are not reported here. A positive coefficient for Cohen’s *d* in Table 3 indicates an intervention effect. In this section and the next, we use the following cut-off scores to describe effect sizes: $d = .20$ for small, $d = .50$ for medium, $d = .80$ for large (Cohen, 1988), and $d = 1.20$ for very large (Sawilowsky, 2009).

Caregiver-Child Interaction

For the NCATS variables coded from video recordings, results indicated that the groups differed significantly at follow-up on the Caregiver/Child total score, $F(5, 17) = 7.03$, $p = .002$, $R^2 = 0.51$, with a large effect size ($d = 1.02$). Those in the Immediate group had higher scores ($M = 59.00$, $SD = 3.64$) than did those in the Waitlist group ($M = 54.36$, $SD = 5.53$). The two groups also differed significantly at follow-up on the Caregiver/Child Contingency total score, $F(5, 17) = 3.97$, $p = .021$, $R^2 = 0.44$, with a very large effect size ($d = 1.21$). The

Immediate group had higher scores ($M = 24.44$, $SD = 2.18$) than did the Waitlist group ($M = 20.63$, $SD = 3.95$).

Caregiver Measures

The groups also differed significantly on total scores for *Raising a Baby* at follow-up, $F(5, 17) = 45.47$, $p = .000$, $R^2 = 0.74$, with a medium effect size ($d = 0.58$). Caregivers in the Immediate group reported higher scores ($M = 54.00$, $SD = 5.52$) than did those in the Waitlist group ($M = 50.29$, $SD = 7.14$). Those in the Immediate group also reported less total stress (i.e., a higher score; $M = 156.11$, $SD = 16.56$) than did those in the Waitlist group ($M = 138.21$, $SD = 18.21$). The difference between the groups was not statistically significant, although the effect size was large ($d = 1.04$).

Child Behavior Measures

Scores for the ITSEA domains of Internalizing, Externalizing, and Competence indicated a positive intervention effect at follow-up (i.e., lower scores for Internalizing and Externalizing, higher scores for Competence) in the Immediate group (Internalizing: $M = 0.59$, $SD = 0.31$; Externalizing: $M = 0.67$, $SD = 0.28$; Competence: $M = 1.59$, $SD = 0.32$). By contrast, follow-up scores in the Waitlist group were: Internalizing: $M = 0.66$, $SD = 0.18$; Externalizing: $M = 0.96$, $SD = 0.23$; and Competence: $M = 1.24$, $SD = 0.33$. However, these differences were not statistically significant. The effect sizes ranged from small ($d = .29$ for Internalizing) to large ($d = 1.18$ for Externalizing and $d = 1.09$ for Competence).

Discussion

The results of our study confirm previous findings on the efficacy of brief preventive early interventions to promote parenting sensitivity (Bakermans-Kranenburg et al., 2003) and add to the evidence on the efficacy of the PFR program (Oxford et al., 2016; Spieker et al., 2012) in improving caregiver-child sensitive and responsive interaction. Our particular focus on adapting PFR and evaluating its efficacy among AI families on a rural reservation was both novel and significant, as very few early intervention programs have been tested in these settings, despite the elevated risk of developmental problems for AI children. Consequently, our results offer a unique demonstration of the impact of PFR in AI families and add to the sparse literature on early childhood interventions in this population.

The results support our primary hypothesis that, compared with the control condition, the PRF intervention would produce significant positive changes in caregiver sensitivity and child responsiveness. We also found that caregivers and children in the intervention group significantly increased the quality of their contingent responsiveness to one another during interaction. Additionally, caregivers significantly improved their knowledge of the social and emotional needs of toddlers and developed more developmentally appropriate expectations of their children's behavior, although their perceived parenting stress did not change.

Our results are consistent with the findings of two previous randomized controlled trials of the efficacy of PFR. Both Spieker et al. (2012) and Oxford et al. (2016) found that PFR, compared with a control treatment, significantly improved the quality of parent-child interaction, as well as caregivers' knowledge of toddlers' social-emotional needs and level of

developmentally appropriate expectations. These trials, along with the present study, demonstrate that PFR improved critical aspects of parenting that provide building blocks for children to develop secure attachment relationships with their parents (Bakermans-Kranenburg et al., 2003; De Wolff & van IJzendoorn, 1997; Grienberger et al., 2005).

We underscore the magnitude of the effect sizes we obtained, especially regarding our primary hypothesis about intervention effects. Effect sizes ranged from large ($d = 1.02$ for Caregiver/Child Total) to very large ($d = 1.21$ for Caregiver/Child Contingency); indeed, they were even larger than the combined effect size ($d = .33$, defined as moderate) obtained by a meta-analysis of 51 randomized trials ($N = 6,282$) of other brief attachment-based interventions (Bakermans-Kranenburg et al., 2003). Similarly, they were larger than those found in the two previous PFR trials, both of which obtained moderate effect sizes. For parental sensitivity on the NCATS, effect sizes were $d = 0.41$ in Spieker et al. (2012) and $d = 0.20$ in Oxford et al. (2016), and for caregiver knowledge and expectations, they were $d = 0.36$ and $d = 0.35$, respectively. It is not clear why larger effect sizes were found in the current trial, especially because we maintained PFR's core principles, procedures, and components while providing relatively minor adaptations in response to the community. It is possible that outcomes were more sensitive to change in this study due to the nature of the population and setting. PFR research in other Native communities may provide additional insight into these differences in effect sizes.

Notably, the PFR intervention appeared to have a stronger impact on caregivers than on children. We did not find any statistically significant improvements in caregivers' evaluation of their children's behavior, although the effect sizes were large and the differences were in the expected direction. Nevertheless, the children contributed to the quality and connectedness (contingency) of observed caregiver-child interactions, as reflected by improved post-intervention scores on NCATS. Prior PFR studies also have not found significant effects for caregiver reports of child behavior problems, but significant effects have emerged for observational and physiological measures. For example, Oxford et al. (2016) found no PFR effects on children's behavior as assessed by parental report, but an observational measure detected improvement in children's affective communication. Results from the same research also indicated that children in the intervention group were more emotionally regulated during a series of difficult tasks, as measured by respiratory sinus arrhythmia (Hastings, Kahle-Kuipers, Fleming, Lohr, Katz, & Oxford, 2018). Spieker et al. (2012) did not find significant changes in caregiver-reported child behavior problems in their study, but they did find an improvement in children's stress-response physiology in the PFR group (Nelson & Spieker, 2013). The results of these prior studies (and ours) lead us to consider that the effects of PFR on children may be more fine-grained than our caregiver-reported assessment of child behavior could detect. As well, our small sample size may have limited power to detect significant effects on this measure.

Limitations

Certain limitations must be considered when interpreting our results. The total number of participating families was small ($N = 34$) and our study period was brief. In addition, our observations were limited to a single reservation community, so our findings may not

generalize to AI families in other settings. Moreover, attrition was high in the Immediate group, so some randomized families did not receive the complete PFR program. Nevertheless, after evaluating reasons for attrition, we conclude that the acceptability of PFR was not at issue. Rather, most attrition occurred because families became too busy due to changes in jobs or other obligations, or experienced difficult life circumstances that interfered with participation. This pattern may be reservation-specific, or it may be a more widespread challenge in AI/AN communities. We attempted to decrease attrition by being flexible in terms of scheduling home visits and providing an alternative location to meet if a home visit was unacceptable to the family. However, additional alterations in the program format or structure would be worth investigating, to maximize participation and to reach more families.

Conclusions

Regardless of these limitations, our results are notable in terms of the strength of the effect sizes we achieved for the primary outcome and some of the secondary outcomes, as well as the positive perceptions of the intervention program expressed by caregivers in a follow-up survey. These results hold promise for additional early intervention work in Native communities and larger randomized controlled trials of PFR with longer follow-up periods. Of great importance in this study was our collaboration with a tribal community to adapt PFR in ways that aligned with the desires of the community and respected their culture, while retaining the critical elements of the PFR program. In keeping with our community-based approach, we hired and trained community members to fulfill the roles of PFR Provider and Research Visitor, a choice that likely enhanced the acceptability of the program during the study period and may increase its sustainability in the future.

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Figure 1.
Participant flow chart.

Table 1.

Demographic characteristics at baseline by study group

Characteristic	Immediate (<i>n</i>=17)	Waitlist (<i>n</i>=17)
	<i>M (SD) or n (%)</i>	<i>M (SD) or n (%)</i>
Child age, mean months (SD)	18.53 (5.86)	17.29 (5.94)
Child gender, female	11 (65)	7 (41)
Caregiver race		
American Indian/Alaskan Native	10 (59)	15 (88)
White	5 (29)	0 (0)
Mixed race	2 (12)	2 (12)
Marital status		
Married	7 (41)	6 (35)
Divorced or separated	3 (18)	3 (18)
Single	7 (41)	8 (47)
Education		
Less than high school	1 (6)	3 (18)
High school	3 (18)	2 (12)
Some college or more	13 (76)	12 (70)

Table 2.
Caregiver and child measures for Immediate and Waitlist groups at baseline and follow-up

Measure	Baseline						Follow-Up					
	Immediate			Waitlist			Immediate			Waitlist		
	<i>n</i>	<i>M</i>	<i>SD</i>	<i>n</i>	<i>M</i>	<i>SD</i>	<i>n</i>	<i>M</i>	<i>SD</i>	<i>n</i>	<i>M</i>	<i>SD</i>
NCATS												
Caregiver/Child Total	16	56.25	6.13	17	53.23	7.01	9	59.00	3.64	11	54.36	5.53
Caregiver/Child Contingency	16	22.87	3.89	17	20.59	4.77	9	24.44	2.18	11	20.63	3.95
ITSEA												
Internalizing	17	0.60	0.21	17	0.61	0.29	9	0.59	0.31	14	0.66	0.18
Externalizing	17	0.78	0.28	17	0.85	0.20	9	0.67	0.28	14	0.96	0.23
Competence	17	1.34	0.29	17	1.09	0.36	9	1.59	0.32	14	1.24	0.33
Parenting Stress Index ^a	17	152.76	15.75	17	146.89	17.30	9	156.11	16.56	14	138.21	18.21
Raising a Baby	17	49.29	5.32	17	50.65	5.04	9	54.00	5.52	14	50.29	7.14

Note. NCATS = Nursing Child Assessment Teaching Scale; ITSEA = Infant-Toddler Social Emotional Assessment

^aParenting Stress Index: higher scores indicate less total stress.

Table 3.

Linear associations of intervention effect with caregiver and child outcomes (multiple imputation)

Measure	Unstandardized PFR Effect		Significance	Effect Size
	(β) (<i>SE</i>)	95% CI	<i>p</i> value	Cohen's <i>d</i>
NCATS				
Caregiver/Child Total	7.21 (2.36)	2.001, 12.423	.011	1.02
Caregiver/Child Contingency	4.33 (1.39)	1.172, 7.487	.013	1.21
ITSEA				
Internalizing	0.031 (0.08)	−1.151, 0.215	.713	0.29
Externalizing	−0.129 (0.07)	−0.279, 0.019	.084	1.18
Competence	0.162 (0.10)	−0.052, 0.378	.128	1.09
Parenting Stress Index ^a	6.131 (5.44)	−5.444, 17.708	.277	1.04
Raising a Baby	5.443 (1.16)	2.960, 7.925	.000	0.58

Note. Linear regression models were adjusted for caregiver race, baseline values, and time elapsed in months between baseline and follow-up. NCATS = Nursing Child Assessment Teaching Scale; ITSEA = Infant-Toddler Social Emotional Assessment; CI = confidence interval.

^aParenting Stress Index: higher scores indicate less total stress.