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Randomized controlled trial of a primary care-based child obesity prevention intervention on infant feeding practices

Rachel S. Gross, MD, MS¹, Alan L. Mendelsohn, MD², Michelle B. Gross, MS, RD³, Roberta Scheinmann, MPH⁴, and Mary Jo Messito, MD³

¹Department of Pediatrics, Albert Einstein College of Medicine, Children's Hospital at Montefiore, Bronx, NY

²Department of Pediatrics, Division of Developmental - Behavioral Pediatrics, New York University School of Medicine and Bellevue Hospital Center, New York, NY

³Department of Pediatrics, Division of General Pediatrics, New York University School of Medicine and Bellevue Hospital Center, New York, NY

⁴Research and Evaluation Unit, Public Health Solutions, New York, NY

Abstract

Objective—To determine the effects of a child obesity prevention intervention beginning in pregnancy on infant feeding practices in low-income Hispanic families.

Study design—The Starting Early randomized controlled trial enrolled pregnant women at a third trimester visit. Women (n=533) were randomly allocated to a standard care control group or an intervention group participating in prenatal and postpartum individual nutrition/breastfeeding counseling and subsequent nutrition and parenting support groups coordinated with well-child visits. Outcome measures included infant feeding practices and maternal infant feeding knowledge at infant age 3 months, using questions adapted from the Infant Feeding Practices Study II and an infant 24-hour diet recall.

Results—456 families completed 3-month assessments. The intervention group had higher prevalence of exclusive breastfeeding on the 24-hour diet recall (42.7% vs. 33.0%, p=.04) compared with controls. The intervention group reported a higher percentage of breastfeeding vs. formula feeding per day (mean (SD) 67.7 (39.3) vs. 59.7 (39.7), p=.03) and was less likely to introduce complementary foods and liquids compared with controls (6.3% vs. 16.7%, p=.001). The intervention group had higher maternal infant feeding knowledge scores (Cohen's d, 0.29, 95% CI .10 to .48). The effect of Starting Early on breastfeeding was mediated by maternal infant feeding knowledge (Sobel test 2.86, p=.004).

Corresponding/reprint author: Rachel S. Gross MD, MS, Department of Pediatrics, Albert Einstein College of Medicine, Children's Hospital at Montefiore, 3444 Kossuth Avenue, Bronx, New York, 10467, phone (718) 920-2655, fax (718) 652-5707, rgross@montefiore.org.

The authors declare no conflicts of interest.

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Conclusions—Starting Early led to increased exclusive breastfeeding and reduced complementary foods and liquids in 3 month old infants. Findings document a feasible and effective infrastructure for promoting breastfeeding in families at high risk for obesity in the context of a comprehensive obesity prevention intervention.

Trial registration—ClinicalTrials.gov NCT01541761

Keywords

pregnancy; feeding knowledge; Hispanic

Infant feeding practices are linked to excess weight gain and early obesity, such as combination breast and formula feeding and the early introduction of complementary foods. The high prevalence of these potentially modifiable infant feeding practices in groups at high risk of obesity support the need for effective obesity prevention interventions beginning during these critical periods in the life course.

A number of interventions have been shown to improve infant feeding practices. Educational and supportive breastfeeding interventions result in increased knowledge and exclusive breastfeeding. Even though an increasing number of obesity prevention interventions are beginning during infancy these programs have had limited impacts on exclusive breastfeeding. This may be because knowledge, attitudes and intentions about breastfeeding develop during pregnancy and lactation support in the postpartum period is crucial. No comprehensive obesity prevention programs have begun prenatally or used the existing framework of frequent pregnancy and infancy primary care visits and the postpartum hospital stay to reach high-risk families.

To address these limitations, we designed the “Starting Early” obesity prevention intervention to be integrated into prenatal and pediatric primary care and the postpartum hospital stay. We sought to test the efficacy of the intervention on improving maternal infant feeding knowledge and practices in low-income Hispanic families. We hypothesized that compared with a standard care control group, the Starting Early intervention group would demonstrate higher maternal infant feeding knowledge and healthier infant feeding practices, specifically higher prevalence of exclusive breastfeeding and lower prevalence of introducing complementary foods and liquids at infant age 3 months. We also hypothesized that these intervention effects on infant feeding practices would be mediated through maternal infant feeding knowledge.

METHODS

This was a randomized controlled trial to test the efficacy of the “Starting Early” obesity prevention intervention compared with a control group that received routine prenatal and pediatric primary care. This study took place in the primary care prenatal and pediatric clinics and the postpartum ward of a large urban public hospital and an affiliated satellite neighborhood health center in New York City. This study was approved by the Institutional Review Boards of New York University School of Medicine and the Albert Einstein College

of Medicine, as well as Bellevue Hospital Center and the Health and Hospital Corporation (ClinicalTrials.gov: NCT01541761).

We included pregnant women who were: (1) 18 years old; (2) self-identified as Hispanic/Latina; (3) fluent in English/Spanish; (4) with a singleton uncomplicated pregnancy; (5) able to provide phone numbers; and (6) intending to receive care at the study sites. We excluded women with: (1) significant medical or psychiatric illness (eg, cardiovascular disease, lupus, neuromuscular disorders, psychosis, drug addiction); (2) homelessness; and (3) severe fetal anomalies on ultrasound (eg, neural tube defects, chromosomal abnormalities). Women with obesity, diabetes, hypertension, thyroid disease or depression were not excluded. A 3-step process was developed to screen for eligibility (Figure 1; available at www.jpeds.com). Women identified as eligible in this initial screen were then tracked through the prenatal process, and reassessed following the 20 week fetal anatomy scan. For those continuing to meet inclusion criteria, a third and final in-person assessment took place at a third trimester prenatal visit. At that visit, a research assistant confirmed final eligibility for entry into the study. Interested eligible women signed the consent form, and completed a baseline assessment at two prenatal visits.

Randomization was performed for those enrolled women who completed the baseline assessment and attended a prenatal visit 32 weeks gestational age. Women were randomized to intervention or control groups at a prenatal visit by a nutritionist who conducted the intervention, using a random number generator, stratified by site. Group assignments were concealed from the research assistants, who conducted the follow-up assessments.

The Starting Early intervention is a family-centered primary care-based early child obesity prevention intervention designed for low-income Hispanic families beginning in the third trimester of pregnancy and continuing until child age three years old. The intervention is delivered by registered dietitians (RD) with maternal-child health experience who have been trained as Certified Lactation Counselors (CLC) through the Academy of Lactation Policy and Practice and accredited by the American National Standards Institute. The RD/CLCs were all bilingual English/Spanish speakers. The intervention components were: 1) individual nutrition counseling in the prenatal and postpartum periods; 2) nutrition and parenting support groups (NPSG) coordinated with well-child visits; 3) plain language handouts; and 4) nutrition education DVDs. All curriculum and materials were developed in English and Spanish.

A comprehensive curriculum of fifteen lessons, from pregnancy through child age three years old, was developed by experts in maternal-child health, pediatrics, obesity prevention, child development, and nutrition education. Nationally recognized health literacy experts evaluated the curriculum and handouts for language, cultural relevance and literacy and numeracy level. Plain language handouts, which were picture-based with positive messages, and a nutrition education DVD, developed with input from focus groups of Hispanic women participating in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), were used to reiterate messages from each lesson. The individual

counseling sessions in the prenatal and newborn periods and the nutrition and parenting support groups for mother-infant pairs were approximately 45 to 60 minutes long.

After the infants were born, groups of 4–8 mother-infant pairs were formed into a cohort by the infant's birth date. These cohorts attended groups together from the one month visit until the children were 3 years old. This encouraged peer interaction and social support to enhance self-efficacy, knowledge and skills. In the first year of life, the visits occurred at 1, 2, 4, 6, 9, and 12 months old. This was followed by visits every three months in the second and third years of life (15, 18, 21, 24, 27, 30, and 33 months old). The curriculum, which was ecologically informed and included elements from the health beliefs model and social cognitive theory, promoted behavior change by addressing perceived barriers to healthy behaviors. The NPSGs addressed three domains of parenting skills likely to reduce child obesity, including: (1) feeding; (2) activity; and (3) general parenting (eg, soothing infant crying). NPSGs included a lunchtime family meal to encourage modeling of healthy diets and portion sizes, and provide opportunities to demonstrate responsive child feeding. Four intervention sessions occurred prior to the 3-month assessment.

Session 1 consisted of individual RD/CLC prenatal counseling coordinated with a 3rd trimester visit after randomization. Content included discussions about the benefits of breastfeeding and perceived barriers, such as inadequate milk supply, breast pain, infant crying, involving fathers and grandparents, and feeding in public.

Session 2 consisted of individual RD/CLC counseling on the post-partum ward for lactation support and guidance on healthy bottle feeding. Lactation support consisted of detailed individual assessment of breastfeeding, including latch, positioning, pain and perception of milk supply, as well as troubleshooting difficulties and perceived barriers. The RD/CLC used models to demonstrate breastfeeding positions and skin to skin contact. For formula feeding mothers, bottle positioning and formula volumes were discussed. The RD/CLC reviewed hunger and satiety cues and infant soothing methods with all mothers and other care givers, such as fathers and grandparents, and helped them to practice these techniques.

Session 3 was the first nutrition parenting support group (NPSG) coordinated with the 1-month well-child visit. This session focused on introducing the group, discussing the positive and difficult aspects of breastfeeding, identifying infant hunger and fullness cues, and demonstrating infant soothing techniques. Mothers and other caregivers practiced infant soothing techniques such as swaddling, sucking and swinging. A DVD distributed at this group focused on infant feeding and has been shown to improve maternal nutrition knowledge.

Session 4 was an NPSG at the 2-month well-child visit. This group reviewed infant hunger and fullness, as well as infant cues for communication, sleep and discomfort. Specific recommendations for diet content, such as avoiding the early introduction of complementary food or liquids, and feeding frequency and volume were discussed. Infant soothing techniques such as talking, singing and holding were demonstrated and practiced.

The Starting Early intervention and control groups received the same routine prenatal, postpartum and pediatric primary care. Standard prenatal care at the study sites included

food insecurity. Pre-pregnancy weight status, infant sex, delivery type, gestational age and birth weight were obtained from the medical record.

Statistical Analyses

We estimated that 500 pregnant women would need to be enrolled to achieve 80% power to detect a 15% reduction in obesity prevalence at age 3 years, assuming 30% loss to follow-up, and alpha of .05. For the present analysis, the sample of 456 provided >90% power to show an increase in exclusive breastfeeding from 30% to 45%. The data were analyzed by using SPSS version 18.0 (SPSS Inc, Chicago, IL). This was an intent-to-treat analysis, with all subjects allocated to their given group and assessed based on this assignment. We performed univariate analyses to examine baseline distributions of socio-demographic characteristics by group status. We examined bivariate relationships between group status and maternal infant feeding knowledge and infant feeding practices using independent samples t-tests and chi-square analyses for continuous and categorical variables respectively. For continuous variables, effect sizes were obtained using mean differences with associated 95% confidence intervals and Cohen's *d* was calculated. Path analysis was used to determine whether enhanced maternal infant feeding knowledge mediated Starting Early-associated increases in breastfeeding intensity. We followed Baron and Kenny's 4-step process for testing mediation hypotheses. Standardized indirect effects were calculated with SPSS PROCESS using bootstrapping techniques. The Sobel test was used to statistically test for the presence of mediation.

RESULTS

All pregnant women presenting for their first prenatal intake visit between August, 2012 and December, 2014 were identified by their primary care providers and screened for potential eligibility through review of the electronic medical record. Of 1263 potentially eligible pregnant women assessed in person at a third trimester prenatal visit, 330 were ineligible, leaving 933 eligible women. 367 (39.3%) declined to participate (Figure 1). At a follow-up prenatal visit, 533 were randomized to either the intervention group (n=266) or to the control group (n=267). A total of 456 mother-infant pairs completed the 3-month assessment (86.2% of 529 infants born) and were included in these analyses. These analyses included 221 (84.0%) intervention and 235 (88.3%) control mother-infant pairs, with a mean (SD) child age of 3.4 (.6) months.

Baseline characteristics by group are in Table I. The participants were primarily non-US born with high rates of psychosocial stressors, such as depressive symptoms and food insecurity. Groups did not differ for any baseline characteristics, except for lower education in the enrollment sample in the intervention group. Mothers who did not complete the 3-month assessment were similar to those who did, except they were more likely to be US born (32.4% vs. 18.3%, $p=.002$) and to experience prenatal depressive symptoms (45.7% vs. 32.5%, $p=.01$).

All intervention subjects attended the prenatal session following randomization (221/221). 96.4% received post-partum counseling during the hospital stay (213/221) and 56.1% and 58.8% attended the 1-month (124/221) and 2-month (130/221) NPSGs respectively. 41.0%

received all four intervention sessions. 71.4% received three or more. There were no adverse events reported.

The intervention effects on infant feeding practices are shown in Table II. At infant age 3 months, more intervention mothers reported exclusive breastfeeding compared with controls (odds ratio (OR) 1.61, 95% confidence interval (CI) 1.07–2.44). Comparable increases in breastfeeding were verified in the 24-hour diet recall (OR 1.51, 95% CI 1.03–2.21). The intervention group reported higher breastfeeding intensity (the percentage of breast milk feedings per day) (67.7% vs. 59.7%, $p=.03$), and lower percentage of combination feedings per day (giving both breast milk and formula at the same feed) compared with controls (2.0% vs. 4.3%, $p=.03$). Intervention mothers reported less ‘medium’ intensity breastfeeding compared with ‘high’ intensity breastfeeding (OR .51, 95% CI .33–.78). The intervention mothers were less likely to introduce complementary food or liquids (6.3% vs. 16.7%, $p=.001$).

Within the intervention group, attending one or two NPSGs was associated with increased breastfeeding intensity. The percentage of mothers reporting medium or high breastfeeding intensity increased for attending no groups, one group and two groups respectively (67.7%, 82.1%, 85.7%; $p=0.02$). The percentage of mothers reporting introducing complementary food or liquids decreased for attending no groups, one group and two groups respectively (14.3%, 4.5%, 2.2%, $p=.008$).

Table II also presents the intervention effects on knowledge. The intervention group displayed higher knowledge scores than controls (mean difference, 0.51 points; 95% CI, 0.19–.83 points; Cohen’s d , 0.29; 95% CI .10–.48). The intervention group was more likely to respond correctly to 10 of 12 questions, with four reaching statistical significance. Within the intervention group, higher knowledge scores were positively correlated with the number of groups attended ($r=.14$, $p=.04$). Path analysis was used to determine whether knowledge mediated the relationship between participating in the intervention and breastfeeding intensity. Figure 2 (available at www.jpeds.com), which depicts the relationship between the intervention and breastfeeding intensity, demonstrated that the 4 standard criteria for mediation were met: 1) Starting Early intervention was associated with breastfeeding intensity (as a continuous variable) in unadjusted analysis ($p=.03$); 2) the intervention was associated with maternal infant feeding knowledge (the mediator) ($p=.002$); 3) knowledge was associated with breastfeeding intensity ($p<.001$); and 4) the intervention was no longer associated with breastfeeding intensity after adjusting for knowledge ($p=.18$). The standardized indirect effect was 3.5 (95% CI: 1.31–6.08). The Sobel statistic was significant at 2.86 ($p=.004$).

DISCUSSION

Meta-analyses of randomized controlled trials have identified several important components of successful breastfeeding interventions: ‘universal’ intervention versus intervention offered only to women with difficulties; occurrence in both the prenatal and postnatal settings; and incorporation of peer support. The Starting Early Program may have achieved increased prevalence of exclusive breastfeeding and higher breastfeeding intensity because it

incorporated these elements, specifically the universal provision of both prenatal and postnatal intervention components in a supportive peer group setting. Intensive early nutrition counseling for the parents of infants has been shown to produce long-term dietary improvements, by preventing the onset of unhealthy feeding patterns such as excess fat intake. The decreased early introduction of complementary foods and liquids in the Starting Early intervention subjects may be due to the intensive early onset of targeted nutrition and parenting counseling received, compared with control subjects receiving standard primary care.

Several additional factors related to the Starting Early intervention form and content also likely contribute to its significant impact on feeding behaviors. Starting Early used an interactive group model with dietitians and peer support. Intervention mothers attended the NPSG sessions with the same group of families from the time their infants were aged one month until they turned three years old. These groups were led by culturally competent bilingual RD/CLCs, who began working with intervention women during pregnancy. The NPSG content incorporated social learning theory important for adult learning and behavior change. All lessons and materials were prepared in Spanish and addressed poverty-related challenges regarding infant feeding, such as food insecurity, which has been associated with obesity-promoting maternal attitudes during both the prenatal and early infancy periods.

Although current New York State prevalence of exclusive breastfeeding at 3 months is 37%, it is significantly lower in low-income and minority women. Healthy People 2020 aims to increase exclusive breastfeeding to 46% at 3 months. Our intervention comes close to this goal with 42.7% reporting exclusive breastfeeding at 3 months using the 24-hour diet recall. These findings highlight our ability to integrate effective breastfeeding promotion into an early obesity prevention intervention targeting low-income families.

The Starting Early intervention increased maternal infant feeding knowledge beyond that of standard care, which included nutrition education as part of prenatal care and WIC participation. The effect size of the increase in maternal infant feeding knowledge due to the Starting Early intervention is similar to that found in other successful prenatal breastfeeding interventions that address breastfeeding knowledge. Our findings that increased knowledge mediated program effects on increasing breastfeeding intensity further supports education as an essential intervention component.

Starting Early did not significantly affect breastfeeding in the postpartum hospital period. This may be because our intervention did not focus on the components of the Baby Friendly Initiative, such as rooming in, limiting use of formula and staff training. It is possible that hospital-level factors during the newborn period might play a stronger role in influencing infant feeding than our intervention. Ultimately, Starting Early may need to be combined with larger hospital-wide initiatives, in particular the Baby Friendly initiative, in order to enhance exclusive breastfeeding in the postpartum unit.

This study has several limitations. Infant feeding practices were based on maternal report, which can be subject to social desirability biases. However, survey questions were adapted from nationally utilized questions, and validity of these questions is supported by finding

similar exclusive breastfeeding rates using the IFSP questions and the 24-hour diet recall. Another possible limitation may be that the control subject mothers were not offered an attention control intervention in addition to standard prenatal and pediatric primary care. Participating mothers were primarily low-income Hispanic immigrants; results may not be generalizable to other populations. Finally, the follow-up period was only infant age 3 months. At this time it is unknown whether these changes in knowledge and feeding practices will be sustained. Longitudinal follow-up will allow for analyses of the long-term impacts of Starting Early on breastfeeding duration, obesogenic dietary and lifestyle habits, and ultimately child obesity.

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Abbreviations

CLC	Certified Lactation Counselors
CI	Confidence Interval
NPSG	Nutrition and Parenting Support Groups
OR	Odds Ratio
RD	Registered Dietitian
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

References

1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011–2012. *JAMA*. 2014; 311:806–814. [PubMed: 24570244]
2. Taveras EM, Rifas-Shiman SL, Belfort MB, Kleinman KP, Oken E, Gillman MW. Weight status in the first 6 months of life and obesity at 3 years of age. *Pediatrics*. 2009; 123:1177–1183. [PubMed: 19336378]
3. Taveras EM, Gillman MW, Kleinman KP, Rich-Edwards JW, Rifas-Shiman SL. Racial/ethnic differences in early life risk factors for childhood obesity. *Pediatrics*. 2010; 125:686–95. [PubMed: 20194284]
4. Arenz S, Ruckerl R, Koletzko B, von Kries R. Breast-feeding and childhood obesity--a systematic review. *Int J Obes Relat Metab Disord*. 2004; 28:1247–1256. [PubMed: 15314625]
5. Grummer-Strawn LM, Mei Z. Centers for Disease Control and Prevention Pediatric Nutrition Surveillance System. Does breastfeeding protect against pediatric overweight? Analysis of longitudinal data from the centers for disease control and prevention pediatric nutrition surveillance system. *Pediatrics*. 2004; 113:e81–6. [PubMed: 14754976]
6. Kramer MS, Guo T, Platt RW, Vanilovich I, Sevkovskaya Z, Dzikovich I, et al. Feeding effects on growth during infancy. *J Pediatr*. 2004; 145:600–605. [PubMed: 15520757]

7. Harder T, Bergmann R, Kallischnigg G, Plagemann A. Duration of breastfeeding and risk of overweight: A meta-analysis. *Am J Epidemiol*. 2005; 162:397–403. [PubMed: 16076830]
8. Owen CG, Martin RM, Whincup PH, Davey-Smith G, Gillman MW, Cook DG. The effect of breastfeeding on mean body mass index throughout life: A quantitative review of published and unpublished observational evidence. *Am J Clin Nutr*. 2005; 82:1298–1307. [PubMed: 16332664]
9. Procter SB, Holcomb CA. Breastfeeding duration and childhood overweight among low-income children in Kansas, 1998–2002. *Am J Public Health*. 2008; 98:106–110. [PubMed: 18048788]
10. Huh SY, Rifas-Shiman SL, Taveras EM, Oken E, Gillman MW. Timing of solid food introduction and risk of obesity in preschool-aged children. *Pediatrics*. 2011; 127:e544–51. [PubMed: 21300681]
11. Klag E, McNamara K, Geraghty S, Keim S. Associations between breast milk feeding, introduction of solid foods, and weight gain in the first 12 months of life. *Clin Pediatr*. 2015; 54:1059–1067.
12. Heinig MJ, Nommsen LA, Peerson JM, Lonnerdal B, Dewey KG. Energy and protein intakes of breast-fed and formula-fed infants during the first year of life and their association with growth velocity: The DARLING study. *Am J Clin Nutr*. 1993; 58:152–161. [PubMed: 8338041]
13. Haisma H, Coward WA, Albernaz E, Barros A, Victora CG, Wright A, et al. Breast milk and energy intake in exclusively, predominantly, and partially breast-fed infants. *Eur J Clin Nutr*. 2003; 57:1633–1642. [PubMed: 14647230]
14. Bonuck KA, Trombly M, Freeman K, McKee D. Randomized, controlled trial of a prenatal and postnatal lactation consultant intervention on duration and intensity of breastfeeding up to 12 months. *Pediatrics*. 2005; 116:1413–1426. [PubMed: 16322166]
15. Kramer MS, Chalmers B, Hodnett ED, Sevkovskaya Z, Dzikovich I, Shapiro S, et al. Promotion of breastfeeding intervention trial (PROBIT): A randomized trial in the republic of Belarus. *JAMA*. 2001; 285:413–420. [PubMed: 11242425]
16. Ibanez G, de Reynal de Saint Michel C, Denantes M, Saurel-Cubizolles MJ, Ringa V, Magnier AM. Systematic review and meta-analysis of randomized controlled trials evaluating primary care-based interventions to promote breastfeeding in low-income women. *Fam Pract*. 2012; 29:245–254. [PubMed: 21993570]
17. Paul IM, Savage JS, Anzman SL, Beiler JS, Marini ME, Stokes JL, et al. Preventing obesity during infancy: A pilot study. *Obesity*. 2011; 19:353–361. [PubMed: 20725058]
18. Taveras EM, Blackburn K, Gillman MW, Haines J, McDonald J, Price S, et al. First steps for mommy and me: A pilot intervention to improve nutrition and physical activity behaviors of postpartum mothers and their infants. *Matern Child Health J*. 2011; 15:1217–1227. [PubMed: 20957514]
19. Daniels LA, Mallan KM, Battistutta D, Nicholson JM, Perry R, Magarey A. Evaluation of an intervention to promote protective infant feeding practices to prevent childhood obesity: Outcomes of the NOURISH RCT at 14 months of age and 6 months post the first of two intervention modules. *Int J Obes*. 2012; 36:1292–1298.
20. Wen LM, Baur LA, Simpson JM, Rissel C, Wardle K, Flood VM. Effectiveness of home based early intervention on children's BMI at age 2: Randomized controlled trial. *BMJ*. 2012; 344:e3732. [PubMed: 22735103]
21. Hesketh KD, Campbell K, Salmon J, McNaughton SA, McCallum Z, Cameron A, et al. The Melbourne infant feeding, activity and nutrition trial (InFANT) program follow-up. *Contemporary Clinical Trials*. 2013; 34:145–151. [PubMed: 23117076]
22. Black MM, Siegel EH, Abel Y, Bentley ME. Home and videotape intervention delays early complementary feeding among adolescent mothers. *Pediatrics*. 2001; 107:E67. [PubMed: 11331717]
23. Kavanagh KF, Cohen RJ, Heinig MJ, Dewey KG. Educational intervention to modify bottle-feeding behaviors among formula-feeding mothers in the WIC program: Impact on infant formula intake and weight gain. *J Nutr Educ Behav*. 2008; 40:244–250. [PubMed: 18565465]
24. Bonuck KA, Huang V, Fletcher J. Inappropriate bottle use: An early risk for overweight? Literature review and pilot data for a bottle-weaning trial. *Matern Child Nutr*. 2010; 6:38–52. [PubMed: 20055929]

25. Horodyski MA, Olson B, Baker S, Brophy-Herb H, Auld G, Van Egeren L, et al. Healthy babies through infant-centered feeding protocol: An intervention targeting early childhood obesity in vulnerable populations. *BMC Public Health*. 2011; 11:868. [PubMed: 22085421]
26. French GM, Nicholson L, Skybo T, Klein EG, Schwirian PM, Murray-Johnson L, et al. An evaluation of mother-centered anticipatory guidance to reduce obesogenic infant feeding behaviors. *Pediatrics*. 2012; 130:e507–17. [PubMed: 22891225]
27. Sanders LM, Perrin EM, Yin HS, Bronaugh A, Rothman RL. Greenlight Study Team. “Greenlight study”: A controlled trial of low-literacy, early childhood obesity prevention. *Pediatrics*. 2014; 133:e1724–37. [PubMed: 24819570]
28. Scheinmann R, Chiasson MA, Hartel D, Rosenberg TJ. Evaluating a bilingual video to improve infant feeding knowledge and behavior among immigrant Latina mothers. *J Community Health*. 2010; 35:464–70. [PubMed: 20039195]
29. Fein SB, Labiner-Wolfe J, Shealy KR, Li R, Chen J, Grummer-Strawn LM. Infant feeding practices study II: Study methods. *Pediatrics*. 2008; 122:S28–35. [PubMed: 18829828]
30. Johnson RK, Driscoll P, Goran MI. Comparison of multiple-pass 24-hour recall estimates of energy intake with total energy expenditure determined by the doubly labeled water method in young children. *J Am Diet Assoc*. 1996; 96:1140–1144. [PubMed: 8906138]
31. Labbok M, Krasovec K. Toward consistency in breastfeeding definitions. *Stud Fam Plann*. 1990; 21:226–230. [PubMed: 2219227]
32. Bonuck K, Stuebe A, Barnett J, Labbok MH, Fletcher J, Bernstein PS. Effect of primary care intervention on breastfeeding duration and intensity. *Am J Public Health*. 2014; 104:S119–27. [PubMed: 24354834]
33. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med*. 2001; 16:606–613. [PubMed: 11556941]
34. Bickel, G.; Nord, M.; Price, C.; Hamilton, W.; Cook, J. [Accessed February 3, 2016] Guide to measuring household food security. 2000. http://www.fns.usda.gov/sites/default/files/FSGuide_0.pdf
35. Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *J Pers Soc Psychol*. 1986; 51:1173–1182. [PubMed: 3806354]
36. Hayes, A. Introduction to mediation, moderation, and conditional process analysis. A regression-based approach. The Guilford Press; 2013.
37. Renfrew MJ, McCormick FM, Wade A, Quinn B, Dowswell T. Support for healthy breastfeeding mothers with healthy term babies. *Cochrane Database Syst Rev*. 2012; 5:001141.
38. Chung M, Raman G, Trikalinos T, Lau J, Ip S. Interventions in primary care to promote breastfeeding: An evidence review for the U.S. preventive services task force. *Ann Intern Med*. 2008; 149:565–582. [PubMed: 18936504]
39. Rasanen M, Niinikoski H, Keskinen S, Tuominen J, Simell O, Viikari J, et al. Nutrition knowledge and food intake of seven-year-old children in an atherosclerosis prevention project with onset in infancy: the impact of child-targeted nutrition counseling given to the parents. *Eur J Clin Nutr*. 2001; 55:260–267. [PubMed: 11360130]
40. Gross RS, Mendelsohn AL, Fierman AH, Racine AD, Messito MJ. Food insecurity and obesogenic maternal infant feeding styles and practices in low income families. *Pediatrics*. 2012; 130:254–261. [PubMed: 22826569]
41. Gross, RS.; Mendelsohn, AL.; Gross, MB.; Scheinmann, R.; Messito, MJ. Material Hardship and Internal Locus of Control over the Prevention of Child Obesity in Low-Income Hispanic Pregnant Women. *Acad Pediatr*. 2016. <http://dx.doi.org/10.1016/j.acap.2016.02.003>
42. Centers for Disease Control and Prevention. [Accessed October 21, 2014] Breastfeeding report card - United States. 2014. <http://www.cdc.gov/breastfeeding/pdf/2014breastfeedingreportcard.pdf>. Updated 2014
43. US Department of Health and Human Services. Office of Disease Prevention and Health Promotion. [Accessed October 21, 2015] Healthy People 2020. <http://www.healthypeople.gov/2020/default>. Updated 2015

44. Aksu H, Kucuk M, Duzgun G. The effect of postnatal breastfeeding education/support offered at home 3 days after delivery on breastfeeding duration and knowledge: a randomized trial. *J Matern Fetal Neonatal Med.* 2011; 24:354–361. [PubMed: 20608806]
45. Perrine CG, Scanlon KS, Li R, Odom E, Grummer-Strawn LM. Baby-friendly hospital practices and meeting exclusive breastfeeding intention. *Pediatrics.* 2012; 130:54–60. [PubMed: 22665406]
46. Freedland KE, Mohr DC, Davidson KW, Schwartz JE. Usual and unusual care: existing practice control groups in randomized controlled trials of behavioral interventions. *Psychosom Med.* 2011; 73:323–335. [PubMed: 21536837]

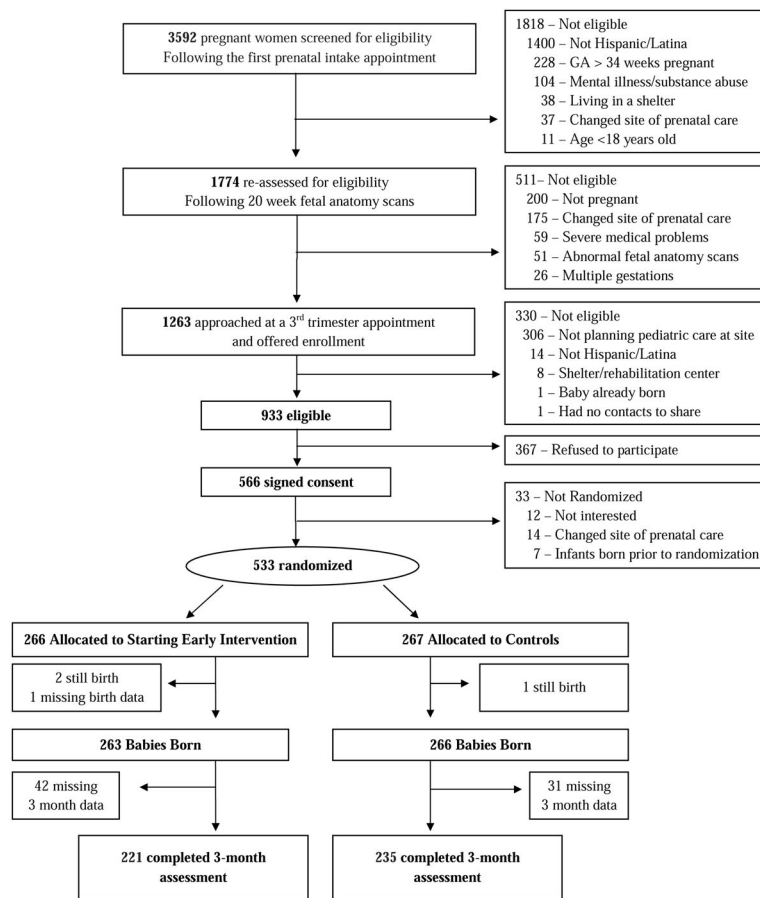


Figure 1.
Participant enrollment and assessment

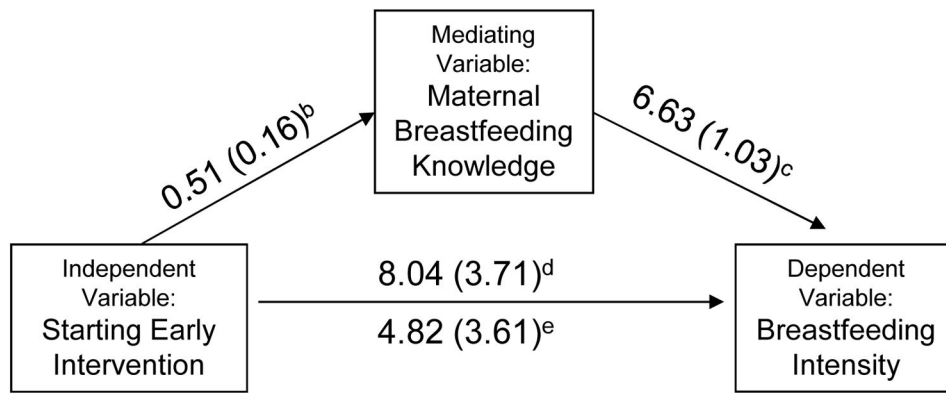


Figure 2. Path analysis – Maternal Breastfeeding Knowledge Mediates the Relationship between the Starting Early Intervention and Breastfeeding Intensity at 3 months^a

Table 1

Baseline Characteristics for the Enrollment Sample

Characteristics	Enrollment Sample (n=533)	
	Control (n=267)	Intervention (n=266)
Age (mean (SD))	27.9 (5.8)	28.5 (6)
Primiparous	107 (40.1)	92 (34.6)
WIC participant	228 (85.4)	237 (89.1)
SNAP participant	95 (35.6)	98 (36.8)
Education (less than high school)	77 (28.8)	100 (37.6)
Married or living as married	191 (71.5)	188 (70.7)
Working	67 (25.1)	67 (25.2)
US born	51 (19.1)	56 (21)
Pre-pregnancy obese status	79 (29.6)	76 (28.5)
Prenatal depressive symptoms	90 (33.7)	91 (34.3)
Household food insecurity	87 (33.5)	74 (28.2)
	Birth Sample (n= 529)*	
Child (Birth)	Control (n=266)	Intervention (n=263)
Male sex	127 (47.7)	132 (50.2)
Cesarean delivery	64 (24.6)	60 (23.4)
Premature < 37 weeks gestational age	5 (1.9)	10 (3.8)
Birth weight (mean (SD))	3.39 (.49)	3.35 (.45)
Large for gestational age (LGA)	32 (12.4)	21 (8.3)

* Birth sample: c-section n=516 (control n=260; intervention n=256); premature n= 527 (control n=265; intervention n=262); birth weight/LGA n=519 (control n=262; intervention n=257).

Table 2
Effects of the Starting Early Intervention on Infant Feeding Practices and Maternal Infant Feeding Knowledge at 3 Months Old

Feeding Practices and Knowledge	Group (n=456)		p-value	Odds Ratio or Mean Difference ^d	95% CI
	Control (n=235)	Intervention (n=221)			
Breastfeeding (BM) in newborn period					
Ever breastfed in the hospital	95.3 %	95.9 %	.82	1.16 ^a	.47 – 2.85
Exclusive BM in the hospital	31.1 %	37.1 %	.20	1.31 ^a	.89 – 1.93
Exclusive BM leaving the hospital	37.9 %	45.7 %	.11	1.38 ^a	.95 – 2.01
Breastfeeding at 3 months old					
Any BM at 3 months	80.4%	83.3%	.47	1.21	.75 – 1.95
Exclusive BM at 3 months	23.4 %	33.0 %	.03	1.61 ^a	1.07 – 2.44
100% BM on 24-hour diet recall ^b	33.0 %	42.7 %	.04	1.51 ^a	1.03 – 2.21
Breastfeeding intensity continuous score (Mean (SD)) ^{b,c}	59.7 (39.7)	67.7 (39.3)	.03	-8.0 ^b	-15.3 – -0.75
Breastfeeding intensity categories ^{b,c}			.006		
Low intensity (< 20% BM)	23.9%	20.5%		.63 ^a	.39 – 1.02
Medium intensity (20–80% BM)	34.6%	23.6%		.51 ^a	.33 – .78
High intensity (> 80% BM)	41.5%	55.9%		REF	
Ever gave BM and formula at the same feeding	31.1 %	22.4 %	.15	.64 ^a	.36 – 1.15
BM and formula at same feed per day (Mean (SD)) ^b	4.3 (14.1)	2.0 (7.2)	.03	2.30 ^b	.22 – 4.38
Other feeding at 3 months old					
Introduced tea, water, juice or cereal in the bottle	16.7 %	6.3 %	.001	.34 ^a	.18 – .64
Maternal infant feeding knowledge^d					
Total knowledge score ^e (Mean (SD))	9.8 (1.90)	10.3 (1.56)	.002	.51	.19 to .83
1. Infant formula is as good as breast milk ^f	69.5%	63.3%	.17	.76	.51 – 1.12
2. If a baby is breastfed, he or she will be less likely to get ear infections	86.3%	90.5%	.19	1.52	.85 – 2.72
3. If a baby is breastfed, he or she will be less likely to get a cough or a cold	88.8%	93.2%	.14	1.73	.89 – 3.35

Feeding Practices and Knowledge	Group (n=456)		p-value	Odds Ratio or Mean Difference ^d	95% CI
	Control (n=235)	Intervention (n=221)			
4. If a baby is breastfed, he or she will be less likely to get diarrhea	81.1%	89.1%	.02	1.91	1.12 – 3.27
5. If a baby is breastfed, he or she will be less likely to become overweight	85.4%	90.5%	.11	1.63	.91 – 2.90
6. Babies should be fed only breast milk for the first 6 months	91.0%	92.3%	.74	1.19	.61 – 2.32
7. Formula is easier to digest than breast milk ^f	87.6%	91.4%	.22	1.51	.82 – 2.78
8. Breastfeeding helps mothers lose weight faster ^g	82.7%	93.6%	<.001	3.08	1.63 – 5.84
9. Most women make enough breast milk for their babies to grow healthy	84.5%	89.6%	.13	1.57	.90 – 2.75
10. Feeding both breast milk and formula at the same feeding may cause you to feed your baby too much ^h	67.2%	78.7%	.006	1.80	1.18 – 2.75
11. Feeding both breast milk and formula increases the amount of your breast milk ^f	77.7%	72.4%	.23	.75	.49 – 1.16
12. You should not add anything to a bottle besides breast milk or formula	81.1%	89.1%	.02	1.91	1.12 – 3.27

^a Odds ratio presented for categorical variables and mean difference presented for continuous variables.

^b n=454 (control n=234, intervention n=220)

^c Breastfeeding intensity is defined as the percentage of all feedings in the past 24 hours that were breast milk using the 24 hour recall.

^d Percentages reflect the percentage of mothers in the control and intervention groups who responded correctly to each of the individual statements.

^e n=450 (control n=230; intervention n=220).

^f Statements in which the correct response was 'false'.

^g n=451 (control n=231; intervention n=218).

^h n=453 (control n=232; intervention n=219).