

# Assessing the Impacts of Pediatric Primary Care Parenting Interventions on EI Referrals Through Linkage With a Public Health Database

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## Abstract

We sought to determine whether pediatric primary care interventions targeting positive parenting among low socioeconomic status mothers resulted in reduced referrals to the New York City Early Intervention Program (NYC-EIP). Participants in Building Blocks (BB) and the Video Interaction Project (VIP) were linked with the NYC-EIP administrative dataset to determine referrals. In all, 139 of 422 study participants (31.4%) meeting inclusion criteria were referred to the NYC-EIP. Although referrals did not differ overall by group (VIP 29.8%; BB 33.8%; control 35.3%), differences were found for mothers with education/literacy of seventh grade or higher (interaction  $p = .02$ ). In that subgroup, VIP was associated with reduced referrals by age 3 years (22.4%; adjusted odds ratio 0.53; 95% confidence interval [0.29, 0.97]), compared with BB (35.0%) and controls (34.3%), with survival analysis showing reduced cumulative risk ( $p = .04$ ). We conclude that VIP resulted in reduced referrals for early intervention evaluation among children of mothers with seventh-grade education or higher.

## Keywords

child development, cognitive development, behavior problems and disorders, disabilities and development delays

Parenting plays a crucial role in early child development, with major impacts on cognitive, language, and social-emotional development (Brooks-Gunn & Markman, 2005; Chazan-Cohen et al., 2009). Interventions aimed at enhancing parenting have emerged as a critical target in

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efforts to reduce poverty-related disparities in child development and academic achievement. Pediatric primary care in particular has been recognized as an effective and low-cost platform for interventions promoting enhanced parenting practices (Garner et al., 2012; Mendelsohn, 2002; Milteer, Ginsburg, & Mulligan, 2012; Weisleder et al., 2016).

Due to federal requirements for health screening and immunizations prior to school entry, children in the United States attend approximately 13 to 15 pediatric primary care visits from birth to age 5, providing an opportunity for the delivery of long-term and population-wide interventions promoting positive parenting activities such as verbal responsiveness, pretend play, and reading aloud (Eckenrode et al., 2010; Landry, Smith, Swank, & Guttentag, 2008; Weisleder & Fernald, 2013). Because children from low-income families often have wide disparities in early development, school readiness, and long-term educational trajectories, interventions based in the pediatric setting have been promoted as a primary prevention strategy to avert poverty-related developmental delays before they arise, acting in a complementary fashion with other programs to potentially reduce the need for more intensive services in the future (Cates, Weisleder, & Mendelsohn, 2016; Peacock-Chambers, Ivy, & Bair-Merritt, 2017).

Several preventive models promoting positive parenting in the pediatric primary care setting have undergone extensive evaluation, including Reach Out and Read (ROR; Klass, Needlman, & Zuckerman, 1999), Healthy Steps (Minkovitz et al., 2003), Video Interaction Project (VIP; Mendelsohn et al., 2005), and Building Blocks (BB; D. H. Clements & Sarama, 2007). ROR promotes shared reading activities in the home through the provision of children's books and anticipatory guidance about book reading to parents during well-child visits beginning at 6 months (Needlman, Toker, Dreyer, Klass, & Mendelsohn, 2005). Despite its low intensity and low cost, studies consistently find that this program results in increased frequency and quality of parents' reading aloud with their children and improved acquisition of expressive language (High, LaGasse, Becker, Ahlgren, & Gardner, 2000; Mendelsohn et al., 2001; Needlman et al., 2005; Zuckerman & Khandekar, 2010). The Healthy Steps program similarly uses parental education to promote child health and development in the broader population during primary care visits and previously through home visitation, and has also been shown to enhance the establishment of daily routines and reduce frequency of physical punishment (Minkovitz et al., 2007). The VIP was designed to build on ROR by providing learning materials such as toys and books in the first weeks of life and adding an interventionist who uses video recordings of the parent and child interacting to promote parents' self-reflection and encourage positive parenting behaviors. Finally, BB provides learning materials and communicates with families through mailed newsletters highlighting positive parenting strategies; it is lower intensity in that it does not include in-person contact but rather is designed to take place remotely through public health and early intervention (EI) systems. Both VIP and BB have also been shown to reduce maternal depressive symptoms (an effect which is thought to be secondary to supporting coping with parental stress), and enhance parent-child interactions, including reading aloud, teaching, playing with toys, and verbal responsiveness (Berkule et al., 2014; Mendelsohn, Dreyer, Brockmeyer, Berkule-Silberman, & Morrow, 2011; Mendelsohn, Huberman, et al., 2011).

In a previous randomized controlled trial (RCT) studying the impacts of VIP relative to a control group, the Bellevue Project for Early Language Literacy and Education Success (the BELLE Project), it was found that VIP resulted in improved child development outcomes in cognitive, language, and social-emotional domains (Mendelsohn et al., 2005; Mendelsohn et al., 2007). In the context of the BELLE Project, the estimated rate of EI eligibility for children who participated in VIP (measured via cognitive and language assessments described in the "Method" section and estimated using 2005 New York State EI eligibility criteria of 2 *SD* below the mean in one developmental domain or 1.5 *SD* below the mean in more than one domain) was found to be lower than the rate for children in a control group; however, this difference did not reach statistical significance (Mendelsohn et al., 2005; Mendelsohn et al., 2007). The current analysis was

also conducted in the context of the BELLE Project, and sought to determine whether VIP resulted in similar reductions in estimated EI eligibility (based on performance on research assessments) as well as reductions in actual referral rates to the New York City EI program based on a linkage between the BELLE and NYC EI datasets.

Previous analyses of VIP outcomes on parenting and child development have revealed that impacts of the program have been moderated by level of maternal education and literacy (Mendelsohn et al., 2005). One possible reason for this is that maternal education and literacy level have been shown to be associated with parenting activities likely to support early child development such as reading aloud and pretend play (Green et al., 2009). In one study, for children whose mothers had at least a seventh-grade education, VIP was associated with a greater than 0.75 *SD* increase in cognitive development. Among mothers who had attended seventh grade, VIP was also associated with a nearly eightfold increase in the percentage of children considered to have normal development, and a trend toward a 50% decrease in the percentage of children who would be considered to have developmental delay (Mendelsohn et al., 2005; Mendelsohn et al., 2007). For children whose mothers had less than seventh-grade education, findings of VIP impacts have been more variable. In the current study, we therefore also sought to determine whether any associations between VIP and reductions in EI referral or estimated EI eligibility were different for children depending on level of maternal education and literacy.

To determine impacts of VIP on EI referral, we used an innovative process to link participants in the BELLE Project with the New York City Department of Health and Mental Hygiene (NYC-DOHMH) EI Program (NYC-EIP) administrative dataset. We also investigated whether reductions in referrals to EI were likely a result of improved child development outcomes. To do this, we compared the occurrence of observed developmental delays among a subset of study participants in intervention and control groups through a composite of cognitive and language testing performed within the BELLE Project.

We sought to answer the following questions: First, is the VIP program associated with reduced referrals to EI programs among a population of children from low–socioeconomic status (SES) families? We hypothesized that participation in VIP would be associated with a reduction in the number of EI referrals relative to a participation in a control group. Next, is a reduction in referrals explained in part by enhancements in child development resulting from participation in VIP? It was expected that participation in VIP would also be associated with reductions in EI eligibility as determined through performance on language and cognitive assessments administered as part of the BELLE Project. Finally, are reduced referrals to EI and estimated EI eligibility moderated by maternal level of education and literacy? In line with previous findings, we expected impacts of VIP to be elevated for children of mothers with higher levels of education and literacy.

## **Method**

### ***Participants and Sampling Procedure***

Enrollment in the BELLE Project was performed in the postpartum ward of an inner-city public hospital serving low-income, primarily immigrant families from November 2005 through October 2008. Consecutive mother–infant dyads meeting inclusion criteria and providing informed consent were enrolled. Inclusion criteria were chosen to provide medical homogeneity, enhance feasibility, and reduce the likelihood of receiving comparable services. Medical criteria were a lack of significant complications requiring extended stay, transfer to a level II/III nursery, or potential adverse developmental consequences; full-term birth at 37 weeks or more; birth weight of 2,500 grams or more; and singleton gestation. Feasibility criteria were mother as the primary caregiver, ability to maintain contact (e.g., working telephone and intention to maintain geographic proximity), and

**Table 1.** Demographics of Parent Population.

	VIP <i>n</i> = 141	BB <i>n</i> = 142	Control <i>n</i> = 139	<i>p</i> <sup>a</sup>
<b>Mother</b>				
Latina	129 (91.5%)	131 (92.3%)	122 (87.8%)	.39
Immigrant	122 (86.5%)	114 (80.3%)	112 (80.6%)	.30
Spanish primary language	107 (75.9%)	34 (71.1%)	101 (72.7%)	.65
Married/partner	114 (80.9%)	120 (84.5%)	111 (79.9%)	.57
Maternal education/literacy at least seventh grade	98 (69.5%)	103 (72.5%)	105 (75.5%)	.53
Low SES <sup>b</sup>	122 (86.5%)	128 (90.1%)	122 (87.8%)	.63
Social risks <sup>c</sup>	33 (23.4%)	32 (22.5%)	34 (24.5%)	.93
<b>Child</b>				
Female gender	72 (51.1%)	73 (51.4%)	68 (48.9%)	.90
First born	58 (58.9%)	57 (58.9%)	50 (64.0%)	.64

Note. VIP = Video Interaction Project; BB = Building Blocks; SES = socioeconomic status.

<sup>a</sup>*p* value comparing demographics across the three groups, based on chi-square.

<sup>b</sup>Hollingshead Socioeconomic Status Level 4 or 5 (categories consistent with low income and poverty).

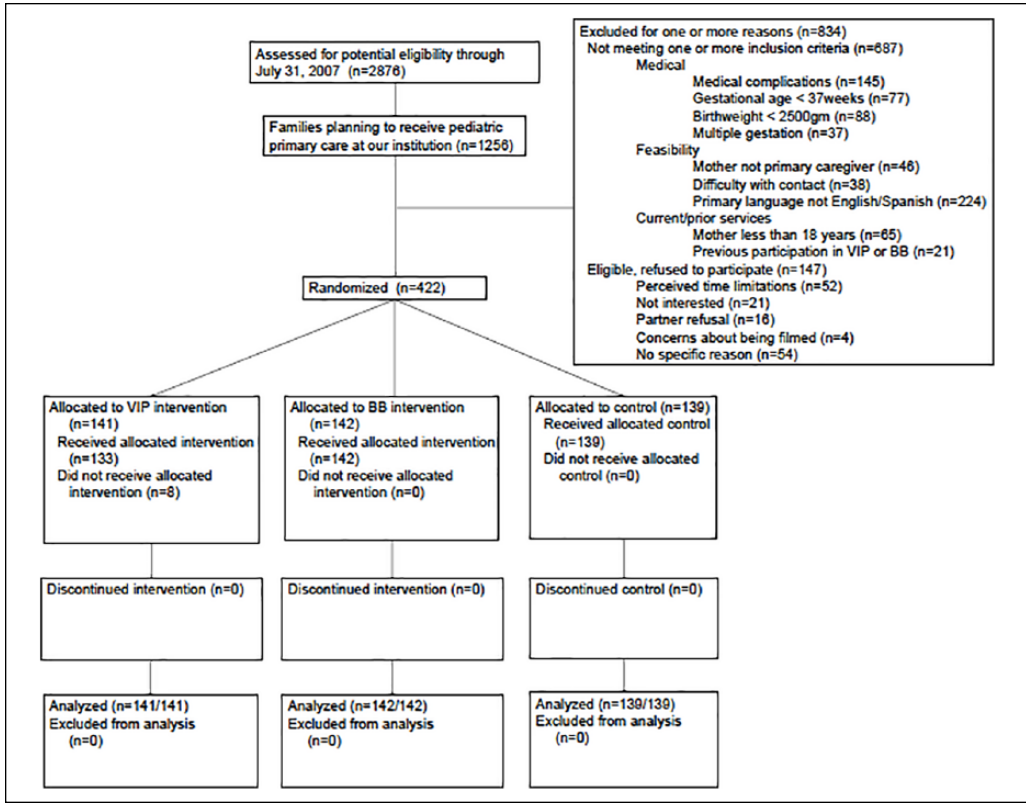
<sup>c</sup>One or more of physical abuse, homeless, child protection, late prenatal care, mental illness.

primary language of English or Spanish. Criteria for no comparable services were maternal age 18 years or older, as adolescent mothers routinely receive parenting services at our institution, and no participation in a prior study of VIP or BB. As shown in Table 1, our study population consisted largely of low-income, Hispanic mothers who were primarily foreign-born and Spanish-speaking.

For the present analysis examining referrals to EI, an additional inclusion criterion was that the child had reached age 3 years 3 months of age by the time the matching process was implemented. This age was chosen because children can be referred to EI up to age 3 years, and a 3-month window was required for the NYC-EIP database (Kids Integrated Data System [KIDS]) to have final information by the time of matching. The matching process was completed in early 2011, due to a narrow window of human subjects approval provided by the New York City Department of Mental Hygiene IRB for matching at this time. Due to this constraint, we were unable to perform matching through age 3 years for the entire sample, and only children born prior to August 1, 2007, met our study criteria. Human subjects approval was provided by the New York University School of Medicine IRB, Bellevue Hospital Center, the New York City Health and Hospitals Corporation, and NYC-DOHMH. The trial was registered at clinicaltrials.gov (NCT00212576).

A total of 422 of 569 dyads (74.2%) meeting study inclusion criteria during this period were enrolled between November 1, 2005, and July 31, 2007, and randomized to VIP (*n* = 141), BB (*n* = 142), and control (*n* = 139; Figure 1). One hundred forty-seven of 569 eligible dyads (25.8%) refused participation, with time limitations cited most frequently. Following enrollment, dyads were randomized to the VIP, BB, or control group using a random number generated by the project director via Microsoft Excel 2003 (Microsoft Corp, Redmond, Washington). Randomization was stratified in blocks of nine to guarantee equal distribution across groups.

All enrolled families were allocated randomly to their intervention group and assessed based on group assignment. VIP families completed a median of 9.5 sessions; 67% of families completed 50% or more of the available sessions, whereas 15% completed fewer than one third (five sessions). Participants were included in the analysis of VIP even if they attended few or no sessions. Eight of 141 families allocated to VIP did not participate in any VIP visits but were still analyzed based on allocation. Sample characteristics for the 422 enrolled families are shown in Table 1. Groups were similar for all sociodemographic characteristics. There were no adverse events related to study participation.



**Figure 1.** Participant enrollment and assessment.  
 Note. VIP = Video Interaction Project; BB = Building Blocks.

## Measures

We assessed sociodemographic and other data characterizing the sample based on parental interview at enrollment. For parents, this included mother's age, country of origin, education, primary language, marital status, and family Hollingshead Socioeconomic Status (Hollingshead, 1975). For children, we obtained information about gender and birth order. In addition, at the 6-month assessment, we assessed word reading as an indicator of maternal literacy in the mother's preferred language using the Woodcock–Johnson III/Bateria III Letter-Word Identification Test (Mather & Woodcock, 2001; Muñoz-Sandoval, Woodcock, McGrew, & Mather, 2005).

The variables of interest in our study included rate of EI referral and estimated rate of EI eligibility. We determined whether BELLE Project participants had ever been referred to the NYC-EIP by matching mother and child data collected as part of the BELLE Project to corresponding data obtained for children referred to NYC-EIP and maintained in the KIDS database. Informed consent was obtained during enrollment for the BELLE Project that allowed for sharing of subject-identifiable information with NYC-EIP. The linking process was performed by an epidemiologist in the Bureau of Early Intervention of the NYC-DOHMH, who had technical expertise regarding the dataset and was blinded to BELLE Project group assignment. Matches were considered present in the KIDS dataset for babies with (a) the same date of birth and (b) the same name listed for either the child or the mother. Names were considered a match if they shared the first three letters of both the first and the last name. Mother's date of birth and most recent zip code were utilized for further confirmation. A positive match was used to define families who had been referred to EI.

We estimated rate of estimated EI eligibility based on measurement of developmental delays through a composite of cognitive and language outcomes assessed by the BELLE Project. Outcomes were measured using the Bayley Scales of Infant and Toddler Development (Bayley, 1993) for cognitive development, the Preschool Language Scale (Zimmerman, Steiner, & Pond, 1992) for language development at 14 and 24 months, and the Clinical Evaluation of Language Fundamentals (Semel, Wiig, & Secord, 2003) for language development at 36 months. Overall rate of measured developmental delay was calculated as a composite of cognitive and language testing performed within the BELLE Project research protocol. For the purposes of analysis, children were considered to be EI eligible if they met New York State EI criteria: that children must be less than 3 years of age and have a confirmed disability or established developmental delay in physical, cognitive, communication, social-emotional, and/or adaptive domains (NYC-EIP, Bureau of Family and Community Health, Department of Health and Mental Hygiene). Further details on EI criteria are defined by New York State Public Health Law (Article 25 Title II-A, SUBPART 69-4). Developmental delays were measured for the subset of BELLE Project children born within the same window (i.e., prior to August 1, 2007) as those matched with the KIDS database. In addition, parents were surveyed when children were 14, 24, and 36 months with probes assessing whether they were currently receiving EI or whether they had ever in the past received EI or any related services such as speech, physical, or occupational therapy.

### **Interventions**

The BELLE Project was a single-blind, three-way RCT, with two intervention groups (VIP and BB) compared with a control group receiving routine well-child care (Mendelsohn, Huberman, et al., 2011). The VIP, BB, and control groups received the same well-child care provided by the same primary care pediatricians, including all routine anticipatory guidance and developmental surveillance as recommended by the American Academy of Pediatrics (Hagan, Shaw, & Duncan, 2007). This included delivery of the ROR program provided as standard of care for all families (Klass, Dreyer, & Mendelsohn, 2009). Reminder telephone calls were made regarding upcoming pediatric visits to equalize primary care across groups.

The VIP intervention occurred at regularly scheduled pediatric visits beginning in the first month of life, with 15 possible sessions offered through age 3 years (Mendelsohn, Huberman, et al., 2011). During VIP sessions, an interventionist met with families in one-on-one sessions for 25 to 30 min. Parent-child dyads were video-recorded during 5- to 7-min play/shared-reading interactions using a developmentally appropriate toy or book provided by the program. The interventionist reviewed the video along with the parent to identify and reinforce responsive interactions and promote parent self-reflection. The video was given to the parent to promote generalization of identified behaviors in the home, and pamphlets were provided with suggestions related to positive parenting during play, reading, and daily routines. Learning materials in the form of toys or books were also provided during these sessions, as well as opportunities for parents to develop their own plans and goals for interacting with their child. When possible, the same interventionist met with each family at each session. Interventionists typically had bachelor's degrees in fields related to young children and received training and supervision by BELLE Project leadership. VIP had an estimated cost of US\$175 to US\$200 per child per year.

The BB intervention also focused on supporting interactions in the context of pretend play, shared reading, and daily routines from birth to 3 years (Mendelsohn, Huberman, et al., 2011). BB utilized mailed information and learning materials to improve parent self-efficacy and to promote positive parenting. Each month, parents were mailed a toy or book, along with a newsletter that provided information on encouraging learning and ideas for interactions around a specific developmental goal. Although BB did not require in-person time, some effort was needed to coordinate mailings and communications with families. Parents were also asked to complete

Ages and Stages Questionnaires (Squires, Bricker, Twombly, & Potter, 2009) to encourage parents become active observers of their child's development. BB has an estimated cost of US\$75 to US\$100 per child per year.

### Data Analysis

Sample size estimates for enrollment in the larger study were based on analyses related to primary specific aims (Mendelsohn, Huberman, et al., 2011), with 675 families providing 80% power to find 0.33 *SD* differences. The subsample of 422 families utilized in this analysis provided 80% power to find a reduction of EI referral from 35% to 20%, with alpha .05. Statistical analyses were performed based on intention-to-treat using SPSS 18.0. We compared randomization groups for likelihood of ever having had an EI referral with logistic regression, in which VIP and BB were dummy coded and compared with controls. Adjusted odds ratios (AORs), absolute risk reductions (ARRs), relative risk reductions (RRRs), and number-needed-to-treat with corresponding 95% confidence intervals (CIs) were calculated.

We also examined whether maternal education (based on survey) and maternal literacy (based on Woodcock–Johnson/Woodcock–Munoz) moderated intervention group impact on EI referral, based on a composite variable calculated by multiplying together a dummy coded variable for maternal literacy/education each at least seventh grade and each of the dummy coded variables for VIP and BB. The role of maternal education/literacy as a moderator of impact on EI referral was assessed through inclusion in models of these composite variables.

To determine whether there were any group differences in pattern or timing of EI referral, we assessed rate of EI referral with survival analysis, tested by log rank (Mantel–Cox) chi-square, using the date that each family was logged into the KIDS database. This enabled us to explore the pattern of differences in rates of referral to EI across the birth to 3-year period. Survival analysis enabled us to take into account variations in EI referral by age and to examine patterns in when EI referral took place. This method allowed us to better assess whether the impact of VIP on referrals to EI tended to correspond with periods of development when delays frequently become visible in low-income populations.

In addition, to provide external validity to our matching process, we compared the EI referral rate (based on inclusion in the KIDS database) with the percentage of families from each group who reported to BELLE Project investigators that they had been referred to EI or related programs during assessment interviews. Finally, to answer the question as to whether any group differences in EI referral as represented by inclusion in the KIDS database may have corresponded to reductions in developmental delays due to the intervention, we also analyzed observational data of child language and cognitive outcomes collected as part of the BELLE Project research protocol at 14-, 24-, and 36-month assessments.

### Results

The matching process identified 139 of 422 BELLE Project participants (31.4%) who were determined to have matches in the KIDS database. These participants were considered to have been referred to EI for the analyses that follow. All 139 participants matched both for baby's date of birth and for child's or mother's name, with 108 (77.7%) matching for both names. Also, 43 of 52 (82.6%) with available data in both datasets further matched for mother's date of birth, while 67 of 91 (73.6%) further matched for most recent zip code.

We determined whether BELLE Project families with matches in the KIDS database also had evidence of EI referral or estimated EI eligibility (i.e., measurable developmental delays) based on data obtained at 14-, 24-, or 36-month BELLE Project assessments. As part of the BELLE Project research protocol, children underwent assessment across several developmental domains

**Table 2.** Impact of Group Assignment on Rate of Referral to EI.

	VIP	BB	Control	VIP vs. control		BB vs. control	
				Adjusted odds ratio (95% CI)	<i>p</i>	Adjusted odds ratio (95% CI)	<i>p</i>
All families ( <i>n</i> = 422)	42/141 (29.8%)	48/142 (33.8%)	49/139 (35.3%)	0.78 [0.47, 1.29]	.33	0.94 [0.57, 1.53]	.80
Subgroup with maternal education/literacy seventh grade or higher ( <i>n</i> = 306)	22/98 (22.4%)	35/103 (35.0%)	36/105 (34.3%)	0.53 [0.30, 0.96]	.04	0.99 [0.58, 1.68]	.96

Note. EI = early intervention; VIP = Video Interaction Project; BB = Building Blocks; CI = confidence interval.

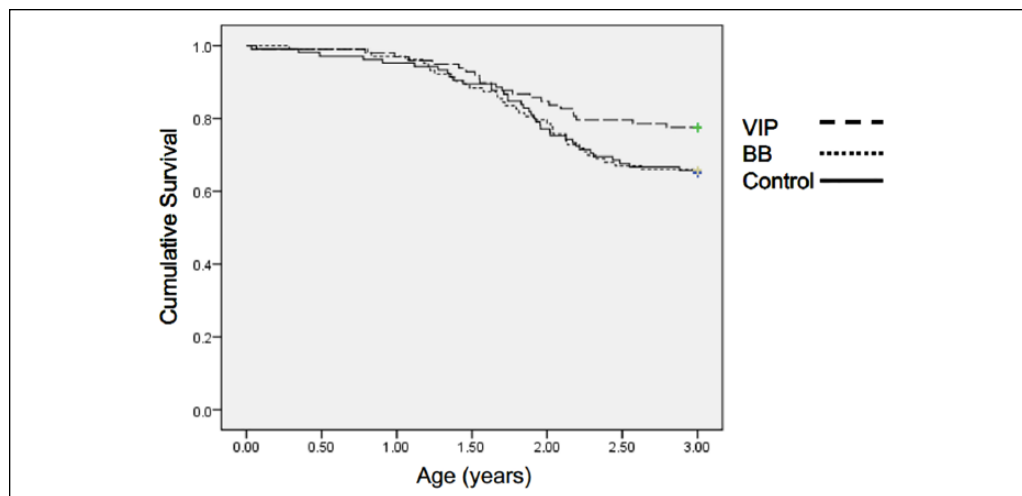
at one or more of these age points. Among 314 families who had participated in at least one of these assessments, 54 either met potential EI eligibility criteria as defined by our research protocol (*n* = 37) or reported receipt of EI services (*n* = 17). Forty-eight of these 54 (88.9%) had matches in the KIDS dataset, providing external validity for the matching process. However, the BELLE Project assessment of EI eligibility was limited because social-emotional development was not assessed comprehensively during BELLE Project assessments prior to 3 years of age, and physical development was not assessed at all, which may have resulted in an underestimate of EI eligibility among study participants. It is possible, therefore, that some or all of the 91 children not found to be EI eligible by our research protocol, yet who were matched in the KIDS database (*n* = 139), were found to be eligible for EI services based on other criteria. Because some families did not complete all possible assessments, those children assessed only at the 14-month BELLE Project assessment but not at 24- or 36-months may also have gone on to receive EI services or develop recognizable delays at a later age that was not assessed by our protocol.

Table 2 shows impacts of group assignment on the rate of having been referred for EI services by age 3 years. For the overall sample, 29.8% of VIP families, 33.8% of BB families, and 35.3% of control families had been referred for EI services. In logistic regression analysis, neither VIP (*p* = .33) nor BB (*p* = .80) were statistically significantly different from controls. However, an interaction was found between level of maternal education/literacy and receipt of VIP (*p* = .005), with impacts found for the subgroup of VIP children whose mothers had at least seventh-grade education/literacy. For mothers with seventh grade or higher education/literacy, 22.4% of VIP children, 35.0% of BB children, and 34.3% of control children had been referred to EI. In multiple logistic regression analyses estimating impacts for this subgroup, VIP children had reduced adjusted odds (AOR 0.53, 95% CI [0.30, 0.96]) of having had an EI referral compared with control children. This corresponded to an ARR of .12 (95% CI [0.01, 0.22]) and an RRR of .34 (95% CI [0.01, 0.57]) for VIP families compared with all other families. Approached from a number needed to treat perspective, approximately nine families (95% CI 5,83) would need to receive VIP to prevent one referral to EI. A similar interaction was not found for BB (*p* = .64).

For the overall sample, no difference was found regarding the pattern or timing of referral across the birth to 3-year period. However, rate of referral through age 3 years for children whose mothers had at least seventh-grade education/literacy was found to be reduced for VIP families compared with all other families in survival analysis with log rank (Mantel-Cox)  $\chi^2 = 4.2$ , *p* = .04. As shown in Figure 2, divergence between VIP and the other two groups began at approximately 1.5 years and widened through age 3 years.

Finally, we assessed overall rate of estimated EI eligibility across the birth to 3-year period based on a composite score of measured cognitive and language delays for the subset of BELLE Project children born within the same window as those matched with the KIDS database. Among





**Figure 2.** Cumulative probability of non-referral to EI by group for children of mothers with seventh grade or higher education/literacy.

Note. EI = early intervention; VIP = Video Interaction Project; BB = Building Blocks.

210 VIP and control families completing one or more assessments within the BELLE Project protocol (74.2% of 283 families included in the matching process), rate of estimated EI eligibility was 12.8% for VIP children, compared with 17.8% for controls (Yates corrected  $\chi^2 = 0.66$ ,  $p = .42$ ). For the subsample of families with maternal education/literacy of seventh grade or higher, rate of estimated EI eligibility was 5.6% for VIP children, compared with 20.8% for controls (Yates corrected  $\chi^2 = 6.1$ ,  $p = .01$ ).

## Discussion

The potential to utilize pediatric primary care as a platform for the promotion of parent-child interaction and reduction in poverty-related disparities in child development is well recognized (Mendelsohn et al., 2013). This study provides evidence that a pediatric primary care-based parenting intervention, VIP, significantly reduced the number of referrals made to EI for evaluation. This finding is in line with previous study of the VIP intervention which has demonstrated enhanced child development outcomes across multiple domains (Mendelsohn et al., 2018; Mendelsohn et al., 2005; Mendelsohn et al., 2007; Weisleder et al., 2016).

Results of the current study also extend previous findings reported about VIP impacts on the need for EI services. Whereas previous studies of VIP have suggested that VIP participation reduced the need for EI services as demonstrated through trends for reductions in the number of children meeting the equivalent of state eligibility standards based on assessments administered in the context of the research protocol (Mendelsohn et al., 2005; Mendelsohn et al., 2007), the current study used an innovative linkage of a clinical trial with a public health database. This study has yielded new evidence of the potential impact of a preventive intervention in addressing poverty-related disparities in child development and early school readiness. Linkages with EI datasets have been performed for longitudinal analyses (Barfield et al., 2008; K. M. Clements, Barfield, Kotelchuck, Lee, & Wilber, 2006), but not, to our knowledge, in combination with clinical trials of pediatric preventive interventions. The validity of the systematic matching process was supported by the observed rate of referral, approximately one third, which is consistent with existing data showing 17.9% of low-income families eligible for EI (Rosenberg, Zhang, &

Robinson, 2008) and Hispanic children having odds ratios of 2.04 to 5.69 for delay (Hillemeier, Morgan, Farkas, & Maczuga, 2011). In New York City, previous reports suggest that nearly 20% of all live births are referred to EI by age 3 (Ensler et al., 2008).

While linking a dataset from a clinical trial with an EI dataset is a primary strength of this study, a potential limitation of the linkage process is the possibility of under-identification of referred families. Because the linkage was performed only for the NYC-EIP KIDS database, referrals to EI programs among families that moved away from New York City may have been missed. Other potential limitations in the matching process include the possibility of duplicate names or inaccurate records, leading to an over- or underestimation of referrals. In this study however, an estimation of EI eligibility as well as report of EI services in the context of a research protocol provided a measure of external validity for the matching process in that 48 of the 54 (89%) families determined through parental interview to be referred to EI were actually in the EI database, suggesting a successful match. It is also possible that those families who refused to participate in the study may limit overall generalizability of study findings. However, we would not expect the rate of moving or an erroneous matching process to differ in relation to group status, and such under-identification is unlikely to have affected our results.

It is also important to note that although referrals to EI represent a marker for potential developmental delay, they do not precisely correspond to need for or eligibility for delivery of services (K. M. Clements et al., 2006). Although our study considered a reduction in EI referrals as a proxy measure for a reduction in the need for EI services, this is only one possible interpretation of our results. Past studies have found that most children in need of EI services do not receive necessary referrals (Rosenberg, Robinson, Shaw, & Ellison, 2013). Low-income families, in particular, may face disparities in referral for and receipt of services (Barfield et al., 2008; Rosenberg et al., 2008). Reductions in the rate of referrals could therefore be viewed as a negative outcome rather than a positive, if it did not occur in the context of a reduction in eligibility for EI through improved child development outcomes. Reduced referrals obtained through participation in VIP could potentially represent increased confidence on the part of parents, or a reluctance or inability to refer to EI services. However, previous studies have found that the relationship-based nature of the VIP intervention, in which parents receive longitudinal social support, increases engagement and investment in children's development, rather than decreasing it (Cates et al., 2018). Existing data thus suggest that an increased rate of pursuing or following up with referrals would be expected among VIP groups. It is also unlikely that group differences in EI referrals among groups could be explained by any disparities in ability to access EI referrals as most families in the study sample in all groups were low SES.

Furthermore, the theory that decreased referral to EI is due to positive effects of VIP participation is supported by data collected as part of the BELLE Project protocol. In line with prior analysis which demonstrated improved child development outcomes resulting from VIP (Cates et al., 2018; Mendelsohn et al., 2005; Mendelsohn, Huberman, et al., 2011; Mendelsohn et al., 2007; Weisleder & Fernald, 2013), results from the current study demonstrated a reduction in eligibility for EI associated with VIP participation, estimated through performance on standardized measures of cognitive and language development administered in the context of the research protocol. Specifically, results indicated an estimated 17.8% eligibility in the control group (20.8% in the subgroup with mothers  $\geq$  seventh-grade education) relative to only 12.8% eligibility in the VIP group (5.6% for mothers with  $\geq$  seventh-grade education). Despite robust group differences, it should be reiterated that these estimated measures of eligibility do not necessarily equate to eligibility as determined by existing EI standards, as the BELLE Project criteria did not assess comprehensively all aspects of development relevant to EI (e.g., physical development). Nevertheless, these results suggest the possibility that VIP participation is associated with reductions in developmental delay, which may potentially result in reduced need for EI services. These findings may have implications for public policy. Although there has been no formal cost

analysis of VIP, current estimates suggest a cost of approximately US\$175 to US\$200 per mother–child dyad per year at scale. To the extent that pediatric primary care interventions like VIP could enable EI evaluations and services to be redirected toward children in need of more intensive intervention, there is potential for increased efficiency in EI expenditures overall.

Results indicated no differences in rate of EI referral as a result of participation in the BB intervention, which is unsurprising given the relatively low intensity of BB. However, although we did not find impacts of BB on EI referrals, we have previously shown that this intervention does lead to some improvements in parent–child interactions and in maternal depressive symptoms (Berkule et al., 2014; Mendelsohn, Huberman, et al., 2011). It is possible that BB may represent an effective approach for a subset of families who do not require as intensive an intervention as VIP. This would be a useful topic of further study.

As discussed previously, prior analyses have found moderation of VIP outcomes with maternal education and literacy (Mendelsohn et al., 2005; Mendelsohn, Huberman, et al., 2011; Mendelsohn et al., 2007). The current study therefore also aimed to determine whether maternal education and literacy would moderate intervention impacts on rate of referral to EI. Consistent with earlier VIP findings, results indicated the greatest reduction in referrals to EI for children whose mothers have seventh-grade education or higher. These findings, taken together with earlier intervention impacts, suggest that higher intensity interventions may be needed to improve child development outcomes in families with very low maternal education/literacy.

Despite being an important first step for demonstrating real-world impacts of a primary care parenting intervention, additional study is needed to determine VIP's impact on need for EI services and expenditures. One potential issue is that generalizability of study results may be limited as the current study is not representative of the entire population of EI children, particularly those with recognized genetic or congenital issues at birth who require EI services, as these individuals were excluded from the present study. Furthermore, similar to our prior analyses of impacts of VIP on EI (Mendelsohn et al., 2005), impacts on EI referral and eligibility were found to be strongest for mothers with at least seventh-grade education/literacy. For mothers of the lowest education level, VIP intervention may not be rigorous enough to significantly alter child development outcomes. Nonetheless, approximately 67% of women below the U.S. poverty line have completed high school or equivalent, suggesting that our intervention findings would be applicable to the majority of low-income families (U.S. Census Bureau American Community Survey, 2011).

In conclusion, our findings suggest that pediatric primary care interventions promoting positive parenting and school readiness may have a community-level impact on patterns of referral for EI services. It is important to note that prevention strategies based in pediatric primary care are likely to represent only one component of a comprehensive effort to address poverty-related disparities in child development in the United States. Nonetheless, these findings support continued refinement of primary prevention strategies in the pediatric setting and consideration of scale-up for such programs as part of a broader population-level public health strategy to address poverty-related disparities. In combination with ongoing EI interventions, programs such as VIP that are delivered in the pediatric primary care setting should be viewed as an additional prevention strategy to optimize child development outcomes at the population level.

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