WELCOME TO FAMILY SPIRIT!

Dear Colleague,

Thank you for taking the time to review the enclosed information about the Family Spirit Program. We are excited to share information about the program history, aims, training, and replication process with you.

The following program information materials are enclosed:

1. Cover Letter (this document)
2. Program Overview
3. Conceptual Model
4. Research Findings
    - 3-Year Outcomes Paper
    - 1-Year Outcomes Paper
    - Methods Paper
5. Curriculum Package Overview
6. Module Lesson Titles
7. Sequential Lesson Schedule
8. Sample Lesson and Materials
9. Evaluation Overview
10. Quarterly Affiliate Report Questions
11. "FS Connect" Membership Overview

Family Spirit is the only evidence-based home-visiting program ever designed specifically for Native American families. Thousands of families have received Family Spirit lessons and services since its inception.

The Johns Hopkins Center for American Indian Health now receives dozens of requests from communities each year seeking to replicate the Family Spirit Program. We are committed to supporting these requests. Please feel free to contact us if you have any questions or would like additional information.

Best regards,

The Family Spirit Team
familyspirit@jhu.edu

FAMILY SPIRIT PROGRAM OVERVIEW

The Family Spirit Program is an evidence-based and culturally tailored home-visiting intervention delivered by Native American paraprofessionals as a core strategy to support young Native parents from pregnancy to 3 years post-partum. Parents gain knowledge and skills to achieve optimum development for their preschool-aged children across the domains of physical, cognitive, social-emotional, language learning, and self-help. The Family Spirit Program consists of 63 lessons taught from pregnancy to age 3. Beginning in 1995, this in-home parent training and support program was designed, implemented, and rigorously evaluated by the Johns Hopkins Center for American Indian Health (JHCAIH) in partnership with Navajo, White Mountain Apache, and San Carlos Apache tribal communities.

The Family Spirit Program aims to:

- Increase parenting knowledge and skills;
- Address maternal psychosocial risks that could interfere with positive child-rearing (drug and alcohol use; depression; low education and employment; domestic violence problems);
- Promote optimal physical, cognitive, social/emotional development for children from 0 to 3;
- Prepare children for early school success;
- Ensure children get recommended well-child visits and health care;
- Link families to community services to address specific needs; and
- Promote parents' and children's life skills and behavioral outcomes across the lifespan.

Family Spirit is currently the largest, most rigorous, and only evidence-based home-visiting program ever designed specifically for Native American families. Evidence from three randomized controlled trials has documented the following program outcomes:

- **Parenting**
  - Increased maternal knowledge[1,2,3,4]
  - Increased parent self-efficacy[3,4]
  - Reduced parent stress[2,4]
  - Improved home safety attitudes[3]
- **Maternal outcomes**
  - Decreased maternal depression[1,2,4]
  - Decreased substance use[4]
  - Fewer behavior problems in mothers[3,4]
- **Child outcomes**
  - Fewer behavior problems in children through age 3 (externalizing, internalizing, and dysregulation)[234]
    - Predicts lower risk of substance use and behavioral health problems over the life course

[1] Barlow A, Varipatis-Baker E, Speakman K, et al *Arch Pediatr Adolesc Med.* 2006;160:1101-1107
[2] Walkup J, Barlow A, Mullany B, et al. *Journal of the American Academy of Child and Adolescent Psychiatry.* June 2009.
[3] Barlow, A, Mullany B, Neault N, et al. *American Journal of Psychiatry.* January 2013.
[4] Barlow A, Mullany B, Neault N, et al. *American Journal of Psychiatry*. February 2015.

Family Spirit is also the first program to provide clear evidence of the effectiveness of paraprofessionals as home visitors to impact behavioral and mental health disparities. The use of Native paraprofessionals is essential in reservation communities where there is a shortage of nurses and cultural barriers to non-Native home visitors.

Thousands of families have received Family Spirit lessons and services. Replication of Family Spirit is now occurring in dozens of reservation-based and urban Native communities across 15 states throughout the country. In addition, two non-Native urban communities with high maternal and child behavioral health disparities have begun to work with Johns Hopkins to implement Family Spirit for their high need populations.

Family Spirit has met the highest standard of the Department of Health and Human Services' (DHHS) HomVEE criteria for an "evidence-based early childhood home visiting service delivery model." In addition, Family Spirit is listed on the National Registry of Evidence-based Programs and Practices (NREPP), a searchable online database of evidence-based mental health and substance abuse interventions. In 2013, Family Spirit received a perfect rating (4.0 out of 4.0) for "Readiness for Dissemination."

FAMILY SPIRIT CONCEPTUAL MODEL

The Family Spirit (FS) conceptual framework is based on G.R. Patterson's model (Figure 1, below) that posits parenting as the critical link between parents' personal characteristics and environmental context and children's individual risks and ultimate outcomes.[1] Thus, the FS intervention is designed to promote mothers' effective parenting and coping and problem-solving skills to address parent factors, such as demographic challenges, family-of-origin problems, and personal stressors.

Key components of the FS intervention include one-on-one home-based parent training to help mothers: 1) provide consistent, responsive care and monitoring and avoid coercive parenting; 2) avoid drug use, which could interfere with effective parenting; and 3) attain coping and life skills to overcome personal and environmental stressors. In addition, FS interventionists are trained to establish a strong, consistent interpersonal bond to facilitate mothers' progress toward goals.

Figure 1: Patterson et al., 1989
Model of Parenting as Mediator of Child Outcomes

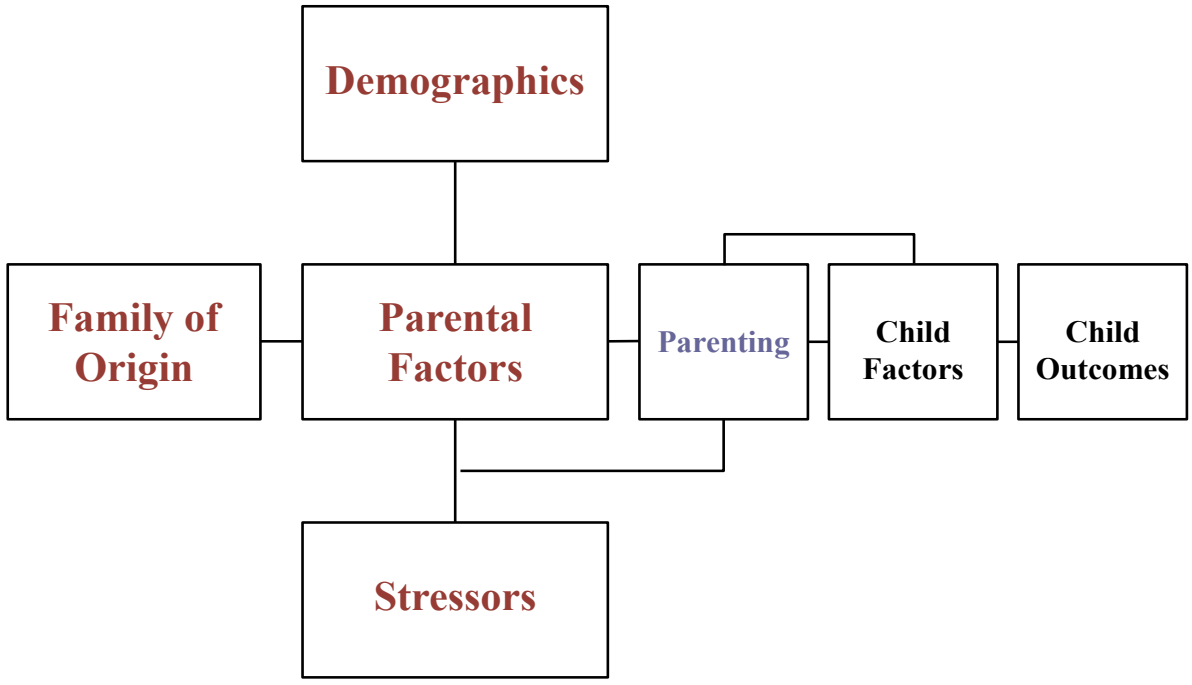
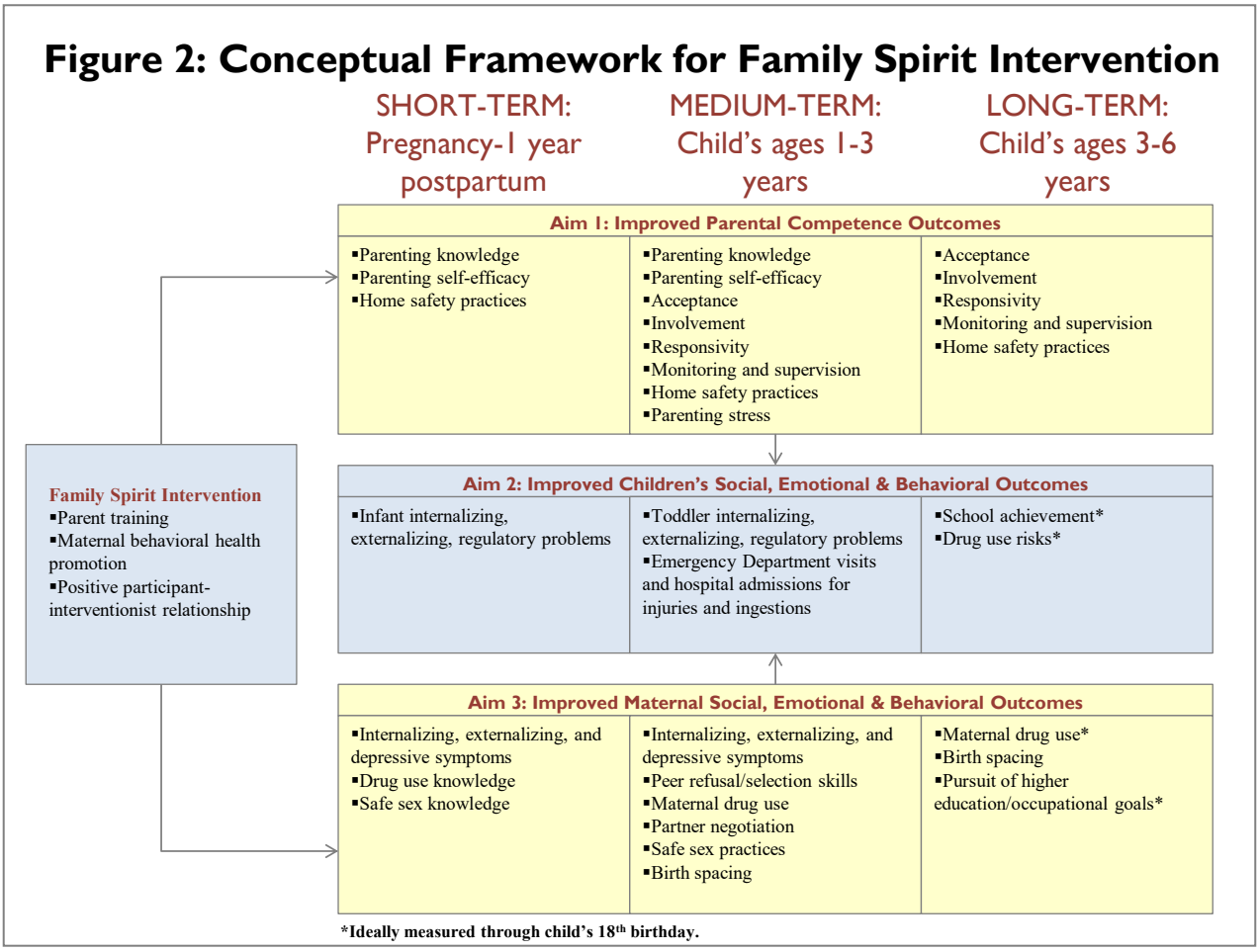


Figure 2, below, illustrates how the FS intervention is designed to impact short, intermediate and long-term maternal and child behavioral and emotional outcomes. It hypothesizes that effective, competent parenting and coping and problem-solving skills are the pathway for reducing long-term maternal and child emotional and behavior problems. This model is supported by a large body of research that has demonstrated ineffective parenting practices in early childhood lead to 1) child behavior problems, academic under-achievement, and peer problems in middle childhood and 2) maladaptive peer group formation, conduct problems, and drug use in adolescence.[2] [3] [4] Parenting knowledge and parental self-efficacy in the earliest phases of parenting are short-term outcomes that become mediators of intermediate and long-term maternal and child behavior outcomes.



[1] Patterson GR, DeBaryshe BD, Ramsey E. A developmental perspective on antisocial behavior. American Psychologist. 1989; 44:329-335.
[2] Vanderheyden A, Witt JC. Proven practices for reducing aggressive and noncompliant behaviors exhibited by young children at home and at school. J La State Med Soc. 2000; 152:485-496.
[3] Pettit GS, Laird RD, Dodge KA, Bates JE, Criss MM. Antecedents and behavior-problem outcomes of parental monitoring and psychological control in early adolescence. Child Dev. 2001; 72:583-598.
[4] Frick PJ, O'Brien BS, Wootton JM, McBurnett K. Psychopathy and conduct problems in children. J Abnorm Psychol. 1994; 103:700-707.

FAMILY SPIRIT RESEARCH FINDINGS

Overview:

In partnership with the Navajo, White Mountain Apache and San Carlos Tribes, the Johns Hopkins Center for American Indian Health has conducted three successive Randomized Controlled Trials (RCTs) to assess the Family Spirit intervention's impact on parenting and maternal and child health and behavior outcomes.

Key Findings:

The first RCT enrolled 53 expectant American Indian teen mothers and their offspring from pregnancy to 6 months postpartum. The main research question addressed the impact of the intervention on teen mothers' child care knowledge, skills, and involvement from baseline at 28 weeks gestation to 6 months postpartum. The outcome measures were infant care knowledge, skills and involvement among the mothers. Mothers in the intervention group had significantly higher parent knowledge scores at 2 and 6 months postpartum as compared to their controls. They also scored significantly higher on maternal involvement scales at 2 months postpartum, and scores approached significance at 6 months postpartum.[1]

The second RCT of the Family Spirit intervention enrolled 167 American Indian teen mothers and their offspring from early pregnancy to 12 months postpartum. The central research question was to assess intervention impact on: 1) teen mothers' parenting knowledge and involvement; 2) children's emotional and behavioral outcomes at one year of age, and 3) mothers' psychosocial outcomes at one year postpartum, including stress, social support, depression and substance use. Participants were mostly teenaged, first-time, unmarried mothers living in reservation communities. At 6 and 12 months postpartum, intervention mothers compared with control mothers had greater parenting knowledge gains. At 12 months postpartum, intervention mothers reported that their children had significantly lower scores in the externalizing domain and less separation distress in the internalizing domain.[2]

The third and most rigorous RCT enrolled 322 expectant American Indian teens from four southwestern tribal communities who were randomized (1:1) to the Family Spirit intervention plus Optimized Standard Care, or Optimized Standard Care alone, and evaluated at nine intervals through 3 years postpartum using self-reports, interviews and observational measures. The intervention's design and theoretical model, evaluation design and methods are described in detail in Mullany et al.[3] Participants were young (mean=18.1 years), American Indian and <32 weeks gestation at the time of enrollment. Retention was >83% across the study period. From pregnancy to 36 months postpartum, intervention mothers had significantly greater parenting knowledge (effect size=0.42) and parenting locus of control (effect size=0.17); fewer depressive symptoms (effect size=0.16) and externalizing problems (effect size=0.14); lower past month marijuana (odds ratio=0.65) and illegal drug use (odds ratio=0.67). Intervention children had fewer externalizing (effect size=0.23), internalizing (effect size=0.23) and dysregulation (effect size=0.27) problems.[4,5]

Each trial corroborated and extended prior findings and provides layered evidence of Family Spirit's impact on reducing intergenerational health disparities of American Indian mothers and children. Family Spirit is the first and only early evidence-based home-visiting program designed for and by American Indian communities; the first to demonstrate efficacy of paraprofessionals; and is uniquely tailored to address the behavioral health disparities that pose the greatest challenges to Native communities.

References:

1. Barlow A, Varipatis-Baker E, Speakman K, et al. Home-visiting intervention to improve child care among American Indian adolescent mothers: A randomized trial. Arch Pediatr Adolesc Med. 2006; 160(11):1101-1107.
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4. Barlow A, Mullany B, Neault N, et al. Effect of a Paraprofessional Home-Visiting Intervention on American Indian Teen Mothers' and Infants' Behavioral Risks: A Randomized Controlled Trial. American Journal of Psychiatry 2013; 170:83–93.
5. Barlow A, Mullany B, Neault N, et al. Paraprofessional Delivered, Home-Visiting Intervention for American Indian Teen Mothers and Children: Three-Year Outcomes from a Randomized Controlled Trial. American Journal of Psychiatry. 2015; 172(2):154-162.

Article

Paraprofessional-Delivered Home-Visiting Intervention for American Indian Teen Mothers and Children: 3-Year Outcomes From a Randomized Controlled Trial

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Objective: The Affordable Care Act provides funding for home-visiting programs to reduce health care disparities, despite limited evidence that existing programs can overcome implementation and evaluation challenges with at-risk populations. The authors report 36-month outcomes of the paraprofessional-delivered Family Spirit home-visiting intervention for American Indian teen mothers and children.

Method: Expectant American Indian teens (N=322, mean age=18.1 years) from four southwestern reservation communities were randomly assigned to the Family Spirit intervention plus optimized standard care or optimized standard care alone. Maternal and child outcomes were evaluated at 28 and 36 weeks gestation and 2, 6, 12, 18, 24, 30, and 36 months postpartum.

Results: At baseline the mothers had high rates of substance use (>84%), depressive symptoms (>32%), dropping out of school (>57%), and residential instability (51%). Study retention was ≥83%. From pregnancy to 36 months postpartum, mothers in the intervention group had significantly greater parenting knowledge (effect size=0.42) and parental locus of control (effect size=0.17), fewer depressive symptoms (effect size=0.16) and externalizing problems (effect size=0.14), and lower past month use of marijuana (odds ratio=0.65) and illegal drugs (odds ratio=0.67). Children in the intervention group had fewer externalizing (effect size=0.23), internalizing (effect size=0.23), and dysregulation (effect size=0.27) problems.

Conclusions: The paraprofessional home-visiting intervention promoted effective parenting, reduced maternal risks, and improved child developmental outcomes in the U.S. population subgroup with the fewest resources and highest behavioral health disparities. The methods and results can inform federal efforts to disseminate and sustain evidence-based home-visiting interventions in at-risk populations.

Am J Psychiatry Barlow et al.; AiA:1–9

The Affordable Care Act authorized $1.5 billion over 5 years for the Maternal, Infant, and Early Childhood Home Visiting Program, legislated on March 23, 2010. Funding is prioritized for state-level dissemination of evidence-based home-visiting programs to support the health and development of at-risk children, with 3% set aside for tribal communities (1).

Several gaps in the evidence base for home-visiting programs threaten the potential public health impact of the Maternal, Infant, and Early Childhood Home Visiting Program (2). First, current home-visiting programs have not been evaluated in low-resource special populations in the United States, including American Indian, new immigrant, and military families (2, 3)—populations that can be difficult to recruit and retain (3). Second, no home-visiting program currently endorsed by the Maternal, Infant, and Early Childhood Home Visiting Program (3, 4) has been designed to target or shown reductions in both maternal drug use and mental health problems known to negatively affect children's early development (5–8) and disproportionately affect mothers in at-risk settings. Third, current home-visiting interventions have not systematically measured intervention impact on children's emotional and behavior outcomes across early childhood (0 to 3 years) that are known to predict better developmental trajectories across the life course (9, 10). Identification of early benefit is critical, given the short grant cycle of the Maternal, Infant, and Early Childhood Home Visiting Program and the need for early markers to indicate positive return on investment. Fourth, the most rigorously evaluated home-visiting programs do not lend themselves to replication in at-risk communities. For example, some interventions require nurse home visitors (11), despite the shortage of nurses in low-resource, culturally diverse communities. Further, reports on home-visiting trials have not included methods or outcomes of intervention fidelity (2). Ensuring intervention fidelity is critical to scaling efforts. Finally, trials that have depended on assessments that employ high-cost professionals or technologies (i.e., direct or videotaped observational assessments) or extended periods of follow-up to identify benefit are often not feasible within disadvantaged populations, such as those targeted

by the Maternal, Infant, and Early Childhood Home Visiting Program.

To address these gaps, the Family Spirit intervention (12–14) is to our knowledge the first in the home-visiting literature to be designed to address behavioral health disparities of the poorest and most underserved population in the United States (15–17), American Indians, and to be evaluated by using state-of-the-science measures of intervention fidelity and early childhood emotional and behavioral development. The intervention targeted American Indian adolescents—who have the highest rates of teen pregnancy, substance use, suicide, and dropping out of school of any racial or ethnic group in the country. Because of a shortage of nurses and the community preference for indigenous home visitors (14), bilingual paraprofessional home visitors from the participating communities were employed and trained to intervention mastery. The existing literature suggests paraprofessional home visitors have influenced some specific outcomes, such as birth outcomes, but have not achieved the broad-based effects on maternal and child health and behavior outcomes that nurse home visitors have (18, 19). Similarly, a Cochrane report examining global evidence for paraprofessional-delivered interventions concluded that while paraprofessionals were effective in specific domains, i.e., immunization uptake and health promotion to prevent acute respiratory infection and malaria, there was yet insufficient evidence to promote paraprofessional practice or policy in other behavioral or mental health domains (20).

The Family Spirit intervention has been evaluated in two shorter, smaller trials with positive maternal outcomes at 6 and 12 months and positive child outcomes at 12 months (12, 13). The aims of this trial were to evaluate the intervention's effects on parental competence (parenting knowledge, locus of control, stress, and behaviors) and maternal behavioral problems that impede effective parenting through early childhood (0 to 36 months postpartum). Secondary aims were to evaluate intervention effects on early childhood emotional and behavioral outcomes. This trial's 12-month outcomes were published previously (14). Here we report results through the final study period, to 36 months postpartum.

Method

Study Design

A multisite, randomized (1:1), parallel-group trial was conducted to assess the efficacy of the Family Spirit intervention for parenting and for maternal and child emotional and behavioral outcomes from 32 weeks gestation to 36 months postpartum. Participants were randomly assigned to receive either the Family Spirit intervention plus optimized standard care or optimized standard care alone. Detailed study methods have been published previously (14). Relevant tribal, Indian Health Service, and Johns Hopkins University research review boards approved the trial. An independent data safety and monitoring board maintained oversight of participant safety.

Participants

Eligible participants were expectant American Indian teens (ages 12–19 years at conception) at no more than 32 weeks gestation from four southwestern reservation communities. Prospective participants were excluded if they were currently participating in other mental or behavioral research or if life circumstances precluded full participation in the intervention protocol, such as severe mental illness or legal status that required high-intensity residential care. Participants were recruited from Indian Health Service clinics, Women, Infants, and Children nutrition programs, and schools and by word of mouth. Potential participants were screened for inclusion and were given a complete description of the study. Research staff obtained assent and parent or guardian consent from participants younger than 18 years and consent from participants who were 18 or older.

The study sites were rural reservation communities with populations of 15,000–25,000, including the White Mountain Apache and San Carlos Apache Reservations in eastern Arizona and the Tuba City and Fort Defiance communities on the Navajo Reservation in northern Arizona.

Interventions

The Family Spirit Intervention was developed over a decade through community-based participatory research (12). The intervention content included 43 structured lessons and followed a culturally congruent format (14). Positive parenting lessons were focused on reducing behaviors (i.e., poor monitoring; coercive interactions; harsh, unresponsive, or rejecting parenting; and abuse/neglect) associated with early childhood behavior problems, including externalizing, internalizing, and dysregulation problems (21–23). Additional content addressed maternal behavior and mental health problems that impede positive parenting, including substance use and externalizing and internalizing behaviors (13). The Family Spirit interventionists, referred to as family health educators (or educators), were required to have a minimum of a high school diploma or GED, at least 2 years of additional job-related education or work experience, and the ability to speak their Native language and English. They delivered lessons one-on-one in the participants' homes, using highly illustrated tabletop flip charts. Each home visit was designed to last no more than 1 hour, and it included a warm-up conversation, lesson content, a question-and-answer period, and summary handouts. Visits occurred weekly through the third trimester of pregnancy, biweekly until 4 months postpartum, monthly between 4 and 12 months postpartum, and bimonthly between 12 and 36 months postpartum (14).

Several strategies were implemented to maintain intervention fidelity: 1) educators had to score at least 80% on Family Spirit content quizzes before administering lessons, 2) study coordinators, who did not deliver the intervention, reviewed the educators' session summary forms for visit duration, lessons completed, and other issues addressed, 3) study coordinators rated a random 20% of audio-recorded lessons for quality and adherence to intervention protocol, and 4) study coordinators conducted in-person quarterly ratings of home visits for protocol adherence.

Optimized standard care consisted of transportation to recommended prenatal and well-baby clinic visits, pamphlets about child care and community resources, and referrals to local services. It also addressed access barriers to health care for young mothers and children, and it overcame concerns that home-visiting programs have operated in parallel, not in partnership, with pediatric care (24). Family health liaisons conducted the optimized standard care and were not trained in the Family Spirit intervention, to avoid contamination of the control condition.

Outcomes

Intervention impact was assessed in three domains: 1) parental competence, 2) maternal emotional and behavioral outcomes, and

3) children's emotional and behavioral outcomes at nine time points: approximately 28 to 32 weeks gestation (baseline), 36 weeks gestation, and 2, 6, 12, 18, 24, 30, and 36 months postpartum. Study assessments were selected for their wide use, strong psychometric properties, cross-cultural validity, and low cost and feasibility for implementation and dissemination in low-resource communities. Assessments are described below with accompanying Cronbach's alpha scores averaged across all time points.

Parental competence. Parenting knowledge was assessed by using a 30-item maternal self-report we created to measure knowledge gains (mean alpha=0.58; baseline, 12, 24, and 36 months). Parenting locus of control was measured with a 27-item maternal self-report of three domains: parent self-efficacy, parent control, and child control (mean alpha=0.84; 2, 6, 12, 18, 24, 30, 36 months) (25). Parenting-related stress was measured by means of the Parenting Stress Index–Short Form, a 36-item maternal self-report instrument (mean alpha=0.94; 24 and 36 months) (26).

The home environment was also assessed, with the Home Observational Measure of the Environment (HOME), a 37-item observational measure completed by an independent evaluator. Separate ratings were made for parental behavior, parent-child interaction, and home environment; the maternal acceptance subscale was omitted owing to concerns regarding cultural appropriateness (mean alpha=0.73; 6, 12, 18, 24, 30, 36 months) (27).

Maternal emotional and behavioral functioning. The Center for Epidemiological Studies—Depression scale (CES-D) is a 20-item self-report and was used to assess maternal depressive symptoms (mean alpha=0.84; baseline, 36 weeks gestation, 2, 6, 12, 18, 24, 30, 36 months) (28). The Achenbach System of Empirically Based Assessments youth self-report is a 112-item scale, and it was used to evaluate externalizing problems (opposition/defiance, rule breaking, and social problems), internalizing problems (anxious/depressed/withdrawn, thought problems), and total problems (mean alpha=0.90; baseline, 6, 12, 18, 24, 30, 36 months) (29).

The drug use subscale of the Voices for Indian Teens, a culturally specific self-report instrument, was used to measure the quantity and frequency of alcohol and drug use (mean alpha=0.73; baseline, 2, 6, 12, 18, 24, 30, 36 months) (30).

Children's emotional and behavioral outcome. The Infant-Toddler Social and Emotional Assessment is a 126-item parental report. It measures children's externalizing behaviors (activity/impulsivity, defiance/aggression), internalizing behaviors (distress/anxiety, inhibition/withdrawal), dysregulation (of sleeping, eating, emotions, sensory experiences), and competence (in attention, compliance, imitation/play, motivation, empathy) (externalizing behaviors, mean alpha=0.84; internalizing behaviors, mean alpha=0.80; dysregulation, mean alpha=0.89; competence, mean alpha=0.89; 12, 18, 24, 30, 36 months). These outcomes are presented both as means and as proportions of participants whose scores were clinically "of concern," i.e., ≤10th percentile (31).

Sample Size

The primary outcome for determining sample size and power was the HOME (27). With 322 participants and an assumption of 25% attrition, alpha=0.05, within-family correlation of r=0.5, and assessment completion rate of four out of the six time points when the HOME was to be administered, the study had 90% power to detect a meaningful public health effect size of 0.33 (32).

Randomization and Blinding

The data manager created the randomization sequence by using Stata 9.0 (StataCorp, College Station, Tex., 2005). Participants were stratified by site, age (12–15 and 16–19 years), and parity (0 and ≥1) and randomized with a 1:1 allocation in blocks of four into two study arms: Family Spirit plus optimized standard care or optimized standard care alone. After enrollment, the paraprofessional family health liaisons telephoned the study coordinator to receive each participant's randomization status. Neither the liaisons, who implemented the optimized standard care condition and self-report assessments, nor the family health educators, who implemented the Family Spirit intervention, were blind to randomization status. Independent evaluators, who administered the Infant-Toddler Social and Emotional Assessment and the HOME, were blind to randomization status.

Statistical Methods

Repeated-measures analyses of covariance (ANCOVAs) were employed to test for hypothesized intervention effects (differences between the intervention and control groups in means for continuous outcomes and in odds ratios for dichotomous outcomes) across the postpartum assessment period (i.e., the main effect of intervention condition in the ANCOVA model). In addition, effect sizes were computed for continuous outcomes; effect sizes were calculated as the estimated group mean difference divided by the square root of the residual covariance estimate. All postpartum assessment points for a given outcome were included in the analysis.

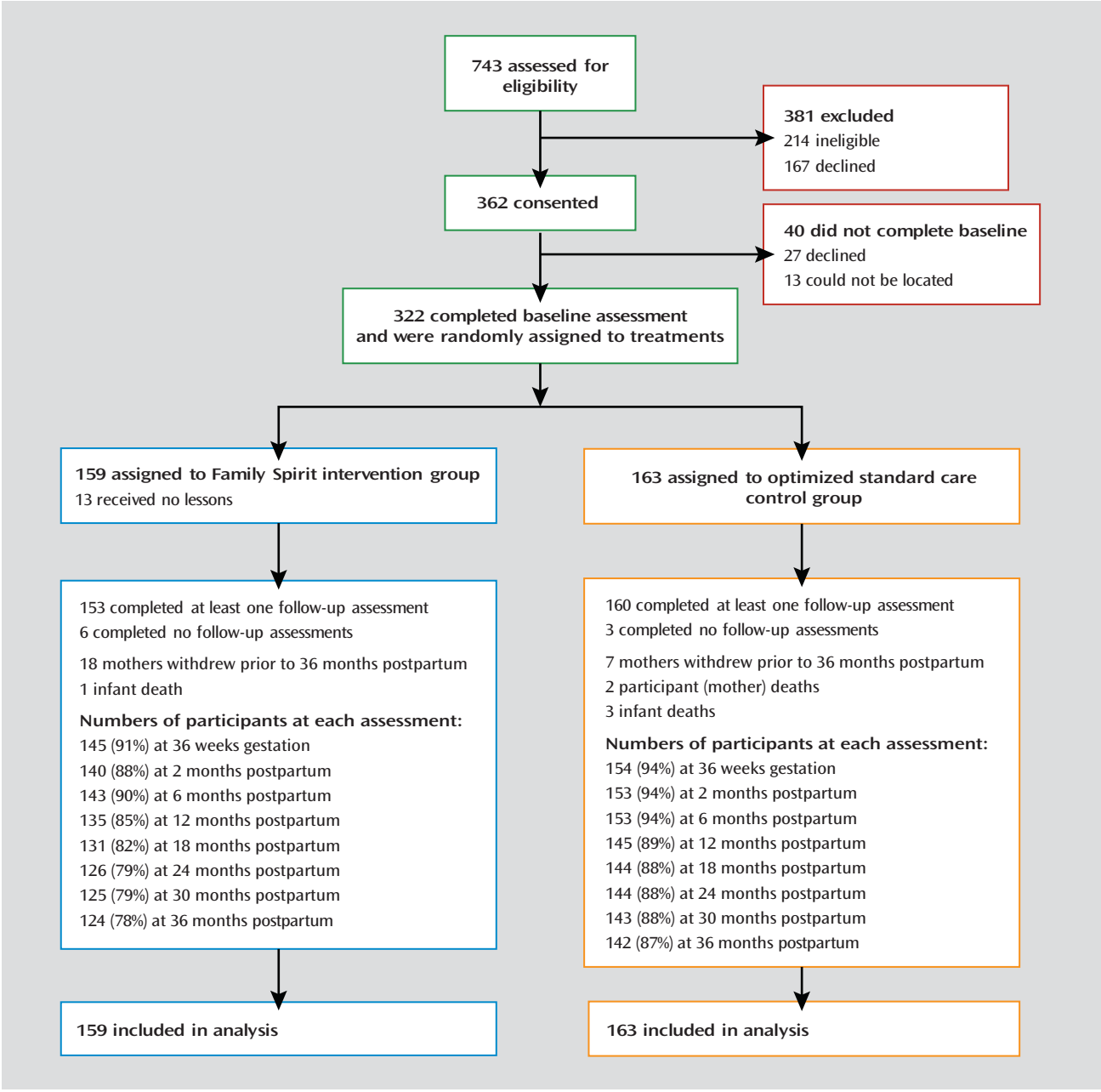
Assessments gathered between 28 and 32 weeks gestation represented baseline values. For the CES-D, the baseline value was the average of scores from the first two time points (i.e., <32 weeks and approximately 36 weeks gestation) to generate a more accurate estimate of depressive symptoms during pregnancy. If the outcome measure was collected at baseline, its value was included in the analysis as a covariate. Other covariates included the mother's age, the sex and age of the child (in months) at the time of assessment (for child outcomes) to adjust for differences between nominal and actual assessment points, and three variables to control for nonequivalence ($0.05<p<0.1$) between study groups at baseline: maternal depressive symptoms during pregnancy, lifetime cigarette use, and alcohol or illegal drug use during pregnancy. The inclusion of relevant covariates also serves to increase statistical power for hypothesis tests by reducing unexplained (error) variance in the models. Factors in the ANCOVA models included study condition, site, and assessment wave.

Analyses were intent-to-treat; all randomly assigned participants were included. Analyses of continuous outcomes were conducted by using SAS PROC MIXED; SAS PROC GLIMMIX was used for dichotomous outcomes. The covariance structure specified for the repeated-measures analysis was banded Toeplitz (33, 34)—three bands for continuous outcomes and two bands for dichotomous outcomes (to facilitate model convergence) and for the Parental Stress Index, which included only two postpartum assessments. The banded Toeplitz structure was selected to parsimoniously model the cross-wave covariation expected in the repeated measures. Consistent with current recommendations (35, 36), missing data were addressed through the application of maximum likelihood estimation (restricted maximum likelihood for continuous outcomes and restricted pseudo likelihood for dichotomous outcomes). In addition, ANCOVA models were employed to examine potential differential attrition associated with baseline outcome and covariate measures.

Results

Of 743 women assessed for eligibility, 381 were excluded (214 were ineligible and 167 declined to participate) and 362 consented to participation. Of these, 322 completed baseline assessments and were randomly assigned between 2006 and 2008 (Figure 1). Within the intervention group, 13 received no Family Spirit lessons. Two mothers

FIGURE 1. Flow of Participants in a Trial of the Family Spirit Paraprofessional-Delivered Home-Visiting Intervention for American Indian Teen Mothers, to 36 Months Postpartum



(both in the control group) and four infants (intervention, N=1; control, N=3) died during the trial. Twenty-five mothers (intervention, N=18; control, N=7) withdrew during the study period. Wave-specific participation rates for postpartum assessments ranged from 92% at 6 months postpartum (N=296; intervention, N=143; control, N=153) to 83% at 36 months postpartum (N=266; intervention, N=124; control, N=142).

Baseline Characteristics

As shown in Table 1, the participants were on average 18.1 years old and were predominantly primiparous, unmarried, and residentially unstable. They had a high lifetime rate of substance use, and one-third had a high level of depressive symptoms. The two treatment groups were similar at baseline, with the exception of three variables that were more common in the intervention group ($0.05>p\leq0.1$): maternal depressive symptoms, use of alcohol during pregnancy, and lifetime cigarette use.

Attrition was higher in the intervention group than in the control group. Attrition in both conditions primarily occurred before 12 months, followed by relatively stable participation through 36 months. Analyses of differential attrition showed

TABLE 1. Baseline Characteristics of Participants in a Trial of the Family Spirit Paraprofessional-Delivered Home-Visiting Intervention for American Indian Teen Mothers

	Intervention Group (N=159)				Control Group (N=163)				Total (N=322)			
Baseline Variable	Mean	SD	N	%	Mean	SD	N	%	Mean	SD	N	%
Sociodemographic characteristics												
Age (years)	18.2	1.4			18.1	1.6			18.1	1.5		
Gestational age (weeks)	25.3	4.3			24.7	4.0			25.0	3.1		
Age group												
12–17 years			67	42.1			69	43.3			136	42.2
≥18 years			92	57.9			94	57.7			186	57.8
Number of children												
0			122	76.7			125	76.7			247	76.7
1			35	22.0			31	19.0			66	20.5
≥2			2	1.3			7	4.3			9	2.8
Currently unmarried			153	96.2			158	96.9			311	96.6
Pregnancy was planned			30	18.9			28	17.2			58	18.0
No contraceptive use at conception			136	85.5			140	85.9			276	85.7
Lives independently with boyfriend			19	12.0			22	13.5			41	12.7
Lives with participant's parents			96	60.8			95	58.6			191	59.7
Lives with boyfriend's parents			26	16.5			33	20.4			61	18.4
Currently in school			63	39.6			68	41.7			131	40.7
Currently employed			12	7.5			11	6.8			23	7.1
Household lacks electricity			11	6.9			8	4.9			19	5.9
Household lacks indoor plumbing			14	8.8			16	9.8			30	9.3
Completed high school or GED			43	27.0			45	27.6			88	27.3
Lived in two or more homes in past year			77	48.4			86	52.8			163	50.6
Language(s) spoken most in home												
Only English			88	55.4			90	55.2			178	55.3
Both English and Native			33	20.8			39	23.9			72	22.4
Only Native			38	23.9			34	20.9			72	22.4
Maternal psychosocial characteristics												
Depression (CES-D) score[a]												
Score ≤16			100	62.9			118	72.4			218	67.7
Score >16			59	37.1			45	27.6			104	32.3
Alcohol use												
Ever used			135	84.9			136	83.4			271	84.2
Used during pregnancy			28	17.6			17	10.4			45	14.0
Age at first use (years)	14.5	1.8			14.7	1.9			14.6	1.8		
Cigarette use												
Ever used			102	64.2			88	54.0			190	59.0
Used during pregnancy			36	22.6			26	16.0			62	19.3
Age at first use (years)	13.1	2.7			13.2	2.7			13.1	2.7		
Marijuana use												
Ever used			130	81.8			124	76.1			254	78.9
Used during pregnancy			23	14.5			20	12.3			43	13.4
Age at first use (years)	13.3	2.2			13.3	2.2			13.3	2.2		
Methamphetamine use												
Ever used			50	31.5			41	25.2			91	28.3
Used during pregnancy			9	5.7			8	4.9			17	5.3
Age at first use (years)	15.5	1.7			15.2	1.8			15.3	1.7		
Cocaine/crack use												
Ever used			44	27.7			37	22.7			81	25.2
Used during pregnancy			4	2.5			2	1.2			6	1.9
Age at first use (years)	14.8	1.5			14.8	1.9			14.8	1.7		

[a] CED-D, Center for Epidemiological Studies–Depression scale.

significant effects for two variables. Women in the intervention group who reported no substance use during pregnancy were more likely to drop out, and participants in the control group who reported never using cigarettes were more likely to remain in the study. Attrition did not favor the intervention group.

TABLE 2. Parental Competence Outcomes to 36 Months Postpartum in a Trial of the Family Spirit Paraprofessional-Delivered Home-Visiting Intervention for American Indian Teen Mothers (N=322)

	Adjusted Mean Score[a]		Difference			
Parental Competence Measure	Intervention Group	Control Group	Mean	95% CI	Effect Size[b]	p
Parenting knowledge self-report[c]	15.94	14.66	1.28	0.70, 1.86	0.42	<0.001
Parental Locus of Control Scale (25)[d]	64.34	66.03	–1.69	–3.00, –0.39	0.17	0.02
Parenting Stress Index (26)[e]	75.53	79.10	–3.57	–7.71, 0.57	0.18	0.10
Home Observational Measurement of the Environment (HOME) (27)[f]	31.73	31.63	0.10	–0.54, 0.73	0.02	0.77

[a] Factors include condition, site, and wave; covariates include baseline parenting knowledge (for parenting knowledge outcome only), maternal depressive symptoms (Center for Epidemiological Studies—Depression scale [CES-D] score) during pregnancy, lifetime use of cigarettes, use of alcohol or any illegal drug during pregnancy, and age of mother.
[b] Estimated condition mean difference divided by the square root of the residual covariance estimate.
[c] Scores range from 0 to 30; higher values indicate more knowledge. Assessed at 12, 24, and 36 months.
[d] Scores range from 27 to 135; lower values indicate greater efficacy. Assessed at 2, 6, 12, 18, 24, 30, and 36 months.
[e] Scores range from 0 to 180; higher values indicate greater stress. Assessed at 24 and 36 months.
[f] Scores range from 0 to 37; higher values indicate better parental behavior. Assessed at 6, 12, 18, 24, 30, and 36 months.

TABLE 3. Maternal Psychosocial and Drug Use Outcomes to 36 Months Postpartum in a Trial of the Family Spirit Paraprofessional-Delivered Home-Visiting Intervention for American Indian Teen Mothers (N=322)

Maternal Outcome Measure	Intervention Group	Control Group	Analysis			
Psychosocial functioning	Adjusted Mean Score[a]	Adjusted Mean Score[a]	Difference	95% CI	Effect Size[b]	p
Center for Epidemiological Studies–Depression scale (CES-D) score[c]	12.48	13.65	–1.17	–2.05, –0.28	0.16	0.01
Achenbach System of Empirically Based Assessments (29) youth self-report T scores[d]						
Externalizing problems	41.35	42.58	–1.23	–2.45, –0.02	0.14	<0.05
Internalizing problems	42.89	43.72	–0.83	–2.17, 0.50	0.09	0.23
Total problems	40.51	41.36	–0.86	–2.10, 0.39	0.10	0.18
Drug use in past 30 days[e]	Estimated %	Estimated %	Odds Ratio[f]	95% CI		p
Alcohol	16.52	15.70	1.06	0.80, 1.41		0.68
Marijuana	10.71	15.58	0.65	0.48, 0.89		0.007
Any illegal drug	12.33	17.27	0.67	0.50, 0.91		0.01

[a] Factors include condition, site, and wave; covariates include baseline CES-D score, lifetime use of cigarettes, use of alcohol or any illegal drug during pregnancy, and age of mother.
[b] Estimated condition mean difference divided by the square root of the residual covariance estimate.
[c] Scores range from 0 to 60; higher values indicate more depressive symptoms. Assessed at 2, 6, 12, 18, 24, 30, and 36 months.
[d] Scores range from 0 to 100; higher values represent more problems. Assessed at 6, 12, 18, 24, 30, and 36 months.
[e] Assessed at 2, 6, 12, 18, 24, 30, and 36 months.
[f] Intervention group in relation to control group.

Intervention Fidelity

Three-quarters (74.2%) of the participants in the intervention group completed more than 50% of the Family Spirit lessons by 12 months postpartum, and 69.8% and 66.7% did so at 24 and 36 months postpartum, respectively. Intervention lessons were completed as planned for 85% of the visits. The average time for lesson visits was 52 minutes.

Parenting Outcomes

As shown in Table 2, across the study period the mothers in the intervention group had significantly more parenting knowledge and parental locus of control. The difference was not significant at $p<0.05$ for parenting stress or observations of the home environment.

Maternal Outcomes

As shown in Table 3, across the study period the mothers in the intervention group had significantly lower scores for depression and externalizing problems. No between-group differences were seen in the score for internalizing problems or the total score on the Achenbach youth self-report measure. Mothers in the intervention group had lower use in the past month of marijuana and illicit drugs (Table 3). No between-group differences were observed for alcohol use.

Child Outcomes

As shown in Table 4, children in the intervention group had lower scores for externalizing problems, internalizing problems, and dysregulation from 12 to 36 months. Fewer children in the intervention group scored in the "of concern" range (≤10th percentile) for externalizing and internalizing problems (Table 4).

Discussion

This study demonstrated the effectiveness of a paraprofessional-delivered home-visiting intervention for American Indian teen mothers' parenting, externalizing problems,

TABLE 4. Children's Socio-Emotional Outcomes to 36 Months Postpartum in a Trial of the Family Spirit Paraprofessional-Delivered Home-Visiting Intervention for American Indian Teen Mothers (N=288)[a]

Infant-Toddler Social and Emotional Assessment[b] Measure	Intervention Group	Control Group	Analysis			
Mean scores[c]	Adjusted Mean[d]	Adjusted Mean[d]	Difference	95% CI	Effect Size[e]	p
Externalizing domain	0.64	0.71	–0.07	–0.12, –0.02	0.23	0.005
Internalizing domain	0.54	0.60	–0.05	–0.09, –0.02	0.23	0.004
Dysregulation domain	0.48	0.55	–0.07	–0.11, –0.03	0.27	<0.001
Competence domain	1.28	1.24	0.04	–0.01, 0.09	0.14	0.09
Clinically at risk (≤10th percentile)	Estimated %	Estimated %	Odds Ratio[f]	95% CI		p
Externalizing domain	17.37	23.79	0.67	0.47, 0.95		0.03
Internalizing domain	9.91	14.64	0.64	0.43, 0.96		0.04
Dysregulation domain	10.47	14.56	0.69	0.46, 1.04		0.08
Competence domain	23.84	22.96	1.05	0.75, 1.46		0.78

[a] Number of children was based on the number of respondents providing covariates and data for the outcome at any postbaseline assessment point.
[b] Administered at 12, 18, 24, 30, and 36 months.
[c] Scores ranged from 0 to 2. For the externalizing, internalizing, and dysregulation domains, higher scores indicate more problems; for the competence domain, higher values indicate greater competence.
[d] Factors include condition, site, and wave; covariates include sex of child, age of child at assessment point, baseline value for Center for Epidemiological Studies–Depression (CES-D) score, lifetime use of cigarettes, maternal use of alcohol or any illegal drug during pregnancy, and age of mother.
[e] Estimated condition mean difference divided by the square root of the residual covariance estimate.
[f] Intervention group in relation to control group.

depression, and substance use and for their children's early emotional and behavioral outcomes from infancy through 36 months postpartum. Findings from previous trials were replicated and extended (12–14). Despite an active control group that connected participants to recommended prenatal and pediatric care, effect sizes were similar in magnitude to those of community-based interventions with recognized public health impact (see reference 32).

Strengths

This study makes several important contributions to gaps (2–4) in the current home-visiting field and to the preventive care and public health literature more generally: 1) the intervention was effective in reducing maternal and child behavior health disparities in the most disadvantaged and hard-to-reach and -retain U.S. subgroup (2, 15, 16); 2) assessment measures identified short-term (12-month) and longer-term (up to 36 month) maternal and child behavioral outcomes and included measures of intervention fidelity—both lacking from previous home-visiting trials; and 3) the trial demonstrated the effectiveness of community-based paraprofessionals as behavioral interventionists—a finding that is increasingly critical for populations with a shortage of nurses or professional health care providers and persistent behavioral and mental health disparities.

The intervention's dual focus on competent parenting and mothers' behavioral and mental health risks that impede competent parenting is likely critical to the success of home-visiting programs in communities that suffer intergenerational behavioral health disparities. To this point, relative to mothers in the control group, mothers receiving the Family Spirit intervention had better parenting knowledge and self-efficacy, while showing fewer externalizing problems and less depression and substance use—maternal behaviors that have been linked to negative parenting practices that predict child behavior problems over the life course (5–8). Meanwhile, children in the intervention group benefited in three developmental domains (externalizing, internalizing, and dysregulation problems) that predict better behavior outcomes in later childhood and adolescence (9, 10); also, a smaller proportion of children in the intervention group scored in the "of concern" range for externalizing and internalizing problems. Moreover, these maternal and child effects were apparent despite baseline group differences, notably maternal depression, that might be expected to reduce response to intervention efforts. Of public health importance for the participating communities, children in the control condition—in spite of receiving optimized pediatric care—had considerably more "of concern" levels of externalizing (23.8%), internalizing (14.6%), and dysregulation (14.6%) problems than the normative sample for these measures (<10%) (31). Given the known risks of early childhood externalizing, internalizing, and dysregulation behaviors for later childhood substance abuse, educational attainment, and obesity (9, 10, 37), this research has implications for reductions in health, education, and mental health problems across the life course. In light of the increasing global burden of behavior-related noncommunicable disease, efforts to scale interventions of the Family Spirit type in high-risk communities deserve the attention of scientists and policymakers alike. Further, according to prior evidence regarding return on investment from nurse home-visiting programs relative to health care and welfare cost savings (38, 39), paraprofessional home visitors, who are more affordable than nurses, could lower health and human service costs, build the capacity of the local work force, and better match consumer preferences for culturally competent providers in high-risk settings.

Home Environment

This study did not find differences in ratings from home observations. Other home-visiting studies have not identified differences until 2 to 4 years postpartum (11, 40). Our lack of findings may be related to a lag in this indicator, the fact that the mothers were highly mobile and unable to establish a stable home environment for their children, or the lack of cultural congruity in several items of the measure, described previously (13, 41).

Limitations

The trial had several potential limitations, including concerns regarding generalizability, response bias with self-report measures, and the large number of study outcomes. In terms of generalizability, the intervention was designed to address the poorest, most at-risk communities in the country. All sites shared substantial behavioral health and sociodemographic disparities similar to or exceeding those of other at-risk communities in the United States and worldwide, but they were diverse in language, culture, and exposure to dominant society norms.

Self- and parent-report measures of maternal and child behavior outcomes from 0 to 3 years postpartum facilitated detection of early intervention benefit and allowed for paraprofessional administration. However, response bias is a concern for maternal self- and parent-report measures. Some of the mothers' self-report scores (i.e., on the Achenbach youth self report) were better than or comparable to those for U.S. all-race samples (29) despite the mothers' early pregnancy, drug use, and challenging living conditions. On the other hand, mothers in both groups reported high rates of depression and substance use, sensitive indicators for under-age respondents, and high rates of "of concern" scores for their infants and toddlers. Other types of assessments, such as biological samples (e.g., cotinine or urine samples) or videotaped and coded observational measures, were not culturally acceptable or financially feasible in this trial. Low-cost, sensitive standardized self-reports can facilitate dissemination and real-time effectiveness monitoring as home-visiting programs are implemented at scale in community settings.

Finally, because of the large number of dependent variables, the likelihood that some significant findings could be due to chance was increased. However, the majority of outcomes showed significant differences, were consistent with the study's theoretical model and hypotheses (14), and replicated and extended findings from previous Family Spirit evaluations (12, 13, 41).

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Dr. Walkup has received free drug and/or placebo from the following pharmaceutical companies for NIMH-funded studies: Eli Lilly (2003), Pfizer (2007), and Abbott (2005); he was paid for a one-time consultation with Shire (2011); he is a paid speaker for the Tourette Syndrome Association–Center for Disease Control and Prevention outreach educational programs; he receives grant funding from the Hartwell Foundation and the Tourette Syndrome Association; and he receives royalties for books on Tourette syndrome from Guilford Press and Oxford Press. Dr. Carter receives royalties from the sale of the Infant-Toddler Social and Emotional Assessment (ITSEA) (under $2,000 per year). The remaining authors report no financial relationships with commercial interests.

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The opinions expressed are those of the authors and do not necessarily reflect the views of the Indian Health Service.

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Article

Effect of a Paraprofessional Home-Visiting Intervention on American Indian Teen Mothers' and Infants' Behavioral Risks: A Randomized Controlled Trial

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Objective: The authors sought to examine the effectiveness of Family Spirit, a paraprofessional-delivered, home-visiting pregnancy and early childhood intervention, in improving American Indian teen mothers' parenting outcomes and mothers' and children's emotional and behavioral functioning 12 months postpartum.

Method: Pregnant American Indian teens (N=322) from four southwestern tribal reservation communities were randomly assigned in equal numbers to the Family Spirit intervention plus optimized standard care or to optimized standard care alone. Parent and child emotional and behavioral outcome data were collected at baseline and at 2, 6, and 12 months postpartum using self-reports, interviews, and observational measures.

Results: At 12 months postpartum, mothers in the intervention group had significantly greater parenting knowledge, parenting self-efficacy, and home safety attitudes and fewer externalizing behaviors, and their children had fewer externalizing problems. In a subsample of mothers with any lifetime substance use at baseline (N=285; 88.5%), children in the intervention group had fewer externalizing and dysregulation problems than those in the standard care group, and fewer scored in the clinically "at risk" range (≥10th percentile) for externalizing and internalizing problems. No between-group differences were observed for outcomes measured by the Home Observation for Measurement of the Environment scale.

Conclusions: Outcomes 12 months postpartum suggest that the Family Spirit intervention improves parenting and infant outcomes that predict lower lifetime behavioral and drug use risk for participating teen mothers and children.

(Am J Psychiatry 2013; 170:83–93)

Nearly half (41%) of American Indian and Alaska Native females begin child-rearing in adolescence, compared with 21% for all races overall in the United States, and bear twice as many children while in their teens compared with the general U.S. population (1, 2). Teen pregnancy and child-rearing are associated with negative maternal outcomes and poor parenting, which put teens' children at higher risk for behavioral health problems in their lifetime (3–5). Compounding the challenge of teen parenting, American Indian and Alaska Native adolescent females experience higher drug use rates and related conduct problems than other U.S. ethnic groups, including school dropout, intentional and unintentional injury, and sexually transmitted disease (1, 6, 7). Native communities have limited professional health care resources for young families and face substantial access barriers to health education and medical and mental health care (8). Despite these challenges, Native communities have an abundance of paraprofessional expertise that can be tapped to address the twin challenges of teen childbearing and drug use. Creating innovative adjunctive health care services utilizing tribes' paraprofessional resources has the potential to break multigenerational cycles of behavioral health disparities for reservation communities.

In the broader U.S. population, early childhood home-visiting interventions promoting maternal parenting have been shown to reduce maladaptive behaviors in middle and later childhood, including poor school performance (9, 10); antisocial (11), delinquent, and aggressive behavior (12); substance use (12–19); and high-risk sex (11).

In recognition of the positive effects of home visiting in the general U.S. population, Congress legislated the Protection and Affordable Care Act of 2010 with a provision authorizing the Maternal, Infant, and Early Childhood Home Visiting Program to respond to the diverse needs of children and families in communities experiencing health disparities. The provision includes substantial funding for home-visiting programs within American Indian and Alaska Native tribal populations.

However, there is little evidence to date for home visiting's effectiveness in American Indian and Alaska Native communities (20) and limited understanding of the unique implementation needs of reservation settings. For example, while the home-visiting literature in the United States has led to a general preference for nurses over paraprofessional

home visitors, there are barriers to nurse home visitors in American Indian reservation communities because of a shortage of local Native nurses and tribal stakeholder preference for Native home visitors (21, 22).

In addition, the most rigorous randomized home-visiting trials have not been able to identify definitive early parenting or infant/toddler outcomes. For example, global improvements in parent-child interactions as measured by the Home Observation for Measurement of the Environment scale have not been consistently positive until 4 years postpartum (23), and differences in emotional and behavioral outcomes for children have not been confirmed before age 3 (23). The lag in outcomes makes it difficult to evaluate the efficacy of home-visiting programs in clinical trials.

Our group has attempted to address simultaneously the behavioral health disparities in American Indian and Alaska Native communities and the gaps in the home-visiting literature through a line of community-based participatory research evaluating the Family Spirit program, a paraprofessional-delivered, home-visiting intervention for American Indian teen mothers and their children, codesigned and evaluated with four tribal reservation communities since 1998. We conducted two previous studies to examine the efficacy of Family Spirit. Our first study (N=53) identified intervention-related changes in parenting knowledge and involvement from pregnancy to 6 months postpartum (22). The second study (N=167) replicated these outcomes until 12 months postpartum and explored behavioral and emotional outcomes in 12-month-old children (21). However, conclusions from these trials were limited by a lack of independent evaluators and high attrition (20), both of which have been overcome in the present study.

The conceptual model underpinning Family Spirit posits parenting as the critical link between parents' personal characteristics and environmental context and their children's emotional and behavioral outcomes from early childhood through adolescence (24, 25). The Family Spirit intervention targets specific negative parenting behaviors associated with infant and toddler externalizing, internalizing, and dysregulation problems. Negative early parenting practices associated with persistent child behavior problems (26) include poor monitoring (27), abuse or neglect (28), coercive interactions (12), and harsh, unresponsive, or rejecting parenting (29).

Early childhood outcomes are assessed with 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 (30) that predict behavior problems in middle childhood and adolescence (11, 31, 32). The intervention employs Native paraprofessionals as home visitors, building local human capital and reflecting American Indian stakeholder provider preferences (25). Our study hypothesis is that intensive parent training by an empathic, trusted home visitor focusing on responsive, nurturing, and attentive parenting, coupled with maternal psychoeducation targeting coping, problem solving, and conflict resolution, will improve parenting and psychosocial function in teen mothers that will translate to positive early child outcomes.

Method

Study Design

The trial is a multisite, randomized, parallel-group trial of the Family Spirit intervention plus optimized standard care compared with optimized standard care alone from pregnancy until 3 years postpartum in four tribal communities across three reservations in Arizona. Masked independent evaluators administered primary parenting and child outcome assessments. Comprehensive participant retention strategies and adverse event reporting were employed (28). A detailed description of the methods and design rationale may be found elsewhere (25). Here we report findings for parenting and maternal and early child behavioral outcomes from pregnancy to 12 months postpartum.

The study was approved by relevant tribal, Indian Health Services, and Johns Hopkins University research review boards. An independent data safety and monitoring board oversaw participant safety.

Objectives

The primary aims of the study were to evaluate whether the Family Spirit intervention plus optimized standard care as compared with optimized standard care alone would significantly 1) improve parenting knowledge, self-efficacy, and behaviors; 2) reduce maternal psychosocial and behavioral risks (drug and alcohol use, depression, conduct problems) that could impede parenting; and 3) improve infant internalizing and externalizing outcomes.

Participants

Participants were eligible if they were pregnant and ≤32 weeks' gestation, 12–19 years of age at conception, American Indian (self-identified), and residing in one of four participating reservation communities. The communities are rural and isolated, with populations ranging from 15,000 to 25,000. Participants provided written informed consent after receiving a complete description of the study. For those under age 18, informed consent was obtained from a parent or guardian and assent from the participant. The trial was conducted between May 2006 and September 2011.

Family Spirit Intervention

Family Spirit consists of 43 highly structured lessons delivered by Native paraprofessionals. The content targets three domains: parenting skills across early childhood (0–3 years); maternal drug abuse prevention; and maternal life skills and positive psychosocial development. The home visitors deliver lessons one-on-one in participants' homes using tabletop flip charts. The flip chart is designed so that the participant views illustrated content that often includes a real-life scenario while the home visitor reviews an outline of key points relating to the scenario and illustration (an illustration of the flip chart is provided in the data supplement that accompanies the online edition of this article). The home visitor is trained to use the lesson outline to create a comfortable teaching dialogue, rather than reading points by rote.

As baseline data suggest, teen mother participants were generally living in stressed and unstable home environments and

often experienced strong feelings of isolation, helplessness, and distress as they struggled to develop their maternal role. Home visitors were recruited for their strong interpersonal skills, capacity to conduct the intervention, and understanding of participants' challenges. The intervention's therapeutic effect was hypothesized to operate through one-on-one teaching of highly structured content by a knowledgeable, empathic Native home visitor. Home visitors' success in developing a warm, professional relationship was viewed as key to retaining and motivating participants to trust and learn from the curriculum over the long intervention period.

Each home visit was designed to last ≤1 hour, including a brief warm-up conversation, conducting the lesson, a question/answer period, and providing summary handouts. Home visits occurred weekly through the end of pregnancy, biweekly until 4 months postpartum, monthly between 4 and 12 months postpartum, and bimonthly between 12 and 36 months postpartum.

Home visitors received extensive training (>80 hours) in trial protocol and intervention delivery and had to demonstrate mastery (≥85%) of the Family Spirit curriculum through written and oral examinations before delivering any intervention. Supervisors conducted quarterly observations of home visitors administering home visits, rating them on protocol adherence, professionalism, and rapport-building. All intervention sessions were audiorecorded, and a random 20% of recordings were reviewed for protocol adherence.

Optimized Standard Care

Optimized standard care consisted of transportation to recommended prenatal and well-baby clinic visits, provision of pamphlets on child care and community resources, and referrals to local services when needed. Optimized standard care was chosen as the control condition because it optimized the standard of care for young mothers and their children within reservation communities, addressed transportation and access barriers to preventive health care, and provided beneficial and ecologically valid services in participants' settings. By providing optimized standard care to both intervention and control groups, the quality and dose of optimized standard care was controlled so that differences between groups could be validly attributed to the Family Spirit intervention.

Randomization and Blinding

After the baseline assessment, eligible participants were randomly assigned in equal numbers to the Family Spirit intervention plus optimized standard care or to optimized standard care alone. Randomization was stratified by site, age (12–15 years versus 16–19 years), and history of previous live births (0 versus ≥1). The data manager created the randomization sequence using Stata, version 9.0 (StataCorp, College Station, Tex.). The study coordinator delivered randomization status by telephone to a staff member who enrolled the participant. Independent evaluators collecting observational and structured interview data were blind to randomization status. Participants and other study personnel were not.

Outcome Measures

Outcome data were collected at four time points during this study period in participants' homes: at baseline (≤32 weeks' gestation) and at 2, 6, and 12 months postpartum. At all four time points, parenting outcomes (parenting knowledge and self-efficacy; maternal acceptance, involvement, and responsivity; and home safety strategies) and mothers' psychosocial and behavioral status (internalizing problems, externalizing problems, and substance use) were collected through self-report questionnaires, in-person interviews, audio computer-assisted self-interviews, and observational assessments. At 12 months postpartum, children's psychosocial and behavioral functioning was assessed using the ITSEA. Measures were selected for their wide standard use, strong psychometric properties, and appropriate cross-cultural validity (see Table S1 in the online data supplement).

Statistical Methods

The primary outcome variable for determining sample size and power at the endpoint of the trial (36 months postpartum) was mother's effective and competent parenting as measured by the Home Observation for Measurement of the Environment scale (33). This instrument was administered every 6 months from 6 to 36 months postpartum. Assuming 25% attrition, completion of four of six assessments, an alpha of 0.05, and a within-family correlation (r) of 0.5, we needed 160 participants per group (minimum total N=320) in order to detect a meaningful public health effect size of 0.33 with 90% power. This sample size also provided adequate power (≥80%) to detect minimum effect sizes of 0.30 on child developmental outcome measures at 12 months postpartum.

Of the 322 participants, 51 (16%) did not complete the parenting assessments and 66 (21%) did not complete the ITSEA at 12 months. Therefore, a multiple imputation approach was employed to manage missing values (34, 35), using a sequential regression multivariate imputation algorithm implemented via IVEware (36) for SAS. The 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 results of identical analyses on each imputed data set were combined using Rubin's established guidelines (34). Intent-to-treat analyses were conducted on all primary and secondary outcome measures. To investigate between-group differences in scalar outcomes, a series of separate analysis of covariance models were fitted for each outcome. Each model included site (treated as a fixed effect) and the following covariates to control for nonequivalence ($p<0.1$) among the treatment groups at baseline: mother's total score on the Center for Epidemiologic Studies Depression Scale (CES-D) (37), whether the mother had ever smoked cigarettes, and whether the mother used alcohol during pregnancy. For binary outcome measures, a series of separate logistic regression models were conducted using the same covariates. All models were first applied to the entire sample and then to the subsample of participants who had endorsed prior alcohol or drug use at baseline (N=285, or 88.5% of sample). Analyses were conducted with SAS, version 9.2 (SAS Institute, Cary, N.C.).

Results

A total of 322 participants were randomly assigned to a study condition (the CONSORT diagram is presented in the online data supplement). Within the intervention group, 12 participants received no Family Spirit lessons (five withdrew from the study and seven remained in the study but elected not to receive lessons). Overall, 19 (6%) participants discontinued the study (11 in the intervention group and eight in the control group), resulting in an attrition rate of 6% by 12 months postpartum. This attrition included one mother (in the control group) and three infants (one in the intervention group, two in the control group) who died prior to 12 months postpartum.

At baseline, participants were predominantly primiparous (76.7%) and unmarried (96.6%), and their mean age

TABLE 1. Baseline Characteristics of American Indian Teen Mothers in a Randomized Controlled Trial of a Home-Visiting Intervention

Characteristic	Intervention Group (N=159)		Control Group (N=163)		Total (N=322)		p
Sociodemographic characteristics							
	Mean	SD	Mean	SD	Mean	SD	
Age (years)	18.15	1.37	18.12	1.57	18.12	1.47	0.84
Gestational age at enrollment (weeks)	25.34	4.25	24.73	4.02	25.04	3.14	0.17
	N	%	N	%	N	%	
Age group							0.97
12–17 years	67	42.14	69	42.33	136	42.24	
18+ years	92	57.86	94	57.67	186	57.76	
Number of children before index pregnancy							0.22
0	122	76.73	125	76.69	247	76.71	
1	35	22.01	31	19.02	66	20.50	
≥2	2	1.26	7	4.29	9	2.80	
Currently unmarried	153	96.23	158	96.93	311	96.58	0.73
Pregnancy was planned	30	18.87	28	17.18	58	18.01	0.69
No contraceptive use at conception	136	85.53	140	85.89	276	85.71	0.93
Lives independently with boyfriend	19	11.95	22	13.49	41	12.73	0.68
Lives with parents	96	60.76	95	58.64	191	59.69	0.70
Lives with boyfriend's parents	26	16.46	33	20.37	61	18.44	0.37
Currently in school	63	39.62	68	41.72	131	40.68	0.70
Currently employed	12	7.50	11	6.75	23	7.14	0.78
Lack electricity in household	11	6.92	8	4.91	19	5.90	0.44
Lack indoor plumbing in household	14	8.81	16	9.82	30	9.32	0.76
Completed high school or General Equivalency Diploma	43	27.04	45	27.61	88	27.33	0.91
Lived in two or more homes in past year	77	48.43	86	52.76	163	50.62	0.11
Language(s) spoken in home							0.71
Only English	88	55.35	90	55.21	178	55.28	
Both English and a Native language	33	20.75	39	23.93	72	22.36	
Only a Native language	38	23.90	34	20.86	72	22.36	
Psychosocial characteristics							
CES-D[a] score for depressive symptoms							0.07
≤16	100	62.89	118	72.39	218	67.70	
>16	59	37.11	45	27.61	104	32.30	
Substance use[b]							
Alcohol							
Ever	135	84.91	136	83.44	271	84.16	0.72
During pregnancy	28	17.61	17	10.43	45	13.98	0.06
Cigarettes							
Ever	102	64.15	88	53.99	190	59.01	0.06
During pregnancy	36	22.64	26	15.95	62	19.25	0.13
Marijuana							
Ever	130	81.76	124	76.07	254	78.88	0.21
During pregnancy	23	14.47	20	12.27	43	13.35	0.56
Methamphetamine							
Ever	50	31.45	41	25.15	91	28.26	0.21
During pregnancy	9	5.66	8	4.91	17	5.28	0.76
Cocaine or crack							
Ever	44	27.67	37	22.70	81	25.16	0.30
During pregnancy	4	2.52	2	1.23	6	1.86	0.39

[a] CES-D=Center for Epidemiologic Studies Depression Scale.
[b] Mean age at first use was 14.6 years for alcohol, 13.1 years for cigarettes, 13.3 years for marijuana, 15.3 years for methamphetamine, and 14.8 years for cocaine or crack; there were no significant differences between groups on this measure for any substance.

was 18.1 years (Table 1). Over half had lived in two or more homes in the previous year. Rates of lifetime and during-pregnancy substance use were higher than those documented for other American Indian and Alaska Native adolescents and for U.S. adolescents of all races during the same study period (38). The study groups were similar at baseline, with the exception of a slightly (but nonsignificantly) higher mean CES-D total score, rate of lifetime

TABLE 2. Summary Findings and Effect Size Estimates for Parental Competence Outcomes at 6 and 12 months Postpartum in a Randomized Controlled Trial of a Home-Visiting Intervention for Teen Mothers, for All Participants[a]

Outcome	Adjusted Mean for Intervention Group (N=159)	Adjusted Mean for Control Group (N=163)	Adjusted Mean Difference	95% CI	Effect Size[b]	p
Parenting knowledge (possible scores, 0–30)						
Baseline	13.04	12.65	0.39	–0.32, 1.10	0.12	0.28
12 months postpartum	15.43	14.08	1.35	0.65, 2.04	0.33	0.001
PLOC Scale, parental self-efficacy subscale[c] (possible scores, 10–50)						
6 months postpartum	22.98	23.83	−0.85	–1.97, 0.28	−0.13	0.14
12 months postpartum	23.21	24.71	−1.51	–2.62, –0.39	−0.23	0.01
HOME scale (possible scores, 0–37)[d]						
6 months postpartum	22.79	22.75	0.04	–1.02, 1.10	<0.01	0.94
12 months postpartum	25.92	25.41	0.51	–0.62, 1.63	0.08	0.38
Home safety measures[e] at 12 months postpartum						
Home safety attitudes (possible scores, 8–40)	29.54	28.61	0.94	0.10, 1.78	0.19	0.03
Home safety practices (possible scores, 0–4)	1.56	1.30	0.26	–0.02, 0.54	0.16	0.07

[a] Adjusted for covariates, which included study site, use of alcohol during index pregnancy, lifetime use of cigarettes, and baseline Center for Epidemiologic Studies Depression Scale score.
[b] Standardized pairwise differences are defined as the average between treatment group difference in outcome scaled by the standard deviation of the outcome. Standardized differences represent treatment effect size estimates on the standard deviation scale of the outcome. Values of 0.2, 0.5, or 0.8 are generally regarded as small, medium, and large, respectively (39).
[c] PLOC Scale=Parental Locus of Control Scale (17).
[d] HOME=Home Observation for Measurement of the Environment (33). HOME scale scores exclude the acceptance subscale, which was omitted because of concerns about cultural and age appropriateness.
[e] Home safety measures are from reference 40.

cigarette use, and rate of alcohol use during pregnancy in mothers in the intervention group compared with those in the control group.

At 12 months postpartum, mothers in the intervention group had higher parenting knowledge, improved parenting self-efficacy, and better home safety attitudes compared with those in the control group (Table 2). Effect size estimates for these differences were 0.33, –0.23, and 0.19, respectively. For mothers with lifetime substance use at baseline, significant differences were similar, although slightly attenuated (Table 3). No between-group differences were seen on the Home Observation for Measurement of the Environment scale at 6 or 12 months postpartum.

Children of mothers in the intervention group had fewer externalizing symptoms (adjusted mean difference=–0.09, 95% CI=–0.16 to –0.01, p=0.03; effect size=–0.19) at 12 months postpartum (Table 4). Table 5 shows that in a subsample of mothers with lifetime substance use at baseline (N=285; 88.5%), children in the intervention group had fewer externalizing and dysregulation problems than those in the control group, with effect sizes of −0.26 and −0.21, respectively. Also in this subsample, significantly fewer intervention children compared with control children scored in the clinically "at risk" range (≥10th percentile) for externalizing (odds ratio=2.15, 95% CI=1.01 to 4.61, p=0.05) and internalizing (odds ratio=1.91, 95% CI=1.02 to 3.60, p=0.04) problems at 12 months postpartum (Table 5).

Within the externalizing domain, the activity/impulsivity subscale was the most improved subscale for the intervention group infants compared with the control infants (adjusted mean difference=–0.10, 95% CI=–0.20 to –0.01, p=0.04). Decreased negative emotionality was the most improved subscale in the dysregulation domain (adjusted mean difference=–0.09, 95% CI=–0.17 to –0.01, p=0.05). Although the competence domain as a whole was not significantly improved, infants in the intervention group had significantly higher scores on the compliance subscale than did those in the control group (adjusted mean difference=0.10, 95% CI=0.01 to 0.19, p=0.02).

At 12 months postpartum, mothers in the intervention group had fewer externalizing behaviors (Table 6). Among all participants and in the subsample of mothers with lifetime substance use at baseline, there were no statistically significant between-group differences seen in past-month substance use at 2, 6, or 12 months postpartum (Table 6 and Table 7).

Adverse Events

Adverse events were recorded by evaluation staff and home visitors and reviewed on a biannual basis by the trial's data safety and monitoring board. The proportion of

TABLE 3. Summary Findings and Effect Size Estimates for Parental Competence Outcomes at 6 and 12 months Postpartum in a Randomized Controlled Trial of a Home-Visiting Intervention for Teen Mothers, for Participants With Any Lifetime Substance Use[a]

Outcome (Possible Score Range)	Adjusted Mean for Intervention Group (N=145)	Adjusted Mean for Control Group (N=140)	Adjusted Mean Difference	95% CI	Effect Size[b]	p
Parenting knowledge (possible scores, 0–30)						
Baseline	13.19	12.78	0.40	–0.35, 1.16	0.13	0.29
12 months postpartum	15.47	14.26	1.21	0.46, 1.95	0.28	0.002
PLOC Scale, parental self-efficacy subscale[c] (possible scores, 10–50)						
6 months postpartum	22.81	23.61	−0.80	–2.00, 0.41	−0.11	0.12
12 months postpartum	22.91	24.41	−1.51	–2.74, –0.28	−0.21	0.02
HOME scale (possible scores, 0–37)[d]						
6 months postpartum	22.81	22.65	0.16	–0.96, 1.28	0.02	0.78
12 months postpartum	25.72	25.19	0.54	–0.66, 1.73	0.08	0.38
Home safety measures[e] at 12 months postpartum						
Home safety attitudes (possible scores, 8–40)	29.40	28.48	0.92	0.02, 1.81	0.17	0.04
Home safety practices (possible scores, 0–4)	1.55	1.26	0.29	–0.02, 0.59	0.18	0.06

[a] Adjusted for covariates, which included study site, use of alcohol during index pregnancy, lifetime use of cigarettes, and baseline Center for Epidemiologic Studies Depression Scale score.
[b] Standardized pairwise differences are defined as the average between treatment group difference in outcome scaled by the standard deviation of the outcome. Standardized differences represent treatment effect size estimates on the standard deviation scale of the outcome. Values of 0.2, 0.5, or 0.8 are generally regarded as small, medium, and large, respectively (39).
[c] PLOC=Parental Locus of Control (17).
[d] HOME=Home Observation for Measurement of the Environment (33). HOME scale scores exclude the acceptance subscale, which was omitted because of concerns about cultural and age appropriateness.
[e] Home safety measures are from reference 40.

TABLE 4. Summary Findings and Effect Size Estimates for ITSEA Outcomes at 12 Months Postpartum, for All Participants[a]

Outcome	Intervention Group (N=156)	Control Group (N=163)	Analysis			
ITSEA outcomes, mean scores (range 0–2)	Adjusted Mean	Adjusted Mean	Adjusted Mean Difference	95% CI	Effect Size[b]	p
Externalizing domain	0.62	0.71	−0.09	–0.16, –0.01	−0.19	0.03
Internalizing domain	0.57	0.62	−0.05	–0.13, 0.03	−0.10	0.23
Dysregulation domain	0.54	0.59	−0.06	–0.12, 0.01	−0.15	0.07
Competence domain	1.07	1.02	0.05	–0.02, 0.13	0.12	0.18
ITSEA outcomes, % clinically at risk	Estimated %[c]	Estimated %[c]	Odds Ratio	95% CI		p
Externalizing domain	13.69	20.62	1.88	0.92, 3.81		0.09
Internalizing domain	20.27	27.16	1.61	0.88, 2.92		0.12
Dysregulation domain	15.80	18.67	1.37	0.70, 2.69		0.36
Competence domain	20.27	17.66	0.86	0.46, 1.63		0.65

[a] ITSEA=Infant and Toddler Social and Emotional Assessment. Analyses adjusted for covariates, which included study site, use of alcohol during index pregnancy, lifetime use of cigarettes, and baseline Center for Epidemiologic Studies Depression Scale score.
[b] Standardized pairwise differences are defined as the average between treatment group difference in outcome scaled by the standard deviation of the outcome. Standardized differences represent treatment effect size estimates on the standard deviation scale of the outcome. Values of 0.2, 0.5, and 0.8 are generally regarded as small, medium, and large, respectively (39).
[c] Percentages are model-based estimates derived from imputed data.

adverse events and serious adverse events was similar between groups after accounting for increased contact time within the intervention group.

Discussion

This is the first methodologically rigorous trial to show efficacy for home visiting by paraprofessionals on early parenting and infants' emotional and behavioral outcomes. A range of parenting measures through 12 months postpartum yielded evidence supporting the impact of the Family Spirit intervention. Short-term effects were most significant for parenting knowledge, followed by self-efficacy and home safety attitudes. Differences on the parent knowledge assessment, a multiple-choice test with items linked directly to home-visiting lesson objectives, indicate that intervention content was successfully taught to teen mothers and provide a proxy for

TABLE 5. Summary Findings and Effect Size Estimates for ITSEA Outcomes at 12 Months Postpartum, for Participants With Substance Use at Baseline[a]

Outcome	Intervention Group (N=145)	Control Group (N=140)	Analysis			
ITSEA outcomes, mean scores (range 0–2)	Adjusted Mean	Adjusted Mean	Adjusted Mean Difference	95% CI	Effect Size[b]	p
Externalizing domain	0.62	0.74	−0.12	–0.20, –0.04	−0.26	0.004
Internalizing domain	0.58	0.65	−0.07	–0.16, 0.02	−0.14	0.11
Dysregulation domain	0.52	0.60	−0.08	–0.15, –0.02	−0.21	0.01
Competence domain	1.06	1.02	0.04	–0.04, 0.12	0.08	0.35
ITSEA outcomes, % clinically at risk	Estimated %[c]	Estimated %[c]	Odds Ratio	95% CI		p
Externalizing domain	13.12	22.40	2.15	1.01, 4.61		0.05
Internalizing domain	19.28	29.70	1.91	1.02, 3.60		0.04
Dysregulation domain	14.00	18.67	1.65	0.75, 3.63		0.21
Competence domain	21.27	16.88	0.77	0.40, 1.50		0.45

[a] ITSEA=Infant and Toddler Social and Emotional Assessment. Analyses adjusted for covariates, which included study site, use of alcohol during index pregnancy, lifetime use of cigarettes, and baseline Center for Epidemiologic Studies Depression Scale score.
[b] Standardized pairwise differences are defined as the average between treatment group difference in outcome scaled by the standard deviation of the outcome. Standardized differences represent treatment effect size estimates on the standard deviation scale of the outcome. Values of 0.2, 0.5, and 0.8 are generally regarded as small, medium, and large, respectively (39).
[c] Percentages are model-based estimates derived from imputed data.

intervention fidelity. Enhanced maternal self-efficacy is a key finding for teen mothers, as maternal role attainment is more challenging for adolescents who are still maturing (43).

Study outcomes for 12-month-old children were consistent with parenting outcomes (i.e., knowledge of responsive and attentive parenting and self-efficacy) and children's stage of development. Significant outcomes on the ITSEA clustered around improved externalizing scores (with the greatest benefit in activity/impulsivity) and subscales within the dysregulation domain (with the greatest benefit in negative emotionality), in addition to improvements in compliance. Subnormal scores on these subscales have been associated with serious behavior problems in later childhood, such as substance abuse, risky sex, and violence toward self and others (44, 45)—priority issues for American Indian communities. The absence of any differences in peer aggression or prosocial peer behavior in 12-month-olds is consistent with the developmental stage of these infants (46).

Within the subsample of substance-using mothers, intervention infants were half as likely to be scored at clinical risk for externalizing or internalizing problems—a critical finding given that children of mothers with substance use are at higher risk for behavior problems (47). This finding is consistent with our theoretical model suggesting that improved parenting may buffer the negative effects of maternal substance use on children.

The fact that mothers in the intervention group reported significantly reduced externalizing behaviors over time also holds promise. However, the study design does not allow us to dismantle how this effect was achieved. Based on our theoretical model, we predicted that Family Spirit's conflict resolution and problem-solving lessons would reduce externalizing behaviors (25); in addition, learning parenting skills may also indirectly improve the mother's mood and behavior, particularly if children are reciprocating positive affect and behavior. Additional research is necessary to corroborate this interpretation.

There were no significant differences between groups at 12 months postpartum for self-reported maternal substance use. Two factors may account for this finding: 1) the Family Spirit intervention evaluated in this trial does not focus on substance abuse prevention until after 12 months postpartum; and 2) there is widespread, frequent exposure to substance use within this population in late adolescence and early adulthood. We are currently enhancing Family Spirit's substance abuse prevention curricula from pregnancy to 1 year postpartum.

Clinical Relevance

The 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 parenting education to prevent maternal and child behavior problems whose trajectories challenge underresourced reservation communities. Evidence from this trial suggests that the Family Spirit intervention could move children in high-risk settings out of clinically meaningful risk for early child behavior problems, with potential impact on both long-term public health and economic benefits. The fact that twice as many control group infants were clinically at risk for poor emotional and behavioral regulation (21% for externalizing and 27% for internalizing problems) compared with a normative U.S. sample (10%) (13, 46) signals the importance of this type of intervention in similarly stressed populations. The greater benefit afforded infants of substance-using mothers is consistent with previous home-visiting trials that found better response among

TABLE 6. Summary Findings and Effect Size Estimates for Maternal Psychosocial and Behavioral Outcomes at 2, 6, and 12 Months Postpartum, for All Participants[a]

Outcome	Intervention Group (N=159)	Control Group (N=163)	Analysis			
Psychosocial outcomes	Adjusted Mean	Adjusted Mean	Adjusted Mean Difference	95% CI	Effect Size[b]	p
CES-D score						
Baseline	13.37	13.40	−0.03	–0.90, 0.83	−0.01	0.94
2 months postpartum	13.06	13.40	−0.34	–1.19, 0.51	−0.07	0.44
6 months postpartum	12.46	13.41	−0.95	–2.09, 0.19	−0.16	0.10
12 months postpartum	11.54	13.41	−1.89	–3.80, 0.06	−0.20	0.06
ASEBA externalizing T-score						
Baseline	41.98	42.21	−0.23	–2.04, 1.59	−0.02	0.81
6 months postpartum	40.09	41.46	−1.37	–3.12, 0.39	−0.13	0.13
12 months postpartum	38.20	40.70	−2.50	–4.89, –0.12	−0.20	0.04
ASEBA internalizing T-score						
Baseline	46.13	46.25	−0.12	–2.00, 1.76	−0.01	0.90
6 months postpartum	43.80	45.12	−1.32	–3.17, 0.53	−0.12	0.16
12 months postpartum	41.48	43.99	−2.51	–5.12, 0.09	−0.19	0.06
ASEBA total problems T-score						
Baseline	42.53	42.93	−0.41	–2.22, 1.41	−0.04	0.66
6 months postpartum	40.27	41.65	−1.38	–3.22, 0.45	−0.13	0.14
12 months postpartum	38.01	40.37	−2.36	–4.90, 0.19	−0.18	0.07
POSIT mental health score						
Baseline	3.32	3.70	−0.37	–0.83, 0.09	−0.14	0.11
2 months postpartum	3.23	3.56	−0.33	–0.77, 0.11	−0.13	0.14
6 months postpartum	3.05	3.30	−0.25	–0.73, 0.23	−0.09	0.30
12 months postpartum	2.77	2.91	−0.14	0.81, 0.54	−0.04	0.70
POSIT substance abuse score						
Baseline	0.65	0.64	0.01	–0.34, 0.36	0.01	0.96
2 months postpartum	0.56	0.61	−0.05	–0.37, 0.27	−0.03	0.78
6 months postpartum	0.39	0.55	−0.16	–0.48, 0.17	−0.08	0.34
12 months postpartum	0.13	0.45	−0.32	–0.80, 0.16	−0.13	0.19
Maternal drug use outcomes (past-month substance use)	Estimated %[c]	Estimated %[c]	Odds Ratio	95% CI		p
Alcohol						
Baseline	4.40	3.07	0.77	0.19, 3.14		0.71
2 months postpartum	17.92	17.81	0.80	0.35, 1.83		0.60
6 months postpartum	16.88	20.02	0.71	0.36, 1.40		0.33
12 months postpartum	25.77	21.55	1.14	0.63, 2.05		0.67
Marijuana						
Baseline	8.18	6.13	1.18	0.49, 2.83		0.71
2 months postpartum	20.63	21.02	0.87	0.44, 1.70		0.68
6 months postpartum	12.39	18.83	0.57	0.29, 1.11		0.10
12 months postpartum	18.91	19.65	0.83	0.44, 1.58		0.57
Any illegal drug						
Baseline	10.06	7.98	1.06	0.48, 2.35		0.88
2 months postpartum	22.89	21.92	0.93	0.49, 1.77		0.84
6 months postpartum	13.82	20.22	0.58	0.31, 1.10		0.09
12 months postpartum	21.34	21.90	0.83	0.44, 1.55		0.55
Any alcohol or illegal drug						
Baseline	12.58	10.43	0.93	0.44, 1.98		0.86
2 months postpartum	32.91	29.10	1.04	0.59, 1.84		0.89
6 months postpartum	27.74	30.78	0.76	0.44, 1.32		0.33
12 months postpartum	38.93	34.64	1.07	0.65, 1.77		0.79

[a] CES-D=Center for Epidemiologic Studies Depression Scale; ASEBA=Achenbach System of Empirically Based Assessment (41); POSIT=Problem Oriented Screening Instrument for Teenagers (42). Covariates included study site, use of alcohol during index pregnancy, lifetime use of cigarettes, and baseline CES-D score.

[b] Standardized pairwise differences are defined as the average between treatment group difference in outcome scaled by the standard deviation of the outcome. Standardized differences represent treatment effect size estimates on the standard deviation scale of the outcome. Values of 0.2, 0.5, and 0.8 are generally regarded as small, medium, and large, respectively (39).

[c] Percentages are model-based estimates derived from imputed data.

TABLE 7. Summary Findings and Effect Size Estimates for Maternal Psychosocial and Behavioral Outcomes at 2, 6, and 12 Months Postpartum, for Participants With Substance Use at Baseline[a]

Outcome	Intervention Group (N=145)	Control Group (N=140)	Analysis			
Psychosocial outcomes (value range)	Adjusted Mean	Adjusted Mean	Adjusted Mean Difference	95% CI	Effect Size[b]	p
CES-D score (0–60)						
Baseline	13.45	13.55	−0.09	–1.03, 0.84	−0.02	0.84
2 months postpartum	13.18	13.55	−0.37	–1.30, 0.56	−0.06	0.43
6 months postpartum	12.62	13.56	−0.93	–2.20, 0.34	−0.13	0.15
12 months postpartum	11.79	13.56	−1.78	–3.91, 0.37	−0.17	0.10
ASEBA externalizing T-score						
Baseline	42.93	43.15	−0.22	–2.19, 1.76	−0.02	0.83
6 months postpartum	41.19	42.39	−1.20	–3.09, 0.69	−0.10	0.21
12 months postpartum	39.44	41.63	−2.19	–4.77, 0.38	−0.16	0.09
ASEBA internalizing T-score						
Baseline	46.89	47.03	−0.14	–2.16, 1.87	−0.01	0.89
6 months postpartum	44.56	46.05	−1.49	–3.45, 0.48	−0.12	0.14
12 months postpartum	42.24	45.07	−2.83	–5.55, –0.11	−0.19	0.04
ASEBA total problems T-score						
Baseline	43.37	43.79	−0.42	–2.40, 1.56	−0.04	0.68
6 months postpartum	41.16	42.60	−1.44	–3.41, 0.54	−0.12	0.15
12 months postpartum	38.95	41.40	−2.46	–5.16, 0.25	−0.17	0.08
POSIT mental health score						
Baseline	3.48	3.93	−0.45	–0.95, 0.05	−0.15	0.08
2 months postpartum	3.40	3.79	−0.38	–0.86, 0.10	−0.13	0.12
6 months postpartum	3.26	3.50	−0.25	–0.77, 0.27	−0.08	0.35
12 months postpartum	3.03	3.07	−0.04	–0.76, 0.69	−0.01	0.92
POSIT substance abuse score						
Baseline	0.62	0.68	−0.06	–0.45, 0.33	−0.02	0.78
2 months postpartum	0.53	0.64	−0.11	–0.46, 0.25	−0.05	0.56
6 months postpartum	0.35	0.57	−0.20	–0.56, 0.16	−0.09	0.27
12 months postpartum	0.10	0.45	−0.35	–0.89, 0.19	−0.12	0.20
Maternal drug use outcomes (past-month substance use)	Estimated %[c]	Estimated %[c]	Odds Ratio	95% CI		p
Alcohol						
Baseline	5.00	3.45	0.77	0.19, 3.15		0.51
2 months postpartum	18.88	18.97	0.81	0.35, 1.89		0.63
6 months postpartum	18.62	21.13	0.77	0.40, 1.50		0.44
12 months postpartum	26.40	23.54	1.07	0.60, 1.93		0.81
Marijuana						
Baseline	9.29	6.90	1.23	0.51, 2.94		0.65
2 months postpartum	22.36	22.30	0.93	0.47, 1.84		0.84
6 months postpartum	13.76	21.17	0.58	0.29, 1.14		0.11
12 months postpartum	19.79	22.09	0.78	0.41, 1.51		0.46
Any illegal drug						
Baseline	11.43	8.97	1.11	0.50, 2.46		0.80
2 months postpartum	24.88	23.22	1.01	0.51, 1.94		0.99
6 months postpartum	15.36	22.74	0.59	0.31, 1.13		0.11
12 months postpartum	22.43	24.62	0.78	0.42, 1.46		0.44
Any alcohol or illegal drug						
Baseline	14.29	11.72	0.97	0.45, 2.06		0.93
2 months postpartum	35.12	30.34	1.12	0.62, 2.03		0.70
6 months postpartum	30.67	33.22	0.81	0.47, 1.41		0.46
12 months postpartum	39.88	38.25	0.97	0.59, 1.62		0.92

[a] CES-D=Center for Epidemiologic Studies Depression Scale; ASEBA=Achenbach System of Empirically Based Assessment (41); POSIT=Problem Oriented Screening Instrument for Teenagers (42). Covariates included study site, use of alcohol during index pregnancy, lifetime use of cigarettes, and baseline CES-D score.

[b] Standardized pairwise differences are defined as the average between treatment group difference in outcome scaled by the standard deviation of the outcome. Standardized differences represent treatment effect size estimates on the standard deviation scale of the outcome. Values of 0.2, 0.5, and 0.8 are generally regarded as small, medium, and large, respectively (39).

[c] Percentages are model-based estimates derived from imputed data.

mothers with "poorer [baseline] psychological resources" (a composite variable including mental health, sense of mastery, and intelligence) (48). These findings suggest that home-visiting interventions may be most critical for young mothers in greater need, particularly those with early initiation of substance use.

Limitations

In general, the study's effect sizes are small but consistent with expected effects from a public health intervention, as opposed to a clinical intervention. Because data are reported up to 1 year postpartum in a trial whose endpoint is 3 years postpartum, outcomes should be considered preliminary and viewed as important findings supporting the efficacy of, and the general theory underlying, the intervention. The study has other, more specific limitations. First, the generalizability from this study to the heterogeneous tribal population in the United States is unclear. However, because participants were enrolled across four diverse Native communities, generalizability is likely greater than for studies conducted on a single reservation. Second, mothers who receive the Family Spirit intervention may have altered responses to self-reports based on social desirability. 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 (e.g., cotinine samples) and videotaped observational measures coded by external blind evaluators. These methods were neither culturally acceptable nor financially feasible in this trial. In addition, use of low-cost standardized measures administered by paraprofessionals increases the potential for replication across other low-resource communities. Third, some measurement bias may exist. In spite of challenging home environments, poor living conditions, and high substance use rates, participant scores on the Home Observation for Measurement of the Environment scale, the Achenbach System of Empirically Based Assessment, and the CES-D were better than or comparable to those for U.S. samples of all races overall (49, 50). These self-reports may require additional construct or content validity, as well as normative data for this adolescent population. Finally, because of the large number of dependent variables, the likelihood of significant findings due to chance is increased. However, all significant results and statistical trends are consistent with the study's theoretical model and hypotheses and extend findings from smaller previous trials (21, 22, 25).

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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

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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

(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 cuturally 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 (Zeitz 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) ≤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 ≤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

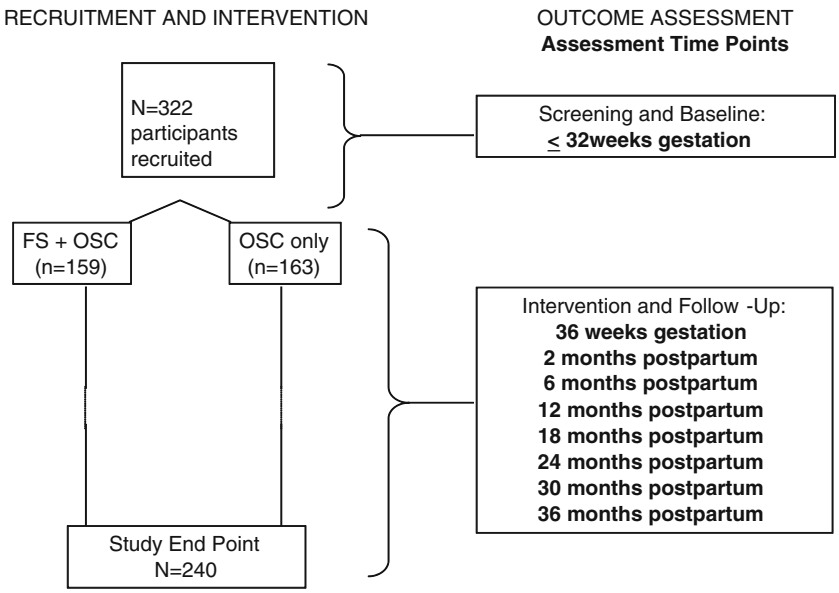

Fig. 1 General design of the Family Spirit trial

was obtained from the parent or guardian and assent from the participant. If a participant was ≥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. ≥ 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

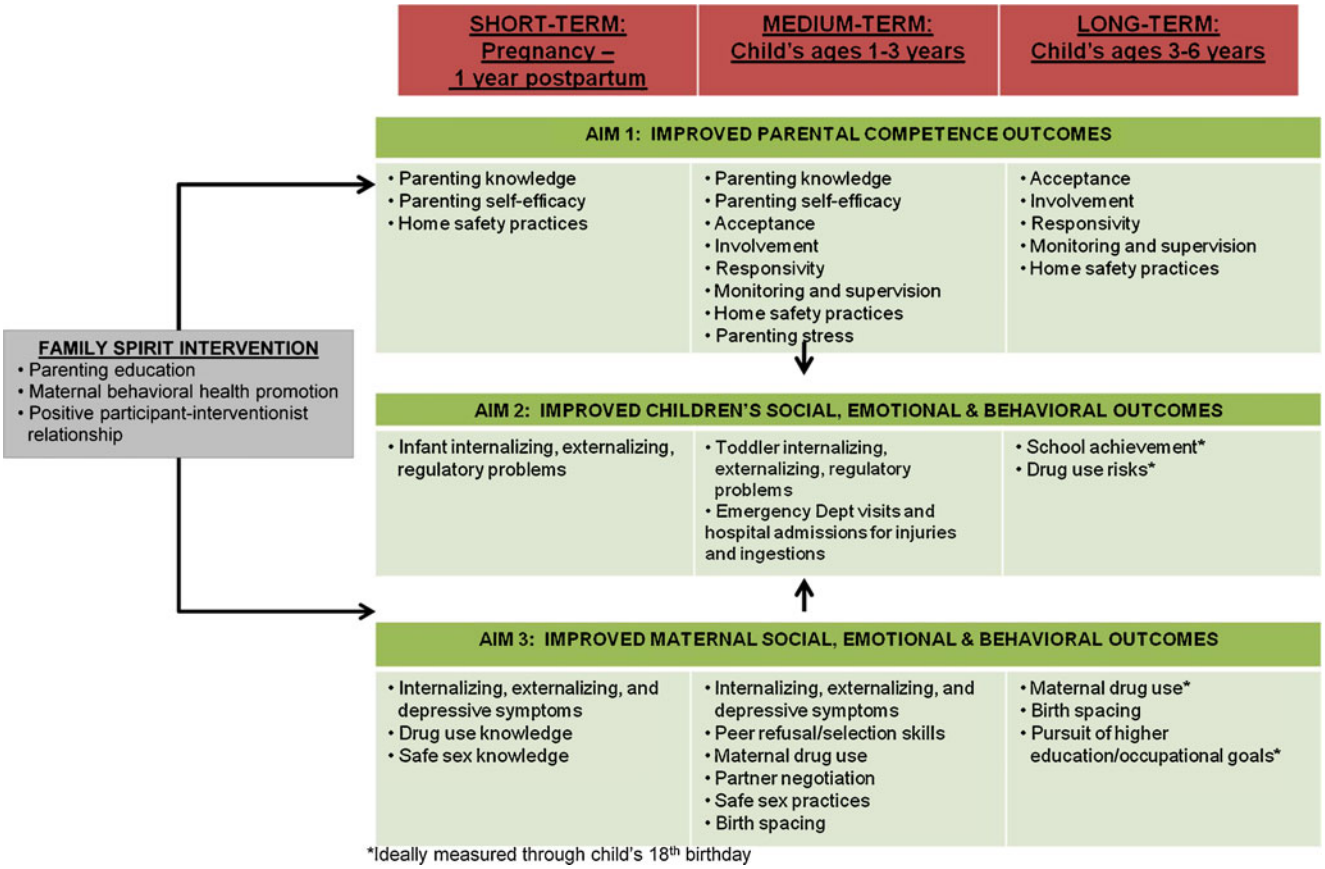

Fig. 2 Conceptual framework for Familly Spirit intervention

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 inter-rater 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[a]	Cronbach's alpha in this sample
Aim 1: Parental competence outcomes				
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 responsivity, 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 (PSOC)	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.
Aim 2: Child psychosocial and behavioral outcomes				
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[b]	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[a]	Cronbach's alpha in this sample
Aim 3: Maternal psychosocial and behavioral outcomes				
Achenbach System Empirically Based Assessment: Youth Self Report (ASEBA) *	112-item self-report assesses broad range of behavior problems and social and academic competence. Three primary scales are derived: internalizing, externalizing, and total problems. Among the most extensively used and tested rating scales available.	Achenbach 2000	S, M	Range from 0.69 to 0.79 across scales
Center for Epidemiological Studies Depression (CES-D) *	20-item scale of depressive symptoms.	Radloff 1977	S, M	0.88
Demographics	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).	Created by study team	M, L	Not applicable.
Voices of Indian Teens (VOIT): Cultural identity	6 items that assess respondent's participation in traditional tribal activities and identity with tribe.	Novins and Mitchell 1998	NA[b]	≥0.70
Voices of Indian Teens (VOIT): Alcohol	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.	Novins and Mitchell 1998	M, L	≥0.70
Voices of Indian Teens (VOIT): Drugs, Ideas, Thoughts & Happenings	13 items cover following topics: quantity and frequency of drug use; types of drugs used; and age of first use	Novins and Mitchell 1998	M, L	≥0.70
Audio Computer Assisted Self-Interview (ACASI)	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.	Created by study team, with questions adapted from DHHS, 2008 and Montana Meth Project 2008.	M, L	To be determined (data not available yet).
Problem Oriented Screening Instrument for Teens (POSIT)	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.	Rahdert 1991	S, M	Range from 0.60 to 0.83 across scales.
Medical Record Review	Maternal medical records reviewed for maternal birth spacing and related outcomes.	Created by study team	M, L	Not applicable.

* Indicates primary outcome measures within each domain.

[a] 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)

[b] 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
Aim 1: Parental competence outcomes												
Parent Knowledge Test	Liaison	15	Self-report	X		X	X	X		X		X
Parental Locus of Control (PLOC)	Liaison	5	Self-report			X	X	X	X	X	X	X
Home Safety Assessment	Evaluator	30	Observation/ self-report	X				X		X		X
Home Observation for Measurement of the Environment (HOME)	Evaluator	60	Observation				X	X	X	X	X	X
Supplement to HOME for Impoverished Families (SHIF)	Evaluator	10	Observation							X	X	X
Adult Adolescent Parenting Inventory (AAPI-2)	Liaison	15	Self-report	X		X	X	X	X	X	X	X
Parental Sense of Competence (PSOC)	Liaison	5	Self-report				X	X	X	X	X	X
Parenting Stress Index – Short Form (PSI-SF)	Liaison	10	Self-report							X		X
Aim 2: Child psychosocial and behavioral outcomes												
Infant Toddler Social Emotional Assessment (ITSEA)	Evaluator	20	In-person interview					X	X	X	X	X
Ages and Stages Questionnaire (ASQ)	Evaluator	30	Observation				X	X		X		X
Child Behavior Checklist (CBCL)	Liaison	20	Self-report							X	X	X
Medical Record Review	Evaluator	0	Chart review									X
Aim 3: Maternal psychosocial and behavioral outcomes												
Achenbach System Empirically Based Assessment: Youth Self Report (ASEBA)	Liaison	15	Self-report	X			X	X	X	X	X	X
Center for Epidemiological Studies – Depression (CES-D)	Liaison	5	Self-report	X	X	X	X	X	X	X	X	X
Demographics	Evaluator	20	In-person interview	X	X	X	X	X	X	X	X	X
Voices of Indian Teens (VOIT): Cultural Identity	Evaluator	5	In-person interview	X	X	X	X	X	X	X	X	X
Voices of Indian Teens (VOIT): Alcohol	Liaison	10	Self-report	X	X	X	X	X	X	X	X	X
Voices of Indian Teens (VOIT): Drugs, Ideas, Thoughts & Happenings	Liaison	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	Liaison	60	Computer interview					X		X		X
Problem Oriented Screening Instrument for Teens (POSIT)	Liaison	10	Self-report	X	X	X	X	X	X	X	X	X
Medical Record Review	Evaluator	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 ≥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 (≥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 (n=159)	Control (n=163)	Total (N=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, *n* (%)			
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), *n* (%)			
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, *n* (%)	153 (96.2)	158 (96.9)	311 (96.6)
Gestational age at enrollment, weeks – Mean (*SD*)	25.4 (4.2)	24.7 (4.0)	25.0 (4.1)
Pregnancy was planned, *n* (%)	30 (18.9)	28 (17.2)	58 (18.0)
Did not use contraception at time of conception, *n* (%)	136 (85.5)	140 (85.9)	276 (85.7)
Live with boyfriend/father of baby, *n* (%)	90 (56.6)	94 (57.7)	184 (57.1)
Live with participant's parent(s), *n* (%)	97 (61.0)	96 (58.9)	193 (59.9)
Live with participant's boyfriend's parent(s), *n* (%)	27 (17.0)	34 (20.9)	61 (18.9)
Length of relationship prior to pregnancy, *n* (%)			
< 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, *n* (%)	63 (39.6)	68 (41.7)	131 (40.7)
Dropped out of school prior to HS graduation/GED, *n* (%)	69 (43.4)	62 (38.0)	131 (40.7)
Highest education attained, *n* (%)			
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, *n* (%)			
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, *n* (%)			
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, *n* (%)			
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, *n* (%)			
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, *n* (%)			
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 ≥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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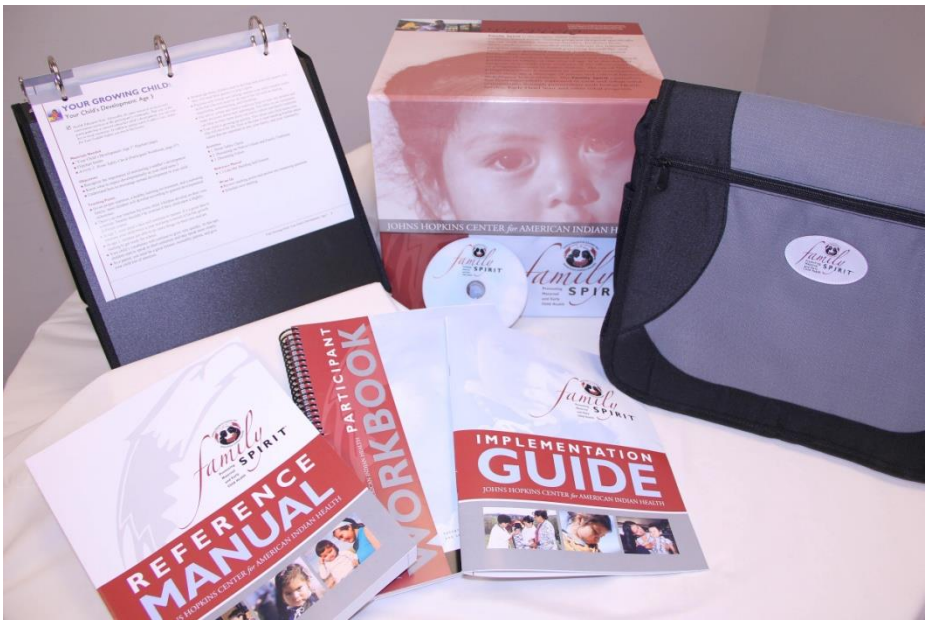
FAMILY SPIRIT CURRICULUM PACKAGE



CURRICULUM COMPONENTS

Each curriculum package comes in a box that includes an Implementation Guide, Family Spirit lessons divided into 6 modules, Health Educator Lesson Plans organized by module and lesson, a Reference Manual for the Health Educator, and a sample Participant Workbook for the participating families. Evaluation materials and participant certificates are also included on a USB drive in the curriculum box.

Implementation Guide

The purpose of the Implementation Guide is to act as a "how-to" for implementing Family Spirit. It includes information about the Family Spirit Program history and its impact on several maternal and child health outcomes, as well as a description of the "essentials" for successfully implementing the program.

Family Spirit Lessons (6 modules)

The Family Spirit lessons are the main teaching materials used to present information to participants. The curriculum consists of six modules: Prenatal Care, Infant Care, Your Growing Child, Toddler Care, My Family and Me, and Healthy Living. There are 63 lessons in total, which can be taught between pregnancy and the child's 3rd birthday (we recommend starting around 28 weeks gestation). The Family Spirit lessons are designed to be taught one-on-one during home visits, but they can also be used in clinic and group settings. Lessons can be administered sequentially or independently, depending on the program structure and participants' needs. Also included with each Family Spirit lesson module is a Health Educator Lesson Plan booklet. The lesson plans provide Health Educators with a comprehensive overview for conducting each lesson with the participants.

Family Spirit Lesson Modules

1. Prenatal Care

This module includes information to help an expectant mother prepare for the arrival of her baby, know what to expect during pregnancy, and how to take care of herself and her baby.

2. Infant Care

This module includes information to help a mother adapt to her life with a new baby, take care of herself, learn basic infant care skills, and how to respond to her baby's various wants or needs.

3. Your Growing Child

This module includes information to help a mother track her child's overall development from 7 months until the child's 3rd birthday. She will also learn how to prepare her child for pre-school through various activities and play.

4. Toddler Care

This module includes information to help a mother build confidence in her parenting skills through daily routine and monitoring. She will also learn basic skills to help her child form healthy habits to last a lifetime.

5. My Family and Me

This module includes information to help a mother develop life skills that will positively influence herself, her child, and her family and friends.

6. Healthy Living

This module includes information to help a mother address and cope with difficult situations. The lessons include 4 main topics: goal-setting to build self-esteem and be a good role model, substance abuse prevention, family planning, and prevention of sexually transmitted infections (STIs). She will learn where she can go to get help, if needed.

Reference Manual

The purpose of the Reference Manual is to provide the Health Educator and participant with further and more in-depth information related to the lesson topics. This manual consists of 3 sections: Reference Manual, Bibliography, and Glossary of Terms. The Reference Manual section includes relevant topics that are referred to in the lesson pages. The Bibliography includes additional resources, many of them web-based resources, which go into more detail about the lesson topics. The Glossary of Terms includes key terms and definitions discussed throughout the curriculum. Each definition provides a reference back to the module and lesson pages where that topic is discussed.

Participant Workbook

The purpose of the Participant Workbook is to provide the participant with handouts and worksheets to reinforce key teaching points. One sample Participant Workbook is included in the curriculum package, and additional copies can be purchased.

Evaluation Materials

A series of evaluation measures and screening tools developed specifically for the Family Spirit curriculum are included on a USB drive within each curriculum box. While not required to implement the curriculum, the evaluation materials are available for use as determined by program requirements.

Participant Certificates

There are 4 participant certificates to be awarded at various times throughout the program. PDF versions are included on the USB drive within each curriculum box. Every participant who gives birth during the Family Spirit Program gets a **"new baby" certificate** from the Health Educator. There is also a **breastfeeding certificate** for mothers who breastfeed their newborns for at least 2 weeks. A **certificate of achievement** allows the Health Educator to recognize general participant achievements as she progresses through the Family Spirit Program. It has a blank line where the Health Educator can fill in the participant's specific achievement, such as successfully receiving three months of Family Spirit lessons. Several of these certificates of achievement can be awarded to the participant. Finally, each participant receives **a certificate of completion** upon exit from the Family Spirit Program, regardless of how long she was enrolled in the program.

Module Lessons: Pregnancy through 3 Years

Prenatal Care

1. Contributing to a Healthy Pregnancy
2. Changes a Woman Goes Through
3. Understanding Gestational Diabetes
4. Baby Proofing and Safety Inside and Outside the Home
5. Preparing for Safe Travel and Outings
6. Playtime Fun and Learning
7. Before and During Labor
8. Time to Push
9. Breastfeeding Basics (Before You Begin/Tips)

Infant Care

1. After Your Baby is Born
2. How to Feed
3. How to Diaper
4. How to Dress
5. Bedtime Safety
6. How to Bathe
7. How to Comfort Your Crying Child
8. How to Protect
9. What to Do if Your Baby is Sick
10. What are Immunizations and Why Do We Need Them?
11. More About Immunizations
12. Parenting Techniques
13. Protecting Children from Abuse and Neglect
14. Introducing Solid Foods to Your Baby
15. Introduction to Oral Health Care
16. Oral Health Care: Getting a Healthy Start

Your Growing Child

1. Your Baby's Developing Senses
2. Beginning Conversations and Recognizing Voices
3. Becoming More Mobile and Developing Fine Motor Skills
4. Understanding Cause and Effect and Separation
5. Developing Hand-Eye Coordination
6. Development of Memory Skills and Becoming Independent
7. Your Child's Development: Age 1
8. Communicating with Your Child
9. Encouraging Early Learning
10. Your Child's Development: Age 2
11. Your Child's Development: Age 3

Toddler Care

1. Daily Routines for Confident and Effective Parenting Part A
2. Daily Routines for Confident and Effective Parenting Part B
3. Monitoring Your Toddler's Routine
4. Safety for Your Toddler
5. Feeding Your Toddler
6. Oral Health Care for Your Toddler
7. Your Child's First Visit to the Dentist!
8. Potty Training Your Toddler
9. When a New Child Enters the Home

My Family and Me

1. Planning for My Family's Future
2. Budgeting for My Family
3. Planning for My Family's Nutrition
4. My Health and My Family's Health
5. The Importance of Exercise
6. Communication and Building Healthy Relationships

Healthy Living

Goal Setting

1. Working Towards a Better You

Substance Abuse Lessons

2. A Look at Drug Use in Our Community
3. Effects of Drug Use on a Developing Baby
4. Effects of Drug Use on Our Families and Loved Ones
5. Skills for Healthy Living Part A
6. Skills for Healthy Living Part B

Family Planning Lessons

7. Understanding Reproduction
8. Planning Ahead
9. Your Family Planning Options
10. Understanding Paternity

STI Lessons

11. Protecting Your Sexual Health
12. Learning More about STIs

SEQUENTIAL LESSON SCHEDULE

The table below illustrates the suggested lesson chronology for participants who are receiving Family Spirit sequentially. The table includes the session number, lesson title, module where the lesson can be found, lesson duration, and ideal gestational stage and/or child's age at the time of the lesson. While there are 63 lessons in the Family Spirit Program, we suggest implementing them in 52 home-visit sessions, as outlined below. Sessions 1-12 should be taught weekly through birth; sessions 13-23 should be taught weekly through 3 months post-partum; sessions 24-29 should be taught bi-weekly through 6 months post-partum; sessions 30-45 should be taught monthly through 22 months post-partum; and sessions 46-52 should be taught bi-monthly until the child's 3rd birthday. Here are the acronyms that are used in the table in reference to each module: Prenatal Care (PC); Infant Care (IC); Your Growing Child (YGC); Toddler Care (TC); My Family and Me (MFM) and; Healthy Living (HL).

Session #	Lesson	Module	Duration	Schedule
1	Contributing to a Healthy Pregnancy	PC-1	1 hour	28 weeks
2	Working Towards a Better You	HL-1	1 hour	29 weeks
3	Changes a Woman Goes Through	PC-2	45 mins	30 weeks
4	A Look at Drug Use in Our Community	HL-2	1 hour	31 weeks
5	Effects of Drug Use on a Developing Baby	HL-3	45 minutes	32 weeks
6	Understanding Gestational Diabetes	PC-3	1 hour	33 weeks
7	Baby Proofing and Safety Inside and Outside the Home	PC-4	45 mins	34 weeks
	Bedtime Safety	IC-5	35 mins	
8	How to Feed	IC-2	1 hr 10 m	35 weeks
9	How to Diaper	IC-3	35 mins	36 weeks
	How to Dress	IC-4	35 mins	
10	Breastfeeding Basics (Before You Begin / Tips)	PC-9	50 mins	37 weeks
	How to Bathe	IC-6	40 mins	
11	Before and During Labor	PC-7	45 mins	38 weeks
	Time to Push	PC-8	40 mins	
12	Preparing for Safe Travel and Outings	PC-5	30 mins	39 weeks
	Understanding Paternity	HL-10	30 mins	
13	After Your Baby is Born	IC-1	40 mins	2 wks post- partum
	How to Comfort Your Crying Child	IC-7	35 mins	

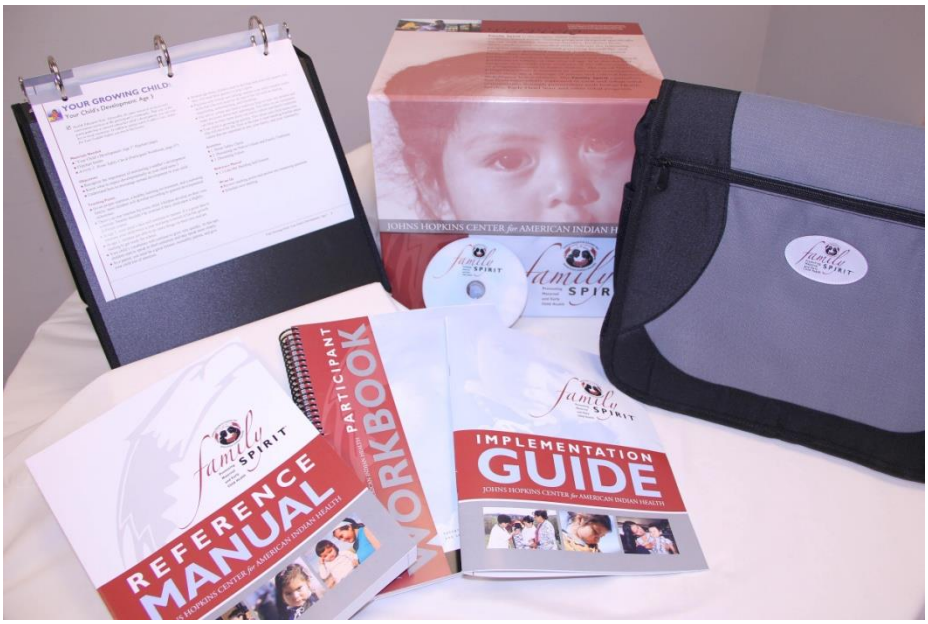
14	Understanding Reproduction	HL-7	40 mins	3 weeks
	How to Protect	IC-8	35 mins	
15	Effects of Drug Use on Our Families and Loved Ones	HL-4	1 hour	4 weeks
16	Your Family Planning Options	HL-9	1 hr 5 m	5 weeks
17	Planning Ahead	HL-8	40 mins	6 weeks
18	What to Do if Your Baby is Sick	IC-9	35 mins	7 weeks
	What are Immunizations and Why Do We Need Them?	IC-10	40 mins	
19	More About Immunizations	IC-11	40 mins	8 weeks
20	Parenting Techniques	IC-12	1 hr 30 m	9 weeks
21	Protecting Your Sexual Health	HL-11	55 mins	10 weeks
22	Learning More about STIs	HL-12	55 mins	11 weeks
23	Protecting Children from Abuse and Neglect	IC-13	40 mins	12 weeks
	Playtime Fun and Learning	PC-6	30 mins	
24	Introduction to Oral Health Care	IC-15	30 mins	14 weeks
	Oral Health Care: Getting a Healthy Start	IC-16	40 mins	
25	Introducing Solid Foods to Your Baby	IC-14	40 mins	16 weeks
26	Communication and Building Healthy Relationships	MFM-6	45 mins	18 weeks
27	Skills for Healthy Living Part A	HL-5	45 mins	20 weeks
28	My Health and My Family's Health	MFM-4	1 hr 25 m	22 weeks
29	Skills for Healthy Living Part B	HL-6	1 hour	24 weeks
30	Your Baby's Developing Senses	YGC-1	45 mins	7 months
31	Beginning Conversations and Recognizing Voices	YGC-2	45 mins	8 months
32	Becoming More Mobile and Developing Fine Motor Skills	YGC-3	45 mins	9 months
33	Understanding Cause and Effect and Separation	YGC-4	45 mins	10 months
34	Developing Hand-Eye Coordination	YGC-5	45 mins	11 months
35	Development of Memory Skills and Becoming Independent	YGC-6	45 mins	12 months
	Your Child's First Visit to the Dentist!	TC-7	30 mins	
36	Daily Routines for Confident and Effective Parenting Part A	TC-1	1 hr 10 m	13 months
37	Safety for Your Toddler	TC – 4	50 mins	14 months
38	Your Child's Development: Age 1	YGC - 7	1 hour	15 months
39	Daily Routines for Confident and Effective Parenting Part B	TC-2	50 mins	16 months
40	Monitoring Your Toddler's Routine	TC-3	1 hour	17 months
41	Oral Health Care for Your Toddler	TC-6	50 mins	18 months
42	Feeding Your Toddler	TC-5	50 mins	19 months

43	Budgeting for My Family	MFM-2	1 hour	20 months
44	Planning for My Family's Future	MFM-1	1 hr 25 m	21 months
45	Potty Training Your Toddler	TC-8	40 mins	22 months
46	Your Child's Development: Age 2	YGC-10	1 hour	24 months
47	The Importance of Exercise	MFM-5	45 mins	26 months
48	Communicating with Your Child	YGC-8	1 hour	28 months
49	Encouraging Early Learning	YGC-9	1 hour	30 months
50	Planning for My Family's Nutrition	MFM-3	40 mins	32 months
51	When a New Child Enters the Home	TC-9	35 mins	34 months
52	Your Child's Development: Age 3	YGC-11	1 hr 10 m	36 months

FAMILY SPIRIT SAMPLE LESSON

The Family Spirit curriculum consists of 63 lessons to be taught between pregnancy and the child's 3rd birthday. The uniquely designed curriculum package includes:

- Implementation Guide
- Family Spirit lessons divided into 6 modules
- Health Educator Lesson Plans
- Reference Manual
- Sample Participant Workbook
- Evaluation Materials and Participant Certificates on a USB flash drive
- A messenger bag and flipchart binder for easy transportation



For each of the Family Spirit lessons, there are materials to guide and assist the Health Educator in delivering the lesson. Attached you will find a sample of all materials related to *Contributing to a Healthy Pregnancy*, taken from the Prenatal Care Module:

- Health Educator Lesson Plan
- Lesson pages
- Reference Manual
- Bibliography
- Participant Workbook

CONTRIBUTING TO A HEALTHY PREGNANCY

Health Educator Lesson Plan

BASIC PRESENTATION

Audience

This lesson can be taught to a first-time pregnant woman or a woman who has been pregnant in the past. As the Health Educator, you should maintain flexibility to adapt the lesson administration based on the age and education level of the participant. There are also a number of opportunities for her partner or other family members to be involved (including her mother, if she does some of the household cooking).

Objectives

The overall purpose of this lesson is to familiarize the participant with the following topics:

- Prenatal growth and development
- The importance of prenatal care
- What to expect during prenatal visits
- Effects of harmful substances on a pregnant woman and her child
- Nutrition during pregnancy
- Weight and body changes that can occur during pregnancy

This lesson also stresses the importance of taking care of oneself during pregnancy, both physical and emotionally.

Materials Needed

- "Contributing to a Healthy Pregnancy" flipchart pages
- Flipchart binder
- Measurement aids, including a ruler/measuring stick, grain of rice, kidney bean, lime, avocado, banana, ear of corn, head of cabbage, cantaloupe, pumpkin (to demonstrate size of baby at various stages of growth in the uterus)
  - The ruler/measuring stick should extend to at least 20 inches
- *Activity 1: Food Diary* (Participant Workbook, page 3)

Time Required

In general, this lesson should take approximately 1 hour to teach. It may take more or less time, depending on the background knowledge of the participant and whether she asks a lot of questions.

AGENDA

- Warm-up (5 minutes)
- Review previous lesson and follow-up with referrals (5 minutes)
- Introduction to the lesson (5 minutes)
- Teach the lesson (35 minutes)
  - Activity 1: Food Diary (5 minutes)
- Wrap-up (5 minutes)

SAMPLE

DESCRIPTION OF THE ACTIVITIES

Warm-Up

It's important to make the participant feel comfortable, secure, and open to asking questions. Use this time during the warm-up as an opportunity to engage in casual conversation. For example, ask the participant how far along she is in her pregnancy. Find out whether this is her first pregnancy. Ask her how things are going in her pregnancy and in life in general. If this is the first time meeting with the participant, it's especially important to get to know her well.

Review Previous Lesson and Follow-Up with Referrals

It may make sense for this lesson to be the first lesson, but if it isn't the participant's first lesson, take a few minutes to review the previous lesson, including any questions that the participant may have had about it since you last saw her. If referrals were made to medical or social services, follow-up to see if they were sought, and what the outcomes were (if appropriate). Include this information on the Session Summary Form.

Introduction to the Lesson

Explain the purpose of this lesson to the participant: "Today we will learn about the different stages of pregnancy. We will also discuss prenatal care and learn how to have a healthy pregnancy, including what to eat, so you can give your baby a healthy start."

Teaching the Lesson

Page 2: Prenatal Care: Contributing to a Healthy Pregnancy

- On the overview page of the lesson, list the lesson objectives and teaching points.
- Note: In some AI/AN cultures, preparations for the baby aren't discussed in great detail before the child is born. Please be mindful of the local understandings and practices associated with pregnancy. At the same time, be aware that having a healthy pregnancy is the top priority for this lesson and all lessons that follow in the Prenatal Care module.

Pages 3-4: Prenatal Development

- In this section, reference each image on page 3, but use the table on page 4 to help guide the participant through the different stages of growth that the baby will experience during pregnancy.
- Consider using a measurement aid such as a ruler/measuring stick and/or items identified above in Materials Needed section of this lesson to demonstrate the baby's size at each time point.
- Help her become excited about experiencing the different stages by highlighting milestones in the baby's development and ways she can bond with her unborn baby.
- Especially if the participant is around 24 weeks gestation or later, encourage her to read to, talk to, and sing to her baby.
  - Babies' hearing is developed at this time.
  - Research has shown that babies whose mothers talk to and sing to them prenatally recognize and respond to their mother's voice after being born.
- Reference Manual 1 also provides terms more detailed information about each stage of the developing baby.

Pages 5-6: Prenatal Care and Your Birth Plan

- All participants should already be receiving prenatal care, but this is a good time to check and make sure she's receiving care and encourage her to attend all visits.
- Help her think of some questions she can ask her doctor at the next appointment.
- If the participant is interested, you can share information with her about how pregnancy is tested and how due dates are determined by referring to Reference Manual 2.

SAMPLE

- In Reference Manual 3, find more information on pelvic exams.
- If possible, provide the participant with some referrals to local childbirth preparedness and relaxation classes. See Reference Manual 4.

Pages 7-8: Staying Healthy for Your Growing Baby

- This section addresses the importance of harmful and healthy substances and foods during pregnancy.
  - The information about substances is very important. Find out in a non-judgmental way if the participant smokes, drinks alcohol, or uses drugs. If the participant indicates that she may be using substances, or that she has a substance use problem, refer her to an agency in the community.
  - Reference Manual 5 asks that you prepare a list of some options for the participant in her community related to substance abuse treatment and smoking cessation programs.
  - You can also refer to substance abuse lessons in the Healthy Living module for further information about this topic. Specifically, **Healthy Living: Effects of Drug Use on a Developing Baby** is focused on what different drugs can do to a fetus during pregnancy.

Pages 9-10: Eating Healthy for Your Growing Baby

- Review the importance of healthy eating during pregnancy.
- Share the different food groups, and focus on eating a variety of foods from each group.
- Encourage the participant to take a daily prenatal vitamin.
- Healthy eating can be confusing for many people. Reference Manuals 6-10 provide additional information about nutrition specific to pregnant women.

Pages 11-12: Activity 1: Food Diary

- This activity page can be found in the Participant Workbook on page 3.
- Talk about nutrition guidelines with the participant, according to the United States Department of Agriculture (USDA). Ask her if she's eating the recommended amounts of various food groups (refer to the table on page 12 of this lesson).
  - Note: The participant will probably be more familiar with the Food Pyramid than the new MyPlate format that the USDA now supports.
  - Many of the guidelines are the same for recommended serving sizes, so it may be useful to refer to both during this lesson to avoid confusion.
- You can use the meal plan ideas from Reference Manual 7: Sample Menu for Pregnancy to get ideas for how to incorporate a variety of healthy foods from each food group.
- For this activity, ask the participant to write down her food choices over the course of one normal day.
- Review the recommended amounts and serving sizes of foods according to the USDA's food guidelines (page 12 of this lesson).
- In a supportive and non-judgmental way, compare her choices with these recommended amounts. Praise her in areas where she's eating recommended amounts of healthy foods, such as vegetables and fruits.
- Point out areas where she can improve. Work together to make a plan for what she can eat to improve her health, using the Food Pyramid/MyPlate as a guide.
- Focus on simple and healthy meal alternatives.
- Consider making a referral for her to visit a WIC representative or IHS registered dietician who may help her develop strategies for healthier eating.

Pages 13-14: Weight Gain During Pregnancy

- Before you present the information on page 14 to the participant, discuss her response to the scenario about weight gain.
  - Be sure to involve the participant's partner if he's sitting in on the lesson. Get his opinion about how he can be supportive of the participant.

SAMPLE

- Encourage the participant to have a discussion with her doctor about her weight if she has any concerns.
  - Remember that this can be a sensitive subject for the participant, so approach the discussion in a considerate and non-judgmental way.

Wrap-Up

Review the objectives and main points of the lesson. Finish the session by asking the participant if she has any questions or comments. Supply her with referrals, if necessary. Schedule the next session.



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PRENATAL CARE:

Contributing to a Healthy Pregnancy



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PRENATAL CARE:
Contributing to a Healthy Pregnancy

Materials Needed
- "Contributing to a Healthy Pregnancy" flipchart pages
- Flipchart binder
- Measuring aids, including a ruler/measuring stick, grain of rice, kidney bean, lime, avocado, banana, ear of corn, head of cabbage, cantaloupe, pumpkin (to demonstrate size of baby at various stages of growth in the uterus)
  - The ruler/measuring stick should extend to at least 20 inches.
- *Activity 1: Food Diary* (Participant Workbook, page 3)

Objectives
- Understand the baby's stages of development in the womb
- Know how to have a healthy pregnancy for mom and baby
- Understand a woman's nutrition needs during pregnancy
- Know how much weight a woman is expected to gain during pregnancy and how the weight helps her and the baby

Teaching Points
- A baby develops from 2 cells, the sperm and the egg, over the course of 40 weeks.
- Regular prenatal care is important for a healthy pregnancy and a healthy baby.
- Anything that a pregnant woman eats, drinks, or smokes travels to the baby through the mother's blood and the placenta. Alcohol and drugs are very harmful to the baby.
- Healthy eating during pregnancy is important for the growth and development of mom and baby.
- Some weight gain is a normal part of a healthy pregnancy and baby. The change in weight and shape may require an adjustment.
- Our native culture and family traditions help us raise our children and make decisions about their upbringing. The elders in our community can help us learn more about our native culture and family traditions.

Activities
- Scenarios
- 1. Food Diary
- 2. Discussing Our Native Culture and Family Traditions

Reference Manual
- 1. The Developing Baby
- 2. How Pregnancy and Due Dates are Determined
- 3. Pelvic Exams
- 4. Pregnancy and Childbirth Classes
- 5. Referrals to Addiction Counseling and Smoking Cessation Programs
- 6. Caloric Adaptations for Pregnant Women
- 7. Sample Menu for Pregnancy
- 8. More about Calories and Food Labels
- 9. Serving Sizes and Examples
- 10. Vitamins and Minerals – What Pregnant Women Need

Wrap-Up
- Review teaching points and answer any remaining questions
- Schedule the next meeting

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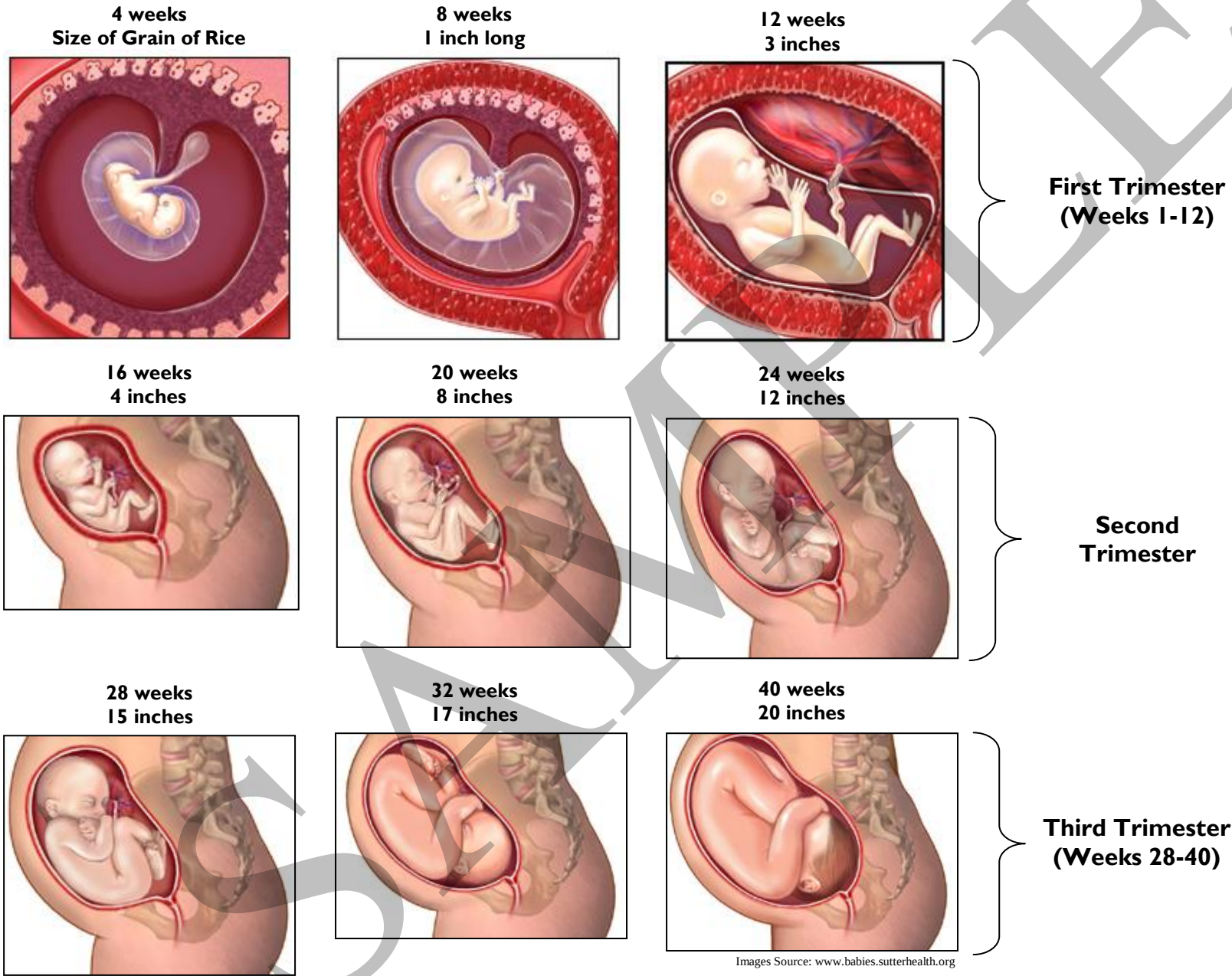
PRENATAL DEVELOPMENT



Images Source: www.babies.sutterhealth.org

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PRENATAL DEVELOPMENT

TEACHING POINT

A baby develops from 2 cells, the sperm and the egg, over the course of 40 weeks.

Review the teaching point with the participant.

- **A baby goes through major development before birth. The baby's stages of development are often described in three trimesters. Trimester literally means three parts.**
  - In general, the first trimester is 12 weeks long, and the second and third trimesters are each about 14 weeks long.
    - These are just approximate lengths. Total gestation (time in the mother's womb) is about 40 weeks.

☑ *Health Educator Note: Ask the participant which stage of pregnancy she's in right now. Help her identify where her baby's at from the table below. Use a ruler/measuring stick or other items, such as those listed on the overview page (Page 2), to demonstrate the actual size of her baby. The ruler/measuring stick should extend to at least 20 inches.*

☑ *See Reference Manual 1: The Developing Baby*

First Trimester	4 weeks	Smaller than a grain of rice	Brain, spinal cord, intestines, arms, and legs begin to form.
	8 weeks	1 inch	Heart begins to beat. Fingers and toes start to develop.
	12 weeks	3 inches	Circulatory and urinary systems start working. The sex organs begin to develop.
Second Trimester	16 weeks	4 inches	Develops sucking and swallowing reflexes.
	20 weeks	8 inches	Eyebrows, eyelashes, and hair start to grow. Mom may start to feel the baby moving around.
	24 weeks	12 inches	Opens eyes and can see and hear. With intensive care, *may* survive outside of the womb. This is a great time to begin singing and talking to your baby. S/he will recognize your voice after s/he is born!
Third Trimester	28 weeks	15 inches	Starts to pick up weight rapidly in last 12 weeks. Begins to suck thumb and hiccup. Responds to stimuli like light, sound, and pain.
	32 weeks	17 inches	A lot of brain growth occurs during this month and continues even after the baby is born. All of the organs have developed except for the lungs. One of the most significant problems that premature babies suffer from is called *respiratory distress syndrome* and is caused because their lungs have not yet fully matured.
	36-40 weeks	20 inches	The lungs mature during these final weeks. The baby may seem less active during this month as it drops lower into the mother's pelvis in preparation for delivery.

SAMPLE

PRENATAL CARE AND YOUR BIRTH PLAN



SAMPLE



PRENATAL CARE AND YOUR BIRTH PLAN

TEACHING POINT

Regular prenatal care is important for a healthy pregnancy and a healthy baby.

Review the teaching point with the participant.

- **Why is prenatal care so important?**
  - Your doctor can help determine an accurate gestational age of the baby so that you know when she will be born and how well she is growing.

    ☑ *See Reference Manual 2: How Pregnancy and Due Dates are Determined*

  - Your doctor will give you prenatal vitamins to ensure healthy growth and development of your baby.
  - Your doctor will monitor signs of illness or complications in both you and your baby.

- **What to expect at your prenatal visits:**
  - If this is your first visit to see the doctor, she may ask you lots of questions about your personal medical history and your family's medical history.
  - On your first visit:
    - The doctor may give you a test to make sure that you're pregnant.

      ☑ *See Reference Manual 2: How Pregnancy and Due Dates are Determined*

    - You may have an exam to check your uterus and a Pap smear to check the health of your cervix (the opening to the uterus).

      ☑ *See Reference Manual 3: Pelvic Exams*

  - The doctor may use special equipment so you can see the baby and hear the heartbeat – this can help determine your due date, the baby's size, and the baby's heart rate.
  - At about 18 weeks, you may be able to find out whether you're having a boy or a girl.
  - The doctor may check your uterus and cervix.
  - The doctor may ask for a urine or blood sample.
  - The doctor will take your blood pressure.

- **You should see your doctor about seven different times throughout your pregnancy.**
  - First visit
    - Visit a clinic as soon as you find out you're pregnant (most doctors want to see you at about eight weeks).
  - Beginning of pregnancy – 32 weeks gestation
    - You should see your doctor every month.
  - 32-36 weeks gestation
    - You should see your doctor every other week.
  - 36 weeks gestation – birth
    - You should see your doctor every week.

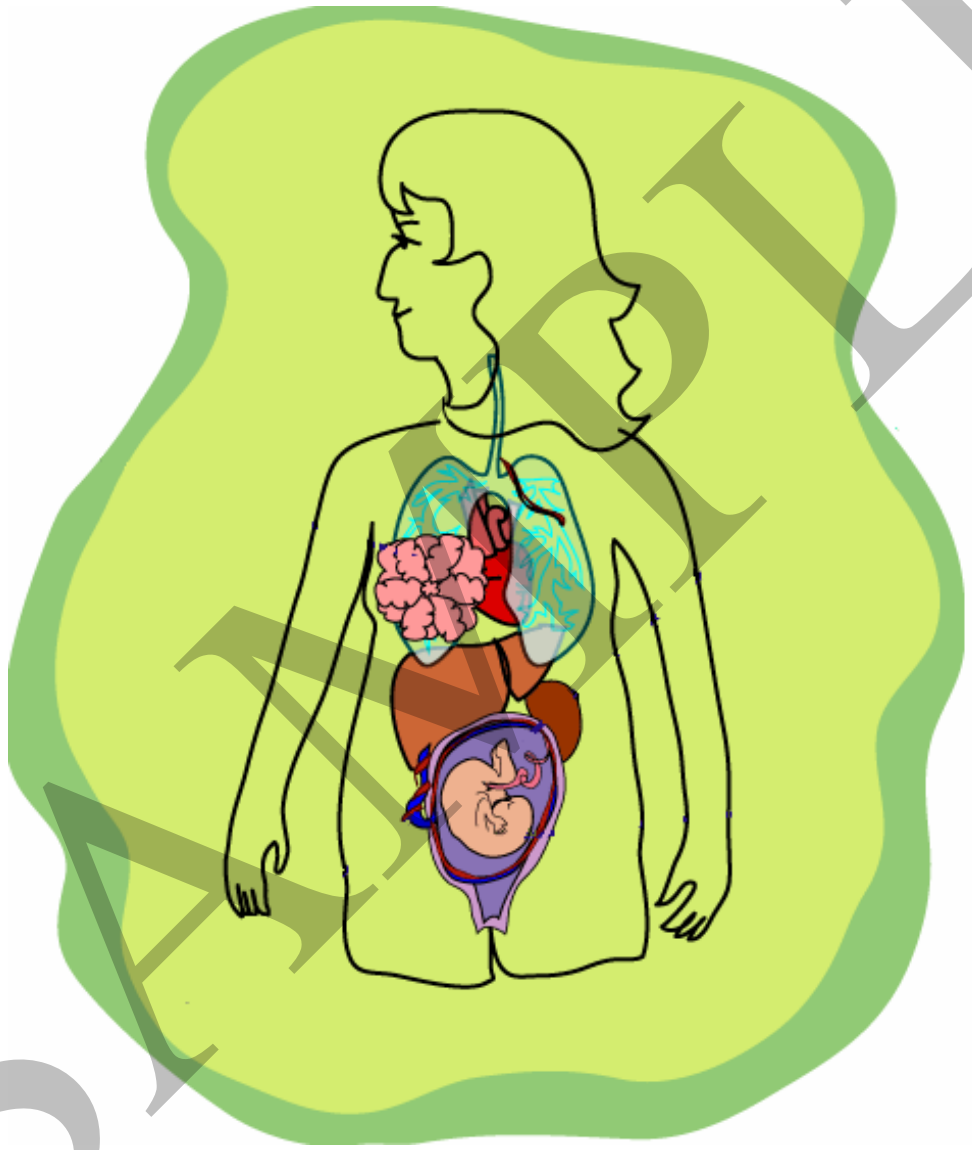
- **Your doctor is there to answer your questions.**
  - It's often helpful to write your questions down at home when you think of them, and then bring them in to your next appointment.

- **Your doctor and you can discuss a plan for birth and pain management.**

  ☑ *See Reference Manual 4: Pregnancy and Childbirth Classes*

SAMPLE

STAYING HEALTHY FOR YOUR GROWING BABY



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STAYING HEALTHY FOR YOUR GROWING BABY

TEACHING POINTS

Anything that a pregnant woman eats, drinks, or smokes travels to the baby through the mother's blood and the placenta. Alcohol and drugs are very harmful to the baby.

Review the teaching points with the participant.

- **Substances that a pregnant woman takes into her body (such as foods, liquids, smoke, or needles) will travel through her blood to the baby.**

- **It's important that a woman doesn't drink alcohol, smoke cigarettes, or do other drugs during her entire pregnancy, starting from when she tries to get pregnant or from when she finds out she's pregnant.**
  - These substances are harmful to a growing baby. They can cause problems with delivery and throughout the baby's life.

  ☑ *See Reference Manual 5: Referrals to Addiction Counseling and Smoking Cessation Programs*

- **Alcohol used during pregnancy can cause brain damage to a baby, leading to Fetal Alcohol Spectrum Disorders (FASD), which have lifelong effects.**
  - Fetal Alcohol Spectrum Disorders include Fetal Alcohol Syndrome (FAS) and Fetal Alcohol Effects (FAE).
  - These disorders can cause babies to be physically and mentally retarded or delayed. They can also cause behavioral problems and/or learning disabilities.

- **Smoke from cigarettes or marijuana increases the risk of miscarriage, labor complications, low birth weight, and Sudden Infant Death Syndrome (SIDS). The baby can be affected by both smoke from the mother and secondhand smoke (when the mother breathes in other people's smoke in her home or in the community).**

- **The effects of methamphetamine (also called meth or "g") are dangerous. Meth stays in the body for a long time, so there's more time for the baby to be damaged or still-born.**

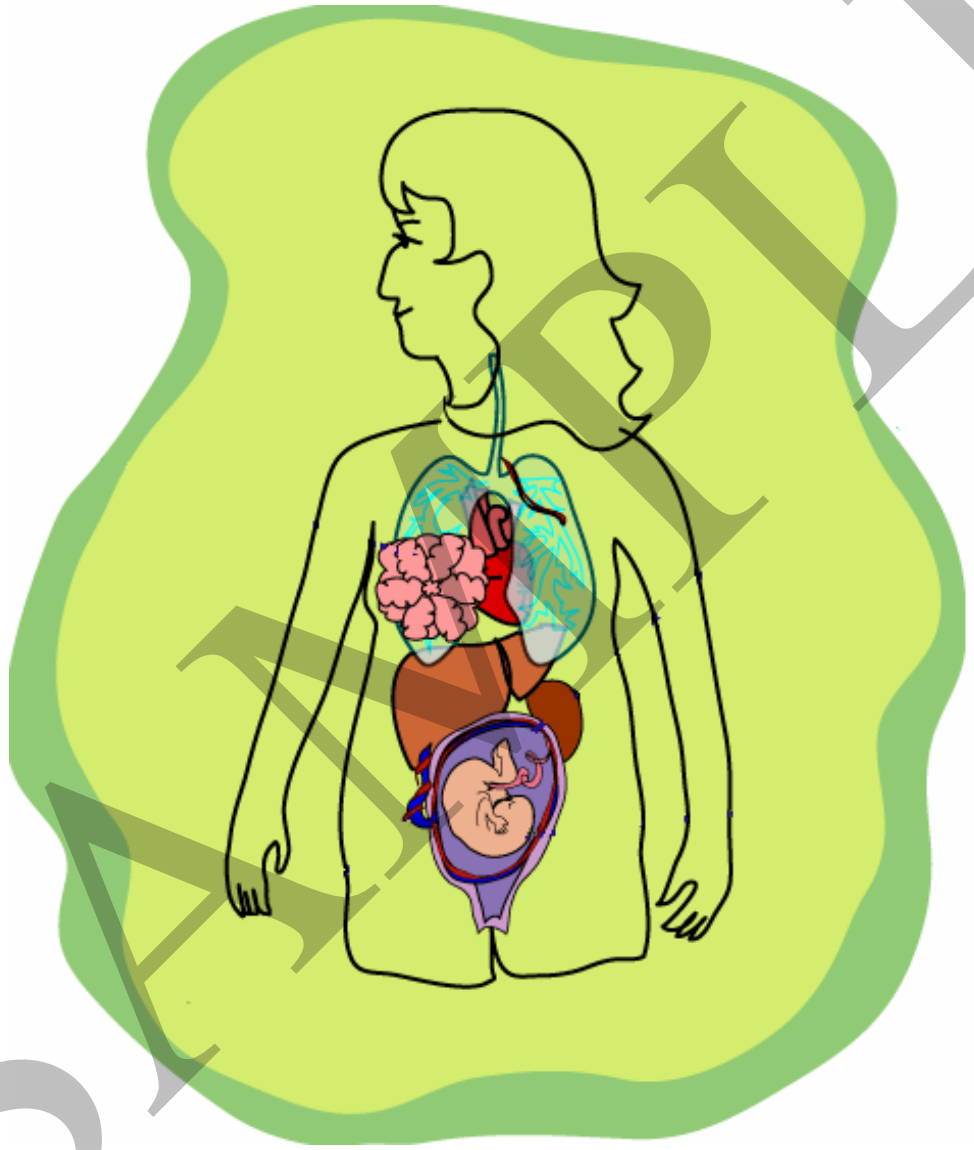
- **Medicine that you get from a doctor or a drug store (such as cold medicine or painkillers) may be harmful to a baby.**
  - Check with your doctor before taking any medicine when you're pregnant.

- **Caffeine should be avoided during pregnancy. It limits the absorption of iron (a mineral your body needs), and it can dehydrate you (pregnant women need plenty of water). Besides coffee and tea, soft drinks also have lots of caffeine in them.**

☑ *See Healthy Living: Effects of Drug Use on a Developing Baby for more information about the effects of substances during pregnancy.*

SAMPLE

EATING HEALTHY FOR YOUR GROWING BABY



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EATING HEALTHY FOR YOUR GROWING BABY

TEACHING POINT

Healthy eating during pregnancy is important for the growth and development of mom and baby.

Review the teaching point with participant.

- **Healthy eating during pregnancy is a gift a mother gives to her baby that lasts a lifetime.**
  - It feels good to do things that are good for you and your baby.

- **Some people think women need to "eat for two" during pregnancy. This isn't true. Eat a healthy, balanced diet.**

  ☑ *See Reference Manual 6: Caloric Adaptations for Pregnant Women; Reference Manual 7: Sample Menu for Pregnancy; and Reference Manual 8: More about Calories and Food Labels*

- **Healthy diets include foods from the five main food groups: fruits, vegetables, grains, protein foods, and dairy. Try to eat a variety of foods from each group every day.**
  - Examples of fruits: apples, oranges
    - Fresh or canned fruit, 100% fruit juice, dried fruit
  - Examples of vegetables: spinach, peppers, broccoli, peas
    - Aim for a variety of colors.
    - Fresh is best, but frozen or canned are okay if you can't find fresh.
  - Examples of grains: whole wheat bread, tortilla, pita, rice, pasta, cooked cereal
  - Examples of protein foods: canned or fresh meat, poultry, fish, beans, eggs
  - Examples of dairy: milk, yogurt, cheese
    - Aim for low-fat versions of these foods.

  ☑ *See Reference Manual 9: Serving Sizes and Examples*

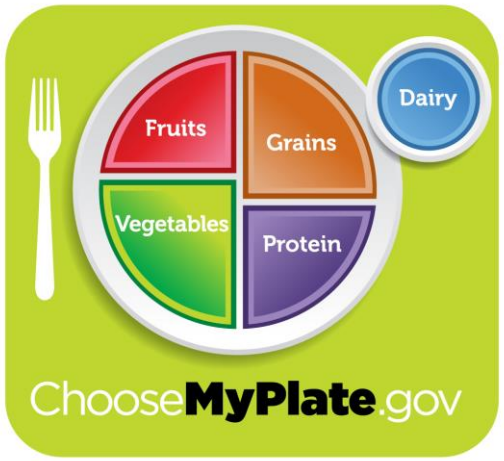
- **In addition to a variety of healthy foods, pregnant women need to consume lots of vitamins and minerals. These can be found in prenatal vitamins/mineral supplements, which you should get from your doctor.**

  ☑ *See Reference Manual 10: Vitamins and Minerals – What Pregnant Women Need*

SAMPLE

ACTIVITY 1: FOOD DIARY

In your food diary, write down the foods that you normally eat in one day. Record the items you drink. Record any drugs (legal or illegal) that you use. Are there any changes you can make to help you and your baby? What healthy things can you eat/drink more of? What is one thing that you will stop eating/drinking/using during your pregnancy?





Food Group	Recommended Amount Per Day (for women 19-30 years old)
Fruits	2 cups
Vegetables	2.5 cups
Grains	3 ounce equivalents
Protein Foods	5.5 ounce equivalents
Dairy	3 cups
Oils	6 teaspoons

SAMPLE

ACTIVITY 1: FOOD DIARY

In your food diary, write down the foods that you normally eat in one day. Record the items you drink. Record any drugs (legal or illegal) that you use. Are there any changes you can make to help you and your baby? What healthy things can you eat/drink more of? What is one thing that you will stop eating/drinking/using during your pregnancy?

☑ *Health Educator Note: Make sure the participant has a copy of this activity page. It can be found on page 3 of the Participant Workbook. Encourage her to write down everything she eats and drinks in one day. Review the recommended amounts from each food group (image to the right).*

Based on her food diary, point out areas where she does well. In a non-judgmental way, point out areas where she can improve and think about some alternatives to her current choices. Below are some menu ideas to help guide you. In addition, see Reference Manual 7: Sample Menu for Pregnancy.

- **Here are some examples of serving sizes from each food group:**
  - Fruits: 1 cup = 1 apple, banana, or orange; 1 melon wedge; ½ cup of chopped fruit or berries; 1 cup 100% fruit juice
  - Vegetables: 1 cup = 2 cups raw leafy greens; 1 cup other vegetables, chopped; 1 cup vegetable juice
  - Grains: Common portions and ounce equivalents – 2 regular slices of whole wheat bread = 2 ounce equivalents; 1 cup cooked rice = 2 ounce equivalents
  - Protein Foods: Common portions and ounce equivalents – 1 small lean hamburger = 2-3 ounce equivalents; 1 small chicken breast half = 3 ounce equivalents; 1 egg = 3 ounce equivalents; 1 cup bean soup – 2 ounce equivalents
  - Dairy: 1 cup milk; 1 snack size container (4 ounces) = ½ cup; 1 slice processed (American) cheese = 1/3 cup milk
  - Oils: Vegetable oils are all included in this category. In addition, many foods are rich in oils, including margarine, mayonnaise, dressings, peanut butter, and nuts. It's best to eat these foods sparingly.

- **Ask your doctor to help you plan for a healthy diet during your pregnancy.**

Food Group	Recommended Amount Per Day (for women 19-30 years old)
Fruits	2 cups
Vegetables	2.5 cups
Grains	3 ounce equivalents
Protein Foods	5.5 ounce equivalents
Dairy	3 cups
Oils	6 teaspoons

SAMPLE

WEIGHT GAIN DURING PREGNANCY

Your partner picks you up to go to a family gathering. You're standing in front of the mirror looking at your belly, which has grown in the last few weeks. You can't believe how much your body has changed when you think about how you looked before you got pregnant. What do you do? What can you do to feel better about yourself?



SAMPLE



WEIGHT GAIN DURING PREGNANCY

Your partner picks you up to go to a family gathering. You're standing in front of the mirror looking at your belly, which has grown in the last few weeks. You can't believe how much your body has changed when you think about how you looked before you got pregnant. What do you do? What can you do to feel better about yourself?

TEACHING POINTS

Some weight gain is a normal part of a healthy pregnancy and baby. The change in weight and shape may require an adjustment.

Review the scenario with the participant, and then review the teaching points.

☑ *Health Educator Note: If the participant's partner is involved in the lesson, discuss some ways that he can be supportive of the participant.*

- **Weight gain, within guidelines, is a crucial part of a healthy pregnancy.**
- **Many women feel unattractive at times, but it's a very special experience to be pregnant. Women also feel very beautiful during this time.**
- **It helps to understand where the weight goes:**

Weight Gain Breakdown (for someone who is normal weight)	
Baby	7 ½ pounds
Placenta	1 pound
Amniotic Fluid	2 pounds
Growth of Uterus	2 pounds
Mother's Breast Tissue	3 pounds
Mother's Blood Volume	4 pounds
Fluids in Mother's Tissue	4 pounds
Mother's Fat Stores	7 pounds
Total	**30 ½ pounds (average)**

- For someone who is underweight (BMI less than 18.5), weight gain should be 28-40 pounds.
- For someone who is normal weight (BMI 18.5-24.9), weight gain should be 25-35 pounds.
- For someone who is overweight (BMI 25.0-29.9), weight gain should be 15-25 pounds.
- For someone who is obese (BMI greater than or equal to 30.0), weight gain should be 11-20 pounds.
  - If you do not know your BMI, ask your doctor to measure it for you.
  - Talk to your doctor about healthy weight gain during your pregnancy.

☑ *Health Educator Note: You can also use the BMI Chart on page 109 of the Participant Workbook to help her calculate her BMI, if she knows her height and weight.*

- **Pregnant women can control their weight gain by eating a healthy diet and doing low-impact exercise (walking, swimming) at least four times a week.**
  - Start small. Have a nutritious snack and take a walk. Build up from there.
  - Include your partner in your healthy eating and exercise. Take a walk together, and remember that you're sharing this experience.

SAMPLE

OUR NATIVE CULTURE AND FAMILY TRADITIONS



SAMPLE



OUR NATIVE CULTURE AND FAMILY TRADITIONS

TEACHING POINTS

Our native culture and family traditions help us raise our children and make decisions about their upbringing. The elders in our community can help us learn more about our native culture and family traditions.

Review the teaching points with the participant.

- **Long ago, a native family included all extended family members.**
  - Each day had a routine for eating, working, socializing, and resting.
  - Each family member had their jobs to do – taking care of the home, gathering food and wood, and child care.
  - Living in a small group/community, all members helped in every aspect of life.
    - Men worked together to build homes and hunt for food, and women raised the children together and cooked their meals together.

- **Today many native families continue this type of lifestyle, with the encouragement of our elders.**
  - Our elders teach us of the old ways and remind us to take pride in our native culture, family traditions, and family values.

- **Activity 2: Discussing Our Native Culture and Family Traditions**
  - Were elders involved in your upbringing? What did they teach you?
    - Which teachings do you think will help you raise your child? How would you like elders to be involved in the upbringing of your child?
  - Besides teaching us about our past and helping us raise our children, elders can also help us continue to carry on our native ways.
    - Knowing which parts of our native culture and traditions are important to you can help you decide what to teach your child.
      - Which traditions are important in your family?
      - What kinds of traditional activities do you take part in daily, weekly, monthly, and yearly?
      - Which celebrations are important to your native culture?
      - What memories do you have of traditional events that you participated in as a child?
      - Which ceremonies do you want your child to take part in? What would you like your child to learn from these traditions?
      - What have you learned from traditional activities that will be helpful to you in raising your child?
      - How often are traditional foods prepared by your family?
      - Who do you consider is an elder in your family? Would you go to this elder for advice?

- **Involving your child in native culture and family traditions will help him/her learn about him/her and his/her past, having a long-term impact on his/her self-esteem.**
  - S/he will begin to learn who s/he is in the world and how s/he fits in and feel connected to a unique culture and special way of life.
  - S/he will know that s/he is valued by you, your family, and the community.

SAMPLE

CONTRIBUTING TO A HEALTHY PREGNANCY

Reference Manual

CONTENTS:

1. The Developing Baby
2. How Pregnancy and Due Dates are Determined
3. Pelvic Exams
4. Pregnancy and Childbirth Classes
5. Referrals to Addiction Counseling and Smoking Cessation Programs
6. Caloric Adaptations for Pregnant Women
7. Sample Menu for Pregnancy
8. More about Calories and Food Labels
9. Serving Sizes and Examples
10. Vitamins and Minerals – What Pregnant Women Need

SAMPLE

1. THE DEVELOPING BABY

Prior to 9 weeks gestation, the developing baby is called an **embryo.** From 9 weeks to birth, the developing baby is called a **fetus.** See below for information about development milestones and characteristics of the embryo or fetus at each stage. Because pregnancy is counted from the first day of the last menstrual period, ovulation and conception occur at week 2 in this description. Measurement aids (such as a ruler) may be helpful to demonstrate actual size.

Pre-implantation

Week 1 (3rd week of pregnancy)

- The egg is fertilized by the sperm.
- The fertilized egg implants in the endometrial lining of the uterus.

Week 2 (4th week of pregnancy)

- Embryonic cells burrow in the uterine lining. They will eventually form the **placenta**.
  - The placenta is the organ in the uterus that transports nourishment to the fetus and removes waste.

Embryonic Period

Week 3 (5th week of pregnancy-first missed menstrual period)

- The early spinal cord and heart tubes begin to develop.

Week 4 (6th week of pregnancy)

- The embryo measures 4 millimeters long (1/8 inch) and begins to curve into a C-shape.
- Arm buds begin to form.

Week 5 (7th week of pregnancy)

- The embryo measures 8 millimeters long (1/4 inch).
- The eyes and mouth begin to form.

Week 6 (8th week of pregnancy)
- The embryo measures 1/2 inch in length.
- Lungs begin to form.

Week 7 (9th week of pregnancy)
- Spontaneous limb movements may be detected by ultrasound.
- All essential organs have begun to form.

Week 8 (10th week of pregnancy)
- The embryo measures 30 millimeters long (1.2 inches).
- Intestines rotate.
- The external ear takes its final shape.

Fetal Period

Weeks 9-12 (11th-14th weeks of pregnancy)
- The fetus reaches a length of 8 centimeters long (3.2 inches).
- The head makes up about half of the fetus' total size.
- The face resembles a human face.
- The eyelids stay closed until about Week 28.
- The fetus can make a fist and suck its thumb.
- It may be possible to tell if the fetus is a boy or girl.

Weeks 13-16 (15th-18th weeks of pregnancy)
- The fetus reaches 15 centimeters long (6 inches).
- Fine hair develops on the head.
- The fetus makes active movements, and sucking motions are made with the mouth.

Week 18 (20th week of pregnancy)
- The fetus reaches 20 centimeters long (8 inches).
- Eyebrows, eyelashes, and toe- and fingernails appear.
- The mother can usually feel the fetus moving.
- The fetal heartbeat can be heard with a stethoscope.

Week 22 (24th week of pregnancy)
- The fetus is 28 centimeters long (11.2 inches).
- The fetus weighs about 1 pound 10 ounces.
- Alveoli (air sacs) are forming in the lungs.

Weeks 23-26 (25th-28th weeks of pregnancy)
- The fetus is 38 centimeters long (15 inches).
- The fetus weighs about 2 pounds 11 ounces.
- The brain develops rapidly.
- The respiratory system, while still developing, can now exchange gases. Some babies born during this time can survive, but the chance of death or permanent disability is extremely high.

Weeks 27-31 (29th-33rd weeks of pregnancy)
- The fetus is 15-17 inches long.
- The fetus weighs about 4 pounds 6 ounces.
- The amount of body fat increases rapidly.
- Bones are fully developed but are still soft.

SAMPLE

Week 34 (36th week of pregnancy)
- The fetus is approximately 16-19 inches long.
- The fetus weighs approximately 5 pounds 12 ounces to 6 pounds 12 ounces.
- Fingernails reach the end of the fingertips.

Weeks 35 to 38 (37th to 40th weeks of pregnancy)
- The fetus is considered full-term at the 37th week.
- Head hair is now coarse and thicker.

2. HOW PREGNANCY AND DUE DATES ARE DETERMINED

Recognizing Signs of Pregnancy

A delayed or missed period is one of the most common signs of pregnancy. Other signs include swollen and tender breasts, tiredness, nausea, bloating, and the need to urinate more often.

Urine and blood pregnancy tests measure the presence of a specific pregnancy hormone (hCG) in a woman's body. It's an important marker of pregnancy, and it increases as the pregnancy progresses.

Urine Test	Blood Test
Can be done at home	Can only be done by a doctor
hCG levels need to be very high in blood before detected in urine (need to wait longer to determine pregnancy through urine test)	Can detect pregnancy very early
Negative urine pregnancy test doesn't mean you aren't pregnant	Very sensitive: can correctly identify when you are pregnant or not

Women should still see their doctor if they know or even suspect that they're pregnant.

Negative test: If an at-home test results in a negative test result, the doctor should confirm that result or at the very least investigate what has brought on the symptoms that lead the woman to believe she's pregnant.

Positive test: Even a positive test should be confirmed by the doctor. Some tests are positive even if the woman isn't pregnant!

How Due Dates are Determined

- The date can be estimated by adding 40 weeks to the first day of a woman's last menstrual period. Alternately, she can add seven days to the first day of her last menstrual period and then add nine months to that.
- Doctors can use a machine called an **ultrasound** to determine the size of the baby and estimate the due date from that.

SAMPLE

3. PELVIC EXAMS

Definition and Purpose

A **pelvic exam** is a routine exam that's performed in a doctor's office on women of reproductive age. It allows the doctor to examine the woman's cervix and take cellular samples for laboratory analysis. Pelvic exams are able to detect sexually transmitted infections (STIs) and can provide early diagnosis for some forms of cancer that affect the genitalia. Pelvic exams are a routine part of female preventive care.

Description

As a patient, a woman will be asked to wear a gown and lie down on the examining table. She will be asked to place her feet in either stirrups at the end of the bed, or knee rests, and to move her hips to the end of the table. The doctor will inspect the external genitalia, and then s/he will insert a tool called a **speculum** into the vagina. A speculum holds the muscular walls of the vagina open so that the doctor can examine the cervix. This part will last for approximately one or two minutes, and the doctor will use a small brush to sweep some cervical cells onto a laboratory slide, which is called a **Pap smear.** When this is finished, the speculum will be removed, and the doctor may use his/her fingers to examine the shape and characteristics of the vaginal wall and the cervix. S/he will also be able to feel the uterus and ovaries by applying pressure with the other hand on the woman's belly.

Preparation

Urinate right before having a pelvic exam, and remove any tampons. Douching before a pelvic exam is discouraged, and sexual intercourse should be avoided if a Pap smear will be performed. The exam should not be painful or uncomfortable, so let your practitioner know if it is. Because the vagina is a muscle, it can become tense if you're nervous. Try your best to relax by breathing deeply.

4. PREGNANCY AND CHILDBIRTH CLASSES

Classes are a helpful way for pregnant women (and often their partners) to learn what to expect during pregnancy and childbirth. Classes can begin in the first trimester, or in the third trimester with a greater focus on labor and delivery. Check with your doctor's office or your Early Head Start program for different options.

Lamaze Technique:

This technique is the most widely used in the United States. The **Lamaze** philosophy says that birth is a normal, natural, and healthy process, and there are a number of things that you can do to make the process more comfortable. Classes focus on relaxation during labor and constructive uses of breathing and distraction to lessen a woman's perception of pain.

Bradley Method (also called "Husband-coached-birth"):

This method relies on the active participation of the baby's father to act as a coach during labor. This method also aims to avoid medication use until absolutely necessary.

SAMPLE

5. REFERRALS TO ADDICTION COUNSELING AND SMOKING CESSATION PROGRAMS

☑ *Health Educator Note: Refer to Healthy Living: A Look at Drug Use in Our Community: Reference Manual 1: Local Substance Abuse Resources for local information about addiction counseling in the participant's community. You will need to gather information for the participant about where services are available in the participant's community. In addition, you can find information about smoking cessation programs from the local health clinic or by calling 1-800-LUNGUSA (1-800-586-4872).*

Local Resources:

_____

_____

_____

_____

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_____

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_____

6. CALORIC ADAPTATIONS FOR PREGNANT WOMEN

Some women need to adjust the number of calories they intake while they're pregnant. It used to be believed that women needed to consume an additional 300 calories per day during pregnancy, but this idea has recently been altered to reflect the fact that each pregnant woman has different food needs. Some will need to consume more, and others will be just fine with their current intake. Ask your doctor how many extra calories are right for you.

If your doctor tells you to increase the number of calories you consume during pregnancy, get your extra calories from low-fat dairy products, lean meats and proteins, or whole grains. Having permission to eat extra does not mean that you should be eating more cake and fast food.

SAMPLE

7. SAMPLE MENU FOR PREGNANCY

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
Breakfast 2 Whole grain waffles 2 T peanut butter 1 c skim milk	**Breakfast** 1 egg 1 corn tortilla 1 T chili sauce ¼ c cantaloupe 6 oz orange juice 1 c skim milk	**Breakfast** 1 bagel 1 T lite cream cheese 1 c fruit yogurt ½ c orange juice	**Breakfast** Oatmeal cereal Banana 1 sl. While wh toast 2 tsp jam 1 c skim milk	**Breakfast** Peanut butter and banana sandwich on whole wheat bread 1 c skim milk	**Breakfast** 1 lg pancake 1 T margarine 2 T maple syrup 1 c juice	**Breakfast** Scrambled eggs Whole wheat toast 2 tsp jam Small banana 1 c skim milk
Snack 1 c low-fat cottage cheese ½ c pears	**Snack** 1 c vanilla yogurt ¼ c dried apricots	**Snack** Banana 1 slice nut bread	**Snack** Apple 2 T peanut butter	**Snack** Orange Whole wh. or bran muffin	**Snack** 1 c yogurt Grapes	**Snack** Raisin bran muffin Orange 1 c skim milk
Lunch 2 sl veggie pizza Tossed salad 1 T lite dressing 1 c diced melon	**Lunch** Steak fajita ½ c beans Tossed salad 1 T lite dressing 1 can tomato juice	**Lunch** 1 c chili w/ beans and beef or turkey Handful wheat crackers 1 c skim milk	**Lunch** 2 c bean soup Whole grain roll 1 T margarine Cucumber and tomato salad 1 c skim milk	**Lunch** Chef salad (w/ egg, cheese and turkey) 1 T lite dressing Whole wheat roll 1 c skim milk	**Lunch** Cheeseburger Baked potato Small milkshake	**Lunch** Turkey and cheese sandwich on whole wheat bread Small bag baked potato chips Pear 1 c skim milk
Snack ½ c pudding 3 graham crackers	**Snack** Cheese and veggie quesadilla	**Snack** 3 c air-popped popcorn Baby carrots	**Snack** **Fruit yogurt** **Whole grain muffin**	**Snack** ¼ c peanuts ¼ c raisins	**Snack** Raw veggies and low calorie dip	**Snack** 1 bag peanut M&Ms
Dinner 5 oz broiled sirloin steak ½ baked potato 1 T margarine 1 T low-fat sour cream 1 c steamed zucchini 1 c skim milk	**Dinner** 4 oz chicken 1 c rice ½ c squash ½ c peas 1 c skim milk	**Dinner** 4 oz baked salmon 1 c pasta 1 c broccoli Dinner roll 1 c skim milk	**Dinner** Tofu and veggie stir fry ½ c brown rice ½ c corn Decaf tea (hot/iced)	**Dinner** Spaghetti and meatballs w/ tomato sauce Tossed Salad w/ low calorie dressing Cantaloupe wedge	**Dinner** 4 oz broiled halibut ½ c wild rice 1 tsp margarine 5 asparagus spears Decaf tea	**Dinner** Pork chop Mashed potatoes Broccoli Whole wh roll
Snack 1 c raisin bran cereal 1 c skim milk	**Snack** 1 c flan 1 c skim milk	**Snack** 1 slice angel food cake ½ c strawberries 2 T lite whipping cream	**Snack** **1 c hot cocoa with 1% or skim milk** **Graham crackers**	**Snack** 1 c skim milk Celery sticks with peanut butter	**Snack** Sliced or fresh peach	**Snack** Low-fat frozen yogurt

8. MORE ABOUT CALORIES AND FOOD LABELS

Nonfat Milk
Serving Size 8 fl oz (240mL)
Servings Per Container 2

Amount Per Serving	
Calories 80	Calories from Fat 0
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Cholesterol less than 5mg	1%
Sodium 130mg	5%
Total Carbohydrate 12g	4%
Dietary Fiber 0g	0%
Sugars 11g	
Protein 8g	

Vitamin A 8% • Vitamin C 4%
Calcium 30% • Iron 0% • Vitamin D 25%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

One of the purposes of eating is to give our bodies energy, or fuel. A **calorie** is a unit for measuring energy. The more calories you consume, the more **energy** you will have. Unfortunately, humans only need so much energy. Most adults need about 2,000 calories each day. If you consume more than what you need, the extra calories will be converted and stored as fats. This is how people become overweight.

Almost all of the food you eat should have a nutritional label that gives you all the information about your food, including how many calories are in one serving. To the left is a label for **skim (nonfat) milk**. The label says how many **servings** are in the container, and how big each serving is. One serving is 8 fluid ounces, or one cup. This serving contains 80 calories, but none are from fat. This means that all of the calories in this milk can be used as a healthy source of energy for your body. Keep in mind, if you consume too many calories, these will still stick around, but they are still a better choice. This label also shows us how much of our daily vitamin requirement we are getting. Calcium is important during pregnancy, and milk is a great source (30% of the daily recommended value).

SAMPLE

Whole Milk
Serving Size 8 fl oz (240mL)
Servings Per Container 2

Amount Per Serving	
Calories 150	Calories from Fat 70
	% Daily Value*
Total Fat 8g	12%
Saturated Fat 5g	25%
Cholesterol 35mg	12%
Sodium 125mg	5%
Total Carbohydrate 12g	4%
Dietary Fiber 0g	0%
Sugars 11g	
Protein 8g	

Vitamin A 6% • Vitamin C 4%
Calcium 30% • Iron 0% • Vitamin D 25%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

The next label, to the left, comes from a container of **whole milk**. You can see that each serving, which is again a cup, has 150 calories, and 70 of those are from fat! It has the same amounts of protein and calcium as skim milk, so the only difference is the extra calories and fat, which you don't need.

To the right is a label for **whole wheat bread.** How many slices of bread does this label consider to equal 1 serving? How many calories are in one serving? What important vitamins and minerals are we getting by eating this bread?

Whole Wheat Bread

Nutrition Facts
Serving Size 2 slices (52g)
Servings Per Container 11

Amount Per Serving	
Calories 130	Calories from Fat 25
	% Daily Value
Total Fat 2.5g	4%
Saturated Fat 0g	0%
Trans Fat 0g	
Polyunsaturated Fat 1g	
Monounsaturated Fat 0g	
Cholesterol 0mg	0%
Sodium 240mg	10%
Total Carbohydrate 23g	8%
Dietary Fiber 3g	12%
Sugars 4g	
Protein 6g	

Vitamin A	10%	Vitamin C	0%
Calcium	10%	Iron	6%
Vitamin D	10%	Vitamin E	10%
Thiamin	6%	Riboflavin	4%
Niacin	6%	Folic Acid	4%

*Percent (%) Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower based

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 * Carbohydrate 4 * Protein 4

9. SERVING SIZES AND EXAMPLES

The United States Department of Agriculture (USDA) is responsible for setting the standard for what people in the U.S. should eat and how much. The USDA lists 5 food groups: fruits, vegetables, grains, protein foods, and dairy. They also provide recommendations for oils and empty calories (sweets and fats).

In the following section, you are told how much a serving size is for each food group and what counts as one serving. These recommendations apply to women 19-30 years old. Always consult your doctor to determine what's best for you.

Fruits include any fruit or 100% fruit juice. Fruits may be fresh, canned, frozen, or dried, but try to choose packaged fruits that don't contain added sugars. Try to eat plenty of fruit for snacks and desserts, and choose them over juice (which often has added sugar and calories).
Try to eat a variety of types and colors.
Servings: 2 cups of fruits are recommended daily. One cup of fruit:

1 cup of cut-up fruit
1 cup 100% fruit juice
½ cup dried fruit

Some examples of one cup of fruit:

½ large apple (3.25" in diameter)
1 cup orange juice
½ cup raisins

Vegetables include any vegetable or 100% vegetable juice. Vegetables can be raw, cooked or frozen, and served in any way. Vegetables vary widely, and the best advice is to eat as many different kinds of vegetables as possible. A good rule of thumb is to eat as many different colors as possible.
Servings: 2 ½ cups of vegetables are recommended daily. One cup of vegetables:

1 cup of raw or cooked vegetables (such as carrots, peas or green beans)
1 cup 100% vegetable juice
2 cups of raw, leafy greens (such as spinach or kale)

SAMPLE

Grains include anything that is made from wheat, rice, oats, cornmeal, or barley. Examples of grains are bread, pasta, tortillas, and breakfast cereals. Grains can be broken down into whole grains and refined grains. **Whole grains** include things made from whole-wheat flour, brown rice, bulgur (cracked wheat), oatmeal and whole cornmeal. **Refined grains** have been milled, and are often white, like white flour, white rice, and white bread.
Servings: 6 ounce equivalents of grains are recommended daily. Half of these should be **whole grains**. Examples of one ounce equivalents include:

1 cup cereal, flakes
1 slice of bread
1 6-inch tortilla
4-6 crackers
½ cup cooked rice, 1 ounce dry rice
½ cup cooked pasta
½ hamburger or hotdog bun
2 x 5 ½-inch kneel down bread
1 small potato

Meat and Protein Foods includes meat, poultry, dry beans or peas, fish, eggs, nuts, and seeds. Meats should be lean, and try to substitute fish, nuts, and seeds as much as possible for the benefits of the healthy oils that they contain.
Servings: 5 ½ ounce equivalents of meats and proteins are recommended daily. Ask your doctor if you need to consume more meat and protein foods during pregnancy. Examples of once ounce equivalents include:

1 ounce of meat, poultry, or fish
1 sandwich slice
1 egg
¼ cup cooked beans
½ ounce nuts

Here are some common portions and their ounce equivalents in this category:

1 small lean hamburger = 2-3 ounce equivalents
1 small chicken breast half = 3 ounce equivalents
1 can of tuna, drained = 3-4 ounce equivalents
3 egg whites = 2 ounce equivalents; 3 egg yolks = 1 ounce equivalent
1 cup bean soup = 2 ounce equivalents

A note about eating fish during pregnancy: Some fish contain high levels of mercury that can be harmful to a fetus. Avoid eating any shark, swordfish, king mackerel and tilefish. Eat other fish in moderation (no more than two servings per week).

Milk and dairy includes all fluid milk and many foods that are made from milk, including yogurt and cheese. Milk is very important for pregnant women and their growing babies.
Servings: 3 cups of milk or milk products is recommended daily. This is the equivalent of:

1 cup of milk
1 cup of yogurt
1 1/2 ounces of natural cheese
2 ounces of processed cheese

SAMPLE

Oils include fats that are liquid at room temperature. They're found in a variety of foods, like fish and nuts, and are commonly added to foods in the form of cooking oils or margarines. While oils are made from fats, they contain essential fatty acids that other fats don't. If you can choose between oils and solid fats (like butter or lard), choose oil. Within the oil family, some are better for you than others. When cooking, use canola or olive oil, which are low in saturated (bad) fats. If you eat fish, choose salmon or another fish that is high in omega-3 fatty acids. Buy margarine that is unhydrogenated.

Empty calories are the calories that aren't essential to your health, and are **extra** calories. These calories include fats such as butter and margarine, ice-cream, and potato chips. Basically, you should try to minimize these as much as possible. Instead of having ice cream or cake, eat some fresh fruit. Instead of potato chips, try a handful of dried fruits, nuts (including almonds and walnuts) and seeds.

10. VITAMINS AND MINERALS – WHAT PREGNANT WOMEN NEED

Nutrient	Why?	What food is it found in?
Folic Acid*	Prevents neural tube defects like spina bifida in babies. The baby's neural tube eventually becomes the brain and spinal cord.	Breakfast cereal, spinach, orange juice
Calcium	Prevents loss of calcium in the mother (since babies need it too). Babies use calcium to develop healthy hearts, bones, and teeth.	Yogurt, cheese, milk**, broccoli, spinach, dried beans
Iron	Needed to maintain energy for red blood cells, which carry oxygen throughout the mother's and baby's bodies. Good for a baby's brain development.	Red meat, eggs, dried beans, green leafy vegetables, iron-fortified cereals

**It's good to start getting folic acid before your next pregnancy.*
***Calcium pills can be used by people who have an allergy to lactose/dairy products.*

SAMPLE

CONTRIBUTING TO A HEALTHY PREGNANCY

Bibliography

LESSON CONTENT REFERENCES

Provided below are some references related to various topics presented in the lesson. Additional references may not be provided for all lesson pages. Many of the references are website references, so you will need access to a computer and the Internet in order to view them. Refer to any of these references when you need more information about a specific topic or if you get any questions from the participant that you aren't able to answer.

Prenatal Development, pages 3-4

Murkhoff, H., & Mazel, S. (2008). *What to Expect® When You're Expecting* (4th ed.). New York, NY: Workman Publishing Company, Inc.

What your baby looks like this week. *BabyCenter®*. Retrieved December 13, 2013 from http://www.babycenter.com/fetal-development-week-by-week

- Find full color images of a baby's development week by week until birth!

Slideshow: Fetal Development Month by Month. *WebMD®*. Retrieved December 13, 2013 from http://www.webmd.com/baby/ss/slideshow-fetal-development

- Scroll through a slideshow with real images of a baby and how it develops through pregnancy. There are also short descriptions of each month.

Fetal Development. *American Pregnancy Association.* Retrieved December 13, 2013 from http://www.americanpregnancy.org/duringpregnancy/fetaldevelopment.htm

- Information on this website is presented by trimester, and within each trimester it's broken down into weeks.

Prenatal Care and Your Birth Plan, pages 5-6

Taking Care of You and Your Baby While You're Pregnant. *FamilyDoctor.org sponsored by the American Academy of Family Physicians.* Retrieved December 13, 2013 from http://familydoctor.org/familydoctor/en/pregnancy-newborns/your-body/taking-care-of-you-and-your-baby-while-youre-pregnant.html

- Information on the webpage above covers everything from prenatal care to healthy living to taking medications to sex during pregnancy.

Pregnancy week by week: Prenatal care: First-trimester visits. *Mayo Clinic.* Retrieved December 13, 2013 from http://www.mayoclinic.com/health/prenatal-care/PR00008

- This article lays out the details of the first prenatal care visits during pregnancy in the first trimester.

Pregnancy week by week: Prenatal care: Second-trimester visits. *Mayo Clinic.* Retrieved December 13, 2013 from http://www.mayoclinic.com/health/prenatal-care/PR00093

- This article lays out the details of the prenatal care visits during the second trimester.

Pregnancy week by week: Prenatal care: Third-trimester visits. *Mayo Clinic.* Retrieved December 13, 2013 from http://www.mayoclinic.com/health/prenatal-care/PR00094

- This article lays out the details of the prenatal care visits during the third trimester.

Staying Healthy for Your Growing Baby, pages 7-8

Murkoff, H.E., Eisenberg, A., and Hathaway, S.E. (2002). *What to Expect® When You're Expecting, Third Edition.* Workman Publishing: New York.

Grab and Go: Fact Sheets and Brochures. *Fetal Alcohol Spectrum Disorders: Center for Excellence sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA).* Retrieved December 13, 2013 from http://fasdcenter.samhsa.gov/grabGo/factSheets.aspx

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- This website has links to several brochures about various issues related to FASD. There is even a fact sheet specific to FASD and Native Americans.

Staying Healthy During Pregnancy. *KidsHealth® sponsored by Nemours®*. Retrieved December 13, 2013 from http://kidshealth.org/parent/pregnancy_center/your_pregnancy/preg_health.html#
- All that you need to know about keeping your body healthy during pregnancy for you and your baby.

Eating Healthy for Your Growing Baby, pages 9-10

Health & Nutrition Information for Pregnant & Breastfeeding Women. *USDA: ChooseMyPlate.gov.* Retrieved December 13, 2013 from http://www.choosemyplate.gov/pregnancy-breastfeeding.html
- Go to this website to find information about nutritional needs and tips for pregnant women.

Pregnancy week by week: Pregnancy nutrition: Healthy-eating basics. *Mayo Clinic.* Retrieved December 13, 2013 from http://www.mayoclinic.com/health/pregnancy-nutrition/PR00108
- These guidelines are for a woman who has normal weight and gets 30-60 minutes of exercise a day.

Staying Healthy During Pregnancy. *KidsHealth® sponsored by Nemours®*. Retrieved December 13, 2013 from http://kidshealth.org/parent/pregnancy_center/your_pregnancy/preg_health.html#
- All that you need to know about keeping your body healthy during pregnancy for you and your baby.

Weight Gain During Pregnancy, pages 13-14

Murkhoff, H., & Mazel, S. (2008). *What to Expect® When You're Expecting* (4th ed.). New York, NY: Workman Publishing Company, Inc.

Health & Pregnancy: Gain Weight Safely During Your Pregnancy. *WebMD®*. Retrieved December 13, 2013 from http://www.webmd.com/baby/guide/healthy-weight-gain
- This article describes where the weight goes during pregnancy and how much weight is safe to gain.

Your pregnant body: Weight gain during pregnancy. *March of Dimes®*. Retrieved December 13, 2013 from http://www.marchofdimes.com/pregnancy/yourbody_weightgain.html
- Easy-to-read information about gaining the right amount of weight during pregnancy.

Eating for Two When Over- or Underweight. *American Pregnancy Association.* Retrieved December 13, 2013 from http://www.americanpregnancy.org/pregnancyhealth/eatingfortwo.html
- This article discusses the importance of weight gain during pregnancy and how much you should gain, at what rate.

REFERENCE MANUAL CONTENT REFERENCES

Below you will find references for each Reference Manual within the lesson.

Reference Manual 1: The Developing Baby

Fetal Development. *National Institutes of Health: MedlinePlus.* Retrieved December 13, 2013 from http://www.nlm.nih.gov/medlineplus/ency/article/002398.htm

Reference Manual 2: How Pregnancy and Due Dates are Determined

Pregnancy Symptoms – Early Signs of Pregnancy. *American Pregnancy Association.* Retrieved December 13, 2013 from http://www.americanpregnancy.org/gettingpregnant/earlypregnancysymptoms.html

Murkhoff, H., & Mazel, S. (2008). *What to Expect® When You're Expecting* (4th ed.). New York, NY: Workman Publishing Company, Inc.

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BIBLIOGRAPHY SAMPLE

Reference Manual 3: Pelvic Exams
Women's Health: Pelvic Examination. *WebMD®*. Retrieved December 13, 2013 from http://women.webmd.com/pelvic-examination

Reference Manual 4: Pregnancy and Childbirth Classes
Birthing Classes. *KidsHealth® from Nemours.* Retrieved December 13, 2013 from http://kidshealth.org/parent/pregnancy_center/preparing_parenthood/birth_class.html

Reference Manual 5: Referrals to Addiction Counseling and Smoking Cessation Programs

☑ *The Health Educator needs to look at Healthy Living: A Look at Drug Use in Our Community: Reference Manual 1: Local Substance Abuse Resources. The Health Educator will need to gather information for the participant about services in her community.*

Reference Manual 6: Caloric Adaptations for Pregnant Women
Murkhoff, H., & Mazel, S. (2008). *What to Expect® When You're Expecting* (4th ed.). New York, NY: Workman Publishing Company, Inc.

Reference Manual 7: Sample Menu for Pregnancy
Colorado Department of Public Health and the Environment. (2006).

Reference Manual 8: More about Calories and Food Labels
Learning About Calories. *KidsHealth® sponsored by Nemours®*. Retrieved December 13, 2013 from http://kidshealth.org/kid/nutrition/food/calorie.html

Figuring Out Food Labels. *KidsHealth® sponsored by Nemours®*. Retrieved December 13, 2013 from http://kidshealth.org/kid/stay_healthy/food/labels.html

Reference Manual 9: Serving Sizes and Examples
United States Department of Agriculture: ChooseMyPlate.gov. Retrieved December 13, 2013 from http://www.choosemyplate.gov/

Bachman, K., Duncan, R.M., & Pelican, S. (1998). *Ethnic and Regional Food Practices: A Series: Navajo Food Practices, Customs, and Holiday.* The American Dietetic Association, American Diabetes Association.

Reference Manual 10: Vitamins and Mineral - What Pregnant Women Need
Adapted from Nutrients & Vitamins For Pregnancy. *American Pregnancy Association.* Retrieved December 13, 2013 from http://www.americanpregnancy.org/pregnancyhealth/nutrientsvitaminspregnancy.html

SAMPLE

CONTRIBUTING TO A HEALTHY PREGNANCY



Things to remember from this lesson:

- **It takes about 40 weeks for a baby to develop from 2 cells: sperm and egg.**



First Trimester:

4 weeks	Smaller than a grain of rice
8 weeks	1 inch
12 weeks	3 inches

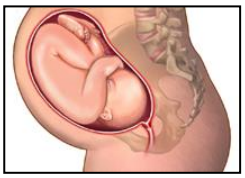
By the end of your first trimester:
- Your baby's heart begins to beat!
- Many parts of the body start to develop: brain, spinal cord, intestines, arms, legs, fingers, and toes.



Second Trimester:

16 weeks	4 inches
20 weeks	8 inches
24 weeks	12 inches

By the end of your second trimester:
- Your baby's eyes open, and she can see and hear! Now is a great time to sing and talk to your baby.
- Parts of the body continue to develop: eyebrows, eyelashes, and hair.
- You may start feeling the baby move around.



Third Trimester:

28 weeks	15 inches
32 weeks	17 inches
36-40 weeks	20 inches

By the end of your third trimester:
- Your baby begins to suck her thumb and hiccup.
- Most organs have developed, except for the lungs.
- A lot of brain growth happens.

Images Source: www.babies.sutterhealth.org

- **Make sure you go to all of your prenatal care appointments. They are important for a healthy pregnancy and a healthy baby.**
  - You should visit a clinic as soon as you find out you are pregnant.
  - You will see your doctor about 7 different times during your pregnancy.
    - Beginning of pregnancy until third trimester: once a month
    - Weeks 32-36 of pregnancy: every other week
    - Weeks 36 until delivery: once a week

Remember…
Alcohol and drugs are very harmful to your baby. Anything you drink, eat, or smoke travels to your baby through your blood and the placenta.

- **Eat healthy during your pregnancy.**
  - It is important for good growth and development for you and your baby.
- **It is normal to gain some weight during pregnancy, but sometimes you can gain too much or too little.**
  - Check with your doctor if you have questions about your weight gain.
- **Start thinking now about any native traditions you want to teach your baby.**
  - Our native culture and family traditions help us raise our children and make decisions about their upbringing.
  - Elders in our community can help us learn about our native culture and family traditions.

SAMPLE

ACTIVITY 1: FOOD DIARY

✍ In the table below, write down all the foods you normally eat in one day. Write down all the items you drink. Write down any drugs (legal and illegal) that you use.

Food Diary		
How Much	What Kind	Time

SAMPLE

FAMILY SPIRIT EVALUATION OVERVIEW

A series of evaluation tools have been developed or identified to monitor program fidelity, ensure quality implementation of the program, assess and screen participants, and measure the impact of the Family Spirit Program on participants. The majority of these tools have been tested and used in the Family Spirit research trials; those that have not been used in the Family Spirit trials have been widely used and validated in similar populations.

Affiliate Reporting Requirements

Family Spirit affiliates have varying levels of resources and goals for program evaluation. All Family Spirit affiliates are required to collect process data and report it back to the Family Spirit Program on a routine basis. **Required forms include: the Session Summary Form, Tracking Log, Quality Assurance Form, and Health Educator Independent Knowledge Assessments.** The Session Summary Form and Tracking Log may be replaced with site-specific tools, as long as the same fields are captured. Process data are reported back to the Family Spirit Program as a way to monitor the numbers of families served across affiliate sites, monitor fidelity to the program content and structure, and provide ongoing technical assistance as needed.

Additional evaluation measures may be required for affiliates wishing to implement Family Spirit with high fidelity, and/or for whom this is a requirement by their funding source. These requirements are determined during the pre-training process with each affiliate. The Family Spirit Program can provide additional consultation to interested programs on assessing process and outcome data to measure program impact and continuously improve service delivery.

Family Spirit Evaluation Measures

The detailed tables below provide an overview of all of the Family Spirit evaluation measures available for use by affiliates:

Process Measures

NAME OF INSTRUMENT:	DESCRIPTION:	COMPLETED BY:	RECOMMENDED TIMEPOINT:	BENCHMARKS/ OUTCOMES ADDRESSED
1) Session Summary Form*	A form summarizing the details of each visit that the Health Educator completes with a family, including: length of visit, purpose of visit, location of visit, people present at visit, lesson(s) taught, referrals made, challenges or concerns, issues to follow-up on, next visit date.	Health Educator	Every visit	■ Fidelity to program structure ■ Quality assurance ■ Coordination and referrals for other community resources ■ Information/ training provided to participants
2) Quality	A form completed by the	Health Educator	Quarterly (Every	■ Fidelity to

Assurance Form*	Health Educator Supervisor on a quarterly basis for each Health Educator. The Supervisor will observe a home visit and assess the Health Educator on specific tasks grouped according to three domains: 1) visit structure; 2) relationship with participant; and 3) adherence, competence and flexibility.	Supervisor	Three Months); more often if there are concerns with the Health Educator's performance	program structure ■ Quality assurance
3) Independent Knowledge Assessments*	A series of 5-item multiple choice tests, one for each lesson within the Family Spirit curriculum. Health Educators must score 80% or higher on each test before they are certified to teach the lesson to a participant.	Health Educator	Prior to Teaching A Lesson for the First Time; Repeat Test Every 12 Months	■ Quality assurance ■ Health Educator knowledge
4) Participant Tracking Log*	An electronic file that lists all enrolled participants and dates of scheduled and completed visits.	Health Educator	Update Daily as Visits are Completed	■ Fidelity to program structure ■ Quality assurance
5) Health Educator Weekly Report To Supervisor	A weekly summary report used to document all participant activities that week, such as number of participants seen, number of missed appointments, reasons for missed appointments, number and type of referrals made, training needs, supply needs, concerns, and recommendations or possible solutions.	Health Educator	Last Day of Each Work Week	■ Fidelity to program structure ■ Quality assurance ■ Coordination and referrals for other community resources
6) Supervisor Response to Health Educator Weekly Report	A response form completed by the Health Educator's Supervisor to address concerns or needs raised in the Health Educator Weekly Report. This form is completed only when there are concerns or needs noted.	Health Educator Supervisor	As Needed (When a Concern or Need is Raised in the Home Visitor Weekly Report)	■ Quality assurance
7) Satisfaction Questionnaire**	A self-report form filled out by the participant to gather feedback about the lessons, home visits, and Health Educator, using both multiple choice questions and open-ended questions.	Participants	Every Six Months after Enrollment	■ Quality assurance
8) Health Educator Referral Form	A form completed each time the Health Educator makes a referral to a community agency. The top third of the form is given to the community agency, the middle third of the form is given to the participant, and the bottom third is retained by the Health Educator.	Health Educator	As Needed (When a Referral is Made)	■ Coordination and referrals for other community resources

9) Exit Form	A form documenting the conclusion of a participant's participation in the program and reason(s) for exit.	Health Educator	Last Visit	■ Quality assurance

Screening and Outcome Measures for Mothers

NAME OF INSTRUMENT:	DESCRIPTION:	COMPLETED BY:	RECOMMENDED TIMEPOINT:	BENCHMARKS/ OUTCOMES ADDRESSED
10) Demographic Form	A form filled out via structured interview to obtain detailed information about the participant's personal and family demographics and contact information.	Evaluator (if available) or Health Educator	Every Six Months, including First and Last Visit	■ Tradition/culture ■ Education/ employment ■ Housing ■ Pregnancy and parenting attitudes ■ Prenatal substance use ■ Breastfeeding ■ Health insurance
11) Post-partum Form	A form filled out through a brief interview that collects information regarding the birth of the baby.	Evaluator (if available) or Health Educator	Within Two Weeks of Delivery	■ Delivery circumstances ■ Breastfeeding ■ Car seat safety
12) Comprehensive Knowledge Assessment**	A 40-item multiple choice test to assess knowledge gains related to lesson objectives of the Family Spirit curriculum. This is designed for use with participants receiving Family Spirit lessons sequentially.	Participant receiving FS lessons sequentially	Every Six Months including First and Last Visit	■ Parent knowledge
13) Independent Knowledge Assessments	A series of 5-item multiple choice tests, one for each lesson within the Family Spirit curriculum, designed for use with participants receiving the Family Spirit lessons independently, rather than sequentially.	Participant receiving FS lessons independently	Before and After Each Lesson	■ Parent knowledge
14a) and 14b) Maternal Depression Scales**	The Centers for Epidemiological Studies-Depression Scale-Revised (CESD-R) [1] is a validated and widely used 20-item self-report depression scale. If a client scores over 16 (out of 60), she may be experiencing a depressive illness and should be referred to local mental health services. *Or* The Edinburgh Postnatal Depression Scale [2-3] is a 10-question self-rating scale that was specifically designed for women who are pregnant or have just had a baby, however	Participant	Every Two Months, Including First and Last Visit	■ Screening for maternal depression ■ Parent emotional well-being or parenting stress

	it has also been shown to be an effective measure for general depression in the larger population. If a client scores above 13, she may be experiencing a depressive illness and should be referred to local mental health services.			
15) Maternal Social and Emotional Assessment	The Achenbach System of Empirically Based Assessment (ASEBA®) [4] is a 112-item self-report scale that can be used to assess externalizing problems (opposition/defiance, rule breaking, and social problems), internalizing problems (anxious/depressed/withdrawn, thought problems), and total problems. (Note: There is a brief scale for adolescents.)	Participant	Every Six Months, Including First and Last Visit	■ Social behavior, emotional development, and emotional well-being of the parent
16) Alcohol and Drug Use Questions**	A self-report questionnaire adapted from the alcohol and drugs scales of the Voices of Indian Teens (VOIT) [5] Survey. Topics include: quantity and frequency of alcohol and drug use; age of first use; and lifetime history of use.	Participant	Every Six Months, Including First and Last Visit	■ Parent substance use
17) Parent Self-Efficacy and Competence**	One subscale from the Parent Locus of Control (PLOC) [6] Measure is administered as a self-report to assess parental competence.	Participant	Every Six Months, Beginning at Six Months Post-Partum	■ Parent self-efficacy ■ Parent emotional well-being or parenting stress
18) Parent Stress**	The short form of the Parent Stress Index (PSI-SF) [7] administered to assess parenting stress.	Participant	Every Six Months, Beginning at Six Months Post-Partum	■ Parenting stress
19) Parent-Child Interaction Tool	The Parenting Observations of Children: Checklist of Observations Linked to Outcomes (PICCOLO) [8] is a 29-item observational tool to assess supportive parenting behaviors across four areas: 1) affection, 2) responsiveness, 3) encouragement, and 4) teaching.	Evaluator (if available) or Health Educator	Every Six Months, Beginning at Twelve Months Post-Partum	■ Parent-child interactions
20) Domestic Violence	The Hurt, Insulted, Threatened with Harm and Screamed (HITS) [9] Domestic Violence Screening Tool is a widely used 4-item self-report measure. Scores range between 4-20, and a score greater than 10 indicates risk for domestic violence abuse.	Participant	Every Six Months, Including First and Last Visit	■ Domestic Violence
21) Home Safety Check	An observational measure used to check for basic home safety	Evaluator (if available) or Health	Every Six Months, Including First and	■ Home safety check, including

	in the home where the mother and child live.	Educator	Last Visit	safe car and safe sleep practices
22) Medical Chart Review Form – Mother	A Medical Chart Review Form used to collect data from mother's medical records regarding Emergency Department visits. A medical release form must be signed by the mother prior to accessing any medical chart data.	Evaluator (if available) or Health Educator	After Participant Exit	■ Prenatal care ■ Inter-birth intervals ■ Maternal visits to ED ■ General maternal health

Screening and Outcome Measures for Children

NAME OF INSTRUMENT:	DESCRIPTION:	COMPLETED BY:	RECOMMENDED TIMEPOINT:	BENCHMARKS/ OUTCOMES ADDRESSED
23) Child Development Screen	The Ages and Stages Questionnaire (ASQ) [10] is both a structured interview and observational assessment that allows the parent to understand the child's development. The ASQ is designed to identify infants and toddlers who may have developmental delays so that families can be referred for additional services.	Evaluator (if available) or Health Educator	Every Two Months, Beginning at Two Months Post-Partum	■ Child physical health and development ■ Child cognitive skills ■ Child communication skills
24a) and 24b) Child Social and Emotional Development Scales**	The Brief Infant Toddler Social Emotional Assessment (BITSEA) [11] is a 44-item scale that assesses infant behavior for ages 12-36 months including: Externalizing, Internalizing, Dysregulation, and Competence domains. *Or* The Ages and Stages Questionnaire: Social Emotional (ASQ:SE) [12] is both a structured interview and observational assessment to screen social-emotional competence in young children. It is modeled after the ASQ[10] and is designed to be used in conjunction with the ASQ or another child development screen.	Participant	BITSEA: Every Six Months, Beginning at Twelve Months Post-Partum ASQ:SE: Two Months Post-Partum, Six Months Post-Partum, and Every Six Months Following	■ Child social behavior, emotional development, and emotional well-being
25) Medical Chart Review Form – Child	A Medical Chart Review Form used to collect data from children's medical records regarding Emergency Department visits and childhood injuries. A medical release form must be signed prior to accessing any medical chart data.	Evaluator (if available) or Health Educator	After Participant Exit	■ Well-child visits ■ Child visits to ED ■ Child injuries ■ General child health

Required forms for all affiliate sites.

***** Recommended forms for monitoring program fidelity.***

References:

1. Eaton WW, Muntaner C, Smith C, Tien A, Ybarra M. Center for Epidemiologic Studies Depression Scale: Review and revision (CESD and CESD-R). In: Maruish ME, ed. The Use of Psychological Testing for Treatment Planning and Outcomes Assessment. 3rd ed. Mahwah, NJ: Lawrence Erlbaum; 2004:363-377
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7. Abidin RR. Parenting Stress Index, 4th ed Short Form. 4th ed. Lutz, FL: PAR; 2012 Available from: http://www4.parinc.com/Products/Product.aspx?ProductID=PSI-4:SF.
8. For PICCOLO technical information and references, go to: http://www.brookespublishing.com/resource-center/screening-and-assessment/piccolo/
9. Sherin KM, Sinacore JM, Li XQ, Zitter RE, Shakil A. HITS: a short domestic violence screening tool for use in a family practice setting. *Fam Med.* 1998:30(7); 508-512.
10. Bricker D & Squires J (1999). *Ages & Stages Questionnaires: A parent-completed, child-monitoring system, Second edition* Paul H. Brookes Publishing Co.
11. Karabekiroglu K, Briggs-Gowan MJ, Carter AS, Rodopman-Arman A, Akbas S. The clinical validity and reliability of the Brief Infant-Toddler Social and Emotional Assessment (BITSEA). *Infant Behav Dev.* 2010 Aug 25.
12. Bernt, F. (2017). Test review of Ages & Stages Questionnaires®: Social-Emotional, Second Edition. *and* DiStefano, C. (2017). Test review of Ages & Stages Questionnaires®: Social-Emotional, Second Edition. In J.F. Carlson, K.F. Geisinger, & J.L. Jonson (Eds.), *The twentieth mental measurements yearbook.*

QUARTERLY AFFILIATE REPORT

Each quarter, the Family Spirit Affiliate Liaison will contact affiliates to provide any technical assistance on program sustainability and implementation, as well as collect process data about implementation. The following topics are addressed during the quarterly report meeting:

- Primary lesson administration method and setting
- Enrollment numbers
- Number of home visits in last 3 months
- Demographic information about mothers and children
- Home visitor information and caseload
- Quality assurance process
- Recruitment successes and challenges
- Overall program successes and challenges
- Evaluation and fidelity
- Number of graduates
- Sustainability
- Program-specific needs and requests

If you have any questions about the quarterly reports, please contact us at familyspirit@jhu.edu.

FS CONNECT MEMBERSHIP

We are pleased to introduce you to **FS Connect**, a series of services designed to make access to Family Spirit resources easy and efficient.

The key features and benefits you will receive as a **FS Connect** Member include the following:

- Technical Assistance from a Family Spirit Affiliation Liaison following the Family Spirit Training
- Quarterly Check-ins with an Affiliate Liaison, who can assist with troubleshooting and answering questions during implementation of the Family Spirit Program
- Family Spirit quarterly newsletter with updates about the program and other relevant news, publications, and information from the maternal and child health field
- Connection to other Family Spirit affiliates for knowledge sharing
- Topic-based webinars conducted throughout the year

Launched in January 2016… **FS Connect** Member Portal where members will have access to the following:

- Online library of evaluation tools
- Forum for knowledge sharing
- Webinars, presentations, and videos
- Shared resources for program implementation
- Calendar of events

Additional services may be included in membership in the future, including web-based data entry/storage and access to training/curriculum materials through the **FS Connect** Member Portal.

If you have any questions about the **FS Connect** Membership and what it includes, please don't hesitate to contact us at familyspirit@jhu.edu.