Prenatal and Pediatric Primary Care–Based Child Obesity Prevention Program: A Randomized Trial

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OBJECTIVES: To determine impact of a primary care–based child obesity prevention intervention abeginning during pregnancy on early childhood weight outcomes in low-income Hispanic families.

abstract

METHODS: A randomized controlled trial comparing mother–infant pairs receiving either standard care or the Starting Early Program providing prenatal and postpartum nutrition counseling and nutrition parenting support groups targeting key obesity-related feeding practices in low-income groups. Primary outcomes were reduction in weight-for-age *z*-scores (WFAzs) from clinical anthropometric measures, obesity prevalence (weight for age \geq 95th percentile), and excess weight gain (WFAz trajectory) from birth to age 3 years. Secondary outcomes included dose effects.

RESULTS: Pregnant women (n = 566) were enrolled in the third trimester; 533 randomized to intervention (n = 266) or control (n = 267). Also, 358 children had their weight measured at age 2 years; 285 children had weight measured at age 3 years. Intervention infants had lower mean WFAz at 18 months (0.49 vs 0.73, P = .04) and 2 years (0.56 vs 0.81, P = .03) but not at 3 years (0.63 vs 0.59, P = .76). No group differences in obesity prevalence were found. When generalized estimating equations were used, significant average treatment effects were detected between 10-26 months (B = -0.19, P = .047), although not through age 3 years. In within group dose analyses at 3 years, obesity rates (26.4%, 22.5%, 8.0%, P = .02) decreased as attendance increased with low, medium, and high attendance.

CONCLUSIONS: Mean WFAz and growth trajectories were lower for the intervention group through age 2 years, but there were no group differences at age 3. Further study is needed to enhance sustainability of effects beyond age 2.



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WHAT THIS STUDY ADDS: In this randomized trial of lowincome Hispanic mother—infant pairs, the Starting Early Program led to lower weight trajectories and weight-for-age *z*-scores through age 2 years, although not sustained at age 3 years. Increased intervention exposure was associated with greater impacts.

To cite: Messito MJ, Mendelsohn AL, Katzow MW, et al. Prenatal and Pediatric Primary Care–Based Child Obesity Prevention Program: A Randomized Trial. *Pediatrics*. 2020; 146(4):e20200709 Obesity prevalence in the United States remains high, with widespread socioeconomic, racial, and ethnic disparities.^{1,2} Groups with lower education and income and racial and ethnic minority groups have the highest rates.³ Elevated weight, even during infancy, significantly contributes to later obesity⁴ and decreased socioeconomic achievement across the life-course.⁵⁻⁷

The high cost and disease burden of obesity,⁸ and its resistance to treatment once established, underscores the need for effective primary prevention for high-risk groups before obesity develops to prevent disparities.^{9,10} Although childhood obesity prevention trials beginning in pregnancy or infancy have reported weight impacts, most were conducted either outside the United States^{11–13} or in middleincome US communities.^{14,15} These trials have been limited to first-time mothers and used home visiting platforms¹⁶ not available to the majority of US children at high risk of obesity.¹⁷ Scalable models with broader reach for at-risk communities are needed.

Primary health care during pregnancy and infancy has great potential to serve as a platform for the primary prevention of adverse health outcomes because visits are frequent and widely attended. There is also potential to lower cost by using existing administrative infrastructure and decreasing needs for additional transportation, missed work, and child care.¹⁸ Although prenatal and pediatric primary care can reduce adverse maternal and infant outcomes, including maternal and neonatal morbidity,¹⁹ prematurity, and low birth weight,²⁰ it has not significantly impacted the rising rates of obesity, particularly among lowincome, Hispanic children.²¹ Currently, there are no comprehensive child obesity prevention programs in the United

States designed for integration into prenatal and pediatric primary care.

We developed the Starting Early Program (StEP), a primary health care-based child obesity prevention intervention, to address these limitations. StEP was developed to capitalize on the reach and scalability of primary care during pregnancy and early childhood and was specifically designed for low-income, Hispanic communities. Previous reports documented StEP impacts on feeding and activity at ages 3 and 10 months.²²⁻²⁴ Primary aims were to examine intervention effects on child weight outcomes compared with controls receiving standard care. We hypothesized that the intervention group would have reduced weightfor-age z-scores (WFAzs), obesity prevalence, and weight gain trajectories from birth through 3 years compared with the controls. Secondary analyses examined how intervention dose related to child weight outcomes.

METHODS

Study Design

We conducted a randomized controlled trial to test the efficacy of StEP compared with standard care. The study was conducted in prenatal and pediatric clinics of an urban public hospital and an affiliated health center in New York City. Pregnant women were enrolled in a prenatal clinic and were followed until their child reached the age of 3 years. The New York University Grossman School of Medicine and New York City Health + Hospitals Institutional Review Board approved this study and it was registered on clinicaltrials.gov (NCT01541761).

Participants

We included pregnant women who were ≥ 18 years old, Latina or Hispanic, English- or Spanishspeaking, with a singleton uncomplicated pregnancy, who planned pediatric care at our study sites. We excluded women with severe medical or psychiatric illness or fetal anomalies. Our 3-step eligibility screening process was previously described.^{22,23} Interested eligible women signed informed written consent, and completed baseline assessments. Enrollment occurred between August 2012 and December 2014. Women were randomly assigned after 32 weeks' gestational age by using computergenerated random numbers, with a block size of 10, stratified by site. Group assignments were concealed from research assistants conducting follow-up.

StEP

StEP is a family-centered, strengthsbased program using social cognitive theory²⁵ to promote healthy behaviors. StEP is delivered by bilingual English- and Spanishspeaking registered dietitians who are certified lactation counselors. Its main components are prenatal nutrition counseling, postpartum lactation support, and nutrition and parenting support groups coordinated with pediatric visits. Fifteen sessions were delivered, including 2 individual (third trimester; postpartum) and 13 group sessions at 1, 2, 4, 6, 9, 12, 15, 18, 21, 24, 27, 30, and 33 months.

Intervention content was based on guidelines from National Academy of Medicine,^{9,26,27} American Academy of Pediatrics,^{28,29} and the US Department of Agriculture.³⁰ Prenatal and postpartum sessions assessed feeding intentions, barriers, lactation, and bottle-feeding. Group sessions with 4 to 8 mother-child pairs addressed feeding, activity, and parenting and included a family meal to model healthy behaviors and practice skills (Supplemental Table 5). We assessed fidelity during 74% of sessions and found that 97% provided all curriculum components.

The intervention used 4 strategies. First, sessions used a multimodal approach, with didactics, interactive demonstrations, and hands-on practicing. Second, individualized counseling used motivational interviewing and goal setting. Third, group structure facilitated interaction, peer modeling, and social support. Last, the ecologically informed curriculum was sensitive to poverty-related risks, health literacy, and cultural differences. The curriculum, developed by dietitians and pediatricians with extensive experience working with low-income Hispanic families, targeted common behaviors.^{31,32} Plain-language, picture-based handouts and bilingual videos^{33,34} reinforced the curriculum.^{35–37} Health literacy experts provided feedback on language, literacy, numeracy, and cultural appropriateness.38

Both groups were offered standard prenatal, postpartum, and pediatric primary care, including 1 prenatal nutrition consultation, 1 childbirth or breastfeeding class, as-needed lactation support, and pediatric visits according to American Academy of Pediatrics guidelines.³⁹ To enhance retention, families received frequent reminder mailings and calls for intervention and assessment sessions and were reimbursed for time spent in assessment activities.

Assessments

Primary outcomes were reduction in WFAz from clinical anthropometric measures, obesity prevalence (weight for age [WFA] \geq 95th percentile), and excess weight gain (WFAz trajectory) from birth to age 3 years.

Child Anthropometrics

Anthropometrics were obtained from birth through age 3 years on the basis of clinical measurements, with supplemental research measurements for the final assessment at age 3. Both clinical and research measurements were obtained by using Seca scales and infantometers from birth through 23 months and stadiometers for children aged \geq 2 years. Weight and recumbent length (<2 years) or height (\geq 2 years) were measured.

Clinical anthropometrics from birth to 3 years were collected from medical record review. Data were obtained from weights and lengths or heights performed by medical assistants. Clinical anthropometrics were used for 3 reasons: (1) practical difficulties in collecting research measures for families randomized to the intervention, because the sessions were integrated into well-child visits, potentially leading to bias in ascertainment across groups; (2) high frequency of clinical measures (every 1-3 months) increased power to evaluate trajectories; and (3) feasibility of studying obesity prevention in real-world health care settings. In addition, research staff measured weight and height at the final 3-year assessment, to the nearest 10th of a kilogram and centimeter.

Infant birth weight, sex, and gestational age were used to generate birth weight z-scores with Fenton growth curves.40 Although our original intent was to use *z*-scores based on weight and length or height, we identified biologically implausible variations in clinically obtained lengths or heights.⁴¹ Among 3-yearolds for whom both clinical and research-based anthropometrics were collected (n = 219), the mean (SD) height-for-age z-scores generated from clinically measured and research-measured heights were significantly different $(-0.10 \ [1.06])$ vs -0.21 [0.93], P = .01), suggesting decreased validity for clinicallymeasured heights. In contrast, there was no significant difference between clinically-measured and researchmeasured mean WFAz (0.60 [1.12] vs 0.61 [1.17], P = .65).

Between birth and 3 years, WFAz were calculated by the World Health Organization Anthro macro.⁴² For ages 2 and 3 years, weight status was defined by WFA percentiles, with \geq 85th and \geq 95th designated as overweight and obese. Trajectory analyses used all clinically measured weights from birth to 3 years. Crosssectional group comparisons were performed at 6 month intervals from birth to 3 years, by using clinically measured WFAz obtained within 60 days of the given age.⁴³ At age 3 years, when research-based anthropometrics were available, analyses were performed by using World Health Organization WFA percentiles \geq 85th and \geq 95th and BMI z-scores, based on the Centers for Disease Control and Prevention 2000 growth charts.44

Family Characteristics

Baseline characteristics, collected by survey, included age, parity, education, employment, Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and Supplemental Nutrition Assistance Program (SNAP) participation, marital status, country of origin, depressive symptoms,⁴⁵ food insecurity,⁴⁶ and social support.⁴⁷ Prepregnancy BMI was obtained from the medical record; BMI \geq 30 was classified as obese.⁴⁸

Statistical Analyses

The study was powered to detect impacts on obesity prevalence reduction. To achieve 80% power to detect 15% obesity reduction with 30% loss to follow-up ($\alpha = .05$), we needed \geq 500 participants.⁴⁹ Analyses were based on intent-totreat, by using SPSS version 23 (SPSS Inc, Chicago, IL), Stata 15, and R. We examined bivariate relationships with mean WFAz and weight status at 6month intervals using independent samples *t* tests and χ^2 analyses for continuous and categorical variables. At age 3 years, we repeated analyses using WFAz and BMIz generated from research measurements. Using nonparametric regression techniques,³⁶ we generated growth trajectories, including 95% confidence intervals at each time point, which allows for crosssectional comparison of groups. We used multiple endpoint adjustment methods^{50,51} to allow for multiple comparisons at different time-points, accounting for repeated measures within subjects. Using generalized estimating equations (GEEs) with an exchangeable working correlation matrix, we then estimated an average treatment effect (ATE), with baseline growth allowing for a quadratic or cubic response, depending on the time interval. Because baseline education differed between groups, we performed sensitivity analyses adjusting for education with comparable results (Supplemental Tables 6, 7).

We performed within-intervention group analyses based on tertile of attendance. Cutoffs reflected the sample distribution, and high dose corresponded to attending \geq 70% of activities. For these analyses, we examined unadjusted and adjusted relationships between dose and interval mean WFAz and weight status using ANOVA and χ^2 analyses. Because of variability in intervention dose (number of sessions attended), and to explore dose effects using the entire sample, we also used instrumental variable (IV) analysis.52 An IV analysis identifies an instrument (measured variable), which is correlated with a variable of primary interest (dose) that has no direct path from the instrument to the outcome, operating exclusively through the variable of primary interest. Our instrument was randomization, satisfying both requirements, which allows us to correct for differential receipt of the intervention using a 2-stage least squares approach.⁵³ To allow comparison of dose analyses with ATE estimates, we report an IV effect size scaled by multiplying the IV dose effect by the average number of intervention sessions in the period.

RESULTS

Study Sample

All pregnant women at their first prenatal visit between August 2012 and December 2014 were screened for eligibility; follow-up was completed in June 2018 when all children had reached 3 years of age. Of 933 eligible pregnant women, 566 (61%) consented and 533 were randomized to intervention (n = 266)or control (n = 267) groups, with 529 live births (Fig 1). Our primary anthropometric outcomes from clinical measurements were available for 358 (67.7%) children at 2 years and 285 (53.9%) children at 3 years. Research assistants measured children's weights (research weight measurements) if the 3-year survey was done in person (versus telephone). Research measures were obtained on 254 children (134 control; 120 intervention). No adverse events were reported. For trajectory analyses, there was at least 1 recorded clinical weight on 525 children between birth and age 3, ranging from 1 to 26 per child, with an average of 12.8 per child. Of these 525 children, 99% had at least 1 weight recorded in year 1, 88% in year 2, and 81% in year 3.

Groups did not differ at baseline, except intervention mothers had less education (Table 1). Birth weight z-score was not significantly different between intervention and control groups (-0.05 vs 0.02, P = .36). Intervention children had slightly more weight measurements than controls (14.89 vs 14.11; P = .04). Children with weight measurements at 3 years had higher mean birth weight (3.43 vs 3.32, P = .01) and mothers who were older (28.9 vs 27.5 years, P = .01), less likely to be US born (15.4% vs 25.4%, $P \leq .01$), and more likely to receive SNAP benefits

(43.2% vs 28.2%, $P \le .01$) compared with those without a 3-year weight. Among participants with a 3-year weight, intervention mothers were older (29.7 vs 28.2 years, P = .03), less likely to have graduated high school (56.8% vs 68.8% P = .04), and more likely to receive WIC (92.4% vs 84.3%, P = .04), compared with controls.

Child Weight Outcomes

Intervention infants had significantly lower mean WFAz at 18 months (0.49 vs 0.73, P = .04) and 2 years (0.56 vs 0.81, P = .03) but not at 3 years (0.63 vs 0.59, P = .76) (Table 2). Obesity prevalence was not significantly different between groups at any age point, including 2 years (WFA \geq 85th percentile, 33.5% vs 39.4%, P = .11; WFA \geq 95th percentile, 17.0% vs 22.9%, P = .16) and age 3 years (WFA \geq 85th percentile, 36.4% vs 30.1%, P = .26; WFA \geq 95th percentile, 16.7% vs 15.7%, P = .82)(Table 3).

Trajectory analyses demonstrated that by age 6 months, the groups began to become distinct, with lower WFAz for the intervention group, with the difference diminishing by 30 months (Fig 2). ATE analysis using GEE and cubic baseline growth restricted to the 10 to 26 month interval, which corresponds to the interval endpoints used in the 12 month and 2 year analyses above, yielded an ATE of B = -0.19, P = .047.

Among the subset with researchmeasured anthropometrics at 3 years, the intervention group had similar mean WFAz (0.62 vs 0.63, P = .91) and rates of overweight (33.3% vs 35.8%, P = .68) and obesity (16.7% vs 15.7%, P = .83) as controls. Similar analyses conducted by using mean BMIz and weight status based on Centers for Disease Control and Prevention standards did not show group differences.

Intervention Dose

Of 15 possible sessions, the mean number attended was 7.75 (4.5), with





highest tertile \geq 10 by age 2 years and \geq 11 by age 3 years. In within group analyses (Table 4), the 2-year mean WFAz decreased as attendance increased with low, medium and high attendance (0.92, 0.59, 0.37, P < .01),

and obesity rates decreased (25.9%, 22.6%, 9.8%, P = .01). At 3 years, the mean WFAz decreased as attendance

 TABLE 1 Baseline Characteristics of Sample Randomized to Receive StEP Versus Standard Care

 Control (n = 533)

	Control, n (%)	Intervention, n (%)
Mother (prenatal)	267	266
Age, mean (SD)	27.9 (5.7)	28.6 (6.1)
Primiparous	107 (40.1)	92 (34.6)
Education (less than high school) ^a	77 (28.8)	100 (37.6)
Working	67 (25.1)	67 (25.2)
Married or living as married	191 (71.5)	198 (70.7)
US born	51 (19.1)	56 (21.1)
Prenatal depressive symptoms ^b	90 (33.7)	91 (34.3)
Low social support	53 (19.8)	53 (19.9)
Household food insecurity	88 (33.0)	77 (29.0)
WIC participant	228 (85.4)	237 (89.1)
SNAP participant	95 (35.6)	98 (36.8)
Prepregnancy obese status	82 (30.7)	81 (30.5)
Child (birth)	266	263
Girls	139 (52.3)	131 (49.8)
Cesarean birth	58 (21.7)	46 (17.9)
Premature $<$ 37 wk gestational age $^{ m c}$	6 (2.3)	10 (3.6)
Birth wt, mean (SD) ^c	3.40 (0.49)	3.36 (0.45)
Birth wt z-score ^c	0.02 (0.91)	-0.05 (0.81)

^a Significant at $P \leq .05$.

^b n = 532

^c n = 521.

increased (0.90, 0.74, 0.41, P = .03), and obesity rates decreased (26.4%, 22.5%, 8.0%, P = .02). When using the interval of 10 to 26 months, the IV effect of -0.033(P = .037 [asym.]; P = .047 [boot.]) multiplied by 6.1 (mean number of doses in range) yields -0.20, consistent with GEE findings.

DISCUSSION

StEP, a prenatal and pediatric primary care-based early child obesity prevention intervention targeting low-income Hispanic families, resulted in lower standardized weights and trajectories between ages 1 and 2 years, although

TABLE 2	StEP	Impacts	on	WFAz	at	6-Month	Intervals
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.14
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—
.08
_
.04
.03
.50
—
.76

—, not applicable.

^a Anthropometric data used for these analyses were obtained by medical record review.

these findings were not significant at 3 years. No significant group differences were found in obesity prevalence. The absolute *z*-score difference among intervention infants was 0.24 at 18 months and 0.25 at 2 years, close to that achieved by home visiting interventions, in populations with less obesity. These effect sizes are similar to those referenced by the 2017 US Preventive Services Task Force report, which concluded that for children ≥ 6 years with obesity, a BMI z-score reduction of 0.20 to 0.25 was a suitable threshold for clinically important change associated with improved cardiovascular and metabolic risk factors.⁵⁴ In dose analyses, increased StEP exposure was associated with lower mean WFAz and obesity prevalence. Children receiving high dose had obesity rates at 2 and 3 years that were $\sim 60\%$ lower than those receiving low dose.

Achieving weight impacts in child obesity prevention trials, particularly those designed for at-risk groups, has proved difficult.55,56 A recent series of well-designed trials focusing on lowincome minority children failed to impact weight.^{57,58} Several trials beginning during pregnancy or infancy, demonstrated only behavioral improvements.^{11,12,59} Researchers of 2 trials of home visiting interventions enrolling firsttime mothers reported significant weight reductions. Healthy Beginnings in Australia reported a BMI reduction of 0.29 at age 2,13 although not sustained at age 5.60 **Researchers of Intervention Nurses** Start Infants Growing on Healthy Trajectories (INSIGHT), conducted in primarily middle-income white U.S. families with low rates ($\sim 8\%$) of obesity, found that intervention infants had lower weight-for-length percentiles (57.5% vs 64.4%) and overweight status (5.5% vs 12.7%) at 12 months¹⁵ and lower BMI z-scores at 3 years (-0.28).¹⁴ Notably, StEP achieved comparable weight

TABLE 3 StEP Impacts on Obesity Prevalence at Age 2 and 3 Years

Age	п	WFA \geq 85th percentile, <i>n</i> (%)	Р	WFA \geq 95th percentile, <i>n</i> (%)	Р
2 y			.11		.16
Control	170	67 (39.4)	_	39 (22.9)	
Intervention	188	59 (33.5)		32 (17.0)	
3у			.26		.82
Control	153	46 (30.1)	_	24 (15.7)	_
Intervention	132	48 (36.4)	_	22 (16.7)	_

—, not applicable.

reductions through age 2 years among U.S. children at highest risk of obesity, with low-income, Hispanic ethnicity, and high maternal obesity. Furthermore, this effect was achieved by using the underused health care platform^{11,12,61,62} and without limiting to first-time mothers.

Research to establish the optimum dose is limited. Authors of a recent US Preventive Services Task Force report found that at least 26 hours was required to achieve clinically meaningful weight reductions, with greater contact associated with larger effects.⁶³ However, the dose needed for obesity prevention remains unknown. A recent systematic review was unable to detect clear relationships between dose and weight, and recommended further study of dose.⁶⁴ Our findings exploring the dose effects of



FIGURE 2

Impact of StEP on WFAz trajectory from birth to age 3 years. Lines represent nonparametric growth trajectory estimates for the intervention (dashed line) and control (solid line) groups ages 0 to 36 months. The darker bands represent 95% confidence intervals at each time point; the lighter bands are 95% confidence intervals adjusted for correlated repeated measures within subjects.

a preventive intervention during pregnancy and early childhood begin to fill these gaps. The StEP dose received was >50%, equivalent to similar health care-based programs.^{11,65} Although our findings demonstrate that weight impacts are detected in those receiving at least 5 sessions, maximum impacts are noted in those receiving at least 10, informing recommendations for the dose needed.

This study has several strengths. We were able to successfully recruit, follow and demonstrate weight impacts in a disadvantaged group. The failure of several large trials to impact weight in high-risk preschoolers highlights the urgent need for earlier prevention.55 StEP provides an infrastructure for adding support for high-risk families into frequent health care visits, facilitating scalability, and allowing for seamless intervention from pregnancy through early childhood. Future researchers will explore whether changes in feeding styles and practices, or child sleep, activity, and screen time, serve as mediators of StEP weight impacts.

One limitation was using medical record reviews to obtain anthropometrics. Although researchers have demonstrated that clinical- and research-measured weights correlate well, inaccuracies are common in clinically measured length and height⁴¹; therefore, WFAz was used. Another limitation is that we did not track adherence to wellchild visits or whether control families learned about the StEP curriculum from other families or providers. Given variability in dose received, future studies need to reduce participation barriers. Lack of sustained effects at age 3 years highlight the need to target the changing multifactorial causes of obesity when children have greater behavioral independence and exposure to obesogenic environments.

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TADLE 4 WILLIN	intervention	Group I	Dose	Ellects	011	Mean	WFAZ	anu	WFA	Percentile	Galegories

	Within Intervention Group Dose Effects								
	Low Attendance (0–4 Sessions)	Medium Attendance (5–9 sessions)	High Attendance (10–12 sessions)	Р	Adjusted P ^a				
Age 2 y									
Sample No. Continuous, mean (SD)	58	84	61	—	_				
WFAz	0.92 (1.17)	0.59 (1.13)	0.37 (0.97)	.02	<.01				
Categorical, <i>n</i> (%) WFA ≥85th percentile	26 (44.8)	28 (33.3)	14 (23.0)	.04	<.01				
WFA ≥95th percentile	15 (25.9)	19 (22.6)	6 (9.8)	.06	.01				
Age 5 y Sample No. Continuous, mean (SD)	53	71	72	_	_				
WFAz	0.90 (1.27)	0.74 (1.32)	0.41 (1.06)	.07	.03				
Categorical, n (%) WFA \geq 85th percentile	21 (39.6)	28 (39.4)	21 (29.2)	.35	.66				
WFA \geq 95th percentile	14 (26.4)	16 (22.5)	6 (8.0)	.02	.02				

—, not applicable.

^a Adjusted *P* value obtained using multiple linear and logistic regression controlling for maternal education (did not complete high school versus completed high school), country of origin (not born in the United States versus born in the United States), parity (first child versus not first child), and prepregnancy obesity (BMI <30 vs BMI \geq 30).

CONCLUSIONS

A health care-based child obesity prevention program from pregnancy

through early childhood led to healthier weight trajectory and lower standardized weight in the first 2 years of life, although the prevalence and degree of obesity was not significantly different at age 3 years. Dose-dependent reduction in obesity prevalence was found. Further study is needed to determine if enhanced program engagement can sustain early effects beyond age 2 years.

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ABBREVIATIONS

ATE: average treatment effect GEE: generalized estimating equation IV: instrumental variable SNAP: Supplemental Nutrition Assistance Program StEP: Starting Early Program WFA: weight for age WFAz: weight for age WFAz: weight-for-age z-score WIC: Special Supplemental Nutrition Program for Women, Infants, and Children

Dr Messito conceptualized and designed the study, supervised acquisition of data, analyzed data, reviewed the analyses, drafted the initial manuscript, and reviewed and revised the manuscript; Dr Mendelsohn substantially contributed to the conception and design of the study and to analysis and interpretation of data and revised the manuscript; Dr Katzow substantially contributed to analysis, interpretation and review of data analyses, and manuscript content and revised the manuscript for important intellectual content; Dr Scott substantially contributed to analysis and interpretation of data, conducted and reviewed data analyses, and revised the manuscript for important intellectual content; Dr Vandyousefi substantially contributed to analysis and interpretation of data, analyzed data, reviewed the manuscript for important intellectual content; Dr Gross conceptualized and designed the study, supervised acquisition of data, analyzed data, reviewed the analyses, and reviewed and revised the manuscript; and all authors approved the final version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved and approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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