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TECHNICAL REPORT

National Evaluation of Safe Start Promising Approaches

Results Appendix A: Bronx, New York

In Jaycox, L. H., L. J. Hickman, D. Schultz, D. Barnes-Proby, C. M. Setodji, A. Kofner, R. Harris, J. D. Acosta, and T. Francois, *National Evaluation of Safe Start Promising Approaches: Assessing Program Outcomes*, Santa Monica, Calif.: RAND Corporation, TR-991-1-DOJ, 2011

Sponsored by the U.S. Department of Justice's Office of Juvenile Justice and Delinquency Prevention



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INFRASTRUCTURE, SAFETY, AND ENVIRONMENT

This research was sponsored by the U.S. Department of Justice's Office of Juvenile Justice and Delinquency Prevention and was conducted under the auspices of the Safety and Justice Program within RAND Infrastructure, Safety, and Environment and under RAND Health's Health Promotion and Disease Prevention Program.

Library of Congress Control Number: 2011935596

ISBN: 978-0-8330-5822-5

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Published 2011 by the RAND Corporation
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BRONX, NEW YORK, SAFE START OUTCOMES REPORT

ABSTRACT

The Bronx Safe Start program developed a medical home for children exposed to violence that included a multidisciplinary assessment, child-parent psychotherapy (CPP), and intensive case management. The overall goal of the program was to improve the outcomes of children (ages 0–6) exposed to violence. A full description of the program can be found in *National Evaluation of Safe Start Promising Approaches: Assessing Program Implementation* (Schultz et al., 2010). The evaluation of this program consisted of a randomized controlled trial of the intervention, with randomization occurring at the family level. A total of 166 families were recruited into the study, and 103 (62 percent) and 88 were retained at six and 12 months, respectively. The participants in the study were all minorities and largely impoverished, with about half of the children scoring in the clinical range for child posttraumatic stress disorder (PTSD) symptoms and about three-quarters of caregivers reporting parenting stress in the clinical range at baseline. Those who participated in the intervention arm received an array of services, with the vast majority completing multidisciplinary assessments and case management, and a majority participating in dyadic therapy. Among families retained at six months, almost all (89 percent) received the multidisciplinary team assessment, developmental screening, and case management sessions, 80 percent received dyadic therapy, and 94 percent received case management referrals. Given the number of participants in this study, we had an 80-percent chance to detect a medium-to-large intervention effect of 0.56 at six months, when intervention services were still ongoing, and to detect a medium-to-large intervention effect of 0.61 at 12 months. Some significant improvements were observed in the intervention group over time in the behavior problems, parenting stress, and social-emotional competence domains, but they generally did not differ from changes observed in the control group. At 12 months, two differences between groups were observed in changes on primary outcome variables, but they were in opposite directions and did not persist once demographics were controlled. Examination of those who received low, medium, or high doses of the intervention services again revealed few statistically significant differences, despite changes in the expected direction, for the most part. Although it is possible that the services as implemented in this study were not effective in improving outcomes for children in the intervention group relative to controls, there are several other possible

explanations for the results presented here. The lack of difference between groups over time could reflect a sample size limitation—and thus a lack of statistical power to observe a small-to-medium intervention effect, intervention effects in the enhanced usual care arm of the study caused by contact and case management, increased recognition of symptoms as a function of the intervention, insufficient time to observe intervention effects, or a lack of a meaningful difference between the intervention and the control arms on the particular outcomes measured.

INTRODUCTION

The Bronx Safe Start program is located in the borough of the Bronx, New York. In 2003, more than 14,000 children were referred for abuse or neglect to child protective services in the Bronx (St. Barnabas Hospital, 2004).

Initial efforts to respond to the need for services for children victimized by abuse, neglect, and exposure to domestic violence included the creation of the St. Barnabas Hospital Children’s Advocacy Center in 2000 (St. Barnabas Hospital, 2004). However, in 2004, the Bronx Safe Start program was proposed to address ongoing service gaps, including (1) limited identification of children’s exposure to violence, (2) the lack of short- and long-term intervention services for this population, and (3) poor coordination of intervention service providers and services (St. Barnabas Hospital, 2004).

The Bronx Safe Start program was created in the spirit of the American Academy of Pediatrics “medical home,” a model of delivering primary care that is accessible, continuous, comprehensive, family centered, coordinated, compassionate, and culturally effective. Specifically, the goals of the program were to implement organizational changes within the Children’s Advocacy Center necessary to create the medical home model; to improve identification of children exposed to violence by domestic violence advocates, pediatricians, and child protective service workers; and to increase access to developmentally appropriate services for children and their families.

The Bronx Safe Start program sought to achieve these goals through the use of a multidisciplinary assessment, CPP, and case management. In prior evaluations of CPP, CPP showed medium intervention effects on PTSD symptoms and behavior problems (0.63 and 0.64, respectively; Lieberman, Van Horn, and Ghosh Ippen, 2005). However, this particular mix of services had not been evaluated previously.

The outcomes evaluation detailed here presents data relevant to the question of whether the Bronx Safe Start program, as implemented within this project, improves outcomes for children exposed to violence.

BRONX SAFE START

- **Intervention type:** Medical home for children exposed to violence, including multidisciplinary assessment, CPP, and case management
- **Intervention length:** One year or longer
- **Intervention setting:** Hospital clinic-based services
- **Target population:** Children living in the Bronx who were exposed to, experienced, or witnessed family or community violence
- **Age range:** 0–6
- **Primary referral sources:** St. Barnabas Hospital pediatricians, Children’s Advocacy Center, and Emergency Department; mental health and domestic violence agencies

INTERVENTION

The medical home included three components: multidisciplinary assessments, CPP, and intensive case management. The intervention period lasted approximately one year, but families were welcome to return to the medical home at any point to receive additional help. All services were provided in a clinic setting. The program elements are described briefly below. For a full description of the Safe Start intervention as it was delivered, see Schultz et al. (2010).

The intervention began with a preliminary multidisciplinary assessment to determine the needs and strengths of each child and family. The initial multidisciplinary assessment included developmental and behavioral pediatrics, psychosocial, and medical evaluations, as well as assessment scores from the research evaluation. The developmental pediatric evaluation was conducted initially as part of the multidisciplinary assessment evaluation to establish a baseline for the child. It included standard developmental screenings to assess motor skills, language skills, and achievement for older children. A psychologist and social worker conducted a psychosocial evaluation of the family that included behavioral observations and administration of the Child Behavior Checklist (CBCL; Achenbach, 1991).

After completion of the multidisciplinary assessment, the team met to discuss their findings, determine provisional diagnoses, develop the individualized treatment plan, and produce a summary report, which was later discussed with the family. The report was used to guide ongoing treatment and was reviewed quarterly by the

assessment team. If developmental or behavioral needs were identified, the children were followed as often as considered necessary. At any time, families could decline services or postpone them for a later time as desired.

The therapeutic component involved parent-child dyadic therapy using the Lieberman model for CPP. CPP is a relationship-based intervention designed for use with children up to age six. It can be used with any parent-child dyad whose relationship has been impacted by negative circumstances, including family violence. CPP integrates psychodynamic, attachment, trauma, cognitive-behavioral, and social learning theories (National Child Traumatic Stress Network, 2008). There are two components in CPP: assessment and treatment, with information gained during the assessment used to inform the treatment component. In the intervention component, child-parent interactions are the focus of six intervention modalities aimed at restoring a sense of mastery, security, and growth and promoting congruence between bodily sensations, feelings, and thinking on the part of both child and parent and in their relationship with one another (National Child Traumatic Stress Network, 2008). This therapy was delivered on a weekly basis for up to a year.

The Bronx Safe Start program also included intensive case management. A family coordinator (social work assistant) was hired to assist with this component. Case management activities were performed to coordinate services for the families, to prevent duplication of services when dealing with community agencies, and to support families in getting their needs met. A social worker, therapist, and family coordinator engaged in ongoing assessment of the family's needs and provided support and referrals for services. Specifically, program staff conducted pre-intake activities (e.g., calling families to confirm an appointment one or two days in advance) and post-intake activities (e.g., helping to arrange services, helping to maintain the family in services by checking on whether families were continuing in services).

Efforts to monitor the quality of the program included the Bronx Safe Start staff participating in an initial three-day training on CPP with one of the model developers. Throughout the implementation, the service providers had access to materials that described the treatment model, the Safe Start program, and the implementation plans. The model developer initially provided biweekly phone consultation and supervision, increased to once weekly and continued at this rate for the remainder of the project, alternating between the developer and another expert. A licensed clinical social worker with the Children's Advocacy Center provided an additional hour of on-site clinical supervision once weekly, reviewed all case notes, and participated in each multidisciplinary team meeting.

METHOD

Design Overview

The design of this study was a block randomized controlled trial, with randomization occurring at the family level within age groups (0–2 years or 3–6 years old) and eligible children recruited after families were referred to the program. Families assigned to the treatment condition entered the medical home to receive services within the program for as long as they needed them. Families in the control group received enhanced usual care, including follow-up calls every other month to provide support and referrals. All families were provided with a detailed community resources guide created by the Bronx Safe Start program, which was updated regularly. Child outcomes and contextual information were assessed at baseline, six, 12, 18, and 24 months. The study reported here took place between July 2006 and July 2010. A previous version of this report covering the period of July 2006 through October 2009 was completed earlier. This report updates the earlier report by adding data collected during the nine-month extension.

Evaluation Eligibility Criteria

Families were required to be proficient in either English or Spanish. Children age 6 or younger who lived in the Bronx and had been exposed to, experienced, or witnessed family or community violence that resulted in (1) injury or hospitalization of the child; (2) injury, hospitalization, or death of a parent or anyone close to the child; (3) the child seeing the injury or death of anyone in the community; or (4) the child feeling threatened and/or in danger of being injured or killed were eligible for the Safe Start program.

Additionally, eligibility for the CPP component required meeting one or more of the following criteria: (1) a parent and/or the Safe Start Treatment Team are concerned about the child's behaviors or symptoms; (2) the child's symptoms of psychological, behavioral, or emotional distress have persisted for more than three months; (3) the child's caretaker is unable to be emotionally attuned to the child's needs; (4) the child was exposed to, experienced, or witnessed, severe family or community violence that resulted in injury or hospitalization of the child; resulted in injury, hospitalization, or death of a parent or anyone close to the child; or resulted in the child seeing the severe injury or death of anyone in the community; (5) the child has a score on the Trauma Symptom Checklist for Young Children (TSC-YC) that falls within the ranges for having borderline or significant symptoms of PTSD; (6) the parent has a score on the Parenting

Stress Index—Short Form (PSI-SF) that fall within the 80th percentile or above; (7) the child has a score on the Social Skills Rating System (SSRS) score of “fewer” for the scales for cooperation, assertion, or self-control; or (8) the child has a score on the Brief Infant Toddler Social Emotional Assessment (BITSEA) that is “of concern.”

When more than one child in a family was in the eligible age range, the target child who would be the focus of the research assessments was selected by the child’s mother, based on who she perceived had the greatest need. However, if a child with the greatest need could not be identified, the child with the closest birth date to the date of enrollment was selected as the target child for the evaluation.

Randomization Procedures

On enrollment into the study, the children were randomized into intervention or control groups using a block randomization procedure that allowed for approximately the same number of children in the intervention and control groups (see Chapter Four of the main document [http://www.rand.org/pubs/technical_reports/TR991-1.html]). Because of the possibility that the impact of the intervention could differ by child age, the sample was stratified into two groups. One group of children was recruited from birth up to 3 years of age and the other group of children between 3 and 6 years old.

Measures

The measures used in this study are described fully in Chapter Two of the main document (see http://www.rand.org/pubs/technical_reports/TR991-1.html). The measures were uniform across the national evaluation but prioritized within each site as to the relevance to the intervention under study. Given the nature of the Bronx Safe Start intervention, the outcomes were prioritized as shown in Table 1.

Table 1
Prioritized Outcome Measures for Bronx Safe Start

Primary Outcome Measures			
<i>Domain</i>	<i>Source/Measure</i>	<i>Age of Child</i>	<i>Respondent</i>
PTSD Symptoms	Trauma Symptom Checklist for Young Children	3–6 years	Caregiver
Behavior/Conduct Problems	BITSEA and Behavior Problem Index	1–6 years	Caregiver
Social-Emotional Competence	ASQ	0–2 years	Caregiver
Social-Emotional Competence	BITSEA and SSRS (Assertion and Self-Control)	1–6 years	Caregiver
Caregiver-Child Relationship	BERS-2 (Family Involvement)	6 years	Caregiver
Caregiver-Child Relationship	Parenting Stress Index	All	Caregiver
Violence Exposure	Caregiver Victimization Questionnaire	All	Caregiver
Secondary Outcome Measures			
<i>Domain</i>	<i>Measure</i>	<i>Age of Child</i>	<i>Respondent</i>
Social-Emotional Competence	BERS-2 (School Functioning, Affective Strengths)	6 years	Caregiver
Social-Emotional Competence	SSRS (Cooperation)	3–6 years	Caregiver
Violence Exposure	Juvenile Victimization Questionnaire	All	Caregiver
Tertiary Outcome Measures			
<i>Domain</i>	<i>Measure</i>	<i>Age of Child</i>	<i>Respondent</i>
School Readiness/Performance	Woodcock-Johnson III	3–6 years	Child
Background and Contextual Factors	Everyday Stressors Index	All	Caregiver

NOTE: ASQ = Ages and Stages Questionnaire, BERS-2 = Behavior and Emotional Rating Scales—2, BITSEA = Brief Infant-Toddler Social and Emotional Assessment, SSRS = Social Skills Rating System.

Enrollment and Retention

Bronx Safe Start received most of its referrals from St. Barnabas Hospital pediatricians, the Children’s Advocacy Center, the Emergency Department, and mental health and domestic violence agencies. When referrals were received or clients walked in, program staff met with the family to complete the intake process, provided necessary support and referrals for services, and completed the baseline assessment with eligible families who consented to participating in the program. Often some initial case management (e.g., referrals to community resources) occurred prior to enrollment in the Safe Start program to address crisis issues with the families. After the assessment, the project manager implemented the random assignment procedures and informed the family and the referral source.

According to data submitted on its Quarterly Activity Reports through the fall of 2009, Bronx Safe Start enrolled 54 percent of the families referred to the program. The

most common reasons that families did not enroll were caregiver-related issues, such as lack of interest (50 percent), lack of time (19 percent), and other issues (31 percent).

In Table 2, we present the number and percentage of all enrollees who were eligible for participation at each data collection time point. At a minimum, a completed caregiver packet is necessary for a family to be included in the outcome analyses. Overall, Bronx Safe Start was able to retain just over 60 percent of families at the first three follow-up assessments (at six, 12, and 18 months) and slightly over half at the 24-month assessment.

Table 2
Retention of Enrollees Eligible to Participate in Assessments at Each Time Point

	Caregiver Assessment				Child Assessment			
	6 Months	12 Months	18 Months	24 Months	6 Months	12 Months	18 Months	24 Months
Intervention								
Received	57	47	35	22	47	42	33	21
Expected*	89	75	56	40	72	73	54	39
Retention Rate	64%	63%	63%	55%	65%	58%	61%	54%
Control								
Received	46	41	28	16	38	39	27	15
Expected*	77	64	47	31	61	63	47	31
Retention Rate	60%	64%	60%	52%	62%	62%	57%	48%
Overall								
Retention Rate	62%	63%	61%	54%	64%	60%	59%	51%

* The number of expected assessments for longer-term assessments differs from the number who entered the study because the field period for collecting data in this study ended before all families entered the window of time for assessments at 12, 18, or 24 months.

Special Issues

The Bronx Safe Start program had slower-than-expected enrollment into the project and struggled with retention of families over time. In addition, the program developed strategies to engage families in the control condition via bimonthly phone calls and limited case management as needed to keep families safe. For a full discussion of the program implementation, see Schultz et al. (2010).

Analysis Plan and Power Calculations

First, we conducted descriptive analyses to summarize the sample baseline characteristics: age, gender, race or ethnicity, family income, child’s violence exposure, and the outcome variables. Because this was a randomized experimental design, we did not expect any major differences between the two groups at baseline. However, to be

certain, we tested for differences in child and caregiver characteristics between intervention and control group children using t-tests and chi-square tests.

To assess the effect of the Safe Start intervention, we primarily examined differences between children in the intervention and control groups at six months. It is important to consider the power this study has for such an analysis. One way to describe power is by using the effect size difference between the two groups being compared. The effect size is a standardized measure of the strength of association between an intervention and an outcome and is defined as the average difference in an outcome between the intervention and control groups divided by the common standard error. The effect size measure is commonly classified as small if it is about 0.2, medium if it is about 0.5, and large if it is about 0.8 (Cohen, 1998).

At the nominal 0.05 significance level, with 103 children observed at both baseline and six months, with 57 of them in the intervention and 46 in the control group, we can expect only a 17-percent chance to detect a small intervention effect and a 70.5-percent chance to detect a medium intervention effect, but we will have an 80-percent chance to detect a medium-to-large intervention effect. CPP has been demonstrated to have medium intervention effects on PTSD symptoms and behavior problems (0.63 and 0.64, respectively) in prior studies (Lieberman, Van Horn, and Ghosh Ippen, 2005). However, within the intervention model under study here, not all families would receive CPP, and many would also receive intensive case management and other services. Thus, the effect size expected was difficult to estimate, but we expected it might be medium. Given the sample size in this study, there was an 80-percent chance (the usual nominal) to detect a medium to large intervention effect of size 0.561, similar to the intervention effect observed in previous studies. However, given that the intervention length was open-ended and could last a year or more, full intervention effects may not be observed at six months. For the 12-month follow-up with 88 (47 intervention, 41 control) participants remaining in the study, we have an 80-percent chance to detect an intervention effect of 0.605 or more, a medium-to-large effect size according to Cohen's 1988 effect size classification. Statistical power was dampened by several factors other than overall sample size. The range of children's ages meant that the full data were not available for some measures because not all children were in the age range eligible to complete that measure. Further, the corrections for the multiple statistical tests being conducted also reduced power. The low statistical power in this study must be kept in mind in interpreting results.

We examined differences between the intervention and control groups using an intent-to-treat approach, which includes in analyses all those assigned to the

intervention group, regardless of the amount of services received. As discussed in Chapter Four of the main document (see http://www.rand.org/pubs/technical_reports/TR991-1.html), comparisons of a control group only to those who complete services (or receive a predetermined amount of services) is likely to bias results. That is, those that do not engage in services or drop out prior to completion may be systematically different than those who remain. Ideally, analyses would take into account the type and amount of services received to account for dosage variability. We explore this issue of “dose” of intervention as described in the following paragraphs.

To examine differences between the intervention and control groups using the intent-to-treat approach described above, we present baseline and follow-up estimates of primary, secondary, and tertiary outcomes for both groups when the sample size is greater than or equal to five. We compare groups via chi-square or t-tests at each time point, compare means within groups across time, and examine difference in differences to comparing the two groups on changes over time between baseline and the six- and 12-month assessments (when the sample size is at least ten per group). Where the sample size is over 20 in each group (i.e., at the six- and 12-month follow-up), we conducted multiple linear regressions on the different continuous outcomes and linear probability regressions on the dichotomous outcomes to test for the difference in difference via main effects and the interaction between intervention status and time after controlling for baseline characteristics (parent and child age, gender, race, and exposure to violence). These baseline characteristics were selected to correct for any potential imbalance in the groups by relevant demographic characteristics.

To examine outcomes related to the as-treated sample, those families that took part in the intervention services offered, we examined the outcome means for families that took part in the intervention services offered, broken down into groups that received a low dose of the intervention, a medium dose, and a high dose. Since children with more need are likely to receive more services, we would expect this selection scheme to possibly present an unforeseeable bias, with families more in need receiving more services. To account for this selection bias related to service dosage, we used the propensity score-matching method to pair families in each dosage group with families with similar needs in the control group. The matching paired families based on similar baseline scores on the outcome measure of interest. The analyses then examined the difference in differences between the intervention and control groups for each dosage group at follow-up. Note that in this analysis, the full control group is used in the matching of each of the dosage levels. We examine only primary outcomes with this method, in recognition that it is exploratory and preliminary.

When conducting large numbers of simultaneous hypothesis tests (as we did in this study), it is important to account for the possibility that some results will achieve statistical significance simply by chance. The use of a traditional 95-percent confidence interval, for example, will result in one out of 20 comparisons achieving statistical significance as a result of random error. We therefore adjusted for false positives using the False Discovery Rate (FDR) method (Benjamini and Hochberg, 1995). Our assessments of statistical significance were based on applying the FDR procedure separately to all of the primary, secondary, and tertiary outcome tests in this report using an FDR of 0.05. For instance, with 11 test models with covariates conducted among the primary outcomes, this led to adopting a statistical significance cutoff of 0.005 in the covariate-adjusted difference in difference results. With only six secondary outcomes with enough sample sizes to allow for modeling with covariates, the FDR significance level adopted was 0.008, while such significance level was set at 0.010 for the tertiary outcomes (only five outcomes). In the discussion of results, we have also identified nonsignificant trends in the data, defined as those tests with p-values of less than 0.05 but not exceeding the threshold established using the FDR method to adjust for multiple significance tests. While these trends may suggest a practical difference that would be statistically significant with a larger sample size, they must be interpreted with caution because we cannot rule out that the difference was due to chance because of the multiple significance tests being conducted.

Table 3
Bronx Safe Start Sample Characteristics for Families in the Baseline Assessment Sample*

	Combined		Intervention		Control		Test for Comparison P-Value
<i>Child Characteristics</i>	<i>N</i>	<i>Mean</i>	<i>N</i>	<i>Mean</i>	<i>N</i>	<i>Mean</i>	
Age	166	4.3	89	4.2	77	4.4	0.56
CR Violence Exposure	166	3.5	89	3.4	77	3.7	0.36
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	
<i>Gender</i>							
Male	104	62.7	54	60.7	50	64.9	0.57
Female	62	37.3	35	39.3	27	35.1	
<i>Race/Ethnicity</i>							
Hispanic	115	69.3	58	65.2	57	74.0	0.34
Black	27	16.3	15	16.9	12	15.6	
Other	24	14.5	16	18.0	8	10.4	
<i>Caregiver Characteristics</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	
<i>Family Income Level</i>							
Less than \$5,000	46	39.0	27	45.0	19	32.8	0.19
\$5,000–\$10,000	31	26.3	14	23.3	17	29.3	
\$10,001–\$15,000	12	10.2	9	15.0	3	5.2	
\$15,001–\$20,000	6	5.1	2	3.3	4	6.9	
\$20,001–\$30,000	9	7.6	3	5.0	6	10.3	
More than \$30,000	14	11.9	5	8.3	9	15.5	
<i>Relationship to Child</i>							
Parent-Guardian	163	98.2	88	98.9	75	97.4	0.48
Other Relationship	3	1.8	1	1.1	2	2.6	

NOTE: CR = Caregiver Report. Percentages may not total 100 percent because of rounding.

RESULTS

Baseline Descriptive Statistics

For the descriptive statistics, we provide the characteristics for the full enrolled sample at baseline, where the sample size is large enough to examine differences across time. As shown in Table 3, the baseline sample was composed of 63 percent males and had an average age of 4.3 years (range 0–7, with 80 percent of children ages 3–6). Children in the sample were described by caregivers as predominately Hispanic (69 percent) with some black (16 percent) or other race/ethnicity children (15 percent). Most children’s families had low incomes. Caregivers reported that the children had been exposed to an average of 3.5 types of violence in their lives prior to the baseline assessment. There were no significant differences between families in the intervention group as compared with families in the control group at baseline. In the sample of families that were retained at six months, the demographics were similar to those at

baseline, again with no statistically significant differences between the intervention and control group (data not shown).

We also examine the Bronx sample at baseline on two outcomes (PTSD symptoms and parenting stress) to describe the level of severity on these indexes among families entering the project (Table 4). At baseline, caregivers of 46 percent of boys reported PTSD symptoms in the “significant” range, as did caregivers of 53 percent of girls. For the caregiver-child relationship, 73 percent of the sample had total stress levels that fell in the “clinical” range (76 percent for boys and 68 percent for girls). For the different subscales, 63 percent of the sample had clinical levels on the parental distress subscale, 50 percent had clinical levels on the parent-child dysfunctional interaction subscale, and 66 percent had clinical levels on the difficult child subscale.

Table 4
Baseline Assessment Estimates for Bronx Safe Start Families

	Combined		Boys		Girls	
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
CR PTSD Symptoms for Ages 3–10						
Normal	54	41.2	36	42.9	18	38.3
Borderline	13	9.9	9	10.7	4	8.5
Significant	64	48.9	39	46.4	25	53.2
CR Total Parenting Stress for Ages 0–12						
Parental Distress—Clinical	104	62.7	64	61.5	40	64.5
Parent-Child Dysfunctional Interaction—Clinical	83	50.0	54	51.9	29	46.8
Difficult Child—Clinical	110	66.3	70	67.3	40	64.5
Total Stress—Clinical	121	72.9	79	76.0	42	67.8

NOTE: CR = Caregiver Report.

Finally, we examined differences between the intervention and control group at baseline for Bronx’s primary, secondary, and tertiary outcomes (see this report’s appendix). Primary outcomes included PTSD symptoms, behavioral problems, some aspects of social-emotional competence, caregiver victimization, and parenting stress. No statistically significant differences were observed between the groups overall on these measures (see Table A.1, first column). Likewise, no statistically significant differences or trends were observed between the intervention and control groups in relation to secondary or tertiary outcome variables at baseline (see Tables A.2, and A.3, first column).

Uptake, Dosage, and Process of Care

Family-level service data were recorded by the program on the follow-up Family Status Sheet and submitted at six-month intervals following initial enrollment (see Chapter Two of the main document [http://www.rand.org/pubs/technical_reports/TR991-1.html] for a description). Tables 5a and 5b below show the type and amount of services received by the families assigned to the intervention group. As described fully in the program implementation report (Schultz et al., 2010), the Bronx Safe Start intervention services began with a multidisciplinary assessment and were followed with services tailored to the families' needs based upon that assessment.

Table 5a presents the results for services received for all families who were initially enrolled in the intervention group, regardless of whether they continued to participate in the ongoing research assessments. The data displayed in Table 5a include services received by summing all time points reported by the program, with a maximum of 24 months of service provision. Service data for at least one follow-up wave were available on 88 of the 89 initial Bronx intervention group enrollees. As shown in Table 5a, the majority of these families (75 percent) received the multidisciplinary team assessment. About 74 percent received case management referrals to other sources of service or assistance. Sixty-four percent received dyadic therapy, and 83 percent received direct case management service sessions (i.e., phone or in-person interaction with clients or service providers for service coordination and support), with an average of 17 or 14 sessions, respectively, of each type delivered for those that participated. A much smaller percentage received follow-up pediatric care or developmental assessment within the Safe Start program (11 percent and 12 percent, respectively).

The program reported information on the reason that the services ended for 76 of the 88 families who received any combination of Safe Start services. Of these, all families were reported to have successfully completed the developmental screening, but only 25 (32 percent) were reported to have successfully completed all the intervention components in which they participated after that, with the others dropping out or otherwise ending services early.

Table 5a
Services Received by Bronx Safe Start Intervention Families (Baseline Sample)

Service	Number with Service	Percentage with Service*	Range	Distribution	Mean	Median
Dyadic Therapy (CPP)	56	64%	1-46	1-4 27% 5-12 21% 13-27 25% 28+ 27%	17	13
Case Management	73	83%	1-74	1-2 26% 3-6 23% 7-16 26% 17+ 22%	14	6
Multidisciplinary Team Meeting and Developmental Screening	66	75%	1-6	1 39% 2 30% 3-4 14% 5-6 17%	2	1
Case Management Referrals	65	74%	1-22	1-2 26% 3-4 23% 5-9 28% 10+ 23%	6	4
Pediatric Care	10	11%	1-8	1-2 80% 3-8 20%	2	1
Developmental Follow-Up Visit	12	14%	1-9	1 67% 2-6 17% 7-9 16%	3	1

* The denominator is the 88 intervention group families with a follow-up Family Status Sheet at the six-month assessment point.

NOTE: Percentages may not total 100 percent because of rounding.

Table 5b shows the services received by that subgroup of intervention group families who participated in the six-month follow-up research assessment. These are the 57 families included in the intervention group in the six-month analysis sample for the Bronx program. Table 5b shows the services they received within the six-month period between baseline and the six-month assessment. Almost all (89 percent) of these families received the multidisciplinary team assessment, developmental screening, and case management sessions, whereas 80 percent received dyadic therapy and 94 percent received case management referrals. Service ending data were reported on only 41 of the 57 families shown in Table 5b, with all families reported as having successfully completed the developmental screening but 37 percent of them dropping out or otherwise ending services early afterwards.

Table 5b
Six-Month Services Received by Bronx Safe Start Intervention Families (Six-Month Analysis Sample)

Service	Number with Service	Percentage with Service*	Range	Distribution	Mean	Median
Dyadic Therapy (CPP)	46	80%	1–24	1–4 24% 5–8 20% 9–12 28% 13+ 28%	10	9
Case Management	53	94%	1–61	1–2 26% 3–6 36% 7–16 17% 17+ 21%	11	5
Multidisciplinary Team Meeting and Developmental Screening	51	89%	1–4	1 47% 2 39% 3 10% 4 4%	2	1
Case Management Referrals	41	72%	1–17	1–2 27% 3–4 29% 5–9 24% 10+ 20%	6	4
Pediatric Care	8	14%	1–6	1 75% 2–6 25%	2	1
Developmental Follow-Up Visit	2	4%	1–3	1 50% 3 50%	2	1

* The denominator is the 57 intervention group families with a follow-up Family Status Sheet at the six-month assessment point who participated in the six-month research assessment.
 NOTE: Percentages may not total 100 percent because of rounding

Outcomes Analysis

We begin by examining differences in primary, secondary, and tertiary outcomes between the intervention and control group at each follow-up assessment point. We then analyze changes in mean scores over time both within the intervention and control groups and between the groups. For these analyses, we used an intent-to-treat approach that included all families allocated to the intervention, regardless of the level of service they received. Finally, we present descriptive data on intervention group families that received varying levels of services, as compared to similar controls, on primary outcomes only.

Comparison of Means

A summary of differences between the intervention and control group at each assessment point for Bronx's primary, secondary, and tertiary outcomes are depicted in this report's appendix (Tables A.1, A.2, and A.3).

Primary outcomes included PTSD symptoms, behavioral problems, some aspects of social-emotional competence, caregiver victimization, and parenting stress. There were not enough data to examine personal and social competence for children age 2 and younger. At the six-month follow-up assessment, no statistically significant differences were observed between the groups overall on these measures. However, one observable nonsignificant trend was noted in which caregivers in the intervention group were more likely to report exposure to any non-domestic violence trauma than those in the control group. However, because of the multiple significance tests being conducted, this trend did not reach statistical significance and thus may be due to chance. Further, there were no statistical differences or trends observed between the intervention and control groups at the 12-, 18-, or 24-month assessment points.

Secondary outcomes include some aspects of social-emotional competence and child victimization (see Table A.2). No statistically significant differences were observed between the groups overall on these measures. However, two observable nonsignificant trends were noted in which caregivers in the intervention group reported higher levels of child affective strengths and better functioning at 24 months. However, because of the multiple significance tests being conducted, this trend did not reach statistical significance and thus may be due to chance. There were no differences or trends noted between the intervention and control groups at six, 12, or 18 months. A summary of differences between the intervention and control group at each assessment point for Bronx's tertiary outcomes is depicted in Table A.3. Tertiary outcomes include caregiver problems and child school readiness and performance. No statistically significant differences or trends were observed between the intervention and control groups in relation to the tertiary outcome variables at any time point examined.

Mean Differences over Time

Table 6 shows differences over time for Bronx's primary outcomes, comparing changes for each individual family between baseline and six months. Primary outcomes included child PTSD symptoms and behavior problems, caregiver victimization, and aspects of social-emotional competence and caregiver-child relationship. In the second column of numbers in Table 6, the mean change between six-month scores and baseline scores is shown for each group. The comparison here is whether there was significant

change on the outcomes for the families in each group separately (rather than a comparison of one group with the other). Statistically significant changes in scores within groups were observed on several primary outcome variables, including reductions in the caregiver's report of child behavioral problems (intervention and control groups); scores on the difficult child, parent-child dysfunction, and total parenting stress scales (intervention only); and the caregiver's report of experience of any domestic violence (both groups), as well as significant increases in the caregiver's report of child self-control (intervention only). Decreases in the caregiver's own experience of victimization would be expected to decrease because of time frame differences: The assessment at baseline was for the year prior to entering the project, whereas the assessment at six months was for victimization in the six months between the two assessments. In addition, observable nonsignificant trends were noted for the caregiver's report of total traumatic events experienced (intervention and control groups), improvements in child assertion (intervention only), some aspects of the caregiver's report of parenting stress, and the caregiver's report of own exposure to non-domestic violence traumatic events. The statistical test of differences in differences in unadjusted models (third column in Table 6) compares the amount of mean change for the intervention group families with the amount of mean change for the control groups between the baseline and six-month assessment. These comparisons revealed no statistically significant differences in change between intervention and control groups at six months (third column in Table 6), even when covariates were included (fourth column in Table 6).

At 12 months, 11 significant differences were observed within groups in changes between the baseline assessment and the 12-month follow-up as well (data not shown): nine in the intervention group and two in the control group (see the second column in Table 9). However, at 12 months, the differences in differences analysis showed two significant differences over time between groups (see the third column in Table 9): Caregivers in the control group reported larger decreases in their reports of domestic violence than the intervention group, whereas caregivers in the intervention group reported larger decreases in parent-child dysfunction than those in the control group. These differences did not persist once covariates were included in the models (fourth column in Table 9). There was also one nonsignificant trend in the data, showing larger decreases in total parenting stress in the intervention group than in the control group between baseline and 12 months, but this finding did not persist once the correction for multiple tests was used.

At 18 months, we again observed within-group changes between the baseline and the follow-up assessment, with nine observed in the intervention group versus four in the control group (data not shown). At the 18-month assessment, one significant difference in difference was observed, with the intervention group reporting larger decreases in caregiver exposure to domestic violence than the control group, but, again, this finding did not persist once covariates were included in the model.

At 24 months, seven differences between baseline and the follow-up were observed in the intervention group, compared with one in the control group, but no statistically significant difference in differences were observed (data not shown). The sample size did not allow for models including covariates at this follow-up point.

Table 7 shows differences in mean scores over time for Bronx's secondary outcomes. Secondary outcomes included aspects of social-emotional competence and the child's exposure to violence. The second column of results shows within-family mean changes between six-month and baseline scores for each group. Statistically significant changes in scores were observed in both groups on several secondary outcomes in the caregiver report of child's violence exposure domain, including reductions in total types of victimization experiences, assault, maltreatment, and witnessing of violence, as would be expected given differences in the timeframe (at baseline assessments covered the child's entire life, whereas at six months they covered just the time period between the two assessments). The statistical test of differences in differences in unadjusted models (third column in Table 7) that compares the two groups on within-family mean changes from baseline to six months revealed no statistically significant differences. However, one observable nonsignificant trend was noted between intervention and control groups. For the caregiver's report of the child's school functioning, the intervention group reported improvement, whereas the control group reported decreases on average. However, because of the multiple significance tests being conducted, this trend did not reach statistical significance and thus may be due to chance. In adjusted models (fourth column in Table 7), there were again no statistically significant differences.

The same pattern of results was observed in the 12-month and 18-month assessments, with significant decreases on four of the five violence exposure measures over time in both the intervention and control groups (see Table 10 for 12-month outcomes; 18-month data are not shown). Reductions on these measures would be expected given the timeframes on the scales, with the baseline report framed to cover lifetime exposure to different types of violence, and the 12-month assessment covering exposure to those same types of violence during the period since the prior assessment.

In addition, at both waves, there was a reduction in child cooperation reported by caregivers in the control group (see Table 10). At 24 months, a similar pattern was seen in terms of decreases in child violence exposure, but this time the change in child cooperation was noted in the intervention group but not the control group. However, there were no observed differences in differences in unadjusted or adjusted models (see Table 10 for 12-month outcomes; other data are not shown) at any time point.

Table 8 shows differences over time for Bronx's tertiary outcomes. Tertiary outcomes included caregiver resource problems and the child's school readiness/performance. For both the intervention and control group, there were no statistically significant within-family mean changes in scores from baseline to six months. However, two nonsignificant trends were observed in changes in reductions in caregiver report of personal problems and changes in child performance on the letter-word identification test. Further, the statistical tests in unadjusted and adjusted models that compare the two groups on within-family mean changes from baseline revealed no differences at six months, although there was a nonsignificant trend for differences in caregiver personal problems in unadjusted models. However, because of the multiple significance tests being conducted, these trends did not reach statistical significance and thus may be due to chance.

At 12 months, there was a statistically significant decrease observed in the child's performance on the passage comprehension test over time within both groups, as well as significant decreases in caregiver reports of personal and resource problems in the intervention group, but no observed differences in differences or differences in unadjusted or adjusted models (see Table 11). At 18 and 24 months, these changes in performance in the passage comprehension test were again observed in both groups, as well as a decrease in caregiver report of personal problems at 12 months and significant changes in performance on the applied problems test at 24 months. However, there were no observed differences in differences in unadjusted or adjusted models (data not shown) at either time point.

Table 6
Changes in Means for Primary Outcome Variables Between Baseline and Six-Month Assessment and
Group-Level Comparison of Mean Changes

Primary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
PTSD Symptoms					
CR Child PTSD Symptoms for Ages 3–10	Intervention	47	–2.04	1.34	1.81
	Control	37	–3.38		
Behavior/Conduct Problems					
CR Child Behavior Problems for Ages 1–18	Intervention	53	–0.43 *	–0.15	–0.44
	Control	46	–0.28 *		
Social-Emotional Competence					
CR Child Assertion for Ages 1–12	Intervention	52	0.20 #	0.08	0.26
	Control	45	0.11		
CR Child Self-Control for Ages 1–12	Intervention	52	0.31 *	0.19	0.39
	Control	45	0.12		
Caregiver-Child Relationship					
CR Parental Distress for Ages 0–12	Intervention	57	–2.35 #	–1.00	–1.18
	Control	46	–1.35		
CR Parent-Child Dysfunction for Ages 0–12	Intervention	57	–3.04 *	–2.12	–2.15
	Control	46	–0.91		
CR Difficult Child for Ages 0–12	Intervention	57	–4.39 *	–2.04	–4.28
	Control	46	–2.35 #		
CR Total Parental Stress for Ages 0–12	Intervention	57	–9.77 *	–5.16	–7.61
	Control	46	–4.61 #		
CR Family Involvement for Ages 6–12	Intervention	12	2.58	2.01	
	Control	14	0.57		

Table 6—continued

Primary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
Violence Exposure					
CR Caregiver Total Number of Traumatic Experiences	Intervention	57	-0.14 #	0.08	0.04
	Control	46	-0.22 #		
CR Caregiver Experience of Any Non-DV Traumas ^d	Intervention	57	0.05	0.14	0.13
	Control	46	-0.09 #		
CR Caregiver Experience of Any Domestic Violence ^d	Intervention	57	-0.46 *	0.11	0.02
	Control	46	-0.57 *		

^a This column reflects within-family mean changes between the baseline and six-month scores for each group separately. * indicates a significant paired t-test of differences over time.

^b This column reflects the group-level comparison of within-family mean changes from baseline to six months. * indicates a significant t-test of group differences.

^c This column reflects the estimate of the difference between the two groups' within-family mean change from baseline to six months, controlling for age, gender, ethnicity, income, and violence exposure at baseline. * indicates a significant test for the estimate.

^d This outcome is a categorical variable, and the unadjusted within-family mean change and the group-level comparison are changes in proportion, while the covariate adjusted group-level comparison is the difference in proportions obtained from a linear probability model.

NOTES: CR = Caregiver Report, DV = domestic violence. # indicates a nonsignificant trend in the t-test (p<0.05 but does not meet the FDR correction threshold). Mean change estimates are not shown when the group size is fewer than ten, and comparisons are not shown when the group size is fewer than ten for either group. Adjusted model results are not shown when the group size is fewer than 20 for either group.

Table 7
Changes in Means for Secondary Outcome Variables Between Baseline and Six-Month Assessment and
Group-Level Comparison of Mean Changes

Secondary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
Social-Emotional Competence					
CR Child Affective Strengths for Ages 6–12	Intervention	12	1.17	0.10	
	Control	14	1.07		
CR Child School Functioning for Ages 6–12	Intervention	12	3.33	4.48 #	
	Control	14	-1.14		
CR Child Cooperation for Ages 3–12	Intervention	37	0.54	-0.31	1.63
	Control	34	0.85		
Violence Exposure					
CR Total Child Victimization Experiences for Ages 0–12	Intervention	57	-2.53 *	0.30	0.78
	Control	46	-2.83 *		
CR Child Maltreatment for Ages 0–12	Intervention	56	-0.66 *	0.08	0.34
	Control	46	-0.74 *		
CR Child Assault for Ages 0–12	Intervention	57	-0.44 *	0.15	0.26
	Control	46	-0.59 *		
CR Child Sexual Abuse for Ages 0–12	Intervention	56	-0.05	-0.01	0.00
	Control	45	-0.04		

Table 7—continued

Secondary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
CR Child Witnessing Violence for Ages 0–12	Intervention	57	-1.42 *	0.04	0.03
	Control	46	-1.46 *		

^a This column reflects within-family mean changes between the baseline and six-month scores for each group separately. * indicates a significant paired t-test of differences over time.

^b This column reflects the group-level comparison of within-family mean changes from baseline to six months. * indicates a significant t-test of group differences.

^c This column reflects the estimate of the difference between the two groups' within-family mean change from baseline to six months, controlling for age, gender, ethnicity, income, and violence exposure at baseline. * indicates a significant test for the estimate.

NOTES: CR = Caregiver Report. # indicates a nonsignificant trend in the t-test ($p < 0.05$ but does not meet the FDR correction threshold). Mean change estimates are not shown when the group size is fewer than ten, and comparisons are not shown when the group size is fewer than ten for either group. Adjusted model results are not shown when the group size is fewer than 20 for either group.

Table 8
Changes in Means for Tertiary Outcome Variables Between Baseline and Six-Month Assessment and Group-Level Comparison of Mean Changes

Tertiary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
Background and Contextual Factors					
CR Caregiver Resource Problems	Intervention	57	-1.58	-1.43	-2.37
	Control	46	-0.15		
CR Caregiver Personal Problems	Intervention	57	-2.09 #	-1.02	-3.73
	Control	46	-1.07		
School Readiness/Performance					
Letter Word Identification for Ages 3–18	Intervention	34	4.41 #	6.57 #	-0.27
	Control	31	-2.16		
Passage Comprehension for Ages 3–18	Intervention	39	-2.33	-0.27	-0.08
	Control	33	-2.06		
Applied Problems for Ages 3–18	Intervention	37	0.92	-0.19	-1.99
	Control	36	1.11		

^a This column reflects within-family mean changes between the baseline and six-month scores for each group separately. * indicates a significant paired t-test of differences over time.

^b This column reflects the group-level comparison of within-family mean changes from baseline to six months. * indicates a significant t-test of group differences.

^c This column reflects the estimate of the difference between the two groups' within-family mean change from baseline to six months, controlling for age, gender, ethnicity, income, and violence exposure at baseline. * indicates a significant test for the estimate.

NOTES: CR = Caregiver Report. # indicates a nonsignificant trend in the t-test ($p < 0.05$ but does not meet the FDR correction threshold). Mean change estimates are not shown when the group size is fewer than ten, and comparisons are not shown when the group size is fewer than ten for either group. Adjusted model results are not shown when the group size is fewer than 20 for either group.

Table 9
Changes in Means for Primary Outcome Variables Between Baseline and 12-Month Assessment

Primary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
PTSD Symptoms					
CR Child PTSD Symptoms for Ages 3–10	Intervention	38	–3.16	3.73	5.55
	Control	35	–6.89 *		
Behavior/Conduct Problems					
CR Child Behavior Problems for Ages 1–18	Intervention	47	–0.38 *	–0.12	0.12
	Control	41	–0.27		
Social-Emotional Competence					
CR Child Assertion for Ages 1–12	Intervention	45	0.41 *	0.14	–0.06
	Control	40	0.27 #		
CR Child Self-Control for Ages 1–12	Intervention	45	0.38 *	0.18	0.03
	Control	40	0.21		
Caregiver-Child Relationship					
CR Parental Distress for Ages 0–12	Intervention	47	–4.83 *	–2.66	–1.85
	Control	41	–2.17		
CR Parent-Child Dysfunction for Ages 0–12	Intervention	47	–3.62 *	–4.35 *	–2.52
	Control	41	0.73		
CR Difficult Child for Ages 0–12	Intervention	47	–4.49 *	–1.44	0.57
	Control	41	–3.05 #		
CR Total Parental Stress for Ages 0–12	Intervention	47	–12.94 *	–8.45 #	–3.80
	Control	41	–4.49		
CR Family Involvement for Ages 6–12	Intervention	10	2.80	3.30	2.30
	Control	14	–0.50		

Table 9—continued

Primary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
Violence Exposure					
CR Caregiver Total Number of Traumatic Experiences	Intervention	47	-0.28 *	-0.06	0.04
	Control	41	-0.22 #		
CR Caregiver Experience of Any Non-DV Traumas ^d	Intervention	47	-0.09	-0.01	-0.03
	Control	41	-0.07		
CR Caregiver Experience of Any Domestic Violence ^d	Intervention	47	-0.36 *	0.32 *	0.29 #
	Control	41	-0.68 *		

^a This column reflects within-family mean changes between the baseline and six-month scores for each group separately. * indicates a significant paired t-test of differences over time.

^b This column reflects the group-level comparison of within-family mean changes from baseline to six months. * indicates a significant t-test of group differences.

^c This column reflects the estimate of the difference between the two groups' within-family mean change from baseline to six months, controlling for age, gender, ethnicity, income, and violence exposure at baseline. * indicates a significant test for the estimate.

^d This outcome is a categorical variable, and the unadjusted within-family mean change and the group-level comparison are changes in proportion, while the covariate adjusted group-level comparison is the difference in proportions obtained from a linear probability model.

NOTES: CR = Caregiver Report, DV = domestic violence. # indicates a nonsignificant trend in the t-test (p<0.05 but does not meet the FDR correction threshold). Mean change estimates are not shown when the group size is fewer than ten, and comparisons are not shown when the group size is fewer than ten for either group. Adjusted model results are not shown when the group size is fewer than 20 for either group.

Table 10
Changes in Means for Secondary Outcome Variables Between Baseline and 12-Month Assessment

Secondary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
Social-Emotional Competence					
CR Child Affective Strengths for Ages 6–12	Intervention	10	0.60	0.60	
	Control	14	0.00		
CR Child School Functioning for Ages 6–12	Intervention	10	2.30	3.59	
	Control	14	-1.29		
CR Child Cooperation for Ages 3–12	Intervention	32	0.69	-1.03	-0.45
	Control	32	1.72 *		
Violence Exposure					
CR Total Child Victimization Experiences for Ages 0–12	Intervention	47	-2.38 *	0.96	1.01
	Control	41	-3.34 *		
CR Child Maltreatment for Ages 0–12	Intervention	47	-0.51 *	0.39	0.53 #
	Control	41	-0.90 *		
CR Child Assault for Ages 0–12	Intervention	47	-0.40 *	0.33	0.28
	Control	41	-0.73 *		
CR Child Sexual Abuse for Ages 0–12	Intervention	46	-0.02	0.05	0.07
	Control	40	-0.08		

Table 10—continued

Secondary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
CR Child Witnessing Violence for Ages 0–12	Intervention	47	-1.45 *	0.27	0.23
	Control	39	-1.72 *		

^a This column reflects within-family mean changes between the baseline and six-month scores for each group separately. * indicates a significant paired t-test of differences over time.

^b This column reflects the group-level comparison of within-family mean changes from baseline to six months. * indicates a significant t-test of group differences.

^c This column reflects the estimate of the difference between the two groups' within-family mean change from baseline to six months, controlling for age, gender, ethnicity, income, and violence exposure at baseline. * indicates a significant test for the estimate.

NOTES: CR = Caregiver Report. # indicates a nonsignificant trend in the t-test ($p < 0.05$ but does not meet the FDR correction threshold). Mean change estimates are not shown when the group size is fewer than ten, and comparisons are not shown when the group size is fewer than ten for either group. Adjusted model results are not shown when the group size is fewer than 20 for either group.

Table 11
Changes in Means for Tertiary Outcome Variables Between Baseline and 12-Month Assessment

Tertiary Outcome		N	Within-Family Mean Changes ^a	Group-Level Comparison of Mean Changes (Unadjusted Model) ^b	Group-Level Comparison of Mean Changes (Adjusted Model) ^c
Background and Contextual Factors					
CR Caregiver Resource Problems	Intervention	47	-2.49 *	-2.37 #	-2.91
	Control	41	-0.12		
CR Caregiver Personal Problems	Intervention	47	-3.00 *	-0.83	-1.84
	Control	41	-2.17 #		
School Readiness/Performance					
Letter Word Identification for Ages 3–18	Intervention	30	4.37 #	1.77	0.53
	Control	32	2.59		
Passage Comprehension for Ages 3–18	Intervention	36	-4.28 *	0.75	1.22
	Control	31	-5.03 *		
Applied Problems for Ages 3–18	Intervention	34	0.24	-1.17	-3.15
	Control	32	1.41		

^a This column reflects within-family mean changes between the baseline and six-month scores for each group separately. * indicates a significant paired t-test of differences over time.

^b This column reflects the group-level comparison of within-family mean changes from baseline to six months. * indicates a significant t-test of group differences.

^c This column reflects the estimate of the difference between the two groups' within-family mean change from baseline to six months, controlling for age, gender, ethnicity, income, and violence exposure at baseline. * indicates a significant test for the estimate.

NOTES: CR = Caregiver Report. # indicates a nonsignificant trend in the t-test ($p < 0.05$ but does not meet the FDR correction threshold). Mean change estimates are not shown when the group size is less than ten, and comparisons are not shown when the group size is fewer than ten for either group. Adjusted model results are not shown when the group size is fewer than 20 for either group.

Safe Start Service Dosage and Changes in Primary Outcomes

To examine any intervention effects of Safe Start service dosage on outcomes, we divided the Bronx intervention families into three dosage groups, as families tend to receive different amounts of services. The Safe Start intervention represented a package of services, rather than a single service of a specific type. Thus, we defined the overall Safe Start dose as a sum of all services together. Because the sample size already substantially reduced statistical power in these analyses, we were unable to further explore whether there may have been different impacts for the different services offered by the site.

Divided into three levels in terms of services received at the six-month mark, the variable defines a low dosage as 14 service contacts or less, a medium dosage as between 15 and 25 service contacts, and a high dosage as more than 26 service contacts. About one-third of the sample fell into each of these groupings. Divided into three levels in terms of services received at the 12-month mark, when there was more opportunity to provide services, the variable defines a low dosage as 18 service contacts or less, a medium dosage as between 19 and 44 service contacts, and a high dosage as more than 45 service contacts. About one-third of the sample fell into each of these groupings.

Since children and families with more need are likely to receive more services, we would expect a selection bias, with higher-need families receiving more services. To account for this selection bias, we used the propensity score-matching method to pair families in each dosage group with families with similar needs in the control group. The matching paired families based on baseline scores on the outcome measure of interest. The analyses examined the difference in mean score changes between the intervention and control groups for each dosage group. Note that in this analysis, the full control group is used in the matching of each of the dosage levels.

At six months, the propensity score-matching analyses for Bronx's primary outcomes (with the exception of family involvement, for which the sample size was too small) showed that across the outcome measures, the high-dosage group generally had mean scores in the expected direction, with higher scores on negatively directed outcomes and lower scores on positively directed outcomes (see Table A.4 in the appendix). These findings show that the high-dosage group usually had more symptoms or problems and thus a greater need for services. However, there was one exception to this pattern in terms of caregiver exposure to trauma and violence. Here, the higher dosage group did

not necessarily report more exposure to these events. The statistical test comparing the two groups on changes in mean scores between baseline and six months revealed only one statistically significant difference between the intervention and control group, with caregivers in the intervention group who received a medium dose of intervention services reporting increases in experience of a non-domestic violence traumatic event, whereas comparable caregivers in the control group reported a decrease on this scale. However, we cannot rule out that this difference between the groups may be due to chance because of the multiple significance tests being conducted (i.e., the group difference did not exceed the more-stringent statistical criterion set using the FDR method). We did not observe a pattern in which larger intervention effects were observed at higher dosages of care. At 12 months, this analysis showed a less clear pattern of severity and dosage, and no clear pattern of intervention effect and dosage was observed.

CONCLUSIONS

This hospital-based intervention was evaluated via a randomized controlled trial, in which the Safe Start intervention was compared to enhanced services as usual. The Bronx Safe Start program recruited 166 families and retained 62 percent of them at six months. The participants in the study were all minorities and largely impoverished, with about half of children scoring in the clinical range for child PTSD symptoms and about three-quarters of caregivers reporting parenting stress in the clinical range. Among families retained at six months, almost all received case management (94 percent) or the multidisciplinary team assessment and developmental screening (89 percent), whereas 80 percent received dyadic therapy and 72 percent received case management referrals.

Given the number of participants in this study, we had an 80-percent chance to detect a medium intervention effect of 0.56 at six months, when intervention services were still ongoing, and to detect a large intervention effect of 0.61 at 12 months. We expected a medium intervention effect, given other research finding intervention effects in this range for the dyadic therapy element. In intent-to-treat analyses, despite mean scores in the intervention and control groups in the expected directions on many variables, no differences between groups over time were detected at six months. In some cases, significant changes were noted in the intervention group, but these changes did not differ

significantly from those observed in the control group. At 12 months, two differences were observed in unadjusted models between groups in changes over time, with the control group reporting larger decreases in caregiver exposure to domestic violence and the intervention group reporting larger decreases in caregiver-child dysfunction, but these changes did not persist once demographics were controlled. Examination of those who received low, medium, or high doses of the intervention services again revealed few statistically significant differences, despite changes in the expected direction for the most part.

Overall, the results did not indicate that the Bronx Safe Start program improved outcomes for children over time, relative to a group of similar children who did not receive the full Safe Start intervention. Despite the rigorous randomized design, firm conclusions about the effectiveness of the Bronx Safe Start program cannot be drawn based on these results, however. Although it is possible that the services as implemented in this study were not effective in improving outcomes for children in the intervention group relative to controls, there are several other possible explanations for the results presented here. The lack of difference between groups over time could reflect a lack of statistical power to observe a small-to-medium intervention effect of the program on the measured outcomes. That is, a larger sample size might have allowed for the detection of statistically significant changes associated with the Safe Start services. Further, the evaluation ended early because of funding constraints when the appropriation for Safe Start was curtailed, which may have affected the sample size. It is possible that interventions focused on violence could heighten caregiver sensitivity to and recognition of a child's symptoms and thus any intervention effect may be obscured by caregiver reports of increased or level symptoms. It is also possible that intervention effects may not be observable at the earlier follow-up time points that are examined here, particularly for interventions that may result in symptoms worsening temporarily before they improve. In this program, the control group received enhanced services during their involvement in the study. These enhanced services may have also served to reduce the amount of difference between the two groups. The inability to detect significant differences between the groups may also have been due to the particular outcomes measured. That is, the Bronx Safe Start program may have improved the lives of children and families in ways that were not measured (or were not measured adequately) in this study.

In sum, although the analyses of data did not clearly reveal impacts of the program at the child and family level, the program demonstrates the promise of working with children in this setting. As noted in the program implementation report (Schultz et al., 2010), the medical home model implemented was novel, and many details of implementation were worked out in the early stages of implementation. In the end, the project benefited from steady referrals from pediatricians in the hospital, and a relatively intensive service mix was established for families. However, there is clearly still a need to continue developing and testing additional strategies for helping children exposed to violence.

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BRONX OUTCOMES APPENDIX

Table A.1
Comparison of Means for Bronx Primary Outcome Variables

Primary Outcome	Group	Baseline		Six Months		12 Months		18 Months		24 Months	
		N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
PTSD Symptoms											
CR Child PTSD Symptoms for Ages 3–10	Intervention	72	48.21	48	48.79	43	47.16	34	43.65	22	41.23
	Control	62	50.68	37	46.73	40	43.90	28	46.18	16	46.94
Behavior/Conduct Problems											
CR Child Behavior Problems for Ages 1–18	Intervention	88	0.57	53	0.31	47	0.42	35	0.19	22	0.26
	Control	77	0.50	46	0.37	41	0.23	28	0.27	16	0.37
Social-Emotional Competence											
CR Child Assertion for Ages 1–12	Intervention	84	-0.36	52	-0.24	45	-0.08	34	-0.17	22	-0.20
	Control	73	-0.45	45	-0.49	40	-0.23	28	-0.24	16	-0.39
CR Child Self-Control for Ages 1–12	Intervention	84	-0.48	52	-0.25	45	-0.30	34	-0.29	22	-0.20
	Control	73	-0.44	45	-0.38	40	-0.28	28	-0.17	16	-0.58
Caregiver-Child Relationship											
CR Parent Distress for Ages 0–12	Intervention	89	35.90	57	35.37	47	32.45	35	31.63	22	30.86
	Control	77	33.96	46	33.70	41	32.71	27	33.41	16	36.31
CR Parent-Child Dysfunction for Ages 0–12	Intervention	89	28.61	57	27.35	47	26.00	35	27.20	22	25.82
	Control	77	25.47	46	25.48	41	27.12	28	27.07	16	28.75

Table A.1—continued

Primary Outcome	Group	Baseline		Six Months		12 Months		18 Months		24 Months	
		N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
CR Difficult Child for Ages 0–12	Intervention	89	36.54	57	33.61	47	34.66	35	33.43	22	32.00
	Control	77	36.31	46	35.65	41	34.73	28	34.68	16	37.19
CR Total Parenting Stress for Ages 0–12	Intervention	89	101.04	57	96.33	47	93.11	35	92.26	22	88.68
	Control	77	95.74	46	94.83	41	94.56	27	95.26	16	102.25
CR Family Involvement for Ages 6–12	Intervention	17	20.65	14	22.36	20	22.00	20	22.90	14	22.79
	Control	22	20.59	15	20.80	20	21.00	18	22.28	11	19.00
Violence Exposure											
CR Caregiver Total Number of Traumatic Experiences	Intervention	89	0.24	57	0.14	47	0.09	35	0.14	22	0.05
	Control	77	0.35	46	0.17	41	0.15	28	0.07	15	0.07
CR Caregiver Experience of Any Non-DV Trauma	Intervention	89	0.13	57	0.23	47	0.09	35	0.03	22	0.00
	Control	77	0.12	46	0.04	41	0.10	28	0.07	16	0.13
CR Caregiver Experience of Any DV	Intervention	89	0.58	57	0.14	47	0.19	35	0.14	22	0.14
	Control	77	0.78	46	0.22	41	0.10	28	0.07	16	0.13

NOTES: CR = Caregiver Report; DV = domestic violence. * indicates statistically significant (p-value<FDR significance criterion); # indicates nonsignificant trend (p<0.05 and >FDR significance criterion). Data are not shown for outcomes when the cell size is fewer than five for either group. Comparisons were not tested when the group size was fewer than ten for either group.

Table A.2
Comparison of Means for Bronx Secondary Outcome Variables

Secondary Outcome	Group	Baseline		Six Months		12 Months		18 Months		24 Months		
		N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	
Social-Emotional Competence												
CR Child Affective Strengths for Ages 6–12	Intervention	17	15.35	14	16.14	20	16.25	20	15.55	14	16.43	#
	Control	22	14.14	15	13.60	20	15.45	18	15.22	11	13.18	
CR Child School Functioning for Ages 6–12	Intervention	17	15.41	14	19.07	20	17.75	20	19.25	14	20.07	#
	Control	22	17.86	15	15.73	20	17.20	18	18.17	11	14.09	
CR Child Cooperation for Ages 3–12	Intervention	62	9.84	43	11.47	39	10.41	31	11.06	19	11.11	
	Control	57	9.82	35	10.29	35	10.80	25	10.68	14	9.14	
Violence Exposure												
CR Total Child Victimization Experiences for Ages 0–12	Intervention	89	3.36	57	1.19	47	1.23	35	0.77	22	0.77	
	Control	77	3.70	46	0.89	41	0.98	28	0.96	16	0.63	
CR Child Maltreatment for Ages 0–12	Intervention	89	0.75	56	0.23	47	0.34	35	0.20	22	0.14	
	Control	77	0.78	46	0.11	41	0.12	27	0.11	16	0.00	
CR Child Assault for Ages 0–12	Intervention	89	0.64	57	0.35	47	0.32	35	0.17	22	0.14	
	Control	77	0.74	46	0.22	41	0.27	28	0.21	16	0.13	
CR Child Sexual Abuse for Ages 0–12	Intervention	88	0.06	57	0.02	47	0.02	35	0.03	22	0.00	
	Control	76	0.05	46	0.02	41	0.00	27	0.00	16	0.00	

Table A.2—continued

Secondary Outcome	Group	Baseline		Six Months		12 Months		18 Months		24 Months	
		N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
CR Child Witnessing Violence for Ages 0–12	Intervention	89	1.82	57	0.42	47	0.38	35	0.20	22	0.32
	Control	76	1.99	46	0.37	40	0.40	28	0.46	16	0.25

NOTES: CR = Caregiver Report; DV = domestic violence. * indicates statistically significant (p-value < FDR significance criterion); # indicates nonsignificant trend (p < 0.05 and > FDR significance criterion). Data are not shown for outcomes when the cell size is fewer than five for either group. Comparisons were not tested when the group size was fewer than ten for either group.

Table A.3
Comparison of Means for Bronx Tertiary Outcome Variables

		Baseline		Six Months		12 Months		18 Months		24 Months	
Tertiary Outcome		N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
Background and Contextual Factors											
CR Caregiver Resource Problems	Intervention	89	17.11	57	15.88	47	15.15	35	15.71	22	15.68
	Control	77	17.23	46	16.80	41	16.76	28	16.71	16	18.06
CR Caregiver Personal Problems	Intervention	89	27.44	57	25.88	47	24.66	35	24.66	22	26.36
	Control	77	27.88	46	26.98	41	25.54	28	26.25	16	26.88
School Readiness/Performance											
Letter Word Identification for Ages 3–18	Intervention	60	-1.27	41	-0.05	40	1.03	32	0.31	21	1.86
	Control	59	3.03	32	5.06	37	5.86	26	6.77	14	-1.21
Passage Comprehension for Ages 3–18	Intervention	68	6.35	41	4.56	40	2.93	30	2.07	21	0.57
	Control	57	6.49	36	4.17	39	2.64	27	-1.56	14	-3.29
Applied Problems for Ages 3–18	Intervention	65	-4.66	43	-3.79	41	-3.34	32	-3.59	21	-0.24
	Control	57	-3.37	38	-2.42	38	-0.82	26	-0.23	15	-3.53

NOTES: CR = Caregiver Report; DV = domestic violence. * indicates statistically significant (p-value < FDR significance criterion); # indicates nonsignificant trend (p < 0.05 and > FDR significance criterion). Data are not shown for outcomes when the cell size is fewer than five for either group. Comparisons were not tested when the group size was fewer than ten for either group

Table A.4
Changes in Means by Dosage Group for Bronx Primary Outcome Variables
Between Baseline and Six-Month Assessment

Primary Outcome	Dosage	Group	N	Baseline Mean	Six-Month Mean	Difference
PTSD Symptoms						
CR Child PTSD Symptoms for Ages 3–10	Low	Intervention	11	44.45	42.91	3.00
		Control	11	45.00	40.45	
	Medium	Intervention	18	49.39	50.78	6.28
		Control	18	50.78	45.89	
	High	Intervention	10	50.40	51.00	6.60
		Control	10	51.20	45.20	
Behavior/Conduct Problems						
CR Child Behavior Problems for Ages 1–18	Low	Intervention	9	0.58	0.09	
		Control	10	0.60	-0.04	
	Medium	Intervention	16	0.64	0.40	-0.03
		Control	18	0.65	0.44	
	High	Intervention	14	0.80	0.44	0.02
		Control	14	0.82	0.44	
Social-Emotional Competence						
CR Child Assertion for Ages 1–12	Low	Intervention	7	-0.37	-0.06	
		Control	9	-0.37	-0.37	
	Medium	Intervention	12	-0.59	-0.41	0.09
		Control	13	-0.75	-0.65	
	High	Intervention	14	-0.77	-0.62	0.07
		Control	14	-0.75	-0.68	
CR Child Self-Control for Ages 1–12	Low	Intervention	13	-0.48	0.11	0.15
		Control	15	-0.55	-0.06	
	Medium	Intervention	17	-0.53	-0.32	0.04
		Control	17	-0.41	-0.25	
	High	Intervention	13	-0.76	-0.66	0.17
		Control	13	-0.77	-0.84	
Caregiver-Child Relationship						
CR Parental Distress for Ages 0–12	Low	Intervention	17	35.65	33.41	-1.88
		Control	17	33.41	33.06	
	Medium	Intervention	16	34.25	33.56	-0.19
		Control	16	37.63	37.13	
	High	Intervention	9	37.44	33.89	
		Control	9	37.33	37.22	
CR Parent-Child Dysfunction for Ages 0–12	Low	Intervention	12	26.92	24.42	1.92
		Control	12	27.00	22.58	
	Medium	Intervention	14	27.00	24.29	0.14
		Control	14	26.50	23.64	
	High	Intervention	4			
		Control	4			

Table A.4—continued

Primary Outcome	Dosage	Group	N	Baseline Mean	Six-Month Mean	Difference
CR Difficult Child for Ages 0–12	Low	Intervention	15	39.07	32.00	-2.33
		Control	15	39.47	34.73	
	Medium	Intervention	21	36.67	34.43	-0.33
		Control	21	37.33	35.43	
	High	Intervention	12	40.83	34.25	-6.75
		Control	12	40.92	41.08	
CR Total Parental Stress for Ages 0–12	Low	Intervention	11	103.10	93.27	-5.82
		Control	11	105.40	101.40	
	Medium	Intervention	18	100.90	96.17	-0.50
		Control	18	100.60	96.33	
	High	Intervention	10	111.00	100.60	-5.80
		Control	10	111.00	106.40	
Violence Exposure						
CR Caregiver Total Number of Traumatic Experiences	Low	Intervention	15	0.33	0.13	0.07
		Control	15	0.47	0.20	
	Medium	Intervention	21	0.24	0.19	-0.10
		Control	21	0.19	0.24	
	High	Intervention	14	0.21	0.07	-0.14
		Control	14	0.21	0.21	
CR Caregiver Experience of Any Non-DV Traumas	Low	Intervention	17	0.18	0.18	0.12
		Control	17	0.18	0.06	
	Medium	Intervention	20	0.15	0.30	0.30 #
		Control	20	0.15	0.00	
	High	Intervention	16	0.06	0.19	0.19
		Control	16	0.06	0.00	
CR Caregiver Experience of Any Domestic Violence	Low	Intervention	16	0.75	0.13	0.00
		Control	16	0.75	0.13	
	Medium	Intervention	17	0.59	0.06	0.06
		Control	17	0.59	0.00	
	High	Intervention	16	0.63	0.31	0.25
		Control	16	0.63	0.06	

NOTES: CR = Caregiver Report; DV = domestic violence. * indicates statistically significant (p-value < FDR significance criterion). Data are not shown for outcomes when the cell size is fewer than five for either group. Comparisons were not tested when the group size was fewer than ten for either group.

Table A.5
Changes in Means by Dosage Group for Bronx Primary Outcome Variables
Between Baseline and 12-Month Assessment

Primary Outcome	Dosage	Group	N	Baseline Mean	12-Month Mean	Difference
PTSD Symptoms						
CR Child PTSD Symptoms for Ages 3–10	Low	Intervention	8	49.56	47.38	
		Control	16	48.00	40.19	
	Medium	Intervention	6	52.57	50.00	
		Control	7	49.00	48.43	
	High	Intervention	12	50.38	49.17	4.72
		Control	13	49.38	44.08	
Behavior/Conduct Problems						
CR Child Behavior Problems for Ages 1–18	Low	Intervention	6	0.69	0.32	
		Control	16	0.84	0.27	
	Medium	Intervention	5	0.32	0.26	
		Control	7	0.94	0.57	
	High	Intervention	9	0.71	0.29	
		Control	10	0.49	0.40	
Social-Emotional Competence						
CR Child Assertion for Ages 1–12	Low	Intervention	8	-0.37	0.10	
		Control	16	-0.46	-0.19	
	Medium	Intervention	10	-0.32	0.33	0.41
		Control	13	-0.67	-0.42	
	High	Intervention	12	-0.57	-0.35	-0.16
		Control	14	-0.48	-0.20	
CR Child Self-Control for Ages 1–12	Low	Intervention	9	-0.56	-0.25	
		Control	17	-0.58	-0.57	
	Medium	Intervention	9	-0.57	0.10	
		Control	10	-0.61	-0.53	
	High	Intervention	9	-0.65	-0.33	
		Control	11	-0.37	-0.43	
Caregiver-Child Relationship						
CR Parental Distress for Ages 0–12	Low	Intervention	9	34.59	26.11	
		Control	17	34.53	32.06	
	Medium	Intervention	10	34.64	28.80	-1.42
		Control	11	34.55	30.36	
	High	Intervention	9	39.11	35.89	
		Control	9	37.44	31.89	
CR Parent-Child Dysfunction for Ages 0–12	Low	Intervention	6	24.77	19.17	
		Control	13	25.08	24.62	
	Medium	Intervention	5	25.86	25.40	
		Control	7	28.43	34.14	
	High	Intervention	8	32.25	27.63	
		Control	8	32.00	31.50	

Table A.5—continued

Primary Outcome	Dosage	Group	N	Baseline Mean	12-Month Mean	Difference
CR Difficult Child for Ages 0–12	Low	Intervention	8	35.88	31.38	
		Control	17	36.12	30.47	
	Medium	Intervention	10	39.46	36.10	–2.24
		Control	13	37.92	35.46	
	High	Intervention	12	38.15	33.00	–4.90
		Control	13	40.85	41.00	
CR Total Parental Stress for Ages 0–12	Low	Intervention	9	101.40	80.22	
		Control	18	100.10	100.90	
	Medium	Intervention	8	98.00	89.25	
		Control	10	95.70	88.00	
	High	Intervention	8	110.30	102.90	
		Control	8	103.30	108.80	
Violence Exposure						
CR Caregiver Total Number of Traumatic Experiences	Low	Intervention	9	0.28	0.00	
		Control	18	0.28	0.06	
	Medium	Intervention	13	0.24	0.08	–0.10
		Control	17	0.18	0.12	
	High	Intervention	15	0.25	0.07	–0.01
		Control	16	0.25	0.06	
CR Caregiver Experience of Any Non-DV Traumas	Low	Intervention	14	0.17	0.07	0.04
		Control	18	0.17	0.06	
	Medium	Intervention	18	0.16	0.00	–0.06
		Control	19	0.16	0.05	
	High	Intervention	17	0.12	0.06	0.06
		Control	17	0.12	0.00	
CR Caregiver Experience of Any Domestic Violence	Low	Intervention	13	0.82	0.23	0.15
		Control	17	0.82	0.06	
	Medium	Intervention	14	0.47	0.07	–0.02
		Control	15	0.47	0.13	
	High	Intervention	16	0.69	0.25	0.06
		Control	16	0.69	0.19	

NOTES: CR = Caregiver Report; DV = domestic violence. * indicates statistically significant (p-value < FDR significance criterion). Data are not shown for outcomes when the cell size is fewer than five for either group. Comparisons were not tested when the group size was fewer than ten for either group.