Promoting Cognitive Stimulation in Parents Across Infancy and Toddlerhood: A Randomized Clinical Trial

Elizabeth B. Miller, PhD[1], Erin Roby, PhD[2], Yudong Zhang, PhD[3], Lerzan Coskun, PhD[1], Johana M. Rosas, PhD[4], Marc A. Scott, PhD[5], Juliana Gutierrez, BA[2], Daniel S. Shaw, PhD[4], Alan L. Mendelsohn, MD[2], and Pamela A. Morris-Perez, PhD[6]

Objective To test the impact of the fully integrated Smart Beginnings model on parental support of cognitive stimulation from 6 to 24 months across infancy and toddlerhood.

Study design This was a single-blind, 2-site randomized clinical trial of the Smart Beginnings intervention. Enrollment took place at birth in postpartum units of hospitals in New York City and Pittsburgh, Pennsylvania, with a consecutive sample of 403 mother–infant dyads. Smart Beginnings combines a Video Interaction Project—14-session universal primary prevention program delivered in the pediatric clinic at the time of well-child visits birth-36 months—with potential for Family Check-Up—3-4 sessions targeted secondary prevention home-visiting program. The principal outcome was parental support of cognitive stimulation assessed via parent survey and video-recorded observations of parent–child interactions. Ordinary least squares and mixed effects regressions were conducted.

Results Families were mostly Black/African-American (50%) or Latinx (42%); all were Medicaid eligible (100%). Smart Beginnings significantly promoted cognitive stimulation during infancy and toddlerhood for most survey outcomes across time, including StimQ common total (effect size [ES] = 0.25, P = .01) and READ Quantity (ES = .19, P = .04) and Quality (ES = .30, P = .001). For the observations, the impact of Smart Beginnings varied by time, with significant impacts at 6 (ES = 0.37-.40, P < .001) and 24 (ES = 0.27-.30, P < .001) months, but not 18 months.

Conclusions Smart Beginnings positively promotes cognitive stimulation from infancy through toddlerhood using the integrated model. This study adds to the body of research showing preventive interventions in pediatric primary care and home visiting can support early relational health including parental support of cognitive stimulation. *(J Pediatr 2023;255:159-65)*.

Trial registration NCT02459327.

The impact of poverty on child development has been documented including reduced opportunities for early learning and long-term disparities in school readiness and educational achievement.[1-6] These disparities are exacerbated by systemic race-related inequities that operate at both the individual[7] and community levels.[8,9] This can cause "toxic stress," the biological process that occurs after prolonged activation of the body's stress response systems in the context of chronic adversity.[10] Parent–child early relational health, which includes parent–child relationship quality, creating/maintaining structure, and providing positive child experiences, including practices such as cognitive stimulation, has been shown to support resiliency in the context of disparities resulting from poverty, racism, and toxic stress.[11,12] Early relational health is a modifiable target for early childhood interventions seeking to support primary prevention of these disparities.[10]

Early childhood preventive interventions have shown potential in promoting children's school readiness by supporting early relational health during the infant and toddler years, including the Nurse–Family Partnership and Early Head Start programs.[13-15] However, such approaches face challenges that limit impact at the individual and population level, specifically in their ability to identify and engage families[16]; be cost effective[17]; and address heterogeneity of risk within low-income families.[18]

The Smart Beginnings model addresses these challenges by integrating 2 interventions with demonstrated efficacy: a health care–based universal primary prevention program and a home-based selective secondary prevention program.

ES	Effect size
H+H	Health+Hospitals
PIDA	Parental Involvement in Developmental Advance
PVR	Parent Verbal Responsivity
READ	Reading Activities
VIP	Video Interaction Project

From the [1]Department of Population Health, and [2]Department of Pediatrics, NYU Grossman School of Medicine, New York, NY; [3]Department of Medical Social Sciences, Northwestern University, Chicago, IL; [4]Department of Psychology, University of Pittsburgh, Pittsburgh, PA; [5]Department of Applied Statistics, Social Science, and Humanities, and [6]Department of Applied Pscychology, New York University, New York, NY

Supported by the *Eunice Kennedy Shriver* National Institute of Child Health & Human Development of the National Institutes of Health under Award Number R01HD076390. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The funders of the trial had no role in the study design; the collection, analysis, and interpretation of the data; the writing of the report; or the decision to submit the paper for publication. The authors declare no conflicts of interest.

https://doi.org/10.1016/j.jpeds.2022.11.013

The Video Interaction Project (VIP)[19] uses pediatric well-child visits to connect families with a coach who facilitates parent–child interactions through provision of learning materials and real-time feedback on families' video-recorded play and reading sessions. The Family Check-Up (FCU)[20] uses home visiting beginning during infancy to deliver additional, targeted services to families identified as having increased needs based on screening performed at that time. The FCU assesses family strengths and vulnerabilities through motivational interviewing and family management training to support positive parent and child behavior.

The Smart Beginnings model uses the pediatric platform to identify families with young children before school entry and builds on existing infrastructure to reduce cost. Heterogeneity in family risk is addressed by tailoring intervention modalities to individual families' needs, with less-intensive services offered to families universally (VIP) and more-intensive services offered as needed to those with greater stressors (the FCU). Both Smart Beginnings programs support parents with early relational health across the developmental stages of infancy and toddlerhood.[21] The Smart Beginnings model increases potential for obtaining population-level reach and maximizing impact for families with young children.[22]

We have documented the effectiveness of the VIP program of Smart Beginnings in engaging traditionally hard-to-reach families and increasing their participation,[23] as well as improving parental support of cognitive stimulation at 6 months.[24] However, there has been no study to date documenting impacts of the fully integrated Smart Beginnings model, in which FCU delivery begins at 6 months for eligible families. The current tests the impact of the fully integrated Smart Beginnings model on parental support of cognitive stimulation at each of three assessment waves; and tests these impacts longitudinally from 6 to 24 months through the developmental stages of infancy and toddlerhood.

Methods

This study was part of the single-blind, 2-site randomized clinical trial of Smart Beginnings with 403 families in New York City (New York City Health+Hospitals [H+H]/Bellevue) and in Pittsburgh (University of Pittsburgh/University of Pittsburgh Medical Center). Informed consent was obtained from all study participants. Institutional review board approval was obtained (New York University [FY2016-408], New York University Grossman School of Medicine [S14-01764], and University of Pittsburgh [STUDY19040158]), and the study is registered in clinicaltrials.gov (NCT02459327).

Intervention Design

The Integrated Smart Beginnings Model. Smart Beginnings is an integrated approach to address socioeconomic status–based disparities in school readiness through 2 tiers—a health care–based universal program (VIP) and a selective prevention program through home visiting (the FCU). **Figure 1** (available at www.jpeds.com). Here, we present findings during which families received intervention delivery from birth through 24 months and were assessed at enrollment, 6 months, 18 months, and 24 months.

VIP. VIP is an evidence-based primary prevention program aimed at promoting early child development and school readiness through facilitating responsive parent–child interactions,[19,25] building on Reach Out and Read.[26] VIP consists of 14 sessions between birth and 3 years, scheduled at well-child appointments. During each session, the family meets with a bachelor's level coach for ~25 minutes. The coach first supports the parent as an active observer and then video-records the parent–child dyad playing or reading together for approximately 3 minutes. The coach immediately reviews the video in real time with the parent to identify and reinforce responsive parenting behaviors, and identify additional opportunities for these behaviors. Finally, the parent is provided with a copy of the video and a personalized pamphlet with plans for interacting with their child at home. In the current study, families could have completed a maximum of 10 sessions through 24 months.

The FCU. The FCU is an evidence-based, home-visiting program designed to reduce early disruptive behaviors by promoting child self-regulation skills. The FCU addresses limitations of traditional parent training programs by incorporating motivational interviewing to focus on concerns most paramount to parents, thereby allowing interventionists to target parents' most pressing issues, leading to brevity and reduced cost.[20,27] The FCU comprises the following: (1) a get-to-know-you initial interview designed to develop a collaborative framework for intervention with the parent consultant, using motivational interviewing to promote parents' readiness to change; (2) an ecological assessment of the family's strengths and challenges based on data from the get-to-know-you, parent-reported questionnaires, and video-recorded observations of parent–child interaction; and (3) a 90-minute feedback session in which the parent consultant discusses strengths and challenges, then identifies family goals. Following the feedback, follow-up family management sessions with the parent consultant are offered to address family goals, with some families choosing to address goals without the assistance of the parent consultant. In the current study, families could have completed all three components by 24 months.

Enrollment and Randomization

We used a 2-phase enrollment process with consecutive sampling. Mothers and infants were enrolled in the postpartum units of NYC H+H/Bellevue from June 2015 to January 2017 and University of Pittsburgh Medical Center Magee Women's Hospital from June 2016 to October 2017. In phase one, families eligible for Medicaid were offered enrollment and informed consent was obtained if they met the following inclusion criteria: (1) child: full-term, singleton, normal birth

weight without significant prenatal or perinatal medical complications, ineligible for early intervention at birth, plans to receive pediatric care at the institution; and (2) parent: primary caregiver/legal guardian, plans to stay in the birth city for 3 years, primary language English or Spanish, no known significant impairment (eg, intellectual disability) or medical complication, no plans to stay in a shelter, baby discharged to mother, no previous participation in VIP or FCU. In phase two, occurring through 6 weeks of age in the outpatient setting, families attending a study visit who continued to meet inclusion criteria were randomized by study personnel to treatment or control groups within site (see **Figure 2**; available at www.jpeds.com).

All families randomly assigned to the treatment condition were offered the VIP component of Smart Beginnings. In addition, treatment families were assessed for eligibility to be offered the FCU. Eligibility for the FCU was determined through annual screening as part of the study's assessments at 6 and 18 months. Treatment families could be eligible for the FCU based on either primary or secondary criteria known to compromise parenting quality.[28] Families met primary criteria if they had 1 of the following: clinical threshold for maternal depressive symptoms, reports of family violence, reports of child welfare agency involvement with the study target child, very low levels of maternal literacy (ie, below sixth-grade reading level[19,29]). Families met secondary criteria if they had elevated scores in screening instruments for 2 of the following domains: child behavior (eg, regulatory/externalizing behaviors), family well-being and support (eg, maternal stress), caregiving (eg, low supportive parenting), and family capital (eg, food insecurity).

Families randomly assigned to the control condition received routine pediatric care.

Outcome Measure: Parental Support of Cognitive Stimulation

Parental support of cognitive stimulation was assessed by research assistants blinded to treatment status—through survey measures and coded video-recorded observations of mother–child interactions at 6, 18, and 24 months. The 6- and 24-month assessments were conducted in laboratory settings, whereas the 18-month assessment was conducted in the target child's home when possible. Families were provided with a modest incentive ($50) for participating in each assessment.

Survey Measures. The $StimQ_2$ is a structured interview measure of caregiver cognitive stimulation (sample $\alpha = 0.76$). It was developed and validated in English and Spanish for populations with low incomes.[30,31] In the current randomized clinical trial, we administered 3 subscales of the $StimQ_2$: (1) Parent Verbal Responsivity (PVR), measuring verbal interactions across 2 components (Everyday Routines, Play and Pretend); (2) Parental Involvement in Developmental Advance (PIDA), measuring teaching activities; and (3) Reading Activities (READ), with 3 components (Quantity, Quality, Diversity of Concepts). A $StimQ_2$ Total score was calculated by summing the subscales and components administered at each wave. In addition, we calculated a StimQ common total score of the 2 subscales of the $StimQ_2$ that were administered at all 3 time points: PVR in Everyday Routines; and READ Quantity and Quality.

Observational Measures. At 6 months, mother–child dyads participated in a structured free play task. At 18 and 24 months, mother–child dyads also participated in additional tasks: clean-up, free play, and 2 teaching tasks. All laboratory- and home-based interactions were video-recorded for later coding. As previously described,[24] coding of the videos was subsequently performed using an adaptation of the Parent–Child Interaction Rating Scales–Infant Adaptation for a global rating of parent–child interactions. Three domains of the Parent–Child Interaction Rating Scales–Infant Adaptation relevant to cognitive stimulation were coded: (1) cognitive development (intention to support learning); (2) language quantity (amount of verbal stimulation); and (3) language quality (quality of verbal stimulation). We then generated a composite measure of "cognitive stimulation" from these 3 domains based on exploratory and confirmatory factor analysis (root mean square error of approximation = 0.00; $\alpha = 0.91$).

Statistical Analyses

Intent-to-treat analyses followed 2 steps and were conducted in Stata 15 (StataCorp LLC).[32] First, ordinary least square regressions were conducted separately at each wave by regressing each cognitive stimulation outcome on treatment status, controlling for site. Second, as participants were assessed longitudinally at 6, 18, and 24 months, mixed-effects models were used, including participants with data from at least one wave on a given outcome.[33] Time was coded 0, 2, and 3 for 6, 18, and 24 months. A random-intercept model and a random-intercept-and-trend model (ie, random slope of time) were compared using model fit statistics. Random effects are assumed to be normally distributed, independent of the Level-1 errors, but are correlated at Level 2, as is common in linear mixed effects models.[33] A quadratic term of time and its random effects was also tested if inclusion of such terms improved model fit. Lastly, as there were multiple outcomes, the Benjamini–Hochberg procedure[34] was used to control for the false discovery rate in computing multiple comparisons.

Results

Descriptive Analyses

The Smart Beginnings sample was composed of mothers with low incomes, with about one-third primiparous. There were no significant differences on baseline sociodemographic characteristics or psychosocial stressors at birth between treatment and control groups within each site (the unit of randomization; $F(9, 350) = 1.11$, $P = .35$; see **Table I**). However, there were several notable between-site differences. The majority of mothers in New York City

Table I. Baseline equivalence of treatment and control groups by site

	New York city (N = 200)		Pittsburgh (N = 203)	
	Smart Beginnings (N = 101)	Control (N = 99)	Smart Beginnings (N = 100)	Control (N = 103)
Characteristics	**Mean (SD)/Proportion of sample**			
Child characteristics				
Sex—female	45%	54%	51%	50%
Mother characteristics				
Race/ethnicity				
Asian	2%	4%	0%	0%
African-American	11%	4%	80%	83%
White	2%	2%	12%	13%
Latinx	81%	88%	5%	2%
Marital status				
Married	33%	31%	6%	3%
Cohabitating partner	45%	53%	38%	35%
Noncohabitating partner	13%	8%	32%	38%
Bio. father current partner	97%	99%	92%	96%
Education				
High school grad	62%	51%	86%	82%
Some college	36%	27%	43%	31%
Primiparous birth	37%	34%	30%	35%
Teenage mother	4%	4%	5%	13%
Family household characteristics				
Income-to-needs ratio*	0.87 (0.67)	0.77 (0.53)	0.68 (0.60)	0.60 (0.60)
Crowding ratio†	1.38 (0.54)	1.43 (0.61)	0.85 (0.30)	0.87 (0.32)
Interview in Spanish	58%	65%	0%	0%

Joint test of all baseline sociodemographic characteristics: $F(9, 350) = 1.11$, $P = .35$.
*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.
†The crowding ratio indicates how many people live per room in the dwelling. A ratio greater than 1 indicates household crowding.

were Latinx (84%), whereas in Pittsburgh they were predominantly Black/African-American (81%, $P < .001$). Furthermore, mothers in New York City also had much greater rates of marriage (32% vs 4%, $P < .001$) and cohabitation (49% vs 37%, $P < .05$), but were less likely to be high school graduates (56% vs 83%, $P < .001$) compared with mothers in Pittsburgh. Participant retention across time was high; retention rates at the 6-, 18-, and 24-month assessments were 90%, 81%, and 82%, respectively. Families with and without complete survey and observational data across all 3 assessment waves were compared on baseline characteristics at birth; there were no differences based on an omnibus F-test.

Research Question 1: Treatment Impact Analyses by Each Wave

Table II (available at www.jpeds.com) shows the observed means of the treatment and control groups, Smart Beginnings impacts estimated from ordinary least square regressions, and effect sizes (ES) at each wave separately (results at 6 months previously published[24]). ES were calculated by dividing the treatment impact by the SD of the control group. For survey outcomes, the Smart Beginnings intervention had significant positive impacts on $StimQ_2$ total at 6 (ES = 0.28, $P = .006$), 18 (ES = 0.21, $P = .049$), and 24 (ES = 0.31, $P = .003$) months; on StimQ common total at 18 (ES = 0.21, $P = .05$) and 24 (ES = 0.31, $P = .003$) months; on READ Quantity at 24 months (ES = 0.23, $P = .03$); on READ Quality at 6 (ES = 0.26, $P = .01$) and 24 (ES = 0.38, $P < .001$) months; on PVR Play and Pretend at 6 (ES = 0.21, $P = .04$. and 24 (ES = 0.25, $P = .04$) months; and on PIDA at 6 (ES = 0.25, $P = .01$) and 24 (ES = 0.35, $P < .001$) months.

For observational measures, the Smart Beginnings intervention had significant positive impacts on cognitive development at 6 (ES = 0.36, $P = .001$) and 24 (ES = 0.29, $P = .02$) months, on language quantity at 6 months (ES = 0.40, $P < .001$), on language quality at 6 (ES = 0.37, $P = .001$) and 24 (ES = 0.28, $P = .03$) months, and the cognitive stimulation factor at 6 (ES = 0.40, $P < .001$) and 24 (ES = 0.27, $P = .03$) months. No significant treatment impacts were found on any observational outcomes at 18 months.

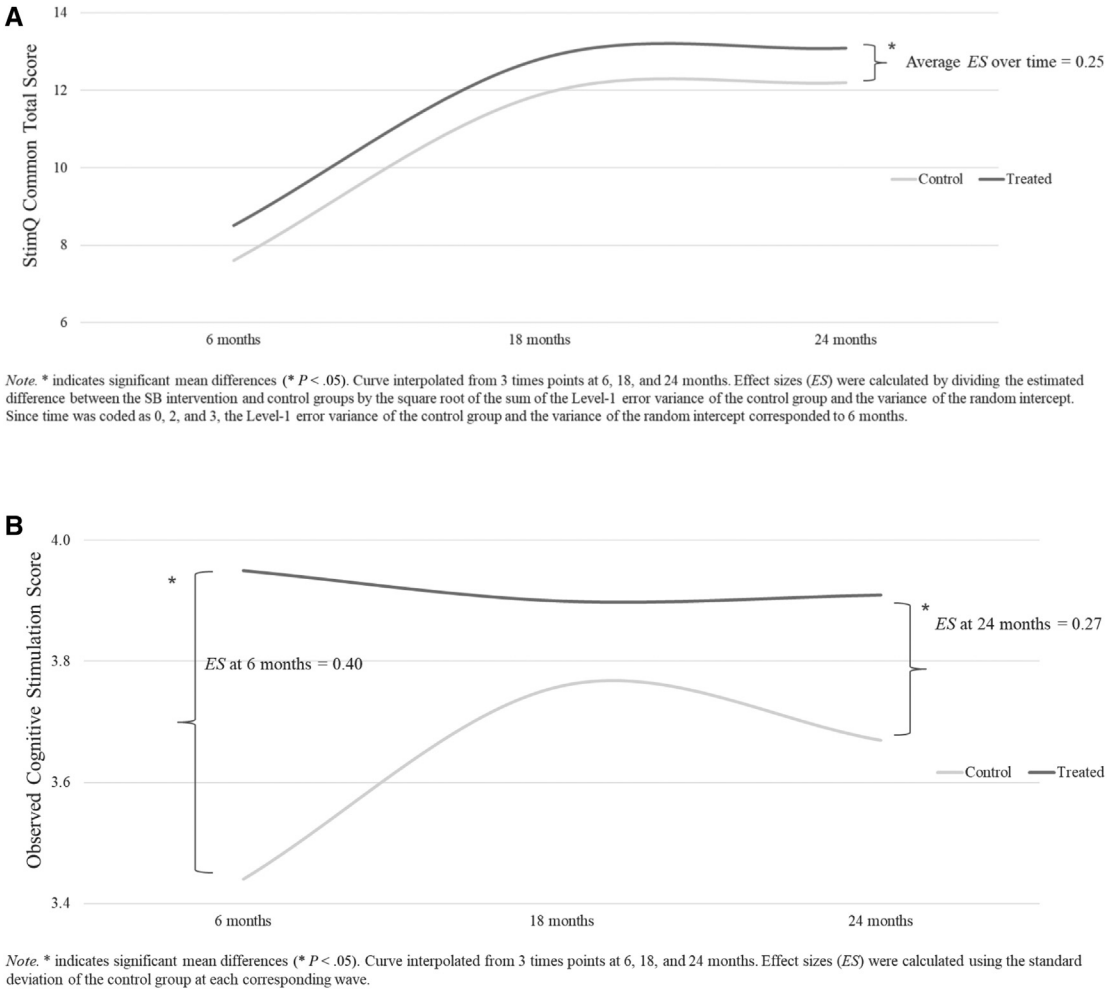
As a robustness check for results for both survey and observational measures, a false discovery rate of .1 was applied to the 9 comparisons at each of the three time points. All significant findings were robust to the Benjamini–Hochberg correction except the treatment impact on $StimQ_2$ total and StimQ common total at 18 months.

Research Question 2: Treatment Impact Analyses Across Time

Table III (available at www.jpeds.com) shows the estimated treatment impacts from mixed effects models across time. Random effects of intercept and linear time and the fixed effect of the quadratic term of time improved model fit and were therefore included in all models. The final models for survey outcomes did not include treatment by time and $time^2$ interactions (Panel A), whereas the final models for observational measures included these interactions to improve model fit (Panel C).

For the survey outcomes (Table III, Panel A), the coefficient for treatment shows the overall impact across 6-24 months for each outcome. As these models did not include time by treatment interactions and were longitudinal in nature, ES were calculated as an overall average over time by dividing the estimated difference between the Smart Beginnings intervention and control groups by the square root of the sum of the Level-1 error variance of the control group and the variance of the random intercept. Results show that the Smart Beginnings intervention had significant positive impacts over time on StimQ common total (ES = 0.25, $P = .01$), READ Quantity (ES = 0.19, $P = .04$), and READ Quality (ES = 0.30, $P = .001$) over time. As an example, Figure 3, A, shows the Smart Beginnings treatment impact on StimQ common total at 6, 18, and 24 months, favoring the intervention group.

For the observational measures, Table III, Panel B shows the overall impact across 6-24 months for each outcome.



Note. * indicates significant mean differences (* $P < .05$). Curve interpolated from 3 times points at 6, 18, and 24 months. Effect sizes (*ES*) were calculated by dividing the estimated difference between the SB intervention and control groups by the square root of the sum of the Level-1 error variance of the control group and the variance of the random intercept. Since time was coded as 0, 2, and 3, the Level-1 error variance of the control group and the variance of the random intercept corresponded to 6 months.

Note. * indicates significant mean differences (* $P < .05$). Curve interpolated from 3 times points at 6, 18, and 24 months. Effect sizes (*ES*) were calculated using the standard deviation of the control group at each corresponding wave.

Figure 3. **A,** Treatment impact on StimQ common total, 6-24 months. **B,** Treatment impact on observed cognitive stimulation factor, 6-24 months.

As with the survey measures, the results show that the Smart Beginnings intervention had significant positive impacts over time on cognitive development (ES = 0.24, $P = .001$), language quantity (ES = 0.20, $P = .004$), language quality (ES = 0.19, $P = .004$), and the cognitive stimulation factor (ES = 0.21, $P = .002$) over time.

However, interaction terms between treatment and time improved model fit for the observational measures (allowing treatment impacts to vary over time), and thus these interaction terms were included in the final models. Consequently, **Table III**, Panel C shows 3 treatment coefficients and ES for each outcome, corresponding to 6, 18, and 24 months. The ES for observational measures were calculated by dividing the estimated mean differences at each wave by the SD of the control group at each corresponding wave (similar to calculations in **Table II**). Findings show that the Smart Beginnings intervention had significant positive impacts for all 4 observational measures at 6 months (cognitive development [ES = 0.37, $P = .001$], language quantity [ES = 0.40, $P < .001$], language quality [ES = 0.37, $P < .001$], and the cognitive stimulation factor [ES = 0.40, $P < .001$]), with no significant positive impacts for any of the measures at 18 months. At 24 months, the impact of the Smart Beginnings intervention had significant positive impacts on cognitive development (ES = 0.30, $P = .001$), language quality (ES = 0.27, $P < .001$), and the cognitive stimulation factor (ES = 0.27, $P < .001$). As an example, **Figure 3**, B, shows the Smart Beginnings treatment impact on the cognitive stimulation factor at 6, 18, and 24 months, favoring the intervention group at 6 and 24 months only.

Similar to previously, as a robustness check for results for both survey and observational measures, a false discovery rate of 0.1 was applied to eight comparisons at each of the 3 time points. All of the significant findings were robust to the Benjamini–Hochberg correction.

Discussion

The Smart Beginnings intervention was significant in promoting cognitive stimulation during infancy and toddlerhood for almost all survey outcomes, including the $StimQ_2$ Total score, the StimQ common total, and 2 components

of the READ subscale–Quantity and Quality. In addition, these impacts and corresponding ES for the surveys did not vary by time. However, for the observational measures of parent–child interactions, the impact of the Smart Beginnings intervention varied by time, with significant impacts at 6 and 24 months, but not 18 months. Results from the longitudinal analyses were consistent with results from the wave-specific analyses.

This study adds to the body of research showing that preventive interventions offered through pediatric primary care and home visiting have utility in supporting early relational health, and in particular, parental support of cognitive stimulation.[35,36] These findings also extend previous work on the Smart Beginnings sample demonstrating improved parental support of cognitive stimulation at 6 months, before the receipt of FCU services for eligible families.[24] The Smart Beginnings intervention continues to positively promote cognitive stimulation outcomes from infancy through toddlerhood using the integrated Smart Beginnings model. These finding show longitudinal impacts of a tiered parenting intervention on parental support of cognitive stimulation, a critical mediator of children's school readiness,[37] across 2 child developmental stages. This finding is notable based on the major changes in child behavior and cognition that occur from infancy to toddlerhood; warm, secure, and trusting relationships with primary caregivers in infancy give way to children's emerging independence and autonomy in toddlerhood.[21] The Smart Beginnings intervention straddles these developmental stages and supports parents through these major transitions. In addition, the study population included 2 sites representing both Latinx and Black/African-American families. Findings therefore support broad generalizability of Smart Beginnings across populations affected by disparities resulting from poverty, systemic racism, and toxic stress.

One of the goals of interventions focused on enhancing parent–child early relational health is to support parents in providing cognitive stimulation that is developmentally appropriate for each stage of childhood. Based on previous evidence demonstrating associations between parent-reported and observed cognitive stimulation,[38] and consistent with previous findings from this trial,[24] we expected to find converging results across the survey and observational measures in the current study. Although the impact of the Smart Beginnings intervention was consistent across time for survey measures, it varied by time for observational measures. Significant positive effects during laboratory observations of parenting were evident at 6 and 24 months, but primarily home-based observations at 18 months did not reveal such effects; however, results still favored the Smart Beginnings intervention group. The literature largely support the generalizability of laboratory-based parent-child interactions to the home[39-41]; however, it is possible that the change in location of observations contributed to the attenuation of treatment effects. It is also possible that the lack of impacts on observational measures at 18 months are the result of normative challenges in child autonomy seeking in the first half of the second year of life, suggesting that interventions should continue to be maximally responsive to parent needs during this period.

Policy statements by the American Academy of Pediatrics[10,42] highlight the need to promote early relational health by layering programs to meet the heterogeneity in needs among families with low incomes and intervening across public health sectors (eg, pediatrics, home visiting, early education) to provide broad, community-level support.[43] Based on the increased recognition that programs should target families across platforms, a number of multilevel, multisector initiatives have been introduced (eg, Get Ready Guilford in North Carolina, First 5 California, NYC H+H 3-2-1 IMPACT, Together Growing Strong), and there is acknowledgment that universal scaling and accessibility of such programs is needed for population-level impact.

Smart Beginnings is well aligned with these recommendations, using a tiered, multisector approach to address early relational health through programs synergistic and efficient in impact and delivery. Smart Beginnings is poised to reach a large number of families in supporting early relational health and in turn, child development, by reducing traditional barriers to engagement (eg, cost, reach). It builds off existing infrastructure, using pediatric primary care as an initial point of contact, and addresses heterogeneity in strengths and risks by offering more intensive services to families facing additional challenges that often compromise the quality of caregiving. Further, Smart Beginnings directly supports positive childhood experiences recognized as critical for all families both in presence and absence of adverse childhood experiences.[44] Expansion of VIP to new Reach Out and Read sites, delivery of FCU in multiple states, countries, and platforms), and implementation of Smart Beginnings in a county-wide implementation of evidence-based parenting programs (The Pittsburgh Study) lend further support for program scalability.[22,45,46] Findings from the current study provide strong support for the efficacy of the integrated Smart Beginnings model. ■

Submitted for publication May 20, 2022; last revision received Oct 14, 2022; accepted Nov 14, 2022.

Reprint requests: Elizabeth B. Miller, PhD, NYU Grossman School of Medicine, 227 East 30th St, New York, NY 10016. E-mail: ebmiller@nyu.edu

Data Statement

Data sharing statement available at www.jpeds.com.

References

1. Dreyer BP. Closing the gap: interventions to ameliorate inequities in early brain development and school performance in poor children. J Pediatr 2020;221:8-10.
2. Golinkoff RM, Hoff E, Rowe ML, Tamis-LeMonda CS, Hirsh-Pasek K. Language matters: denying the existence of the 30-million-word gap has serious consequences. Child Dev 2019;90:985-92.
3. Raikes H, Alexander Pan B, Luze G, Tamis-LeMonda CS, Brooks-Gunn J, Constantine J, et al. Mother–child bookreading in low-income

families: correlates and outcomes during the first three years of life. Child Dev 2006;77:924-53.
4. Duncan GJ, Dowsett CJ, Claessens A, Magnuson K, Huston AC, Klebanov P, et al. School readiness and later achievement. Dev Psychol 2007;43:1428.
5. Duncan GJ, Ziol-Guest KM, Kalil A. Early-childhood poverty and adult attainment, behavior, and health. Child Dev 2010;81:306-25.
6. Reardon SF. The widening academic achievement gap between the rich and the poor: new evidence and possible explanations. In: Duncan GJ, Murnane RJ, eds. Whither opportunity. New York, NY: Russell Sage; 2011. p. 91-116.
7. Brody GH, Chen Y, Murry VM, Ge X, Simons RL, Gibbons FX, et al. Perceived discrimination and the adjustment of African American youths: a five-year longitudinal analysis with contextual moderation effects. Child Dev 2006;77:1170-89.
8. Bailey ZD, Krieger N, Agénor M, Graves J, Linos N, Bassett MT. Structural racism and health inequities in the USA: evidence and interventions. Lancet 2017;389:1453-63.
9. Pachter LM, Coll CG. Racism and child health: a review of the literature and future directions. J Dev Behav Pediatr 2009;30:255.
10. Garner A, Yogman M, Committee on Psychosocial Aspects of Child and Family Health. Preventing childhood toxic stress: partnering with families and communities to promote relational health. Pediatrics 2021;148:e2021052582.
11. Duncan GJ, Yeung WJ, Brooks-Gunn J, Smith JR. How much does childhood poverty affect the life chances of children? Am Sociol Rev 1998; 406-423.
12. Ladd GW, Birch SH, Buhs ES. Children's social and scholastic lives in kindergarten: related spheres of influence? Child Dev 1999;70: 1373-400.
13. 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;34:29-40.
14. Love JM. Making a difference in the lives of infants and toddlers and their families: the impacts of early Head Start. Child Outcomes Research and Evaluation, Office of Planning, Research, and Evaluation, Administration for Children and Families and the Headstart Bureau, Administration on Children, Youth and Families, Department of Health and Human Services; Washington, DC: 2002.
15. Olds DL. The nurse–family partnership: an evidence-based preventive intervention. Infant Ment Health J 2006;27:5-25.
16. Baker CN, Arnold DH, Meagher S. Enrollment and attendance in a parent training prevention program for conduct problems. Prev Sci 2011;12:126-38.
17. Burwick A, Zaveri H. Costs of early childhood home visiting: an analysis of programs implemented in the supporting evidence-based home visiting to prevent child maltreatment initiative. Princeton, NJ: Mathematica Policy Research; 2014.
18. 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;102:1394-400.
19. Mendelsohn AL, Dreyer BP, Flynn V, Tomopoulos S, Rovira I, Tineo W, et al. Use of videotaped interactions during pediatric well-child care to promote child development: a randomized, controlled trial. J Dev Behav Pediatr JDBP 2005;26:34.
20. Dishion TJ, Stormshak EA. Intervening in children's lives: an ecological, family-centered approach to mental health care. Washington, DC: American Psychological Association; 2007.
21. Erikson EH. Childhood and society. 2nd ed. New York, NY: Erikson-N Y Nort; 1963.
22. Shaw DS, Mendelsohn AL, Morris PA. Reducing poverty-related disparities in child development and school readiness: the Smart Beginnings tiered prevention strategy that combines pediatric primary care with home visiting. Clin Child Fam Psychol Rev 2021;24:669-83.
23. Miller EB, Canfield CF, Morris PA, Shaw DS, Cates CB, Mendelsohn AL. Sociodemographic and psychosocial predictors of VIP attendance in smart beginnings through 6 months: effectively targeting at-risk mothers in early visits. Prev Sci 2020;21:120-30.
24. Roby E, Miller EB, Shaw DS, Morris P, Gill A, Bogen DL, et al. Improving parent-child interactions in pediatric health care: a two-site randomized controlled trial. Pediatrics 2021;147:e20201799.
25. Cates CB, Weisleder A, Johnson SB, Seery AM, Canfield CF, Huberman H, et al. Enhancing parent talk, reading, and play in primary care: sustained impacts of the Video Interaction Project. J Pediatr 2018;199:49-56.
26. Needlman R, Toker KH, Dreyer BP, Klass P, Mendelsohn AL. Effectiveness of a primary care intervention to support reading aloud: a multicenter evaluation. Ambul Pediatr 2005;5:209-15.
27. 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.
28. Conger RD, Elder GH Jr, Lorenz FO, Simons RL, Whitbeck LB. Families in troubled times: adapting to change in rural America. Hawthorne, NY, US: Aldine de Gruyter; 1994.
29. Mendelsohn AL, Valdez PT, Flynn V, Foley GM, Berkule SB, Tomopoulos S, et al. Use of videotaped interactions during pediatric well-child care: impact at 33 months on parenting and on child development. J Dev Behav Pediatr JDBP 2007;28:206.
30. Dreyer BP, Mendelsohn AL, Tamis-LeMonda CS. Assessing the child's cognitive home environment through parental report; reliability and validity. Early Dev Parent Int J Res Pract 1996;5:271-87.
31. Mendelsohn AL, Cates CB, Tamis-LeMonda CS, Dreyer BP. StimQ cognitive home environment, https://www.videointeractionproject.org/stimq.html
32. StataCorp LLC. College Station, TX; 2017.
33. Hedeker D, Gibbons RD. Longitudinal data analysis, Vol. 451. Hoboken, NJ: John Wiley & Sons; 2006.
34. Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. J R Stat Soc Ser B Methodol 1995;57:289-300.
35. Peacock S, Konrad S, Watson E, Nickel D, Muhajarine N. Effectiveness of home visiting programs on child outcomes: a systematic review. BMC Public Health 2013;13:1-14.
36. Peacock-Chambers E, Ivy K, Bair-Merritt M. Primary care interventions for early childhood development: a systematic review. Pediatrics 2017;140:e20171661.
37. Brooks-Gunn J, Markman LB. The contribution of parenting to ethnic and racial gaps in school readiness. Future Child 2005;139-168.
38. Zaslow MJ, Weinfield NS, Gallagher M, Hair EC, Ogawa JR, Egeland B, et al. Longitudinal prediction of child outcomes from differing measures of parenting in a low-income sample. Dev Psychol 2006;42:27.
39. Anderson NJ, Graham SA, Prime H, Jenkins JM, Madigan S. Linking quality and quantity of parental linguistic input to child language skills: a meta-analysis. Child Dev 2021;92:484-501.
40. Bornstein MH, Haynes OM, Painter KM, Genevro JL. Child language with mother and with stranger at home and in the laboratory: a methodological study. J Child Lang 2000;27:407-20.
41. Stevenson MB, Leavitt LA, Roach MA, Chapman RS, Miller JF. Mothers' speech to their 1-year-old infants in home and laboratory settings. J Psycholinguist Res 1986;15:451-61.
42. Gitterman BA, Flanagan PJ, Cotton WH, Dilley KJ, Duffee JH, Green AE, et al. Poverty and child health in the United States. Pediatrics 2016;137: e20160339.
43. Roby E, Shaw DS, Morris P, Canfield CF, Miller EB, Dreyer B, et al. Pediatric primary care and partnerships across sectors to promote early child development. Acad Pediatr 2021;21:228-35.
44. Bethell CD, Gombojav N, Whitaker RC. Family resilience and connection promote flourishing among US children, even amid adversity. Health Aff (Millwood) 2019;38:729-37.
45. Dunlap M, Lake L, Patterson S, Perdue B, Caldwell A. Reach Out and Read and developmental screening: using federal dollars through a health services initiative. J Investig Med 2021;69:897-900.
46. Ettinger AK, Ray KN, Burke JG, Thompson J, Navratil J, Chavis V, et al. A community partnered approach for defining child and youth thriving. Acad Pediatr 2021;21:53-62.

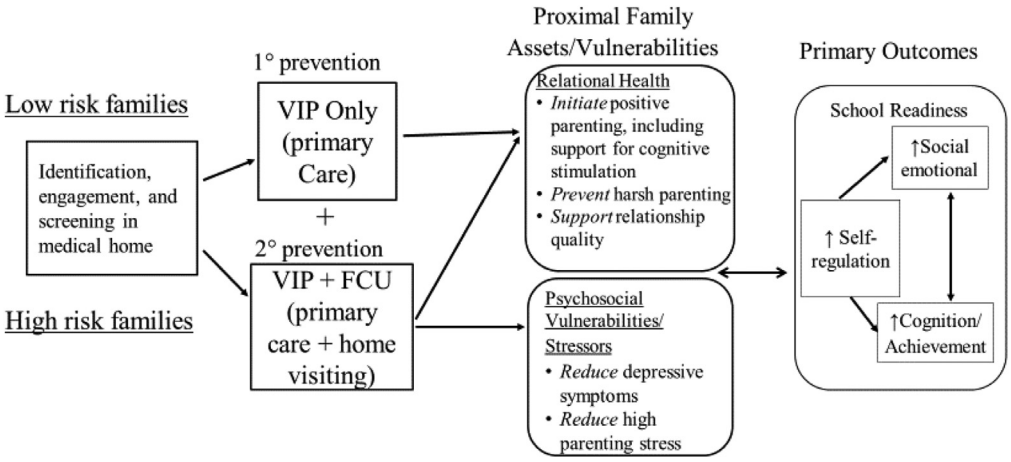


Figure 1. Population-level conceptual model: Smart Beginnings tiered intervention, mechanisms of action.

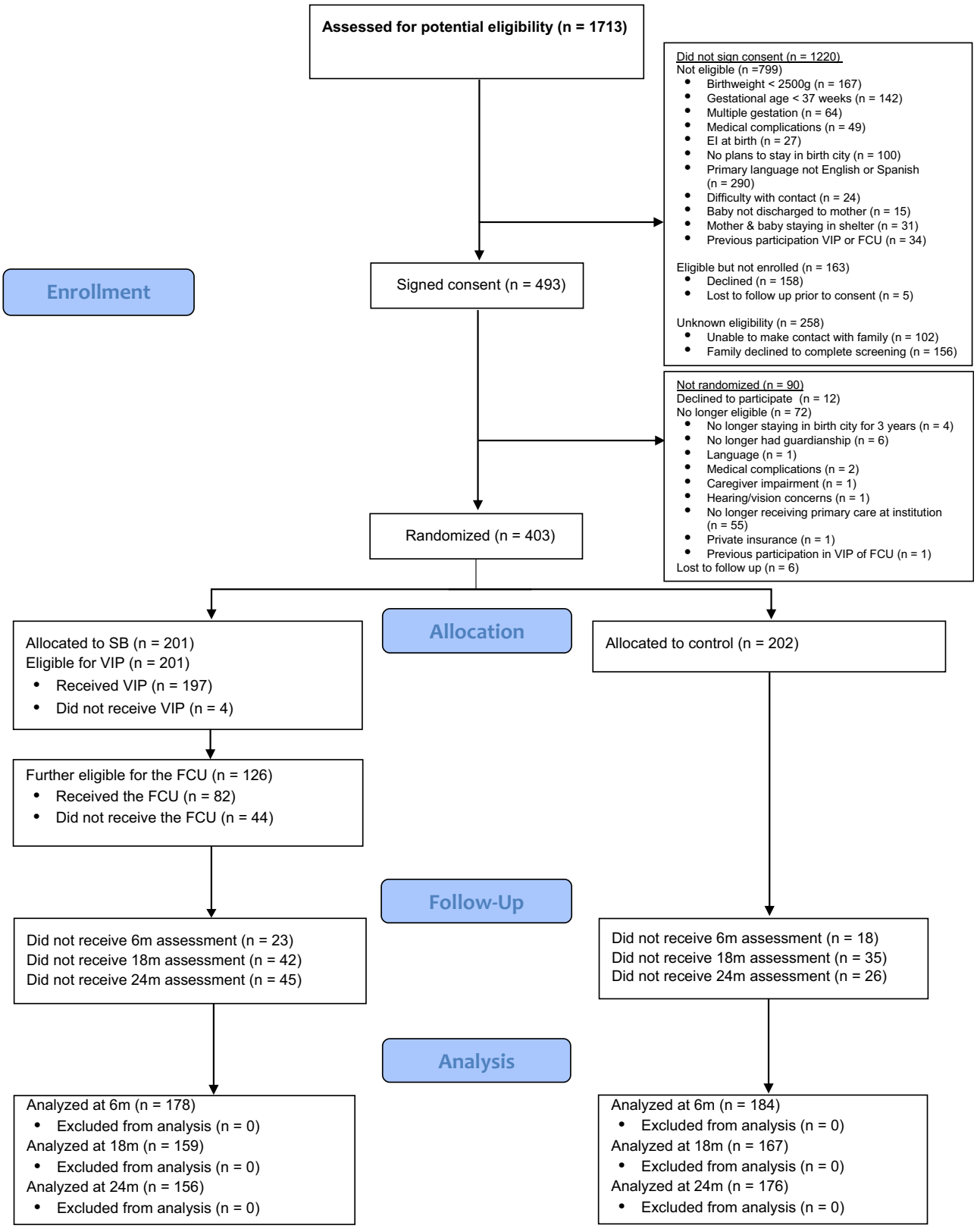


Figure 2. Participant enrollment and assessment in Smart Beginnings. Note: participants who were not eligible for the study may have met more than 1 exclusion criterion and therefore the individual criteria numbers do not sum to the total number not eligible. *EI*, early intervention.

Table II. Observed means of treatment and control groups, treatment impacts, and ES at each wave separately

	6 months					18 months					24 months				
	Treatment	Control	Impact (95% CI)	*P* value	ES	Treatment	Control	Impact (95% CI)	*P* value	ES	Treatment	Control	Impact (95% CI)	*P* value	ES
Survey outcomes															
$StimQ_2$ total*	17.16	15.51	**1.65 (0.48- 2.82)**	**.006**	**0.28**	12.82	11.87	**0.93 (0.002-1.86)**	**.049**	**0.21**	20.53	18.56	**2.03 (0.76-3.74)**	**.003**	**0.31**
StimQ common total†	8.47	7.71	0.76 (−0.004 to 1.53)	.05	0.20	12.82	11.87	**0.93 (0.002-1.86)**	**.049**	**0.21**	13.39	11.98	**1.45 (0.50-2.41)**	**.003**	**0.31**
READ Quantity	3.46	3.11	0.35 (−0.09 to 0.79)	.12	0.16	4.16	3.75	.41 (−0.07 to 0.89)	.10	0.19	4.21	3.67	**0.55 (0.06-1.05)**	**.03**	**0.23**
READ Quality	1.55	1.27	**0.28 (0.06-0.50)**	**.01**	**0.26**	2.76	2.5	0.26 (−0.02 to 0.54)	.07	0.19	3.05	2.52	**0.54 (0.25-0.83)**	**<.001**	**0.38**
PVR Everyday Routines	3.43	3.33	0.11 (−0.26 to 0.48)	.57	0.06	5.91	5.62	0.27 (−0.19 to 0.73)	.25	0.13	6.12	5.79	0.35 (−0.11 to 0.81)	.14	0.16
PVR Play and Pretend‡	4.25	3.88	**0.37 (0.02-0.72)**	**.04**	**0.21**						3.42	3.00	**0.43 (0.10-00.94)**	**.04**	**0.25**
PIDA‡	2.92	2.59	**0.33 (0.06-0.59)**	**.01**	**0.25**						3.77	3.31	**0.45 (0.19-0.70)**	**<.001**	**0.35**
Observational measures															
Parental support for cognitive development	3.62	3.25	**0.37 (0.15-0.60)**	**.001**	**0.36**	3.51	3.41	0.11 (−0.10 to 0.31)	.30	0.11	3.58	3.32	**0.26 (0.03-0.48)**	**.02**	**0.29**
Parental support for language quantity	4.23	3.61	**0.63 (0.29-0.96)**	**<.001**	**0.40**	4.71	4.56	0.13 (−0.16 to 0.41)	.39	0.10	4.48	4.27	0.22 (−0.07 to 0.51)	.15	0.17
Parental support for language quality	4.02	3.47	**0.56 (0.24-0.87)**	**.001**	**0.37**	3.58	3.43	0.15 (−0.08 to 0.38)	.21	0.14	3.75	3.48	**0.27 (0.03-0.51)**	**.03**	**0.28**
Cognitive stimulation factor	3.95	3.44	**0.51 (0.24-0.78)**	**<.001**	**0.40**	3.93	3.8	0.13 (−0.09 to 0.34)	.24	0.13	3.94	3.69	**0.25 (0.02-0.47)**	**.03**	**0.27**

All analyses account for site. ES were calculated using the SD of the control group. Values in bold indicate statistical significance.
*Impact based on difference in raw scores.
†StimQ common total included PVR – Everyday Routines (8 items), and READ – Quantity and Quality (9 items).
‡PVR Play and Pretend and PIDA only administered at 6 and 24 months.

Table III. Treatment impacts 6-24 months from mixed-effects models

Panel A: Survey outcomes (without interactions of treatment by time and time^2)

	Treatment 6-24 mo (95% CI)	*P* value	ES across waves
Survey outcomes (without interactions of treatment by time and time^2)			
StimQ common total	**0.90 (0.22-1.59)**	**.01**	**0.25**
READ Quantity	**0.39 (0.02-0.76)**	**.04**	**0.19**
READ Quality	**0.33 (0.14-0.52)**	**.001**	**0.30**
PVR Everyday Routines	0.19 (−0.13 to 0.51)	.24	0.11

Panel B: Observational measures (without interactions of treatment by time and time^2)

	Treatment 6-24 mo (95% CI)	*P* value	ES across waves
Observational measures (without interactions of treatment by time and time^2)			
Parental support for cognitive development	**0.25 (0.10-0.41)**	**.001**	**0.24**
Parental support for language quantity	**0.32 (0.10-0.54)**	**.004**	**0.20**
Parental support for language quality	**0.27 (0.09-0.66)**	**.004**	**0.19**
Cognitive stimulation factor	**0.27 (0.10-0.44)**	**.002**	**0.21**

Panel C: Observational measures (with interactions of treatment by time and time^2)

Treatment 6 mo (95% *CI*)	*P* value	ES	Treatment 18 mo (95% CI)	*P* value	ES	Treatment 24 mo (95% CI)	*P* value	ES
Observational measures (with interactions of treatment by time and time^2)								
Parental support for cognitive development								
0.38 (0.16-0.60)	**.001**	**0.37**	0.12 (−0.08 to 0.33)	.25	0.13	**0.27 (0.05-0.48)**	**.02**	**0.30**
Parental support for language quantity								
0.64 (0.31-0.96)	**<.001**	**0.40**	0.16 (−0.12 to 0.45)	.26	0.13	0.22 (−0.07 to 0.52)	.14	0.17
Parental support for language quality								
0.56 (0.25-0.86)	**<.001**	**0.37**	0.13 (−0.10 to 0.37)	.27	0.12	**0.26 (0.02-0.50)**	**.03**	**0.27**
Cognitive stimulation factor								
0.52 (0.25-0.78)	**<.001**	**0.4**	0.14 (−0.08 to 0.35)	.21	0.14	**0.25 (0.03-0.47)**	**.03**	**0.27**

All analyses account for site. Values in bold indicate statistical significance.

For outcomes without interactions, ES were calculated by dividing the estimated difference between the Smart Beginnings intervention and control groups by the square root of the sum of the Level-1 error variance of the control group and the variance of the random intercept. Since time was coded as 0, 2, and 3, the Level 1 error variance of the control group and the variance of the random intercept corresponded to 6 months. For outcomes with interactions, ES were calculated using the SD of the control group at each corresponding wave.