

# The Family Spirit Trial for American Indian Teen Mothers and Their Children: CBPR Rationale, Design, Methods and Baseline Characteristics

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**Abstract** The purpose of this paper is to describe the rationale, design, methods and baseline results of the Family Spirit trial. The goal of the trial is to evaluate the impact of the paraprofessional-delivered “Family Spirit” home-visiting intervention to reduce health and behavioral risks for American Indian teen mothers and their children. A community based participatory research (CBPR) process shaped the design of the current randomized controlled trial of the Family Spirit intervention. Between 2006 and 2008, 322 pregnant teens were randomized to receive the Family Spirit intervention plus Optimized Standard Care, or Optimized Standard Care alone. The Family Spirit intervention is a 43-session home-visiting curriculum administered by American Indian paraprofessionals to teen mothers from 28 weeks gestation until the baby’s third birthday. A mixed methods assessment administered at nine intervals measures intervention impact on parental competence, mother’s and children’s social, emotional and behavioral risks for drug use, and maladaptive functioning. Participants are young (mean age=18.1 years), predominantly primiparous, unmarried, and challenged by poverty, residential instability and low educational attainment. Lifetime and pregnancy drug use were ~2–4 times higher and ~5–6 times higher, respectively, than US All Races. Baseline characteristics were evenly distributed between groups, except for higher lifetime cigarette use and depressive symptoms among intervention mothers. If study aims are achieved, the public health field

will have new evidence supporting multi-generational prevention of behavioral health disparities affecting young American Indian families and the utility of indigenous paraprofessional interventionists in under-resourced communities.

**Keywords** American Indian · Substance use · Teen parenting · Home-visiting · Parenting interventions · Randomized trial

## Introduction

The ~1.9 million American Indians and Alaska Natives who reside on reservations or trust lands have the largest health and socioeconomic disparities of any racial or ethnic group in the U.S. (DHHS [Department of Health and Human Services] 2009). While infectious disease and infant mortality rates have fallen sharply over the past three decades, behavioral health disparities including drug abuse, diabetes, obesity, and intentional and unintentional injuries are increasing, particularly among American Indian youth and young adults (DHHS 2009).

Teen parenting, which is common in reservation communities, is a key contributing factor for behavioral health disparities. Births to American Indian teens have increased more rapidly in the past decade than among any other racial or ethnic group (The National Campaign to Prevent Teen and Unplanned Pregnancy 2008). Nearly half (41%) of reservation-based American Indian females have their first child in adolescence, compared to 21% of US All Races (DHHS 2009). Teen childbearing has been associated with a number of negative outcomes that threaten mothers’ ability to parent their children, including postpartum depression

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(Hoffman 2006), domestic violence (Hoffman 2006), child abuse (Stier et al. 1993), and poorer educational and employment outcomes (Perper et al. 2010). Reservation communities also have high rates of poverty, joblessness, school dropout and drug use, which further threaten the capacity of American Indian teen mothers to parent effectively or transition themselves and their children to a healthy adulthood, thus perpetuating an intergenerational cycle of problems for reservation communities.

Three decades of research identify ineffective parenting characterized by poor monitoring (Pettit et al. 2001), hostility and abuse/neglect (Lindhout et al. 2009), coercive interactions (Wong et al. 1999), and harsh, unresponsive or rejecting parenting (Frick et al. 1994) as a mediator of persistent childhood behavior problems (Belsky et al. 2007). The effects of poor parenting early in life result in infant and toddler externalizing and internalizing problems (Lindhout et al. 2009; Vanderheyden and Witt 2000; Wong et al. 1999) that track to poor school performance in the middle years (Campbell 1995; Waylen et al. 2008); anti social (Ramrakha et al. 2007), delinquent and aggressive behavior (Wong et al. 1999); and high-risk sex in adolescence (Ramrakha et al. 2007); and are potent predictors of adolescent drug use and dependence (Brook et al. 1996; Campis et al. 1986; Sartor et al. 2007; Siebenbruner et al. 2006; Wong et al. 1999).

The efficacy of nurse-delivered early home-visiting programs to promote parenting and prevent health and behavioral problems in young mothers and children is well established (Olds 2002). Successful home-visiting interventions in high-risk settings address multiple risk factors within families (Aguilar et al. 2000), and are individualized to contextual factors that challenge parents' abilities to provide a safe and caring environment for their children (Shaw et al. 2003). Young American Indian mothers have a risk profile (low income, young, poor, barriers to health care and education) that is generally targeted by home-visiting interventions. Home-visiting interventions are additionally suited to Native communities based on cultural preferences for family-based approaches (Barlow and Walkup 1998).

Conceived through a decade-long community based participatory research (CBPR) process shared by the Johns Hopkins Center for American Indian Health (hereafter "JHU") and three participating communities (hereafter "tribal partners"), the Family Spirit intervention was designed to promote family-based protective factors and reduce behavioral health disparities among American Indian teen parents and their children. The partners determined that establishing the efficacy of a paraprofessional-delivered home-visiting intervention was critical to serving teen mothers with scarce prevention resources and to sustaining a successful community-driven program.

The aim of this paper is to describe the Family Spirit intervention and the methodology of the randomized

controlled trial evaluating its efficacy ("In Home Prevention of Substance Abuse Risks for Native Teen Families.": 1 R01DA019042-01A1). Specifically, we describe the trial's CBPR approach, study design, and methods, and present baseline characteristics of enrolled participants.

## Methods

### Community Based Participatory Research (CBPR) Approach

CBPR is defined as a collaborative process that "*engages community members, employs local knowledge in the understanding of health problems and the design of interventions, and invests community members in the processes and products of research*" (AHRQ [Agency for Health Research and Quality] 2002). CPBR is increasingly being advocated by national agencies as an essential tool for disadvantaged communities that have been the subject of research, but whose values and priorities were not reflected in the projects (Minkler et al. 2003). Given the contentious history of research in tribal communities, adopting a CBPR approach is essential to ensuring the sensitive development of health interventions that are grounded in cultural traditions and developed with full participation of the communities involved (Davis and Reid 1999). This section summarizes the CBPR processes that dictated decisions regarding the Family Spirit trial design.

In 1995, JHU and its two longest-term tribal partners, located in the southwestern US, set out to address priority behavioral health disparities for American Indian children. Reviewing the constellation of disparities affecting tribal youth—substance abuse, obesity, diabetes, suicide and unintentional injuries—tribal opinion leaders concluded that poor parenting and family dysfunction were primary root causes. While the historical factors that led to widespread family challenges were discussed, tribal stakeholders viewed family-based approaches to promoting effective and competent parenting as a powerful and culturally preferred strategy to avert intergenerational behavioral problems. They also identified the most vulnerable families—teenage parents and their children—as the target population. Stakeholders felt that intervening with teen parents at home would reduce stigma associated with receiving services in public places and overcome transportation, cultural and other access barriers to receiving care at clinics and schools, especially as many expectant teens do not attend school. Further, because most Native teen parents reside with their parents, aunts, uncles and older siblings who may also share in child care, home visits would allow educators to influence care practices of others involved with childrearing.

In-depth interviews with teen parents and a series of round table discussions with community advisory boards informed intervention content. Prioritized topic areas included labor and delivery, parenting, child care and development, family planning, substance abuse prevention, and goal setting for education and employment. Community board members determined curriculum delivery should include a highly visual format with culturally relevant illustrations and the use of stories with which teen parents could identify to punctuate key teachings.

Tribal stakeholders also recommended that local paraprofessionals, with parenting experience and the capacity to speak Native and English languages, serve as home visitors. The shortage of American Indian nurses and cultural barriers to non-Native home visitors drove their argument to utilize Native paraprofessionals. While home-visiting studies in the U.S. have suggested that nurses are more effective than paraprofessionals in impacting maternal and child behavioral outcomes, methodological flaws in studies comparing nurses to paraprofessionals (Olds et al. 2004, 2002; Walkup et al. 2009) limit conclusions. Further, studies in low-resource international settings that share similarities with reservation environments have demonstrated paraprofessionals or “lay health workers” with adequate training are effective (Emond et al. 2002; Jack et al. 2002; Lam et al. 2003; Walt et al. 1989), more culturally accepted (Zeit et al. 1993) and more persuasive for behavior change (Singh 1997) than nurses. Paraprofessionals are also more cost effective than professional health educators (Cufino Svitone et al. 2000; Kegler et al. 2003), a critical benefit in under-resourced settings. Additionally, home-visiting programs have been found to be more successful when providers and participants match on age, parenting status/history and race/ethnicity (McGuigan et al. 2003).

Both JHU 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. Considerable discussion occurred whether to use non-randomized or alternative designs, but the partners ultimately agreed to proceed with a randomized controlled trial comparing Family Spirit to a suitable control condition. Due to the substantial needs of teen mothers in reservation settings, the control condition was designed to provide a meaningful long-term service above and beyond a waitlist or usual care comparison group.

## Trial Design

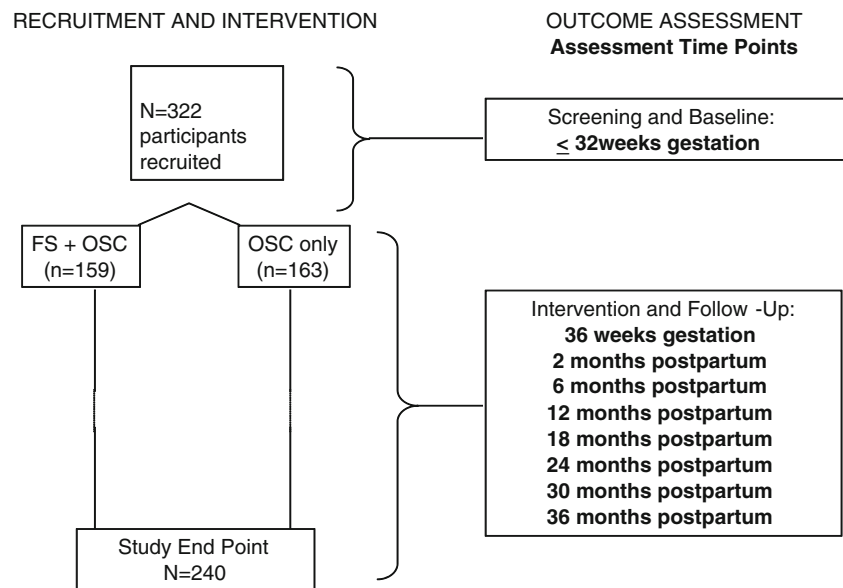
**Pilot Studies** The feasibility of conducting a randomized controlled trial of the Family Spirit intervention was evaluated through two pilot trials of 9-months (Barlow et al. 2006) and 15-months duration (Walkup et al. 2009). For the pilot trials,

the control condition consisted of a home-visiting, breastfeeding education program. The pilot trials determined that randomization was feasible, that both interventions were acceptable and that the Family Spirit intervention impact was promising. Intervention group mothers had improved parenting knowledge, greater maternal involvement, and fewer depressive symptoms compared to mothers receiving breastfeeding education only (Barlow et al. 2006). The second study also indicated that infants of intervention mothers had significantly fewer externalizing and internalizing behaviors at 1 year of age than control infants (Walkup et al. 2009). The latter findings represent the first report of positive infant social and behavioral outcomes in the home-visiting literature. In addition, these studies contributed new evidence regarding the promise of paraprofessional home visitors in the United States. However, there were a number of study limitations, including absence of masked evaluators, limited quality assurance and sample maintenance procedures, and the inability to evaluate longer term maternal and child outcomes.

**Family Spirit Trial Design** The current Family Spirit trial is a randomized (1:1) controlled comparison of the Family Spirit Intervention + Optimized Standard Care (OSC) vs. OSC alone from pregnancy to the baby’s third birthday. Outcomes include maternal and child social, emotional and behavioral health from pregnancy through the child’s first 3 years of life. The period of observation allows for the identification of intervention benefit on important risk factors that portend negative intergenerational cycles of poor maternal and child outcomes. Figure 1 depicts the general trial design.

**Study Area and Population** Study sites included four reservation communities in the southwestern US (referred to as sites 1–4). These communities are rural and isolated, with populations of 15,000–25,000 people each. While the communities are striving to maintain the strengths of their indigenous cultures and languages, they struggle against economic hardship and stressed educational systems. They also experience some of the largest health disparities in the nation, including substance use, mental health, and chronic diseases.

**Recruitment** Eligible participants were expectant American Indian teens (ages 12–19 years at conception)  $\leq 28$  weeks gestation from four reservation communities. Participants were recruited and randomized between May 2006 and May 2008. In January 2007, eligibility criteria were slightly modified to allow for gestational ages  $\leq 32$  weeks. Participants were recruited from Indian Health Services (IHS) clinics, schools, WIC offices, and by word of mouth. Local study staff approached potentially eligible young women and screened them for initial inclusion criteria. Informed consent

**Fig. 1** General design of the Family Spirit trial

was obtained from the parent or guardian and assent from the participant. If a participant was  $\geq 18$  years old, informed consent was obtained from the participant alone. A total of 743 women were assessed for eligibility and 381 were excluded ( $n=214$  were ineligible and  $n=167$  declined to participate). Of the 362 women who gave consent to participate,  $N=322$  women completed the baseline assessment and were randomized (a total of 40 women either declined to complete the baseline assessment or were unable to be located).

**Randomization** After completing the baseline assessment, participants were stratified by site, age (12–15 vs. 16–19 years) and history of previous live births (0 vs.  $\geq 1$ ) with a 1:1 allocation and randomized in blocks of four into two groups: Family Spirit intervention plus Optimized Standard Care (OSC) vs. Optimized Standard Care (OSC) alone. The data manager created the randomization sequence using Stata 9.0 (StataCorp LP 2005), and the study coordinator delivered the randomization status of each individual over the telephone to the unblinded field staff member who had enrolled the participant.

**Sample Size and Power** The primary outcome variable for determining sample size and power for the trial was mother's effective and competent parenting as measured by the Home Observation for Measurement of the Environment (HOME) (Caldwell and Bradley 1979). Effective home-visiting programs have been associated with total HOME score differences of 1–3 points with standard deviations in the range of 4–6 points. Given the relative costs of the Family Spirit intervention, we choose 0.3 as the minimum detectable effect size because this magnitude of effect is feasible, has meaningful public health significance, and is consistent with previous methodologically rigorous studies.

Based on our preliminary studies, we assumed that most participant attrition would occur within the first 6 months, with a total of 25% dropout. We conservatively assumed that we would be able to obtain HOME measures for an average of at least 4 of the 6 possible time points during which it is gathered between 6 and 36 months postpartum. With these assumptions, a Type I error of 5%, 90% power, and a within-family correlation of  $r=0.5$ , we required 120 participants in each study arm at the study end point. Inflating for loss to follow-up, we required 160 participants to be enrolled in each arm, for a total sample size of 320. This sample size will allow us to detect an effect size of 0.33 with 90% power for the HOME, or 0.30 with 84% power.

**Human Research Review Procedures** The study was approved by a total of 11 tribal research review and advisory boards, the Phoenix Area Indian Health Service Institutional Review Board, and the Johns Hopkins Bloomberg School of Public Health Institutional Review Board. Serious adverse events (e.g., participant death or hospitalization) for both mothers and/or their children are reported on a real-time basis to participating IRBs, and tabulated and reported to the trial's Data Safety and Monitoring Board (DSMB). The DSMB meets with study investigators biannually to review study progress and adverse events.

#### Design of the Family Spirit Intervention

**Theoretical Model** The theoretical model underpinning the Family Spirit intervention is based on G.R. Patterson's developmental model which posits parenting as the critical link between parents' personal characteristics and environmental context and their children's individual risks and ultimate outcomes (Patterson et al. 1989). Based on this framework, the

Theory of Planned Behavior (TPB) informed the intervention development (Ajzen 1991). The TPB posits that mothers’ adoption of a targeted behavior will be based on: 1) her beliefs or attitudes toward the value or importance of adopting the behavior, 2) existing social norms that influence her behavior adoption, and 3) her perceived control or ability (i.e., self-efficacy) to carry out the behavior. These three factors in combination affect her behavior intention.

Figure 2 illustrates how the Family Spirit intervention is designed to impact short-, medium- and long-term maternal and child behavioral and emotional outcomes by promoting effective, competent parenting and maternal life skills. It hypothesizes reducing maternal and child emotional/behavioral problems in early childhood will codify a more positive behavioral trajectory for mothers and children over the life course. Behavior change is expected to occur through home-based one-on-one teaching of the structured Family Spirit curriculum by a sensitive, empathic and well-trained indigenous “Family Health Educator.”

Given the heightened risk for substance abuse, high-risk sexual practices and poor birth spacing among American Indian adolescents, the Family Spirit intervention is delivered until 3 years postpartum, to buffer mothers as they re-enter their peer groups and transition to adulthood. Family

Spirit’s home-visiting principles are based on “Healthy Families America/Indiana,” which was selected by the participating communities for its cultural relevance. Healthy Families America (HFA) is defined by 12 key home-visiting principles regarding client service and case management, but does not include specific intervention content (Daro and Harding 1999).

The Family Spirit curriculum lessons focus on three domains: 1) parenting skills across early childhood (0–3 years); 2) maternal drug abuse prevention; and 3) maternal life skills and positive psychosocial development. The American Academy of Pediatrics’ *Caring for Your Baby and Young Child: Birth to Age 5* (Shelov et al. 2004) was selected as the definitive reference for child care and parenting information, and was compatible with tribal and IHS standards of care. Lessons are delivered in a one-on-one format in participants’ homes or other private locations using table-top flip charts. Each visit lasts approximately 1 hour and is structured to include rapport building, review of previous lesson and past referrals, teaching of lessons and related activities, question/answer period and distribution of lesson summary hand-outs.

Several key administrative features associated with effective home-visiting interventions were incorporated in the

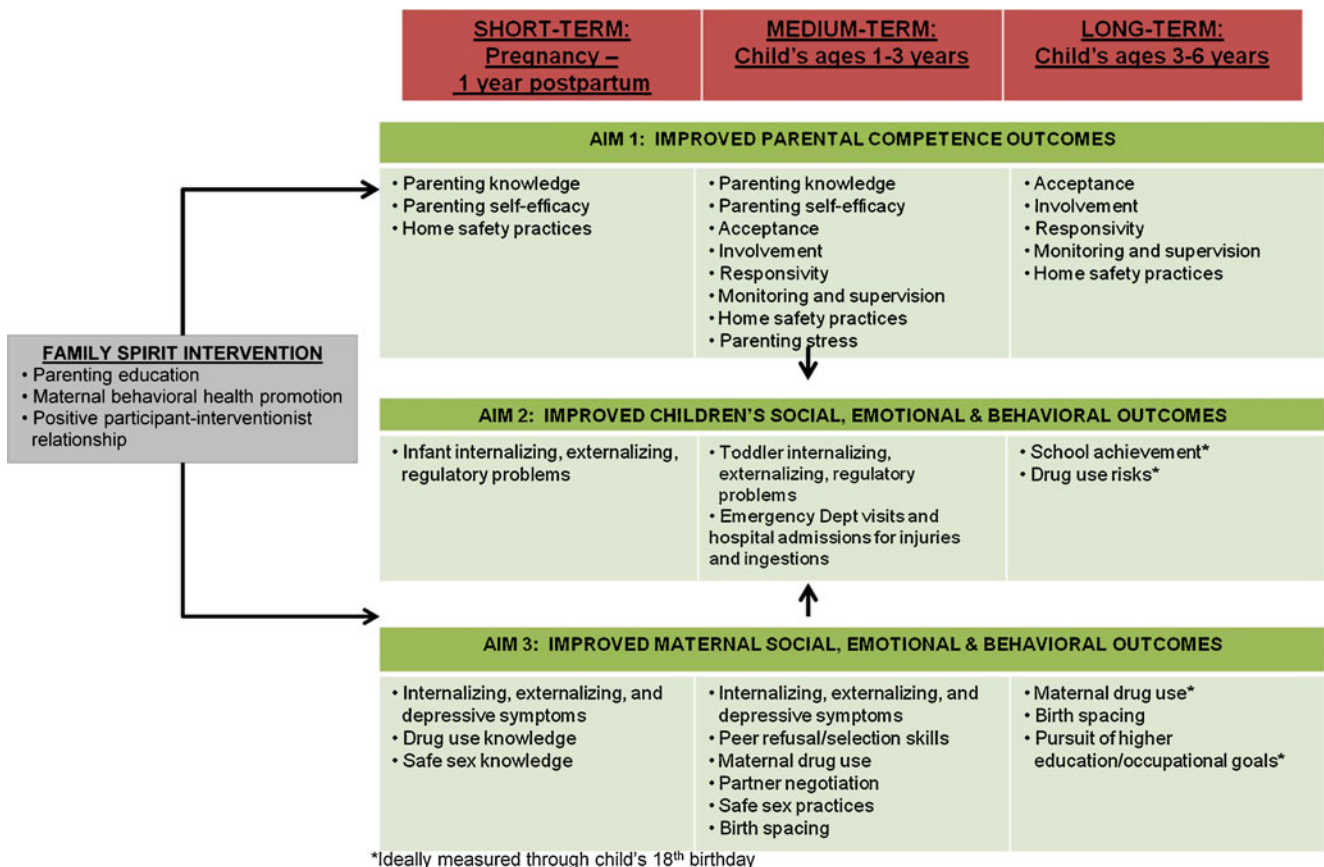


Fig. 2 Conceptual framework for Family Spirit intervention

Family Spirit design, including: adequate dosage of home visits, retention of families, structured supervision for home visitors, and appropriate caseloads. Effective programs have generally planned for ~60 visits over a 1- to 5-year period and aimed to deliver between 32% and 56% of these visits (range 22–33 visits) (Gomby 1999; Gomby et al. 1999). The Family Spirit curriculum includes 43 lessons (delivered over 45 visits), with a minimum effective dose of 50% (22 lessons).

**Staffing Structure** To maximize internal validity, there are three types of paraprofessional roles within the trial: Family Health Educators (the home visitors), Family Health Liaisons and Independent Evaluators. Family Health Educators deliver the Family Spirit curriculum in the home of intervention participants and do not interact with control participants. Family Health Liaisons, who were not trained in the Family Spirit intervention, administer the control condition to intervention and control participants, complete visitation forms at every contact, and monitor participants' completion of self-reports and adverse events. Health Educators and Liaisons are not masked to participants' randomization assignments. Independent Evaluators complete all participants' observational and interview assessments and medical chart reviews and are masked to participants' randomization assignment. All positions are held by female Native paraprofessionals from the participating communities.

**Quality Assurance** Prior to recruitment, paraprofessional staff received extensive training (>80 h) in trial protocol and policies, protection of human research subjects, and intervention delivery (for Educators). Family Health Educators had to demonstrate mastery of the Family Spirit curriculum through written and oral exams. During the first year of employment, supervisors observed educators conducting home visits on a quarterly basis and rated them on professionalism, rapport, interpersonal skills, and protocol adherence. Independent Evaluators were trained by a senior evaluator on all standardized assessments. Quarterly interrater reliability checks have consistently indicated ~95% agreement between raters on primary outcome assessments. Both Educators and Evaluators audiotape each participant visit and a random 20% of tapes are reviewed by study coordinators for protocol adherence.

#### Design of the Control Intervention

The control condition is OSC. OSC consists of transportation assistance to regularly scheduled, clinic-based prenatal and well-baby visits as recommended by the IHS and American Academy of Pediatrics, provision of pamphlets about child care and community resources for parents, and referrals to local services as needed. OSC visits include seven prenatal visits, nine well-baby visits during the first 3 years of life (at

1 week, 2 weeks, and 2, 4, 6, 9, 12, 24 and 36 months postpartum), and four social support visits between years 2 and 3. OSC was chosen as the comparison condition because it optimizes the standard of care of young mothers and their children within reservation communities, addresses transportation and access barriers to preventative health care, and provides beneficial and ecologically valid services in the participants' settings. By providing OSC to both the intervention and control groups, the quality and dose of optimized standard care are controlled so that differences between intervention groups can be validly attributed to the Family Spirit intervention.

#### Retention Strategies

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 (McGuigan et al. 2003). The Family Spirit intervention was staffed to provide regular on-site supervision, weekly cross-site conference calls and quarterly site visits. A policy and procedures manual guides implementation of the curriculum and gives home visitors flexibility to address mothers' and families' scheduling needs. The Family Spirit interventionist caseload ( $n=25$ ) is consistent with optimal retention (Gomby 1999; Gomby et al. 1999).

The primary strategies for retention are delivering high-quality intervention and control conditions in a timely, relevant manner and maintaining consistent contact and positive relationships with study participants. Study staff are trained to reschedule a lesson or assessment visit when participants are facing personal challenges, and provide referral and transportation assistance to address crises that arise during the trial. Staff also distribute quarterly study newsletters, birthday cards for mothers and their babies and annual certificates of program completion. Incentives in the form of Walmart gift cards are given for assessments, and increase with duration of participation in the study (i.e., start at \$10 for initial assessment and increase by \$5 per time point for maximum of \$50 for final assessment).

#### Impact Evaluation

Measurements were selected to assess Family Spirit intervention impact on three outcome domains: (1) *parental competence outcomes* (parenting knowledge and self-efficacy; maternal acceptance, involvement, and responsivity; parenting stress; and home safety strategies); (2) *children's social, emotional, and behavioral outcomes* (internalizing, externalizing and regulatory problems for young children; emergency department visits and hospitalizations for injuries and ingestions); and (3) *teen mothers' psychosocial and behavioral outcomes* (internalizing, externalizing, and depressive

**Table 1** Description and properties of study outcome measures

	Brief description of purpose and scoring mechanisms	Instrument reference/source	Anticipated duration of impact <sup>a</sup>	Cronbach's alpha in this sample
<b>Aim 1: Parental competence outcomes</b>				
Parent Knowledge Test*	30-item multiple-choice test created by the investigator team to coincide with lessons taught in the Family Spirit curriculum and measure cumulative knowledge gains related to lesson objectives. Topics include: pregnancy/labor/delivery, breastfeeding, parenting, home safety, immunizations, and well baby care.	Created by study team	S, M	0.65
Parental Locus of Control (PLOC)*	27-items measure three domains of locus of control; we focused on domain covering parental sense of competence and efficacy in parenting tasks and roles.	Campis et al. 1986	S, M	0.67
Home Safety Assessment*	Includes 8 self-report items regarding attitudes towards home safety for children and approximately 40 observational measures regarding home safety practices (e.g., use of electrical plug covers).	Adapted by study team using questions from Massachusetts Dept of Health 1986	S, M, L	0.57
Home Observation for Measurement of the Environment (HOME)*	Widely utilized checklist observational measure of parental behavior, parent-child interaction, and the home environment. Consists of 45 items that span six sub-scales: maternal responsibility, acceptance, learning materials, variety (life experiences), maternal involvement, and organization of the home.	Caldwell and Bradley 1979	M, L	0.74
Supplement to HOME for Impoverished Families (SHIF)	20-item observational measure of parental behavior, parent-child interaction, child's daily routine, and home environment for children 0–3 living in impoverished settings. Designed to be used in conjunction with the HOME.	Ertem et al. 1997	M, L	0.71
Adult Adolescent Parenting Inventory (AAPI-2)	40-item self-report questionnaire assesses parental beliefs about childrearing and child behavior including: inappropriate expectations, empathy, corporal punishment, role reversal, and power and independence.	Bavolek and Keene 1999	M	Range from 0.70 to 0.82 across scales
Parental Sense of Competence (P SOC)	16-item self-report measures two factors: maternal satisfaction and maternal efficacy	Johnston and Mash 1989	M	0.79
Parenting Stress Index – Short Form (PSI-SF)	36-item self-report measures three domains of parenting stress: parental distress, parent-child dysfunctional interaction, difficult child.	Abidin 1995	M	To be determined (data not available yet). Alphas in reference sample range from 0.60 to 0.90.
<b>Aim 2: Child psychosocial and behavioral outcomes</b>				
Infant Toddler Social Emotional Assessment (ITSEA) *	126-item instrument administered to parents/primary caregivers. Assesses four primary domains of behavior for children ages 12–36 months including: externalizing, internalizing, dysregulation, and competence.	Carter and Briggs-Gowan 1999	S, M	Range from 0.63 to 0.81 across domains
Ages and Stages Questionnaire (ASQ)	30-item caregiver-report questionnaire screens children for developmental delays in five major skill areas: communication, gross motor, fine motor, problem-solving, and personal-social.	Bricker and Squires 1999	NA <sup>b</sup>	To be determined (data not available yet). Alphas in reference sample range from 0.82 to 0.88.
Child Behavior Checklist (CBCL)	99-item self-report checklist assesses behavioral problems and social competencies of children as reported by parents. Three primary scales are derived: internalizing, externalizing, and total problems. The CBCL is one of the most widely utilized child behavioral measures.	Achenbach 2000	M, L	To be determined (data not available yet). Alphas in reference sample range from 0.90 to 0.97.
Medical Record Review	Child medical records reviewed for visits to ED, hospital or clinic for injuries and ingestions.	Created by study team	M	Not applicable.

**Table 1** (continued)

Brief description of purpose and scoring mechanisms	Instrument reference/source	Anticipated duration of impact <sup>a</sup>	Cronbach's alpha in this sample
<p>Aim 3: Maternal psychosocial and behavioral outcomes</p> <p>Achenbach System Empirically Based Assessment: Youth Self Report (ASEBA) *</p> <p>Center for Epidemiological Studies Depression (CES-D) *</p> <p>Demographics</p> <p>Collects a broad range of demographic information including age, socioeconomic, educational and employment status, living situation, marital/partner status, gestational age, past and current health and behavior history, information about the home environment and contact information. We have previously used the measure with success (Walkup et al. 2009).</p>	<p>Achenbach 2000</p> <p>Radloff 1977</p> <p>Created by study team</p>	<p>S, M</p> <p>S, M</p> <p>M, L</p>	<p>Range from 0.69 to 0.79 across scales</p> <p>0.88</p> <p>Not applicable.</p>
<p>Voices of Indian Teens (VOIT): 6 items that assess respondent's participation in traditional tribal activities and identity with tribe.</p> <p>Voices of Indian Teens (VOIT): 92 items cover following topics: quantity, frequency and qualitative aspects of alcohol use; age of first use; family history of alcohol abuse; community, peer, and personal attitudes and beliefs about alcohol.</p> <p>Voices of Indian Teens (VOIT): 13 items cover following topics: quantity and frequency of drug use; types of drugs used; and age of first use</p>	<p>Novins and Mitchell 1998</p> <p>Novins and Mitchell 1998</p> <p>Novins and Mitchell 1998</p>	<p>NA<sup>b</sup></p> <p>M, L</p> <p>M, L</p>	<p>≥0.70</p> <p>≥0.70</p> <p>≥0.70</p>
<p>Existing meth-use surveys were utilized and expanded to create an enhanced meth assessment to be administered via ACASI. Questions focused on substance abuse history and sexual risk taking behaviors. Participants completed ACASIs confidentially on project laptop while questions were read aloud over headphones.</p> <p>139-item self-report assesses broad range of functional areas among teens over 6 subscales, including: substance use, physical health, general mental health, family relationships, peer relationships and aggressive behavior/delinquency.</p> <p>Maternal medical records reviewed for maternal birth spacing and related outcomes.</p>	<p>Created by study team, with questions adapted from DHHS, 2008 and Montana Meth Project 2008.</p> <p>Rahdert 1991</p> <p>Created by study team</p>	<p>M, L</p> <p>S, M</p> <p>M, L</p>	<p>To be determined (data not available yet).</p> <p>Range from 0.60 to 0.83 across scales.</p> <p>Not applicable.</p>

\* Indicates primary outcome measures within each domain.

<sup>a</sup> S=Short-term impact (pregnancy through 1 year postpartum); M=Medium-term impact (between child's ages 1–3 years); L=Long-term impact (between child's ages 3–6 years)

<sup>b</sup> Data from these measures were gathered either as potential moderators of intervention impact or as potentially important covariates; we do not anticipate intervention impact on these measures.



**Table 2** Data collection attributes and schedule

Data collection attributes			Data collection schedule									
Who collects measure	Participant time required (mins)	Mode of administration	Baseline (~28 week gestation)	36 week gestation	2 month postpartum	6 month postpartum	12 month postpartum	18 month postpartum	24 month postpartum	30 month postpartum	36 month postpartum	
<b>Aim 1: Parental competence outcomes</b>												
Parent Knowledge Test	15	Self-report	X		X	X	X	X	X	X	X	
Parental Locus of Control (PLOC)	5	Self-report	X		X	X	X	X	X	X	X	
Home Safety Assessment	30	Observation/ self-report	X									
Home Observation for Measurement of the Environment (HOME)	60	Observation			X	X	X	X	X	X	X	
Supplement to HOME for Impoverished Families (SHIF)	10	Observation							X	X	X	
Adult Adolescent Parenting Inventory (AAPI-2)	15	Self-report	X		X	X	X	X	X	X	X	
Parental Sense of Competence (PSC)	5	Self-report			X	X	X	X	X	X	X	
Parenting Stress Index – Short Form (PSI-SF)	10	Self-report			X	X	X	X	X	X	X	
<b>Aim 2: Child psychosocial and behavioral outcomes</b>												
Infant Toddler Social Emotional Assessment (ITSEA)	20	In-person interview					X	X	X	X	X	
Ages and Stages Questionnaire (ASQ)	30	Observation			X	X	X	X	X	X	X	
Child Behavior Checklist (CBCL)	20	Self-report							X	X	X	
Medical Record Review	0	Chart review									X	
<b>Aim 3: Maternal psychosocial and behavioral outcomes</b>												
Achenbach System Empirically Based Assessment: Youth Self Report (ASEBA)	15	Self-report	X			X	X	X	X	X	X	
Center for Epidemiological Studies – Depression (CES-D)	5	Self-report	X	X	X	X	X	X	X	X	X	
Demographics	20	In-person interview	X	X	X	X	X	X	X	X	X	
Voices of Indian Teens (VOIT): Cultural Identity	5	In-person interview	X	X	X	X	X	X	X	X	X	
Voices of Indian Teens (VOIT): Alcohol	10	Self-report	X	X	X	X	X	X	X	X	X	
Voices of Indian Teens (VOIT): Drugs, Ideas, Thoughts & Happenings	5	Self-report	X	X	X	X	X	X	X	X	X	
Audio Computer Assisted Self-Interview (ACASI): Substance abuse history and sexual risk taking behaviors	60	Computer interview					X				X	
Problem Oriented Screening Instrument for Teens (POSIT)	10	Self-report	X	X	X	X	X	X	X	X	X	
Medical Record Review	0	Chart review									X	

symptoms; family planning; education; employment; and substance abuse). Within each of these domains, primary and secondary outcomes were prioritized developmentally in order to measure short-, medium-, and long-term impact of the Family Spirit intervention. All primary and secondary outcome measures are summarized by domain and described in greater detail in Table 1. Each of the measures was identified as the best or most widely used instrument available for its purpose, with special consideration given to cross-cultural validity and appropriateness. Although almost one-quarter of participants predominantly spoke their Native language within the home, they were all comfortable conversing in English. Thus, assessments were not translated into the participants' Native language; however, study staff administering the instruments were fluent in their Native language and could translate any difficult words or phrases as needed.

Outcome data were collected at nine time points during the study period: Baseline (~28 weeks gestation); 36 weeks gestation; and at 2, 6, 12, 18, 24, 30 and 36 months postpartum. A combination of maternal self-report questionnaires, in-person interviews, audio computer-assisted self interviews (ACASI), observational data, and medical chart data assess study outcomes. Assessment administration lasts approximately 120–350 min, depending on the study time point. Table 2 shows the data collection schedule for the trial.

#### Data Management and Quality Control

Each field site completes and verifies its own data and sends scanned copies to the study coordinating site for re-verification and entry. The data entry operator reviews forms for missing data or outlying values. Regular email updates and cross site phone conferences are used to review and correct errors. Once checked, data are entered into a customized web-based database. A random 10% of assessment forms are validated. If data entry error rates exceed  $\geq 1.5\%$  of all values, forms are double data-entered.

#### Data Analysis

Participants' sociodemographic characteristics and psychosocial and behavioral risks were tabulated and summarized at baseline. The distribution of these characteristics at baseline were compared between intervention and control groups to assess the success of randomization by conducting chi-squared tests of association (for categorical variables) and t-tests for differences in means (for continuous variables).

#### Results

A total of 322 participants were randomized: 83 in Site 1, 65 in Site 2, 69 in Site 3, and 105 in Site 4.

*Baseline Demographics* (Table 3). Comparisons of intervention and control group characteristics show key demographic variables appear evenly distributed between groups at baseline. No measured variables were imbalanced at  $p < 0.05$  level.

The sample is young (mean age 18.1 years), and 75% are first-time mothers. Mean gestational age at the time of enrollment was 25 weeks. Most (82%) mothers reported they did not plan their pregnancies and 86% did not use contraception at time of conception. The majority (61%) had been in a long-term relationship (>12 months) with the babies' fathers before becoming pregnant and 3% were married. Over half (57%) resided with their male partners/boyfriends; almost 60% resided with their own parent(s), while 19% resided with their boyfriends' parent(s).

Approximately 40% were in school at baseline and another 40% had dropped out of school prior to receiving a high school diploma or GED. Community-wide poverty is high; 9% of participants' homes lack indoor toilets and 6% lack electricity. Residential instability is common; 51% had lived in two or more homes in the year before study enrollment. Almost half (45%) speak their Native language. While 53% reported not living by a 'traditional way of life,' 34% reported it was 'very important' to have 'traditional Indian values.'

*Baseline Maternal Psychosocial and Behavioral Risks* (Table 4). Two between-group differences in maternal psychosocial and behavioral risks were detected. More intervention group participants had moderate to high ( $\geq 16$ ) CES-D scores (42.1% vs. 29.5%,  $p < 0.05$ ). In addition, the intervention group reported higher lifetime cigarette use (54.7% vs. 41.7%,  $p < 0.05$ ). There were no other significant between group differences in maternal internalizing or externalizing domains, problem behaviors, or substance use patterns.

#### Discussion

American Indian and Alaska Native communities are in need of innovative services to address serious behavioral health disparities through culturally informed, community-run systems of care. The Family Spirit intervention is the product of an intensive community-based participatory research process initiated in 1995 and characterized by an iterative process that melded participating communities' priorities and empirically supported behavior change and intervention development principles. The current definitive evaluation of the Family Spirit intervention is employing state-of-the-art clinical trial methods—including randomization, use of masked Independent Evaluators and ACASI

**Table 3** Selected sociodemographic characteristics of participants at baseline, by study group

Characteristics	Intervention ( <i>n</i> =159)	Control ( <i>n</i> =163)	Total ( <i>N</i> =322)
Study site			
Site 1	41 (25.8)	42 (25.8)	83 (25.8)
Site 2	31 (19.5)	34 (20.9)	65 (20.2)
Site 3	34 (21.4)	35 (21.5)	69 (21.4)
Site 4	53 (33.3)	52 (31.9)	105 (32.6)
Age at time of conception, <i>n</i> (%)			
12–17 years	67 (42.1)	69 (42.3)	136 (42.2)
18+ years	92 (57.9)	94 (57.7)	186 (57.8)
Parity (# of live births), <i>n</i> (%)			
0	121 (76.1)	121 (74.2)	242 (75.2)
1	35 (22.0)	33 (20.3)	68 (21.1)
≥2	3 (1.8)	8 (4.9)	11 (3.4)
Currently unmarried, <i>n</i> (%)	153 (96.2)	158 (96.9)	311 (96.6)
Gestational age at enrollment, weeks – Mean ( <i>SD</i> )	25.4 (4.2)	24.7 (4.0)	25.0 (4.1)
Pregnancy was planned, <i>n</i> (%)	30 (18.9)	28 (17.2)	58 (18.0)
Did not use contraception at time of conception, <i>n</i> (%)	136 (85.5)	140 (85.9)	276 (85.7)
Live with boyfriend/father of baby, <i>n</i> (%)	90 (56.6)	94 (57.7)	184 (57.1)
Live with participant's parent(s), <i>n</i> (%)	97 (61.0)	96 (58.9)	193 (59.9)
Live with participant's boyfriend's parent(s), <i>n</i> (%)	27 (17.0)	34 (20.9)	61 (18.9)
Length of relationship prior to pregnancy, <i>n</i> (%)			
< 1 month	9 (5.7)	5 (3.1)	14 (4.3)
1 month – 6 months	24 (15.1)	24 (14.7)	48 (14.9)
6 months – 12 months	27 (17.0)	31 (19.0)	58 (18.0)
>12 months	97 (61.0)	99 (60.7)	196 (60.9)
Don't know	2 (1.3)	4 (2.4)	6 (1.9)
Currently in school, <i>n</i> (%)	63 (39.6)	68 (41.7)	131 (40.7)
Dropped out of school prior to HS graduation/GED, <i>n</i> (%)	69 (43.4)	62 (38.0)	131 (40.7)
Highest education attained, <i>n</i> (%)			
Grades ≤11	116 (72.9)	118 (72.4)	234 (72.7)
HS diploma/GED	33 (20.8)	33 (20.2)	66 (20.5)
Some technical/college courses	10 (6.3)	12 (7.4)	22 (6.8)
Lack the following items in household, <i>n</i> (%)			
Indoor toilet facilities	14 (8.8)	16 (9.8)	30 (9.3)
Electricity	11 (6.9)	8 (4.9)	19 (5.9)
Number of homes lived in during past year, <i>n</i> (%)			
1	82 (51.6)	77 (47.2)	159 (49.4)
2–3	68 (42.8)	83 (51.0)	151 (46.9)
4+	9 (5.7)	3 (1.8)	12 (3.7)
Language most frequently spoken in home, <i>n</i> (%)			
Only Native language	38 (23.9)	34 (20.9)	72 (22.4)
Only English language	88 (55.4)	90 (55.2)	178 (55.3)
Both Native and English languages	33 (20.8)	39 (23.9)	72 (22.4)
Live by or follow a traditional way of life, <i>n</i> (%)			
Not at all/not much	77 (48.4)	92 (56.4)	169 (52.5)
Some	54 (34.0)	46 (28.2)	100 (31.1)
A lot	28 (17.6)	25 (15.3)	53 (16.5)
Importance of having traditional Indian values, <i>n</i> (%)			
Not at all important/not very important	34 (21.4)	43 (26.4)	77 (23.9)
Somewhat important	71 (44.7)	63 (38.7)	134 (41.6)
Very important	54 (34.0)	55 (33.7)	109 (33.9)

**Table 4** Selected maternal psychosocial and behavioral risks of participants at baseline, by study group

	Intervention (n=159)	Control (n=163)	Total (N=322)
Parenting knowledge			
Knowledge test score (ranging from 0 to 100%), Mean (SD)	43.6 (11.0)	42.2 (10.5)	42.8 (10.8)
Internalizing, externalizing, and depressive symptoms			
CES-D:			
Mean (SD)	14.9 (8.6)	13.4 (8.0)	14.1 (8.3)
CES-D score ≥16, n (%)*	67 (42.1)	48 (29.5)	115 (35.7)
CES-D score ≥24, n (%)	26 (16.4)	20 (12.3)	46 (14.3)
ASEBA Domains:			
Internalizing – Mean (SD)	11.2 (8.2)	10.1 (8.0)	10.7 (7.9)
Externalizing – Mean (SD)	7.5 (7.3)	6.5 (5.6)	7.0 (6.5)
POSIT Domains:			
Substance use – Mean (SD)	1.5 (2.5)	1.2 (2.1)	1.3 (2.3)
Mental health – Mean (SD)	4.4 (3.3)	4.3 (2.9)	4.4 (3.1)
Family functioning – Mean (SD)	3.1 (2.5)	3.2 (2.5)	3.1 (2.5)
Peers – Mean (SD)	2.9 (2.0)	2.6 (1.9)	2.7 (2.0)
Social – Mean (SD)	3.7 (1.8)	3.6 (1.7)	3.6 (1.7)
Aggressiveness – Mean (SD)	1.9 (1.8)	1.8 (1.6)	1.8 (1.7)
Substance use			
Alcohol:			
Ever used, n (%)	124 (78.0)	122 (74.9)	246 (76.4)
Use during pregnancy, n (%)	28 (17.6)	17 (10.4)	45 (14.0)
Age at first use, yrs – Mean (SD)	14.5 (1.7)	14.7 (1.9)	14.6 (1.8)
Cigarettes:			
Ever used, n (%)*	87 (54.7)	68 (41.7)	155 (48.1)
Use during pregnancy, n (%)	36 (22.6)	26 (16.0)	62 (19.2)
Age at first use, yrs – Mean (SD)	14.4 (2.5)	13.8 (2.9)	14.2 (2.7)
Marijuana:			
Ever used, n (%)	124 (78.0)	117 (71.8)	241 (74.8)
Use during pregnancy, n (%)	23 (14.5)	20 (12.3)	43 (13.4)
Age at first use, yrs – Mean (SD)	13.9 (2.1)	14.1 (2.1)	14.0 (2.1)
Methamphetamine:			
Ever used, n (%)	45 (28.3)	38 (23.3)	83 (25.8)
Use during pregnancy, n (%)	9 (5.7)	8 (4.9)	17 (5.3)
Age at first use, yrs – Mean (SD)	15.8 (1.7)	15.7 (1.7)	15.8 (1.7)
Crack/cocaine			
Ever used, n (%)	41 (25.8)	34 (20.9)	73 (23.3)
Use during pregnancy, n (%)	4 (2.5)	2 (1.2)	6 (1.9)
Age at first use, yrs – Mean (SD)	15.4 (1.5)	15.5 (1.9)	15.5 (1.7)

\**p*<0.05 for test of inequality between groups

technologies, intensive quality assurance for intervention and assessment administration, comprehensive retention strategies and sophisticated data analytic procedures.

To our knowledge, this is the first randomized controlled trial in reservation communities of early childhood home-visitation to address family-based multi-generational risks for behavioral health disparities among American Indian teen mothers and their children. It is unique in its focus on measuring behavioral risks of both adolescent mothers and their

infants over an extended time period. If found to be effective, the Family Spirit intervention has the potential to decrease behavioral disparities for both generations especially as teen mothers transition to adulthood and children transition from early childhood home environments to school settings.

Baseline results of the trial demonstrate that participants have a behavioral risk profile that is appropriate to the aims of the study and that are addressed by the Family Spirit intervention, including demographic risks for ineffective

parenting (teen pregnancy, unstable home lives, low education, marital status), in addition to high rates of alcohol and illicit drug use before and during pregnancy. Although this sample's mean CES-D score (14.1) was better compared to scores reported among other young samples (16.3 among Caucasians and 14.6 among African-Americans) (Franko et al. 2005), roughly 14% of the sample scored in the clinical range for depressive symptoms (CES-D score  $\geq 24$ ), which is within range (10–20%) of nationally representative groups of female adolescents (Franko et al. 2005; Rushton et al. 2002). Mean and median *t*-score values for the sample ranged from 44 to 48 for both the internalizing and externalizing domains on the ASEBA, lower (better) than those reported among national and international samples of youth (Newman et al. 2007; Verhulst et al. 2003). Similarly, participants' POSIT scores, which measure problems in six major functional areas including substance use and mental health, were comparable to those reported among other adolescent samples (Knight et al. 2001).

Lifetime alcohol and cigarette use among the sample were comparable to rates among US All Races adolescents (76.4% vs. 74.3% for alcohol; 48.1% vs. 54.3% for cigarettes). However, lifetime use rates for all other substances were substantially higher in the sample than among US All Races youth: 74.8% vs. 38.4% for marijuana, 25.8% vs. 6.2% for methamphetamine, and 23.3% vs. 7.6% for crack/cocaine (Eaton et al. 2006). Marijuana was the first drug used and at an early age (14.0 years), even before alcohol (14.6 years). Drug use reported during pregnancy was high: 14% for alcohol; 19% for cigarettes; 13% for marijuana, and 5% for methamphetamine. Reported lifetime use of barbiturates and inhalants was low (<5%).

While seemingly contradictory, lower rates of depressive disorders in American Indian adolescents than in other US All Races, in spite of high rates of substance use and PTSD have been reported by others (Barlow and Walkup 1998; Beals et al. 2005). In contrast, a recent longitudinal study of Northern Plains adolescents was able to identify high externalizing problems (i.e., conduct disorder) in pre-teens tracking to high rates of substance abuse disorder and externalizing problems in later adolescence (Whitbeck et al. 2008). The apparently contradictory findings in our study population could be due to a number of factors, including: (a) reporting bias (mothers may be responding in a socially desirable manner in their self-reports, which may reflect a certain stoicism in the face of documented adversity. However, high reported rates of illegal substance use would suggest these mothers approach questions relating to mood/behavior differently than questions about drug use); (b) the study may be using self-reports that have inadequate construct and/or content validity for this population [for example, international studies suggest that depressive symptoms manifest themselves differently across cultures (Huang et al. 2007; Simon et al. 2002), which may

impact lower endorsement of these symptoms]; (c) a broad literature suggests that American Indians and other indigenous peoples demonstrate strong capacity for coping and resilience and low internalizing scores may be reflective of these capacities (Grandbois and Sanders 2009); or (d) there may be a possible buffering effect of pregnancy and childbirth on mood and attitude within the participating communities and Native cultures in general.

This study will continue to employ the maternal and child psychosocial and behavioral measures, ongoing parent-child observational assessments, ACASI substance use assessments, and maternal and child medical chart data to assess between-group differences. We will also have the ability to evaluate convergent and discriminant validity of study measures. Ongoing research is clearly needed to develop culturally appropriate and psychometrically sensitive psychosocial risk measures for American Indian populations.

The Family Spirit trial is significant to American Indian communities and drug prevention science for a number of reasons. After decades of epidemiologic study, there have been no significant intervention advances to overcome persistent family- and community-based behavioral risk, most importantly drug abuse, in reservation communities (DHHS 2009). Barriers to scientific progress have included tribes' historical reluctance to participate in randomized behavioral intervention trials; the lack of culturally appropriate, ecologically sound evidence-based interventions and assessment measures; the lack of tribal human resource capacity for sustaining interventions; and insufficient resources to establish tribal research infrastructure to track the long-term effects of prevention initiatives (Davis and Reid 1999). This trial directly addresses these challenges.

If the Family Spirit intervention is demonstrated to be effective, tribal leaders may have new strategies that are feasible, culturally appropriate and cost-effective to prevent drug abuse and other behavioral challenges in young families. In addition, demonstrating the utility of American Indian paraprofessionals in reservation settings—where there is a paucity of health care professionals and Native home visitors match cultural preferences—could impact national health care policy and prevention approaches in high-need/low-resource populations. Expanding the use of Native paraprofessionals may also promote dissemination among other American Indian communities by simultaneously contributing to the development of human capital in impoverished reservation settings.

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