Improving Parent-Child Interactions in Pediatric Health Care: A Two-Site Randomized Controlled Trial

Erin Roby, PhD,[a] Elizabeth B. Miller, PhD,[a] Daniel S. Shaw, PhD,[c] Pamela Morris, PhD,[b] Anne Gill, PhD,[c] Debra L. Bogen, MD,[c] Johana Rosas, PhD,[c] Caitlin F. Canfield, PhD,[a] Katherine A. Hails, MS,[c] Helena Wippick, BA,[b] Julia Honoroff, BA,[b] Carolyn B. Cates, PhD,[d] Adriana Weisleder, PhD,[e] Kelly A. Chadwick, BA,[c] Caroline D. Raak, MA,[a] Alan L. Mendelsohn, MD[a]

abstract

BACKGROUND AND OBJECTIVES: Heterogeneity in risk among low-income families suggests the need for tiered interventions to prevent disparities in school readiness. Smart Beginnings (SB) integrates two interventions: Video Interaction Project (VIP) (birth to 3 years), delivered universally to low-income families in pediatric primary care, and Family Check-Up (6 months to 3 years), targeted home visiting for families with additional family risks. Our objective was to assess initial SB impacts on parent-child activities and interactions at 6 months, reflecting early VIP exposure.

METHODS: Two-site randomized controlled trial in New York City (84% Latinx) and Pittsburgh (81% Black), with postpartum enrollment and random assignment to treatment (SB) or control. At 6 months, we assessed parent-child interactions through surveys (StimQ, Parenting Your Baby) and observation (video-recorded play, coded by using Parent-Child Interaction Rating Scales – Infant Adaptation).

RESULTS: A total of 403 families were enrolled at child's birth (201 treatment) with 362 (89.8%) assessed at 6 months. Treatment families had increased StimQ, including total score (Cohen's d = 0.28; $P < .001$) and domains reflecting reading (d = 0.23; P = .02) and teaching (d = 0.25; P = .01), and Parent-Child Interaction Rating Scales – Infant Adaptation, including a cognitive stimulation factor (d = 0.40; $P < .001$) and domains reflecting support for cognitive development (d = 0.36; $P < .001$), and language quantity (0.40; $P < .001$) and quality (d = 0.37; $P < .001$). Thus, significant effects emerged across a broad sample by using varied methodologies.

CONCLUSIONS: Findings replicate and extend previous VIP findings across samples and assessment methodologies. Examining subsequent assessments will determine impacts and feasibility of the full SB model, including potential additive impacts of Family Check-Up for families at elevated risk.

[a]*Department of Pediatrics, NYU Grossman School of Medicine and* [b]*Steinhardt School of Culture, Education, and Human Development, New York University, New York, New York;* [c]*Department of Psychology, University of Pittsburgh, Pittsburgh, Pennsylvania;* [d]*School of Natural and Social Sciences, Purchase College, State University of New York, Purchase, New York; and* [e]*Department of Communication Sciences and Disorders, Northwestern University, Chicago, Illinois*

Drs Roby, Miller, Shaw, Morris, and Mendelsohn conceptualized and designed the study, conducted statistical analyses, and drafted the initial manuscript; Drs Bogen, Canfield, Cates, Weisleder, Gill, and Rosas and Ms Hails conceptualized and designed the study and conducted statistical analyses; Ms Chadwich, Ms Honoroff, Ms Raak, and Ms Wippick coordinated and supervised data collection; and all authors reviewed and revised the manuscript, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.

WHAT'S KNOWN ON THIS SUBJECT: Risk heterogeneity in low-income families suggests the need for tiered models to prevent school readiness disparities, but limited research has been used to investigate these issues. Smart Beginnings integrates universal Video Interaction Project during pediatric care with targeted Family Check-Up at home visits.

WHAT THIS STUDY ADDS: A two-site randomized controlled trial of Smart Beginnings replicates and extends previous Video Interaction Project findings across racially and ethnically diverse families in New York City and Pittsburgh, using both survey and observational methods to assess parent-child interactions and cognitive stimulation.

To cite: Roby E, Miller EB, Shaw DS, et al. Improving Parent-Child Interactions in Pediatric Health Care: A Two-Site Randomized Controlled Trial. *Pediatrics*. 2021;147(3):e20201799

Support for parent-child interactions and activities associated with advancement in early development, including reading aloud and play, has been a core component of interventions seeking to prevent disparities.[1–3] Although preventive interventions show significant promise,[4] barriers limit population-level scaling and impact; including (1) identification and engagement of low-income parents before school entry,[5] (2) challenges in participation (eg, transportation, work),[6] (3) heterogeneity in resilience and risk,[7] and (4) high programmatic costs coupled with limited funding.[8]

We developed Smart Beginnings (SB) to address these barriers, using a tiered model delivered from birth to 3 years. SB integrates universal (primary) and targeted (secondary) prevention programs, each focused on promoting positive parent-child interactions. SB's universal prevention program is Video Interaction Project (VIP),[9] which is delivered in pediatric primary health care to maximize identification, engagement, and retention while minimizing costs. VIP's core component is video recording of the parent and child interacting using a provided toy or book, with real-time review to identify and reinforce strengths in the interaction. SB's targeted prevention program is Family Check-Up (FCU),[10] which is provided in the home for families meeting risk criteria on the basis of screening beginning at 6 months, with clinical-level support tailored to family heterogeneity.

SB is currently under study in a two-site randomized controlled trial (RCT) in New York, New York (NYC), and in Pittsburgh, Pennsylvania. Here, we provide results of analyses of parent-child activities and interactions at the first RCT assessment point (age 6 months). This assessment takes place after several months of VIP but before initiation of FCU. Although the 6-month assessment is not a reflection of the full integrated SB model, analyses at this age allow us to address two key gaps:

1. Although VIP has been shown to impact a range of parent and child outcomes,[9,11] previous studies of parental cognitive stimulation have primarily used parent-report surveys, which are reliable and valid but also subject to recall and social desirability biases.[12] Moreover, observational measures account for additional, independent variance.[13] Although one study revealed impacts of VIP on observations of reading aloud at 4.5 years,[11] there have been no observational studies of parent-child interaction more broadly. In the current study, we address this limitation by using observational measures of quality markers of dyadic interactions together with survey measures to comprehensively understand VIP impacts at child age 6 months.
2. Previous studies of VIP have taken place at a single location where the program was developed. Study participants have comprised primarily Latinx immigrant families, and it is unknown whether impacts would extend to broader populations. In addition, although VIP has been manualized with procedures to optimize implementation and delivery, a common challenge for interventions broadly is dilution of impact at new sites in locations distant from the developers.

In the current study, we address both gaps by studying impacts and fidelity of VIP across a broader population at two sites that are diverse in both location (NYC and Pittsburgh) and race and ethnicity (primarily low-income Latinx and Black/African American, respectively).

METHODS

We conducted a single-blind 2-way RCT of SB at two sites: Bellevue Hospital in NYC and University of Pittsburgh Medical Center (UPMC) Children's Hospital of Pittsburgh. The study was registered at www.clinicaltrials.gov (identifier NCT02459327). Institutional review board approval was obtained from New York University (FY2016-408), NYU Grossman School of Medicine (S14-01764), and University of Pittsburgh (STUDY19040158). Research approval was obtained from NYC Health+Hospitals. Families were not compensated for participation in study interventions but received a modest incentive ($50) for participating in the 6-month assessment.

Intervention Design

SB (Integrated Model)

SB includes (1) VIP as a universal primary prevention strategy,[14] provided for all families randomly assigned to the treatment group at birth, and (2) FCU provided for treatment families with identified psychosocial risks beginning at 6 months.[10]

VIP

VIP was designed as an enhancement to Reach Out and Read,[15] a national program that facilitates literacy promotion during routine well-child care. VIP is a strengths-based, family-centered model that addresses parenting assets and vulnerabilities that mediate the impact of poverty on child development. VIP is posited to enhance positive parenting behaviors and, in turn, promote children's school readiness. The VIP 0–3 program includes fourteen 25–30 minute sessions delivered in pediatric primary care from birth to 3 years, aligned with well-child visits and delivered by coaches (bachelor's

level) hired for this project. Coaches receive a 3-day training and continued supervision.

Every VIP session follows the same format, including discussion of the child's development and provision of a developmentally appropriate learning material (book, toy) selected to engage the parent and child in interaction. The coach briefly video records the parent and child interacting with the book or toy and then immediately reviews the video with the parent to identify and reinforce strengths in the interaction and promote self-reflection. The parent is provided with a copy of the video and a personalized pamphlet that includes information about developmental milestones, age-specific suggestions for engaging with their child, and the parent's goals for interacting with their child at home. For example, at 6 months, the coach would talk to the parent about their child's development and milestones (eg, making sounds) and tips for interactions (eg, imitating infant sounds), provide the parent with a developmentally appropriate toy (eg, hand puppets), record the parent and infant interacting, review the video together, highlighting strengths, and help the parent plan for interacting with their infant at home.

FCU

FCU is an evidence-based home-visiting model that seeks to reduce the development of early disruptive behavior and motivate parents to engage in services that improve parenting practices.[16] Whereas VIP begins at birth in the SB model, families do not begin receiving FCU until the infant is 6 months, following the time period of data reported here. Our description of FCU is therefore brief; details of the program's evidence are published elsewhere.[10,16]

Enrollment and Random Assignment

We used a two-phased enrollment process with consecutive sampling. Mothers and infants were enrolled in the postpartum units of NYC Health+Hospitals and Bellevue from June 2015 to January 2017 and UPMC Magee-Women's Hospital adjacent to the UPMC Children's Hospital of Pittsburgh from June 2016 to October 2017. In phase 1, low-income or Medicaid-eligible families were offered enrollment, and informed consent was obtained if they met the following inclusion criteria: (1) the infant is born term, is singleton, has a normal birth weight without significant prenatal or perinatal medical complications, is ineligible for Early Intervention at birth

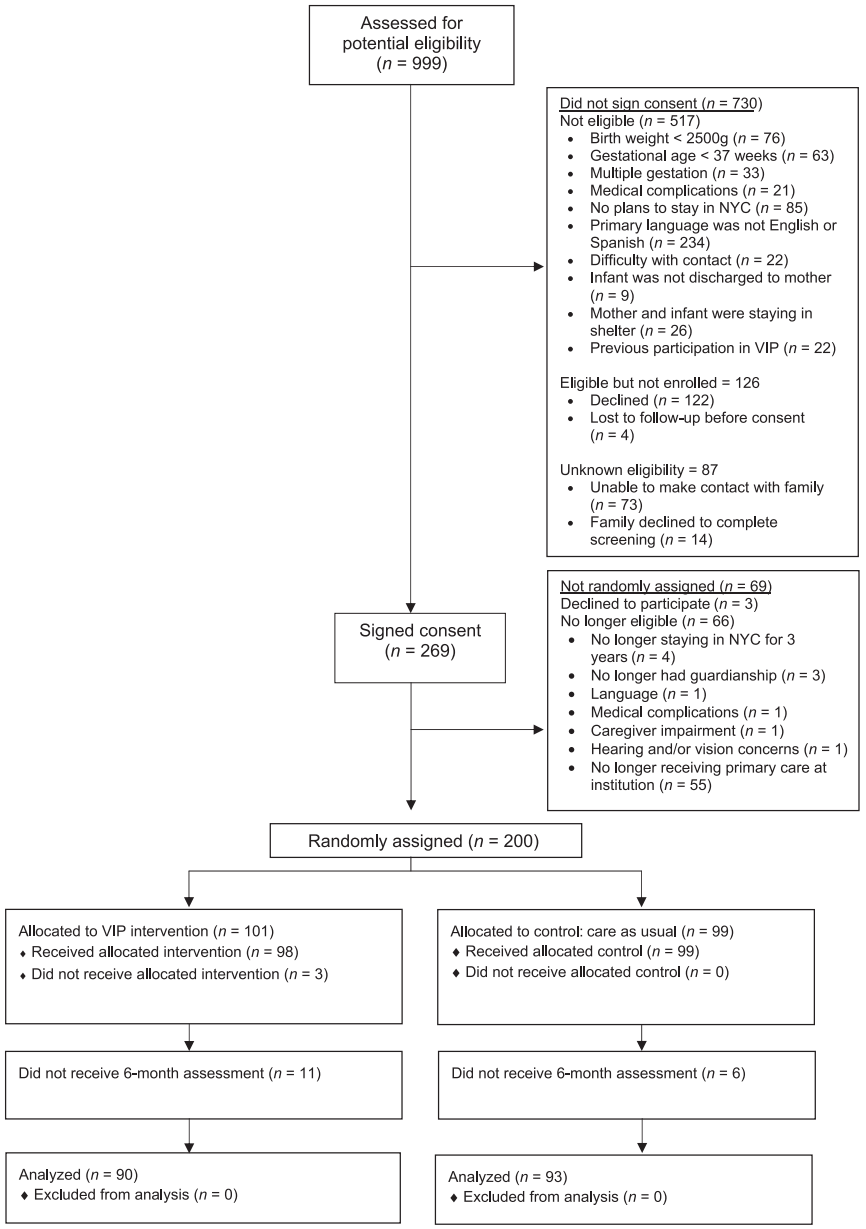

FIGURE 1
Participant enrollment and assessment in NYC. Participants who were not eligible for the study may have met >1 exclusion criteria; therefore, the individual criteria numbers do not sum to the total number not eligible.

(eligibility is comparable across states),[17,18] and plans to receive pediatric care at the institution; and (2) the parent is the primary caregiver or legal guardian, plans to stay in the birth city for 3 years, speaks English or Spanish as their primary language, has no known significant impairment (eg, intellectual disability, schizophrenia) or medical complication, has no plans to stay in a shelter, infant discharged to mother, and has no previous participation in VIP or FCU. In phase 2, occurring through 6 weeks of age in the outpatient setting, families who presented for a study visit and continued to meet inclusion criteria were randomly assigned to treatment or control groups. Although differences in hospital policies resulted in higher rates of participants declining to complete screening in Pittsburgh, the overall percentage of families signing consent among those assessed for potential eligibility was similar (NYC: 27%; Pittsburgh: 31%; Figs 1 and 2).

Assessments

Overall Design

At study enrollment (postpartum), baseline sociodemographic characteristics were assessed by parent survey. At child age 6 months, primary and secondary outcomes related to parenting including cognitive stimulation and parent-child interaction were assessed through survey and observation. All research assistants were blind to the randomization group and trained by project investigators and coordinators, receiving periodic follow-up to maintain fidelity.

Assessment of Cognitive Stimulation and Parent-Child Interaction: Survey Measures

$StimQ_2$ is a structured interview measure of caregiver cognitive stimulation. It was developed and validated in English and Spanish for low-income populations.[19,20] Cronbach's α in the current sample was 0.76. Three subscales of the $StimQ_2$ Infant were administered: (1) Parent Verbal Responsivity (PVR), measuring verbal interactions across 2 subdimensions (Everyday Routines, Play and Pretend); (2) Parental Involvement in Developmental Advance (PIDA), measuring teaching activities; and (3) Reading Activities (READ), with 3 subdimensions (Quantity, Quality, Diversity of Concepts). To ensure accuracy and limit social desirability bias, administration includes prompts for examples and follow-up questions. We calculated total, subscale, and subdimension scores.

Parental warmth was examined as a secondary outcome by using the

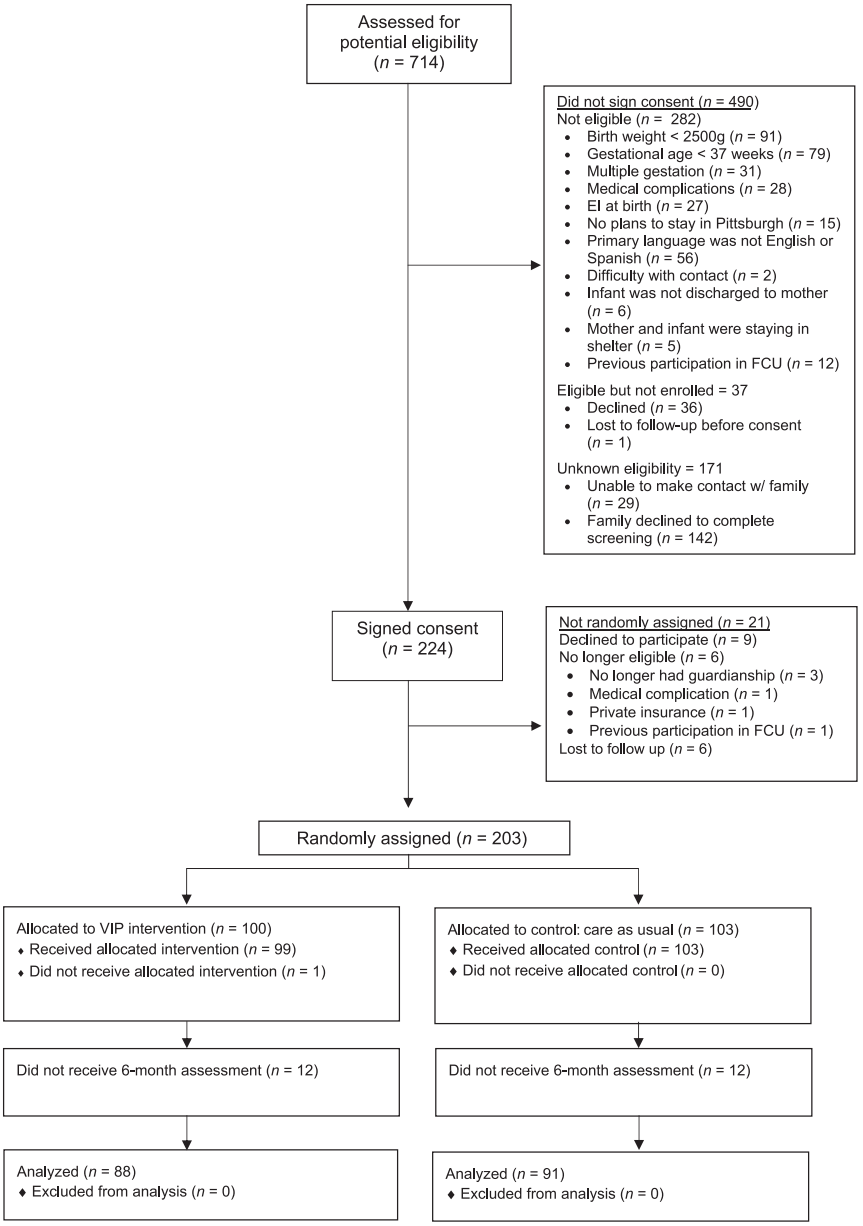

FIGURE 2

Participant enrollment and assessment in Pittsburgh. Participants who were not eligible for the study may have met >1 exclusion criteria; therefore, the individual criteria numbers do not sum to the total number not eligible.

Supporting and Enjoying subscale of the Parenting Your Baby questionnaire. This scale has shown high construct, convergent, and predictive validity.[21] Cronbach's α in this sample ranged from 0.67 to 0.73.

Assessment of Cognitive Stimulation and Parent-Child Interaction: Observational Measures

Observational measures of global parent-child interaction quality were assessed by using video recording and review of 10 minutes of free play. Mothers played with their infant by using toys typically available in homes but not provided in VIP. Coding of the videos was performed by using the Parent-Child Interaction Rating Scales – Infant Adaptation (PCIRS-IA), which assesses the quality of the parent's interactions with their child (C.S. Tamis-LeMonda, PhD, P. Ahuja, PhD, B. Hannibal, PhD, J. Shannon, PhD, M. Spellmann, PhD, unpublished observations).[22,23] Coders blind to participants' treatment condition rated interactions on a 1 to 7 scale. An additional 15% of the interactions were scored by a second coder. Weighted κ ranged from 0.7 to 0.85, indicating satisfactory agreement. Five domains of the PCIRS-IA relevant to child development were coded: parental sensitivity (awareness of child's needs, interests, and capabilities), parental intrusiveness (imposition of own agenda), parental support for cognitive development (intention to support learning), parental support for language quantity (verbal stimulation), and parental support for language quality (richness of language). We then developed a composite measure of "cognitive stimulation" on the basis of exploratory and confirmatory factor analysis demonstrating strong loading of 3 subscales (parental support for cognitive development, language quantity, and language quality). Factor loadings were 0.79, 0.91, and 0.89, respectively (root mean square error of approximation = 0.00). The resulting Cronbach's α for this factor was 0.91.

Statistical Analysis

A total of 400 families in the full sample were needed to provide at least 80% power for a minimally detectable effect size of 0.3 after accounting 25% attrition.[24] Analyses were performed with Stata 14 (Stata Corp, College Station, TX)[25] and on the basis of intent to treat (ie, by group assignment regardless of level of intervention participation). We conducted baseline equivalence tests across the full sample and within each site using t tests and χ^2. Participation in VIP was calculated as the mean number of visits through 6 months and compared across groups by using a t test. Because random assignment occurred within two sites, comparisons of outcomes for the full sample used multiple regression analyses that included fixed effects for the site. For each of these analyses, we calculated mean difference and 95% confidence interval (CI) and Cohen's d as a measure of effect size in SD units. We also performed secondary analyses within each site separately; however, because the study was not powered to detect effect sizes within each site, within-site analyses are exploratory.

TABLE 1 Baseline Descriptive Statistics by Site

	NYC (n = 200)	Pittsburgh (n = 203)
Child characteristics		
Female sex, %	49.0	50.3
Race and/or ethnicity, %		
Asian	1.5	0
Black/African American	8.2	90.1
White	1.0	5.0
Latinx	83.7	2.0
Other	5.6	3.
Child age in mo at assessment, mean (SD)	7.2 (1.6)	7.6 (1.5)
Primary caregiver characteristics, %		
Race and/or ethnicity		
Asian American	3.1	0.0
Black/African American	7.6	81.2
White	2.0	12.4
Latinx	84.3	3.5
Other	3.1	3.0
Marital status		
Married	31.8	4.4
Cohabitating partner	48.7	36.5
Noncohabitating partner	10.8	35.0
Biological father current partner	97.6	94.2
Education		
High school graduate	56.1	83.7
Some college	31.6	37.0
Primiparous birth	35.5	32.5
Teenage mother <20 y	4.0	8.9
Family household characteristics		
Income-to-needs ratio[a], mean (SD)	0.82 (0.60)	0.64 (0.60)
Crowding ratio[b], mean (SD)	1.40 (0.57)	0.86 (0.31)
Language of baseline interview, Spanish, %	61.4	0.0

[a] Income-to-needs ratio of 1.00 indicates that a family is right at the poverty threshold; 2.00 indicates that a family is 200% above that threshold.

[b] The crowding ratio indicates how many people live per room in the dwelling. A ratio >1 indicates household crowding.

RESULTS

Descriptive Analyses

In total, 403 families were randomly assigned: 200 in NYC and 203 in Pittsburgh (Figs 1 and 2). There were many between-site differences, with NYC primarily Latinx and Pittsburgh primarily Black/African American (Table 1). Mothers in NYC had higher rates of marriage and cohabitation and were less likely to be high school graduates. No significant differences emerged between the treatment and control groups across baseline characteristics (Table 2). There were also no significant differences for baseline characteristics among families who were or were not assessed in the full sample (omnibus, $P = .48$) or in either site (omnibus NYC, $P = .26$; omnibus Pittsburgh, $P = .21$).

Families had high rates of participation in VIP. The mean number of VIP visits completed was 3.49 (SD = 0.97) of four possible visits. The mean number of visits completed did not differ between NYC (mean = 3.40; SD = 1.13) and Pittsburgh (mean = 3.58; SD = 0.77), $P = .17$.

Impacts on Cognitive Stimulation and Parent-Child Interactions

Analyses of outcomes related to cognitive stimulation and parent-child interactions for the full sample (Table 3) and for separate exploratory analyses of NYC and Pittsburgh (Table 4) are shown.

TABLE 2 Baseline Equivalence of Treatment and Control Groups by Site

	NYC (n = 200)		Pittsburgh (n = 203)	
	SB (n = 101)	Control (n = 99)	SB (n = 100)	Control (n = 103)
Child characteristics, %				
Female sex	44.6	53.5	51.0	49.5
Race and/or ethnicity				
Asian American	2.0	1.0	0.0	0.0
Black/African American	11.2	5.1	87.9	92.2
White	1.0	1.0	6.1	3.9
Latinx	79.6	87.8	4.0	0.0
Other	6.1	5.1	2.0	3.9
Primary caregiver characteristics, %				
Race and/or ethnicity				
Asian American	2.0	4.1	0.0	0.0
Black/African American	11.1	4.1	79.8	82.5
White	2.0	2.0	12.1	12.6
Latinx	80.8	87.8	5.1	1.9
Other	4.0	2.0	3.0	2.9
Marital status				
Married	32.7	30.9	6.0	2.9
Cohabitating partner	44.9	52.6	38.0	35.0
Noncohabitating partner	13.3	8.3	32.0	37.9
Biological father current partner	96.5	98.8	92.1	96.2
Education				
High school graduate	61.6	50.5	86.0	81.6
Some college	36.4	26.8	43.0	31.1
Primiparous birth	37.4	33.7	30.0	35.0
Teenage mother	4.0	4.0	5.0	12.6
Family household characteristics				
Income-to-needs ratio[a], mean (SD)	0.87 (0.67)	0.77 (0.53)	0.68 (0.60)	0.60 (0.60)
Crowding ratio[b], mean (SD)	1.38 (0.54)	1.43 (0.61)	0.85 (0.30)	0.87 (0.32)
Language of interview, Spanish, %	57.6	65.3	0.0	0.0

[a] Income-to-needs ratio of 1.00 indicates that a family is right at the poverty threshold; 2.00 indicates that a family is 200% above that threshold.

[b] The crowding ratio indicates how many people live per room in the dwelling. A ratio >1 indicates household crowding.

Survey Measures

In the full sample, treatment families scored significantly higher than controls on most dimensions and subdimensions of the $StimQ_2$. This included $StimQ_2$ total (Cohen's $d = 0.28$; $P = .01$), $StimQ_2$ READ ($d = 0.23$; $P = .02$), including Quality ($d = 0.26$; $P = .01$) and Diversity of Concepts ($d = 0.23$; $P = .02$), $StimQ_2$ PVR Play and Pretend ($d = 0.21$; $P = .04$), and $StimQ_2$ PIDA ($d = 0.25$; $P = .01$). In exploratory analyses, NYC treatment families scored significantly higher than controls on $StimQ_2$ READ quality ($d = 0.32$; $P = .04$) and Diversity of Concepts ($d = 0.27$; $P = .049$) and $StimQ_2$ PIDA ($d = 0.34$; $P = .02$). Pittsburgh treatment families scored significantly higher than control group families on $StimQ_2$ total ($d = 0.27$; $P = .046$). Although scores for treatment families were higher than scores for controls in Pittsburgh for $StimQ_2$ PVR ($d = 0.23$; $P = .08$), differences were not statistically significant. There were no differences in mother-reported Parenting Your Baby: Supporting and Enjoying for the full sample or at either site.

Observational Measures

In the full sample, treatment families scored significantly higher than controls on several dimensions of the observations. These included parental support for cognitive development ($d = 0.36$; $P < .001$), language quantity ($d = 0.40$; $P < .001$), and language quality ($d = 0.37$; $P < .001$), as well as the cognitive stimulation factor ($d = 0.40$; $P < .001$). In exploratory analyses, NYC treatment families scored significantly higher than controls on parental support for cognitive development ($d = 0.47$; $P = .01$), language quantity ($d = 0.70$; $P < .001$), language quality ($d = 0.52$; $P < .001$), and the cognitive stimulation factor ($d = 0.60$; $P < .001$). In Pittsburgh, treatment families had higher scores for parental support of cognitive development ($d = 0.26$; $P =$

TABLE 3 Impacts on Cognitive Stimulation and Parent-Child Interactions at 6 Months

	Treatment	Control	Impact[a] (95% CI)	Effect Size[b]	*P*
Survey outcomes					
Cognitive stimulation (StimQ)	17.16	15.51	1.65 (0.48 to 2.82)	0.28	.01
READ	6.52	5.72	0.80 (0.11 to 1.50)	0.23	.02
READ quantity	3.46	3.11	0.35 (−0.09 to 0.79)	0.16	.22
READ quality	1.55	1.27	0.28 (0.06 to 0.50)	0.26	.01
READ diverse concepts	1.51	1.33	0.18 (0.02 to 0.33)	0.23	.02
PVR	7.69	7.21	0.48 (−0.10 to 1.07)	0.16	.10
PVR everyday routines	3.43	3.33	0.11 (−0.26 to 0.48)	0.06	.57
PVR play and pretend	4.25	3.88	0.37 (0.02 to 0.72)	0.21	.04
PIDA	2.92	2.59	0.33 (0.06 to 0.59)	0.25	.01
Parental warmth (PYB)	6.70	6.67	0.03 (−0.06 to 0.12)	0.06	.50
Observational outcomes					
Parent-child interaction (PCIRS-IA)					
Sensitivity	4.11	3.93	0.18 (−0.07 to 0.42)	0.16	.16
Intrusiveness	3.23	3.14	0.10 (−0.20 to 0.40)	0.07	.51
Cognitive development	3.62	3.25	0.37 (0.15 to 0.60)	0.36	.00
Language quantity	4.23	3.61	0.63 (0.29 to 0.96)	0.40	.00
Language quality	4.02	3.47	0.56 (0.24 to 0.87)	0.37	.00
Cognitive stimulation factor	3.95	3.44	0.51 (0.24 to 0.76)	0.40	.00

Combined sample (N = 362 survey, 359 observations). PYB, Parenting Your Baby: Supporting and Enjoying.

[a] Impact based on difference in raw score.

[b] Effect size calculated by using Cohen's d.

.07); however, this was not statistically significant. In Pittsburgh, no differences emerged for language quantity, quality, or the cognitive stimulation factor. There were no differences in sensitivity or intrusiveness either in the full sample or at either site.

DISCUSSION

In this study, we examined impacts of VIP delivered in primary care on cognitive stimulation and parent-child interactions for the first phase of SB. In the full sample, including two sites with racially and ethnically diverse participants, VIP had positive impacts on both survey and observed measures of cognitive stimulation and parent-child interactions at child age 6 months. More specifically, participation in VIP impacted multiple domains of parent-reported cognitive stimulation, including reading, verbal responsivity, and teaching behaviors, and observed measures of parent-child interaction, including parental support for cognitive development, language quantity, and language quality.

Findings replicate previous research revealing VIP impacts on cognitive stimulation and parent-child interactions and extend them by revealing these impacts across a more comprehensive set of survey and observational measures and with families from diverse racial and ethnic groups. These impacts are notable given substantial research demonstrating that such behaviors mediate the relationship between poverty and school readiness,[26,27] with implications for long-term educational trajectories. This replication of findings is especially important in light of challenges in replication in the behavioral sciences more broadly.[28]

Although we did not replicate impacts on parenting warmth using the parent-reported Parenting Your Baby, this null finding may reflect the limited variability within the current sample (93% scored within 1 point of ceiling). Lack of impacts on observed sensitivity and intrusiveness may suggest specificity of VIP in impacting positive aspects of cognitive stimulation or could be a consequence of the assessment being performed in early infancy.[29] It is also possible that additional exposure to VIP or using the full complement of strategies tailored to risk heterogeneity provided in the full SB model may be necessary to affect these behaviors.

Comparable VIP participation across sites supports feasibility for parents from diverse geographic locations and racial and ethnic backgrounds. Although not sufficiently powered (and thus not always resulting in findings that meet standards of statistical significance), exploratory analyses within sites suggest that the VIP intervention resulted in clinically meaningful effect sizes at both sites for both survey and observational measures. For the survey measures, the effect sizes for $StimQ_2$ overall and the $StimQ_2$ READ subscale were similar across sites. Whereas the PVR subscale had a higher effect size in Pittsburgh, the PIDA subscale had a higher effect size in NYC. For the observational measures, although impacts were found in both sites, effect sizes were greater overall in NYC. To put this in perspective, effect sizes of 0.2 to 0.3 (found in both sites for survey measures and in Pittsburgh for several observational measures) are similar to previous reports and are at levels comparable to more intensive programs (eg, home visiting)[30,31] that are considered to be clinically significant.[32] Effect sizes of 0.5 to 0.7 (found for observational measures in NYC) are higher than many studies of other preventive interventions.[30–33] Future studies are needed to interpret potential differences across subdomains and subdimensions between the two sites and determine if the patterns obtained from survey and observation measurements persist longitudinally. Data from

later assessment points within the study will help to address these questions.

This study had many strengths, including a multimethod assessment across a geographically and racially and ethnically diverse sample. There were also some limitations. First, the study was not powered to show differences across the two sites and populations, resulting in exploratory subgroup analyses. Second, because race and ethnicity fully confounded site, the design did not allow consideration of either characteristic separately in interpreting findings. Third, this study took place during a period of specific stressors for immigrant and other racial and ethnic minority families, including heightened racism and discrimination.[34] Experience of stress in these communities may have impacted enrollment and participation in assessments and could have implications for generalizability. Finally, in the current study, we excluded several high-risk populations including newborns qualifying for Early Interventions and preterm or low birth weight infants. Although these exclusions limit generalizability of findings to higher-risk groups, pilot adaptation of SB is currently being implemented for these populations, children in foster care, and those with prenatal opioid exposure. Future research will be necessary to examine the efficacy of SB for parenting and child outcomes in these groups.

CONCLUSIONS

SB is one of the first tiered models linking and integrating evidence-based interventions across pediatric primary care and home visiting to prevent disparities in early development and school readiness. This study revealed that VIP delivered as the first phase of SB had

TABLE 4 Impacts on Cognitive Stimulation and Parent-Child Interactions at 6 Months by Site

	NYC Sample					Pittsburgh Sample					Δ Impact by Site[c]
	Treatment	Control	Impact[a] (95% CI)	Effect Size[b]	*P*	Treatment	Control	Impact[a] (95% CI)	Effect Size[b]	*P*	
Survey outcomes											
Cognitive stimulation (StimQ)	17.11	15.45	1.66 (−0.06 to 3.38)	0.28	.06	17.22	15.58	1.63 (0.03 to 3.23)	0.27	.046	0.03
READ	6.34	5.57	0.87 (−0.09 to 1.83)	0.25	.07	6.70	5.97	0.74 (−0.28 to 1.75)	0.21	.15	0.13
READ quantity	3.35	3.03	0.32 (−0.28 to 0.91)	0.15	.29	3.57	3.19	0.38 (−0.27 to 1.04)	0.18	.25	0.06
READ quality	1.54	1.20	0.34 (0.02 to 0.67)	0.32	.04	1.57	1.35	0.22 (−09 to 0.52)	0.20	.16	0.12
READ diverse concepts	1.45	1.24	0.21 (0.001 to 0.42)	0.27	.049	1.57	1.43	0.14 (−0.08 to 0.36)	0.18	.22	0.07
PVR	7.72	7.43	0.28 (−0.61 to 1.17)	0.09	.53	7.66	6.98	0.68 (−0.08 to 1.45)	0.23	.08	0.40
PVR everyday routines	3.31	3.41	−0.10 (−0.63 to 0.43)	−0.05	.71	3.55	3.24	0.31 (−0.20 to 0.83)	0.17	.23	0.41
PVR play and pretend	4.40	4.02	0.37 (−0.16 to 0.91)	0.21	.17	4.11	3.74	0.37 (−0.10 to 0.84)	0.21	.12	0
PIDA	2.99	2.54	0.45 (0.07 to 0.82)	0.34	.02	2.85	2.64	0.21 (−0.16 to 0.59)	0.16	.27	0.24
Parental warmth (PYB)	6.63	6.58	0.04 (−0.11 to 0.19)	0.09	.58	6.78	6.76	0.02 (−0.08 to 0.12)	0.04	.70	0.02
Observational outcomes											
Parent-child interaction (PCIRS-IA)											
Sensitivity	4.01	3.85	0.16 (−0.20 to 0.52)	0.14	.38	4.20	4.01	0.19 (−0.15 to 0.54)	0.17	.27	0.03
Intrusiveness	3.65	3.32	0.33 (−0.08 to 0.74)	0.24	.12	2.83	2.96	−0.13 (−0.55 to 0.30)	−0.09	.56	0.46
Cognitive development	3.62	3.14	0.48 (0.13 to 0.84)	0.47	.01	3.63	3.36	0.27 (−0.02 to 0.55)	0.26	.07	0.21
Language quantity	4.55	3.44	1.11 (0.58 to 1.64)	0.70	.00	3.92	3.77	0.15 (−0.25 to 0.55)	0.09	.47	0.96
Language quality	4.13	3.35	0.78 (0.31 to 1.26)	0.52	.00	3.92	3.59	0.33 (−0.09 to 0.75)	0.22	.12	0.45
Cognitive stimulation factor	4.08	3.31	0.77 (0.34 to 1.20)	0.60	.00	3.82	3.57	0.25 (−0.08 to 0.58)	0.20	.14	0.52

NYC sample (n = 183 survey, 179 observations), Pittsburgh (n = 179 survey, 180 observations). PYB, Parenting Your Baby: Supporting and Enjoying.

[a] Impact based on difference in raw scores.

[b] Effect size calculated by using Cohen's d.

[c] Difference in treatment impact by site.

impacts on parenting behaviors across two geographically distant sites with mothers from racially and ethnically diverse backgrounds. Although exploratory analyses suggest some potential site differences in impact, clinically meaningful effect sizes were found at both sites, suggesting utility in both communities and generalizability of the program to sites led by individuals outside the original VIP project. Future study at subsequent assessments will further determine impacts and feasibility of the integrated, comprehensive SB model.

ACKNOWLEDGMENTS

We thank many individuals who contributed to this project, including Angelica Alonso, Jenny Arevalo, Adriana Chung, Aida Custode, Fernanda Fernandez, Ashley Griffin, Yuliya Gurevich, Julianna Gutierrez, Jessica Harding, Spenser Kinsey, Jennifer Ledesma, Maya Matalon, Elise Mauren, Maritza Morales-Gracia, Luciane Piccolo, Christopher Rodrigues, Anne Seery, Tracie Stuft, and Mackenzie Whipps. We also thank all of the children and parents who participated in this research and the many research interns who assisted with this project.

ABBREVIATIONS

CI: confidence interval
FCU: Family Check-Up
PCIRS-IA: Parent-Child Interaction Rating Scales – Infant Adaptation
PIDA: Parental Involvement in Developmental Advance
PVR: Parent Verbal Responsivity
RCT: randomized controlled trial
READ: Reading Activities
SB: Smart Beginnings
UPMC: University of Pittsburgh Medical Center
VIP: Video Interaction Project

Deidentified primary data will be made available to interested researchers through the establishment of data sharing agreements. Consistent with National Institutes of Health policy, the time line for release of data will be no later than the acceptance for publication of the main findings from the final data set. Data will be made available to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal. Proposals should be submitted to Pamela Morris (pamela.morris@nyu.edu).

This trial has been registered at www.clinicaltrials.gov (identifier NCT02459327).

DOI: https://doi.org/10.1542/peds.2020-1799

Accepted for publication Nov 17, 2020

Address correspondence to Alan L. Mendelsohn, MD, Department of Pediatrics, NYU Grossman School of Medicine and Bellevue Hospital Center, 550 First Ave, New York, NY 10016. E-mail: alan.mendelsohn@nyulangone.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Funded by the National Institutes of Health (NIH), grant R01HD076390 01-05 and R01HD076390 06-07, Tiger Foundation, Marks Family Foundation, Children of Bellevue, Inc, and Allegheny County Department of Human Services. Drs Roby and Canfield were supported in part by a National Research Service Award from the Health Resources and Services Administration (T32 HP22238), with training supported in part by a New York University Clinical and Translational Science Award (UL1 TR001445) from the National Center for Advancing Translational Sciences, National Institutes of Health. Funded by the National Institutes of Health (NIH).

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Council on Community Pediatrics. Poverty and child health in the United States. *Pediatrics*. 2016;137(4):e20160339
2. Mendelsohn AL, Cates CB, Weisleder A, Berkule SB, Dreyer BP. Promotion of early school readiness using pediatric primary care as an innovative platform. *Zero Three*. 2013;34(1):29–40
3. High PC, Klass P; Council on Early Childhood. Literacy promotion: an essential component of primary care pediatric practice. *Pediatrics*. 2014; 134(2):404–409
4. Love JM, Kisker EE, Ross C, et al. The effectiveness of Early Head Start for 3-year-old children and their parents: lessons for policy and programs. *Dev Psychol*. 2005;41(6):885–901
5. Jimenez ME, Barg FK, Guevara JP, Gerdes M, Fiks AG. Barriers to evaluation for early intervention services: parent and early intervention employee perspectives. *Acad Pediatr*. 2012;12(6):551–557
6. Prinz RJ, Smith EP, Dumas JE, Laughlin JE, Whte DW, Barrón R. Recruitment and retention of participants in prevention trials involving family-based interventions. *Am J Prev Med*. 2001; 20(suppl 1):31–37
7. Heneghan AM, Silver EJ, Bauman LJ, Westbrook LE, Stein REK. Depressive symptoms in inner-city mothers of young children: who is at risk? *Pediatrics*. 1998;102(6):1394–1400
8. Karoly LA. *Investing in Our Children: What We Know and Don't Know About the Costs and Benefits of Early*

Childhood Interventions. Santa Monica, CA: RAND Corporation; 1998

9. Mendelsohn AL, Huberman HS, Berkule SB, Brockmeyer CA, Morrow LM, Dreyer BP. Primary care strategies for promoting parent-child interactions and school readiness in at-risk families: the Bellevue Project for Early Language, Literacy, and Education Success. *Arch Pediatr Adolesc Med*. 2011;165(1):33–41
10. Shaw DS, Dishion TJ, Supplee L, Gardner F, Arnds K. Randomized trial of a family-centered approach to the prevention of early conduct problems: 2-year effects of the Family Check-Up in early childhood. *J Consult Clin Psychol*. 2006; 74(1):1–9
11. Cates CB, Weisleder A, Berkule Johnson S, et al. Enhancing parent talk, reading, and play in primary care: sustained impacts of the Video Interaction Project. *J Pediatr*. 2018;199:49–56.e1
12. Krumpal I. Determinants of social desirability bias in sensitive surveys: a literature review. *Qual Quant*. 2013; 47(4):2025–2047
13. Zaslow MJ, Weinfield NS, Gallagher M, et al. Longitudinal prediction of child outcomes from differing measures of parenting in a low-income sample. *Dev Psychol*. 2006;42(1):27–37
14. Mendelsohn AL, Dreyer BP, Flynn V, et al. Use of videotaped interactions during pediatric well-child care to promote child development: a randomized, controlled trial. *J Dev Behav Pediatr*. 2005;26(1):34–41
15. Needlman R, Fried LE, Morley DS, Taylor S, Zuckerman B. Clinic-based intervention to promote literacy. A pilot study. *Am J Dis Child*. 1991;145(8): 881–884
16. Dishion TJ, Stormshak EA. *Intervening in Children's Lives: An Ecological, Family-Centered Approach to Mental Health Care*. Washington, DC: American Psychological Association; 2007
17. New York State Department of Health. Eligibility criteria. 2005. Available at: https://www.health.ny.gov/community/infants_children/early_intervention/memoranda/2005-02/eligibility_criteria.htm. Accessed September 24, 2020
18. Commonwealth of Pennsylvania. Early intervention services. 2016. www.pacodeandbulletin.gov/secure/pacode/data/055/chapter4226/055_4226.pdf. Accessed September 24, 2020
19. Dreyer BP, Mendelsohn AL, Tamis-Lemonda C. Assessing the child's cognitive home environment through parental report: reliability and validity. *Infant Child Dev*. 1996;5(4):271–287
20. Mendelsohn AL, Cates CB, Tamis-LeMonda CS, Dreyer BP. StimQ cognitive home environment. Available at: https://www.videointeractionproject.org/stimq.html. Accessed October 20, 2020
21. McEachern AD, Dishion TJ, Weaver CM, Shaw DS, Wilson MN, Gardner F. Parenting Young Children (PARYC): validation of a self-report parenting measure. *J Child Fam Stud*. 2012;21(3): 498–511
22. Clark R. The parent-child early relational assessment: a factorial validity study. *Educ Psychol Meas*. 1999; 59(5):821–846
23. NICHD Early Child Care Research Network. Child care and mother-child interaction in the first 3 years of life. *Dev Psychol*. 1999;35(6):1399–1413
24. Faul F, Erdfelder E, Buchner A, Lang AG. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. *Behav Res Methods*. 2009;41(4):1149–1160
25. StataCorp. *Stata Statistical Software*. College Station, TX: Stata Corp LLC; 2015
26. Guo G, Harris KM. The mechanisms mediating the effects of poverty on children's intellectual development. *Demography*. 2000;37(4):431–447
27. Kiernan KE, Mensah FK. Poverty, family resources and children's early educational attainment: the mediating role of parenting. *Br Educ Res J*. 2011; 37(2):317–336
28. Shrout PE, Rodgers JL. Psychology, science, and knowledge construction: broadening perspectives from the replication crisis. *Annu Rev Psychol*. 2018;69:487–510
29. Bohr Y, Putnick DL, Lee Y, Bornstein MH. Evaluating caregiver sensitivity to infants: measures matter. *Infancy*. 2018; 23(5):730–747
30. Olds DL, Robinson J, Pettitt L, et al. Effects of home visits by paraprofessionals and by nurses: age 4 follow-up results of a randomized trial. *Pediatrics*. 2004;114(6):1560–1568
31. Caldera D, Burrell L, Rodriguez K, Crowne SS, Rohde C, Duggan A. Impact of a statewide home visiting program on parenting and on child health and development. *Child Abuse Negl*. 2007; 31(8):829–852
32. Duffee JH, Mendelsohn AL, Kuo AA, Legano LA, Earls MF; Council on Community Pediatrics; Council on Early Childhood; Committee on Child Abuse and Neglect. Early childhood home visiting. *Pediatrics*. 2017;140(3): e20172150
33. Caughy MOB, Huang KY, Miller T, Genevro J. The effects of the Healthy Steps for Young Children Program: results from observations of parenting and child development. *Early Child Res Q*. 2004;19(4):611–630
34. Barajas-Gonzalez RG, Ayón C, Torres F. Applying a community violence framework to understand the impact of immigration enforcement threat on Latino children. *Soc Policy Rep*. 2018; 31(3):1–24