The role and efficacy of native paraprofessional home visitors in reducing behavioral health disparities in indigenous populations
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8.1 INTRODUCTION

This chapter will review the empirical findings presented in Chapters 2-7 and discuss the three trials’ methodological strengths and limitations. Implications of the study methods and results for general practice will also be reviewed, with a particular focus on social, theoretical and clinical relevance to indigenous health care settings worldwide. This chapter concludes with recommendations and directions for future research.

8.2 SUMMARY OF TRIALS AND MAJOR FINDINGS

Overview

The three trials presented in this dissertation represent the first methodologically rigorous line of research in the US to show efficacy for home visiting by paraprofessionals on parenting and child outcomes. It is also the first home-visiting research to identify significant impacts on infants’ emotional and behavior outcomes. These findings have generalizability and implications for addressing behavioral and mental health disparities among indigenous and similarly disenfranchised communities worldwide. Table 1 summarizes the trial designs.

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<th>Table 1: Summary of Family Spirit Intervention Trials</th>
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CHAPTER

8

8.1 INTRODUCTION

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Table 1: Summary of Family Spirit Intervention Trials (continued)

<table>
<thead>
<tr>
<th>Participant Description</th>
<th>Expectant American Indian mothers (recruited during pregnancy) &lt;20 years old at conception</th>
<th>Expectant American Indian mothers (recruited during pregnancy) &lt;22 years old at conception</th>
<th>Expectant American Indian mothers (recruited during pregnancy) &lt;20 years old at conception</th>
</tr>
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<tbody>
<tr>
<td>Study Design</td>
<td>Randomized controlled trial n=28 intervention group n=28 control group</td>
<td>Randomized controlled trial n=81 intervention group n=86 control group</td>
<td>Randomized controlled trial n=159 intervention group n=163 control group</td>
</tr>
<tr>
<td>Control Condition</td>
<td>Breastfeeding support</td>
<td>Optimized Standard Care (transportation and support to get to prenatal and well-baby clinic visits)</td>
<td>Optimized Standard Care (transportation and support to get to prenatal and well-baby clinic visits)</td>
</tr>
<tr>
<td>Assessment Time Points</td>
<td>Baseline (&lt;28 weeks gestation), 2 mos, 6 mos postpartum</td>
<td>Baseline (&lt;28 weeks gestation), 2 mos, 6 mos, 12 mos postpartum</td>
<td>Baseline (&lt;32 weeks gestation), 36 weeks gestation, 2 mos, 6 mos, 12 mos postpartum</td>
</tr>
</tbody>
</table>

Baseline Findings

The participants enrolled in these trials had considerable demographic, socioeconomic, and behavioral health challenges at baseline. They were predominantly young (<19 years old), unmarried, residentially unstable and highly exposed to drugs and alcohol.

There were no notable changes in the participant populations across the three study periods (from 2001-2011), with the exception of possibly increased illicit (methamphetamine) and poly drug use (using many drugs at once). Across the samples, the mean ages of participants ranged from 17.1 to 18.1. Trial 2 differed slightly in eligibility criterion for age – mothers up to age 22 were eligible to enroll – while in Trials 1 and 3, mothers were required to be
<20 years at time of conception. The increased age limit in Trial 2 had to do with some logistical problems in two of the Navajo sites for recruitment early in the trial. Preference was given to teen mothers, but mothers up to age 22 were eligible for Trial 2 only.

The majority (75%) of participants across the trials were first-time mothers, although approximately one-quarter had two or more children in spite of their young age. Very few were married (3% to 7%) or employed (7%-12%) at time of enrollment. Less than one-third had finished high school prior to recruitment. We learned in Trial 2 it was insufficient to ask participants if they had completed high school to understand drop-out status; rather, we needed to know: 1) if they had completed high school and/or 2) if they were currently in school, given that many were still high school age. By Trial 3, finer-grained school status questions allowed us to document at baseline that 27% had finished high school or received the high school equivalent credential (Graduate Education Development), and 41% were still in school. Because one goal of the Family Spirit intervention is to keep mothers in school, these additional data were useful. We also improved our ascertainment of teen mothers’ living situations; while in Trial 1 and 2 we understood that roughly 65% of mothers were living with their parents, in Trial 3, improved survey questions elicited that an additional 18% were living with their boyfriend’s parents, and only 12% were living independently. We also documented that the majority (51%) lived in two or more homes in the past year, important information for guiding home-visiting interventions in high-risk communities.

We also gained clearer understanding of baseline depression rates and substance use patterns over the course of the three trials. By Trial 3, our baseline analysis of depression factored in a clinical cut-off score for the Center for Epidemiologic Studies Depression Scale (CES-D) instrument.¹ The CES-D is scored from 0-60 and a score of 16 or higher is indicative of “mild” to “significant” depressive symptomatology. The CES-D is intended for use as a clinical screen (as opposed to a diagnostic tool) for depression. Higher scores indicate worse symptoms. In Trial 3, we identified that 37% of all mothers (n=322) scored in the clinical range (≥16) for depression at baseline.
Across all three trials, we found that the majority of expectant mothers reported at baseline that they had initiated alcohol and marijuana use prior to age 15 (mean age for alcohol initiation across all three trials was 14.5). Onset of alcohol use before age 15 predicts higher risk for problem substance use in adulthood. Baseline substance abuse data were also more fine-grained by Trial 3, including questions about specific illicit drugs used and age of first use, in addition to alcohol use. Thus, in Trial 3, we captured better data about poly drug use. We learned participants initiated marijuana even earlier than alcohol, and a large portion had also previously used cigarettes (59%), methamphetamine (28%) and cocaine (25%). During the study period, the US experienced a surge in methamphetamine use, a cheap and homemade drug associated with high addiction, morbidity and mortality, and other negative behavioral impacts, including increased spread of HIV, Hepatitis B and C. Public concern for increasing methamphetamine use and the lack of information about patterns of use among vulnerable populations, such as American Indians, was the impetus for the study presented in Chapter 5, “Examining Correlates of Methamphetamine and Other Drug Use in Pregnant American Indian Adolescents.” We learned that lifetime methamphetamine use in our sample of pregnant American Indian teens was up to three times higher than among previous national samples of American Indian adolescents and approximately five times higher than US All Races adolescents. Another important finding was that lifetime methamphetamine use was more highly correlated with lifetime marijuana use than alcohol or other drugs. Clinical implications of this finding are discussed below. The most important discovery from this baseline study was the correlation between teen mother’s baseline and pregnancy substance use and reporting of poor functioning and high conflict in their family of origin.

**Study Outcome Findings**

**Overview.** This research produced consistent highly significant outcomes in parenting knowledge across all three trials and improved maternal involvement, parent self-efficacy, and positive parent attitudes and behaviors (i.e., home safety) in different cohorts at multiple assessment points. In Trials 2 and 3, the longer intervention and assessment period (to 12 months postpartum) allowed us to assess child outcomes, and produced the first
evidence of intervention-related infant (~12 months of age) emotional and behavioral outcomes in the home-visiting literature. We also documented several maternal emotional and behavioral changes, including significantly fewer externalizing behaviors for Trial 3 participants at 12 months postpartum and evidence of less stress, depression and substance use for subsamples of mothers who received the intervention across the three trials. More specific details about study outcomes are organized below by 1) parenting outcomes, 2) infant outcomes, and 3) maternal outcomes.

**Parenting Outcomes.** All three trials showed impact of early intervention on parenting using a range of measures, and as the length and rigor of the trials increased, greater evidence of parenting impact was found. All three trials confirmed highly significant (p<.001) outcomes for parenting knowledge, using a measure with items linked directly to Family Spirit intervention content. In Trial 1, maternal involvement changes were significant (p=.05) at 2 months postpartum and trending (p=0.06) at 6 months postpartum. However, this finding was not repeated in Trial 2 and not measured in Trial 3. In Trial 3, with the benefit of a larger sample and 12 months of follow up, additional significant parenting outcomes were demonstrated, including improved parent self-efficacy (p=.01); home safety attitudes (p=.03) and home safety practices (p=.07). Parent self-efficacy, defined by Teti and Gelfand⁷ as “the degree to which parents perceive themselves as capable and effective in the parenting role,” is an important finding for teenage mothers since maternal role attainment is more difficult for teen mothers who are still maturing to adulthood.⁸ We found no significant results on the Home Observational Measurement of the Environment (HOME) at 6 or 12 months postpartum in any of the trials. There is extensive detail in Chapter 3’s discussion about why this would be expected. In sum, other large home-visiting studies have not been able to identify impacts measured by the HOME until children are >2 years of age.⁹,¹⁰ Our experience suggests that many HOME items may not be developmentally relevant to infants (e.g. “[does child have] toys for literature and music”). Secondly, the HOME may need further cultural adaptation for indigenous populations. For example, our American Indian evaluators noted that some items were culturally irrelevant (e.g., the HOME scores positively for pets in the home, but pets are preferentially kept outside
in the participating communities) and may be biased against economically depressed families (e.g., “Child has a special place for toys and treasures”).

**Children’s Outcomes.** Trial 1 did not assess children’s outcomes, as the assessment period ended at 6 months postpartum and there was no appropriate validated infant measure for behavioral outcomes at 6 months postpartum. Both Trials 2 and 3 identified between group differences in infant outcomes at 12 months, using the Infant Toddler Social and Emotional Assessment (ITSEA), which has strong validity to identify externalizing, internalizing and dysregulation problems as early as 12 months of age that predict related outcomes in middle childhood and adolescence. In both Trials 2 and 3, significant positive outcomes for children at 12 months postpartum clustered in the externalizing domain (with greatest benefit in activity/impulsivity). Trial 2 also identified impacts within subscales of the internalizing domain (i.e., separation distress), while Trial 3 identified additional impacts in the dysregulation domain and compliance domain.

Infants’ study outcomes were consistent with 1) identified parent outcomes and 2) children’s developmental capacities (see Chapter 6).

**Sub-Analyses.** In Trial 3 we undertook a more in-depth analysis of outcomes for children whose mothers reported substance use at baseline (n=285; 88.5% of sample). These children would be expected to be at higher risk for behavior problems. We found children with mothers who were substance users in the intervention had fewer externalizing (p=.004) and dysregulation (p=.01) problems, and fewer scored in the clinically “at risk” range (≤10th percentile) for externalizing (p=.05) and internalizing (p=.04) problems than children of substance-using mothers in the control group. Sub-normal scores (≤10th percentile) on these sub-scales have been associated with serious behavior problems in later childhood, such as substance abuse, risky sex, and violence toward self and others, which are priority issues for American Indian communities. Based on scores for the control group alone, more children in this sample scored in the sub-clinical range (i.e., they are indicated to have behavior or emotional problems requiring clinical evaluation and possible treatment) for both externalizing and internalizing disorders, compared with the general US population samples in which the measure was normed. The indication from the data that the intervention can
move children out of the clinical-risk range is a finding with important public health relevance (see section 8.4).

**Maternal Emotional/Behavioral Outcomes.** In Trial 3, intervention mothers reported significantly fewer externalizing behaviors (p=0.04) at 12 months postpartum. In all three trials, we observed consistent trends toward lower depression scores in intervention mothers at 6 and 12 months postpartum (p=.06-.10). In Trial 3, there were also trends at 6 months postpartum for lower marijuana (p=.10) and illicit drug use (p=.09), and at 12 months, for lower internalizing problems (p=.06) and fewer total behavior problems (p=.07).

**Sub-Analyses.** In Trial 2, we explored if age or education – variables expected to identify mothers with higher psychological resources – modified behavioral or emotional outcomes for mothers. Stratifying by age and education was more feasible in Trial 2 because we had a larger age spread, from 13-22, compared to Trials 1 and 3, in which enrollment was limited to expectant teen mothers. In Trial 2, we found older (18-22 year old versus <17) and more educated (high school degree) intervention mothers had significantly fewer depressive symptoms at 6 months postpartum (p=.05) compared to older and more educated control mothers. Similarly, among more educated mothers (i.e., completed high school or equivalent) regardless of age, intervention mothers reported significantly fewer depressive symptoms (p=.05) and less parenting stress (p=.001) at 2 months postpartum. Older and more educated mothers may have had higher psychological resources to learn and apply intervention content. It is also possible that they had more capacity to self-evaluate their depressive symptoms and parenting stress across time. Further study is needed to corroborate this interpretation.

**8.3 METHODOLOGICAL STRENGTHS AND LIMITATIONS**

**Strengths**

**Overview.** Primary strengths of this research included: a well-executed community-based participatory research (CBPR) approach; a rigorous research design and data analysis approach; a standardized and mixed-
methods measurement battery; strong quality assurance and participant retention strategies; and a pattern of findings that have strong fit with the intervention’s theoretical model. Each of these components is described in detail below.

### Strengths of the Community Based Participatory Research Approach.

As noted in Chapter 1, a community-based participatory research (CBPR) approach was used to design key components of all three trials. International agencies are increasingly recognizing the importance of CPBR as an essential platform for conducting the best possible science. It is an essential tool for working with American Indian and other indigenous communities that have long been the subject of research, but whose values and priorities were often not reflected in those studies.17

The development and evaluation of the Family Spirit intervention occurred over a 16-year period (1996-2011), and was built on a foundation of trust that Johns Hopkins researchers had developed with the communities over a previous 15-year period. For this line of research, we established site-specific and cross-site community advisory boards comprised of key stakeholders to guide every element of the intervention and study design, including: choice of key intervention content and components; setting (home); participant population (teen mothers and children); key administration elements (i.e., providing flexibility to home visitors to schedule visits at times most convenient to teen mothers); and, ultimately, the increasingly rigorous evaluation design – all of which helped to ensure the success of the trials.

Both Johns Hopkins University and tribal partners agreed that demonstrating the efficacy of the Family Spirit intervention and the utility of Native paraprofessional home educators was key to its sustainability within the participating communities. Given a history of research ethics breaches, Native communities can be wary of research particularly when it involves vulnerable populations.18 Considerable discussions occurred as to whether to use non-randomized or alternative designs, but the partners ultimately agreed to proceed with the gold standard – a randomized controlled trial comparing Family Spirit to a suitable and beneficial control condition. Because the needs of teen mothers are substantial in the participating reservation settings,
the acceptability of a control condition required that it provide meaningful and useful service above and beyond a waitlist or usual care comparison group. As was described in Chapter 1, the control condition evolved over time to decrease its potential to dilute intervention results, while remaining beneficial and ecologically valid across all three trials.

In summary, using CBPR was a critical strength in conducting this research and facilitated a process whereby both the intervention and evaluation increased in community relevance, quality and rigor over the study period.

**Strengths of the Research Design.** The three trials evaluating the Family Spirit intervention used the most rigorous research design method – randomized controlled trials – to study the Family Spirit intervention’s impact. In all three trials, we concealed group allocation from study staff that randomized participants, so not to bias group assignment. It is not possible in psychosocial trials for the participants to be blinded to group assignment; however, we took every precaution to keep evaluators and investigators blinded to participants’ group status throughout the duration of each trial. In Trial 3, we also used blinded independent evaluators to protect against measurement bias and carefully selected a control condition with no active parenting education component so we could better isolate the effects of the Family Spirit intervention on participants’ outcomes.

**Strengths of Data Analytic Approach.** We employed an Intent-To-Treat (ITT) data analytic approach for all three trials. This method avoids biases that occur from selective drop-out (as attrition is generally associated with doing poorly) and preserves the experimental integrity of randomization. In Trial 3, we also employed the most current method available for handling missing data – multiple imputation. Our imputation model included relevant baseline demographic characteristics, total scores on outcomes at each assessment point, and indicator variables for study site and treatment condition. Using these variables, 20 imputed data sets were generated and the results of identical analyses on each imputed data set were combined using Rubin’s established guidelines.19
Multiple imputation is preferred over reporting results only for those with complete data, as the latter approach changes both the scientific question and population of interest (i.e., the participant population becomes those who comply with receiving intervention as opposed to those who are offered intervention, as well as those for whom we could collect all outcome assessments). For further proof of efficacy, we did run analyses for those with complete data, and the overall pattern of results was very similar. The main difference between the two approaches was that the effect was stronger in the sample with missing data (as one would expect given that doing poorly is likely associated with attrition). Employing both an ITT and multiple imputation approach held our analyses to the highest possible scientific standards, and produced more valid results.

**Strengths of Measures.** The assessment battery was designed for administration by paraprofessionals and our selection of low-cost standardized measures increased its potential for replication in other indigenous and low-resource settings in the future.

Study measures were carefully chosen in consultation with community advisors as the most acceptable culturally and contextually to the community and the best or most widely used for their purpose. The assessment battery included mixed methods – maternal self-reports, observational assessment by blinded independent evaluators, and medical chart reviews (data not yet published). For the observational assessments, in Trial 3 we used descriptive anchors for each item to promote consistency, and conducted quarterly inter-rater reliability checks, maintaining ~95% agreement between raters on primary outcome assessments.

Also in Trial 3, we introduced an Automated Computer Assisted Survey Instrument (ACASI) to collect data pertaining to the most sensitive topics (substance use, high-risk sex, birth control and family planning). This innovation produced higher endorsement of sensitive behaviors than concurrently used paper and pencil self-report formats. (Data in press.) Using ACASI also helped to: 1) overcome literacy constraints in our population by allowing for participants to listen to questions over headphones; 2) enhanced data quality and efficiency as data are uploaded directly after participants
answer questions; and 3) may have improved data validity by affording the respondents greater privacy in answering questions on the computer. This method may have particular utility to behavioral health trials in other indigenous and low-resource settings.

**Strengths of Quality Assurance and Retention Strategies.** Over the course of the three trials, strong quality assurance methods evolved. Key strategies included: highly structured training and supervision for paraprofessional interventionists and evaluators; the requirement that interventionists had to demonstrate mastery of the intervention through both written and oral exams before teaching it (scoring 85% or higher); a clearly written policy and procedures manual with continuous updates as needed; intervention and assessment fidelity checks including random review of 20% of all audio-taped intervention sessions for home visitors; and quarterly inter-rater reliability assessments for independent evaluators, with demonstrated 95% agreement.

Retention strategies were crafted based on lessons gleaned from published home-visiting trials and from conducting three successive trials in our unique study setting. Retention of families in other home-visiting trials has been linked to supervision and support of interventionists, flexibility in scheduling visits, and consistent involvement of relatives. The Family Spirit intervention was staffed to provide regular on-site supervision, weekly cross-site conference calls and quarterly site visits. Caseloads were designed for optimal retention (n=25), and home visitors were given flexibility to reschedule visits or assessments if participants were facing personal challenges. In Trial 3, we also instituted quarterly study newsletters, birthday cards for mothers and their babies and annual certificates recognizing participants’ progress in the program – all of which were very popular. In addition, we added greater flexibility to our participant drop-out policy. In Trials 1 or 2, if participants missed three or more scheduled appointments, they were dropped from the study. After gaining a better appreciation for the residential instability and frequent crises that arose in participants’ lives, in Trial 3, we allowed participants short breaks from interventions or assessments, as long as they agreed to stay in and rejoin the study at a later time point. These innovations combined allowed us to reduce attrition from
50% in Trial 2 at the 12-month follow-up time point to 6% in Trial 3 at 12 months postpartum.

**Strengths of Theoretical Fit.** Each trial provided successive evidence for the model and underlying hypothesis, culminating in Trial 3. As illustrated in Chapter 1 and 4, our theoretical model predicted that the Family Spirit intervention’s impact on positive parenting, while secondarily reducing parent stressors that can impede positive parenting, will mediate positive behavior outcomes in children. Important support for the theoretical model was derived from our baseline analyses in Trial 3 of correlates of risk for mothers’ illicit drug use, the largest behavioral health disparity in the study population (see Chapter 5). Mothers’ lifetime and pregnancy drug use was most highly correlated with reporting of poor functioning and high conflict in their family of origin. These findings corroborate our theoretical model which posits negative parenting as the mediating factor that predicts child behavior problems across the lifespan, including alcohol and drug use. It also supports the study’s rationale that family-based intervention promoting positive parenting in pregnancy and early childhood has the potential to break intergenerational cycles of drug use and other behavioral health disparities in this population. Outcome findings in Trials 1, 2 and 3 showed significant impacts on parent knowledge, involvement and self-efficacy, and Trial 2 and 3 showed significant impacts on infants’ behavioral outcomes in the intervention versus control groups who were followed to 12 months of age. Trial 2 also documented that knowledge scores were inversely correlated with infant behavioral outcomes (Pearson \( r \) range of \(-0.2 \) to \(-0.5\)), such that the higher the knowledge score, the fewer infant behavioral problems.\(^{23}\) As we continue analyses for Trial 3, we are planning more comprehensive structural equation modeling to further evaluate and estimate causal relationships defined by the model. In the meantime, the sub-analysis in Trial 3 of substance-abusing mothers, revealing more significant intervention impact on children of mothers with lifetime substance use at baseline, provides further evidence for the model. In other words, the theoretical model predicts that improved parenting in the intervention group is buffering the negative effects of maternal substance use on children, which can more easily be detected when comparing substance users across intervention and control groups. In summary, all significant results and
trends were consistent with study’s theoretical model and hypotheses, with Trial 3 corroborating hypotheses and extending findings from the two smaller previous trials.\textsuperscript{25,26}

**Limitations**

**Overview.** The methodological limitations for this research included: 1) high attrition and lack of independent evaluators in Trials 1 and 2, that was corrected in Trial 3; 2) some measurement issues, including ceiling effects on some of the parenting and maternal behavioral and emotional measures; 3) the large number of dependent variables that were measured (or “multiple comparisons”), which increases the likelihood of producing significant findings due to chance; and 4) the need for additional follow up to determine evidence for longer-term effects of the intervention. Each potential weakness is discussed below.

**Attrition.** In Trial 1, more than 23% of participants (12 of 53) dropped from the study before the 6 month assessment point, and in Trial 2, more than 50% (85 of 167) failed to complete the 12-month assessment. These attrition rates weakened the evidence of study impact, in spite of the fact those participants who dropped did not differ significantly on baseline demographic or outcome characteristics. By Trial 3, we introduced several innovative retention strategies that had a dramatic effect on retention: we maintained 94% of the sample to the 12-month postpartum time point. Prior to the publication of Trial 3, a federally contracted systematic review of tribal home-visiting programs conducted in tribal communities concluded that, “None of the home visiting program models included in this review met DHHS [Department of Health and Human Service] criteria for an ‘evidence-based early childhood home visiting service delivery model,’”\textsuperscript{27}p. 8 and the authors cited high attrition rates as a major limitation across all studies, including our first two trials.\textsuperscript{23,24} Trial 3 would now meet the review’s criteria for a high-quality impact study that reported findings for American Indian populations. Our persistence in fielding iterative trials of the Family Spirit intervention produced new understanding about sample maintenance strategies for American Indian and other highly mobile and stressed populations.
CHAPTER 8

**Measurement Challenges. Ceiling effects.** We experienced ceiling effects on several maternal self-reports in which participants’ responses over time consistently clustered on the upper levels of several scales, thus thwarting our ability to detect positive changes overtime. For example, in spite of challenging home environments, poor living conditions and high substance use rates, participants’ scores on the HOME (measure of the home environment), ASEBA (measure of adolescent behavior health status) and CES-D (measure of depressive symptoms) were better or comparable to US All Races samples. More research is needed to determine why these instruments are leading to a ceiling effect in this population. Due to the broad-based ambient risks, one would expect American Indian teen mothers to score below US All Races norms. These instruments may require additional construct and/or content validity, and normative data for American Indian adolescent populations.

**Self-Reports.** We relied on self-reports for many measures, and participants may have altered responses to self-reports based on social desirability. However, the fact that mothers in both groups reported high rates of substance use across time, including illegal drugs, counters a response bias argument. Some studies have corroborated self-reports with biological data (i.e., cotinine samples) and videotaped observational measures coded by external masked evaluators. These methods were neither culturally acceptable nor financially feasible in our studies.

**Multiple Comparisons.** We performed a large number of statistical tests, with an alpha level set at .05. Because of the large number of dependent variables tracked in our study, the likelihood of significant findings due to chance is increased.

There is a wide range of opinions in the statistical literature about how to deal with Type I errors (findings of false “significance”) in randomized controlled trials with multiple outcomes. Some argue to adjust p-values, while others argue it is inappropriate and may lead to incorrect conclusions and inflation of Type II error. We chose not make p-value adjustments. Our main objection to p-value adjustment was that if we reduced the chance of making a Type I error, we also increased the chance of making a Type II error (increasing the chance that effective interventions are not discovered). Ultimately, the debate over the need to adjust for multiple comparisons rests
upon the quality of the science, rigor of the methodology, and the match of
the pattern of findings to the theoretical model underlying the intervention.30
In this line of research, the domains assessed were carefully chosen to reflect
the theory behind the intervention. In Trial 3, all significant results and
trends were consistent with study’s theoretical model and hypotheses and
extend findings from smaller previous trials.23-26

**Need for Long-Term Follow Up.** This line of research has addressed
some of the important limitations in the home-visiting field and extends the
potential benefit of home visiting to American Indian and, potentially, other
indigenous or similarly stressed communities. One-year postpartum
outcomes suggest that home visiting by paraprofessionals can significantly
impact behavioral health disparities associated with teen pregnancy and drug
use by supplementing routine prenatal and well-baby care with parenting
education to prevent maternal and child behavior problems whose
trajectories challenge under-resourced reservation communities. However, a
longer study period is needed to observe the duration of intervention effects
on mothers and children over time. Trial 3 is designed to continue
intervention and assessment until three years postpartum, and will provide
additional evidence about how short-term impacts track to longer-term
outcomes through future analyses. We also continue to seek funds to follow
Trial 3’s study participants for a longer time period, ideally to when mothers’
transition fully to adulthood and their behavioral repertoires are fully
established, and when children transition to school, and their adolescent
behavioral trajectories are more clearly determined.

**8.4 IMPLICATIONS OF METHODS AND RESULTS**

This body of research – both in terms of its Methods and Results – has
potential to make four significant contributions to prevention science:

1) The randomized intervention trials represent a breakthrough in
community-based participatory science in the behavioral health field with
indigenous communities. A long history of research exploitation and distrust
has diminished opportunities for randomized controlled intervention trials in
indigenous communities, especially those targeting culturally and
emotionally sensitive topic areas – such as parenting, substance abuse risk, and related behavior problems. The positive outcomes of these trials, including the employment of Native paraprofessionals as interventionists and independent evaluators, and the usefulness and relevance of the results to indigenous communities (which shoulder an unrivaled burden of behavioral health disparities) has potential to advance important lines of behavioral science for and by indigenous communities.

2) The data provide novel evidence that indigenous paraprofessionals can produce measurable impacts using common and standardized metrics on targeted early maternal and child behavior risks that predict improved behavioral health trajectories for mothers and children in high-risk settings. Because indigenous settings worldwide share similar or worse behavioral health disparities and human resource deficits (lack of trained professionals), this intervention approach begs to be tested in other relevant global settings.

3) Two of the randomized controlled trials (see Chapters 3 and 6) provide evidence of intervention impact on children’s behavioral outcomes at 12 months postpartum, the earliest developmental time point any home-visiting trial has shown emotional and behavioral differences in children. We achieved this by taking advantage of a new child assessment tool – the Infant and Toddler Social and Emotional Assessment – that has high validity to identify children’s behavior problems at 12 months of age that track to later persistent child behavior problems, including conduct disorder, substance use, and high-risk sexual behavior. In addition, children of mothers who were most at risk at baseline (i.e., early initiation of and frequent substance use) benefitted most. This finding signals that effective parent training may buffer high-risk mothers’ offspring from urgent intergenerational behavioral health risks. It also provides evidence that we have important new measurement tools to assess short-term impacts, critical in low resource settings that may have limited funds for longer studies.

4) The impacts from the behavioral health trials also hold promise for similar use of paraprofessionals to innovate mental health care systems, with clear relevance to low income, under-resourced communities with access barriers to clinic-based treatment (see Chapter 7). The World Health Organization predicts mental health disorders, specifically depression, will be the second
leading contributor to the global burden of disease in 2020. Mental health disorders are particularly challenging in developing and, especially, indigenous settings, where data on prevalence and resources to address problems are lacking, and where there may be cultural mismatch of western screening and treatment approaches. Paraprofessional-delivered interventions that focus on prevention and case management hold particular promise in the mental health service domain.

In addition to signifying the generalizability of the findings to other populations and research approaches, these four contributions have social, theoretical and clinical relevance. From a social perspective, the renewal of American Indian and other indigenous populations’ health depends on the development of culturally relevant and innovative health system interventions that participating communities are willing to evaluate in rigorous ways. This line of research provides a case example for future work in this domain. In addition, evidence supporting the employment of paraprofessionals to improve existing health care systems could lead to the engagement of an underutilized indigenous workforce, reduce the cost of health care, and raise the human capital of socioeconomically distressed communities. Finally, the success of the intervention design suggests that a community values-sensitive intervention may be helpful in a variety of cross-cultural settings. From a theoretical perspective, indigenous paraprofessionals may prove the most effective change agents in the behavioral health arena, as they assume multiple roles as mentors, educators and “connectors” within the larger health system. Further, their contributions to both intervention development and assessment adaptation can bring new cross-cultural understanding to the behavior health development field. Finally, the idea of intergenerational (parent-child) intervention and evaluation may have special import to indigenous communities, as family is generally valued as the nexus of strength for individuals. From a clinical perspective, research outcomes suggest that home-visiting by paraprofessionals can address behavioral health disparities associated with teen pregnancy and drug use by supplementing routine prenatal and well-baby care with adjunct, targeted parenting education – particularly important in settings with large health access barriers. Evidence from this series of trials suggests that the Family Spirit intervention could move children in
high-risk settings out of clinically meaningful risk for early child behavior problems, potentially improving the communities’ long-term public health and economic status. Findings also corroborate past evidence that home-visiting interventions may be most critical for young mothers in greatest need. In American Indian and other settings with high endemic rates of substance use, screening for early initiation and pregnancy-related substance abuse could be used to identify mothers and children who could benefit most from the Family Spirit or similarly targeted interventions.

8.5 RECOMMENDATIONS AND DIRECTIONS FOR FUTURE

The findings from this series of trials point to important directions for future research. First, positive study results across three diverse tribal populations suggest that the paraprofessional-delivered Family Spirit intervention could be generalizable to other American Indian and similar indigenous population settings. A larger scale pragmatic effectiveness trial over a longer study period is an obvious next step, incorporating elements from the emerging field of implementation science to study methods to promote sustainable uptake, adoption, and implementation. Dissemination in indigenous settings will require cultural and language adaptations, and may lead to innovations in how the lessons are taught and how the program is evaluated. For example, in discussions with colleagues working with Aboriginal populations in Australia, we have considered the barrier that illiteracy presents to training trainers and mothers with a flipchart-based curriculum, and considered use of portable computer tablets where paraprofessionals could use highly visual and audio-recorded materials as prompts for lesson content. Mobile health (i.e., PDAs) and ACASI technologies could also be integrated to collect evaluation data in rural populations, especially given the low cost and availability of cell phones and PDAs in indigenous settings and the demonstrated utility and effectiveness of ACASI in our study population.

To effect broad-based policy change, a cost effectiveness analysis of the paraprofessional-delivered Family Spirit program is warranted. Previous cost-effectiveness studies in the US have shown significant savings in government spending for mothers who received an early parenting nurse
home-visiting program compared to those who received treatment as usual.\textsuperscript{34} Given the larger disparities and increased lifetime costs from poorer health, education and employment status needs in American Indian communities, in addition to the lower costs of employing paraprofessionals compared to nurses – this line of research is promising and urgent.

Our studies confirmed past findings that mothers with the highest needs are most responsive to the intervention, and should be carefully targeted through screening strategies. However, considering the long duration of the Family Spirit and other similar home-visiting curricula, and the unique individual needs of each mother, a \textbf{modularized intervention and research design approach} could make a valuable public health contribution. Modular design has been applied most commonly to psychotherapeutic approaches, and has been defined in recent literature as:

\begin{quote}
\textit{“…breaking complex activities into simpler parts that may function independently. More specifically, modules are self-contained functional units that connect with other units, but do not rely on those other units for their own stable operations.”}\textsuperscript{35}
\end{quote}

One can imagine a mother who is screened at baseline and found at risk for postpartum depression and early initiation of substance use would receive distinct intervention components compared with a mother whose baseline screening determines risk for obesity and gestational diabetes. Progress in developing “SMART” (Sequential, Multiple Assignment, Randomized Trial) designs to study adaptive interventions or individualized treatment sequences is timely and will aid this research approach.\textsuperscript{35}

Finally, the most practical and important consideration emanating from this research is \textbf{how best to promote the role of paraprofessionals worldwide in behavioral and mental health promotion}. As the evidence base grows, complex issues related to professional versus paraprofessional turf, liability and certification still impede progress toward fully integrating paraprofessionals into health care systems. Professional providers have documented reluctance about delegating tasks requiring clinical skills and certification, while health system administrators express concerns about
liability for their paraprofessional employees' actions. Given the magnitude of the global behavioral and mental health crisis and the severe shortage of trained professionals in indigenous and other rural and low resource communities, the public health community must act swiftly to determine the most effective roles, competencies, training and certification strategies for paraprofessionals. Simultaneously, it is a moral and ethical imperative in historically oppressed and disenfranchised indigenous communities to create an educational career trajectory for paraprofessionals, so that paraprofessional certification is not viewed as a terminal degree. Rather, the goal should be that indigenous community members have equal capacity and opportunity to fill all necessary roles in the ideal health care system that is to serve their populations. In the meantime, continued bi-directional learning interactions between non-Native professionals and Native paraprofessionals working within the same health care system will advance public health knowledge and quality of prevention and care.

Given the rising tide of behavioral health problems across the globe, culturally relevant health systems innovations are needed now. Paraprofessional intervention models that employ locally trained community members is a promising strategy that deserves the combined attention of scientists and policy makers.
REFERENCES


