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

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Abstract

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.

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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.).

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 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 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 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 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 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).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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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								
Age (years)	Mean	SD		Mean	SD		Mean	SD
	18.15	1.37		18.12	1.57		18.12	1.47
Gestational age at enrollment (weeks)	25.34	4.25		24.73	4.02		25.04	3.14
	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	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
Pregnancy was planned	30	18.87		28	17.18		58	18.01
No contraceptive use at conception	136	85.53		140	85.89		276	85.71
Lives independently with boyfriend	19	11.95		22	13.49		41	12.73
Lives with parents	96	60.76		95	58.64		191	59.69
Lives with boyfriend's parents	26	16.46		33	20.37		61	18.44
Currently in school	63	39.62		68	41.72		131	40.68
Currently employed	12	7.50		11	6.75		23	7.14
Lack electricity in household	11	6.92		8	4.91		19	5.90
Lack indoor plumbing in household	14	8.81		16	9.82		30	9.32
Completed high school or General Equivalency Diploma	43	27.04		45	27.61		88	27.33
Lived in two or more homes in past year	77	48.43		86	52.76		163	50.62
Language(s) spoken in home								
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								

Characteristic	Intervention Group (N=159)		Control Group (N=163)		Total (N=322)	p
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
During pregnancy	28	17.61	17	10.43	45	13.98
Cigarettes						0.06
Ever	102	64.15	88	53.99	190	59.01
During pregnancy	36	22.64	26	15.95	62	19.25
Marijuana						0.13
Ever	130	81.76	124	76.07	254	78.88
During pregnancy	23	14.47	20	12.27	43	13.35
Methamphetamine						0.56
Ever	50	31.45	41	25.15	91	28.26
During pregnancy	9	5.66	8	4.91	17	5.28
Cocaine or crack						0.76
Ever	44	27.67	37	22.70	81	25.16
During pregnancy	4	2.52	2	1.23	6	1.86

^aCES-D=Center for Epidemiologic Studies Depression Scale.

^bMean 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.

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.

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	
	Adjusted Mean	Adjusted Mean	Adjusted Mean Difference	95% CI	Effect Size ^b	p
ITSEA outcomes, mean scores (range 0–2)						
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.

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	
	Adjusted Mean		Adjusted Mean		Adjusted Mean Difference	Effect Size ^b
ITSEA outcomes, mean scores (range 0–2)						
Externalizing domain	0.62		0.74		–0.12	–0.26
Internalizing domain	0.58		0.65		–0.07	–0.14
Dysregulation domain	0.52		0.60		–0.08	–0.21
Competence domain	1.06		1.02		0.04	0.08
ITSEA outcomes, % clinically at risk	Estimated % ^c		Estimated % ^c		Odds Ratio	p
Externalizing domain	13.12		22.40		2.15	0.05
Internalizing domain	19.28		29.70		1.91	0.04
Dysregulation domain	14.00		18.67		1.65	0.21
Competence domain	21.27		16.88		0.77	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.

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	Adjusted Mean Difference	95% CI	Effect Size ^b	p
	Adjusted Mean		Adjusted Mean						
Psychosocial outcomes									
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

Outcome	Intervention Group (N=159)	Control Group (N=163)	Analysis	95% CI	p
12 months postpartum	0.13	0.45	-0.32	-0.80, 0.16	0.19
Maternal drug use outcomes (past-month substance use)	Estimated % ^c	Estimated % ^c	Odds Ratio		
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); POSTT=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	Adjusted Mean Difference	95% CI	Effect Size ^b	p
Psychosocial outcomes (value range)									
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

Outcome	Intervention Group (N=145)	Control Group (N=140)	Analysis	95% CI	p
12 months postpartum	0.10	0.45	−0.35	−0.89, 0.19	0.20
Maternal drug use outcomes (past-month substance use)	Estimated % ^c	Estimated % ^c	Odds Ratio		
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); POST=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.