Published in final edited form as:

Acad Pediatr. 2018 April ; 18(3): 324–333. doi:10.1016/j.acap.2017.12.007.

A Randomized Controlled Trial to Prevent Infant Overweight in a High-risk Population

Elizabeth Reifsnider, PhD, RN^a, David P. McCormick, MD^b, Karen W. Cullen, DrPH^c, Michael Todd, PhD^a, Michael W. Moramarco, MS^a, Martina R. Gallagher, RN, PhD^d, and Lucia Reyna, BA^a

^aArizona State University, Phoenix, Arizona

^bUniversity of Texas Medical Branch, Galveston, Texas

^cBaylor College of Medicine, Houston, Texas

^dUniversity of Texas School of Nursing, Houston, Texas

Abstract

Introduction—Infants are at risk of overweight. Infant overweight predisposes child, adolescent, and adult to obesity.

Objectives—We hypothesized that parent education, initiated prenatally, and provided in the home, would reduce the incidence of infant overweight at age 12 months.

Methods—Pregnant obese Latina women were recruited at WIC and randomized to intervention versus control. Intervention subjects received home visits by trained Spanish-fluent community health workers who provided counseling on infant growth, breastfeeding, nutrition, child development, sleep, physical activity, and safety. Promotoras did not visit the control subjects. A research assistant collected outcome data on all subjects.

Results—Compared with controls, parent education did not reduce infant overweight. Infant overweight developed rapidly and was present in 46% of infants by age six months. Infants overweight at six months were likely to be overweight at age 12 months ($r=0.60$, $P<0.0001$). Overweight was more common in formula fed infants at ages six months ($P<0.06$) and 12 months ($P=0.005$). Breastfeeding was less common in families with employed mothers ($P=0.02$) and

Corresponding author: ^bDavid P. McCormick, M.D., Research Professor, Division of General Academic Pediatrics, Department of Pediatrics, University of Texas Medical Branch at Galveston, Primary Care Pavilion, Suite 2.701, 301 University Boulevard, Galveston, TX United States of America. 77555-1119. david.mccormick@utmb.edu. FAX (409) 747-0784. Office: (409) 772-1444.

^aCollege of Nursing and Health Innovation, Arizona State University, 500 N. 3rd Street, MC 3020, Phoenix, AZ 85004-0698. United States of America. elizabeth.reifsnider@asu.edu., mike.todd@asu.edu, michael.moramarco@asu.edu, lucy.reyna@asu.edu

^cUSDA/ARS Children's Nutrition Research Center, Baylor College of Medicine, 1100 Bates Street, Houston, TX, 77030. United States of America. kcullen@bcm.edu.

^dDepartment of Nursing Systems, University of Texas School of Nursing, Texas Medical Center, 6901 Bertner Avenue, Suite 740, Houston, TX 77030-2600. United States of America. martina.r.gallagher@uth.tmc.edu.

Conflicts of Interest: The authors have no conflicts of interest to disclose relevant to this article.

Clinical Trial Registration: U.S. National Institutes of Health, ClinicalTrials.gov. NCT01905072

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

unemployed fathers ($P < 0.01$), but father living with mother at the time of the prenatal visit predicted successful breastfeeding at infant age two months ($P < 0.003$). Compared with formula feeding, overweight at age 12 months was 2.7 times less likely for infants breastfed two months ($P = 0.01$).

Conclusion—The lack of success of the intervention may be explained in part by a high cesarean section rate in the intervention group, food and employment insecurity, and confounding by WIC breastfeeding promotion, which was available to all mothers. Breastfeeding was the most important mediator of infant overweight. The study supports efforts by WIC to vigorously promote breastfeeding.

Keywords

child; infant; obesity; prevention; intervention

Introduction

Overweight occurs during infancy, and may not be diagnosed by providers.¹ Overweight during infancy predicts child, adolescent, and adult obesity.² Prevention is seen as the most effective means to address the epidemic of childhood obesity.^{3,4} Several studies have described interventions to prevent early-onset overweight,^{5,6} but the effects may be difficult to sustain.⁷ Home visitation could provide an effective means of preventing excess weight gain during infancy, when the impact of an intervention could be greatest.⁴ This project focused on a population at increased risk for overweight, women and children of Mexican origin receiving benefits from WIC.⁸ Here we report 12-month outcomes of a prospective clinical trial to test the principal hypothesis: compared with controls, the incidence of infant overweight would be less in infants whose parents had received education in the home, initiated prenatally, and provided by trained community health workers (promotoras).⁹

Methods

Design

This was a prospective randomized controlled study, planned on the model of community-based participatory research, in cooperation with an advisory board consisting of volunteer community leaders, WIC staff, and mothers enrolled in WIC. Institutional review boards at Arizona State University and the state and city health departments approved the informed consent and research protocol.

Setting and study population

Obese pregnant Mexican-American women living in a southwestern metropolitan area were recruited from WIC clinics where the majority of participants were Hispanic, earned below 200% of the federal poverty index and did not complete high school.

Promotora recruitment and training

Promotoras are community health workers without health professional education but who have received six months of formal instruction and community health worker certification.

In the Hispanic culture, a promotora is a trusted person who is sought for advice and disseminates health information by interpersonal networks. Our three research promotoras were Spanish/English-fluent women experienced in providing health education to the local population. Prior to enrollment of the first subject, the investigators and research coordinator provided these women with 320 hours (40 days) of training on research procedures, child development, breastfeeding support, nutrition, parenting, safety, and sleep hygiene. Curricular materials were based on the American Academy of Pediatrics, Bright Futures,^{TM,10} parent education materials obtained from WIC, UTMB general pediatrics developmental questionnaire¹¹ and “How to Feed Your Baby Step by Step”, birth to age 12 months (available upon request). In addition, promotoras attended two five-day lactation support courses provided by the Texas Department of State Health Services, one per month training sessions at the WIC office, 20 hours per year of promotora continuing education credits, and a minimum of two hours per month of individualized training by the investigators on topics identified by the promotoras at the home visits. Investigators performed random fidelity audits and documented adherence to the protocol.

Inclusion/exclusion criteria

Subjects were healthy Latina women in the third trimester, ages 18–40 years, with a pre-pregnancy BMI ≥ 25 , who could receive visitors at home, had a telephone, and did not intend to move away. Excluded were mothers with a high-risk pregnancy, postpartum complications and/or hospitalization and/or separation from the infant. Enrolled mothers meeting exclusion criteria after randomization remained in the study per CONSORT¹² guidelines, but their infants were not followed for study outcomes. Infants born prematurely or with a medical condition that could affect growth were excluded.

Subject recruitment and follow-up by the research assistant

The Spanish/English-language fluent research assistant (RA) visited the homes of women who had expressed an interest at WIC and who had agreed to be randomized. The RA obtained written informed consent and recorded the mothers' pre-pregnancy weights, heights and baseline questionnaire data. Co-investigator MM prepared sealed randomized allocation envelopes using a computerized random number generator. Upon recruitment, MM opened envelopes and assigned mothers in sequence to intervention versus control. The RA enrolled infants at the first postpartum home visit, at age one week, at which time mothers provided birth measurements. The RA was initially blinded to randomization status, but un-blinding occurred for some subjects during the study. The number and identity of these subjects was not assessed. The investigators were not blinded to group assignment. Mothers were paid \$20 for each home visit.

Intervention group

Promotoras made prenatal and postpartum home visits once before delivery and at ages one and two weeks, and two, four, six, nine, and 12 months. During visits, the promotoras discussed infants' growth, health, development, sleep and play/exercise activities. Promotoras documented and plotted nude weight and length (Doran scale, model DS4100, or calculated as the mean of three weights of mother plus nude infant minus mother),

weight-for-length percentile,¹³ breast/formula and solid feedings (number and quantity) and social/developmental issues. Promotoras counseled on feeding at each visit regardless of the infant's growth. Mothers were encouraged to breastfeed and/or to avoid giving excess formula or adding sugar or solids to the bottle. A lactation consultant visited mothers who reported problems with breastfeeding. At each visit mothers in the intervention group received a small gift such as a children's book. Promotoras documented each visit on a SOAP note (Subjective, Objective, Assessment, and Plan). An investigator (DM) abstracted to a spreadsheet and later summarized social/descriptive information from all SOAP notes.

Control group

Mothers randomized to the control group had only measurement visits from the RA.

Subject Safety

Upon learning about health concerns, promotoras discussed these with the investigators and provided parents with guidance as appropriate. Mothers were referred for medical care whenever infants experienced unresolved, emergent, or urgent health issues. Infants received routine preventive health care from their local providers, but no data were obtained regarding these visits.

Data collection for all subjects

At the one-week postpartum home visit, and at infant ages one, six and 12 months, the RA documented the mothers' postpartum heights and weights (Seca scales model 869-1321004 and 19-17-05-224), the infants' supine lengths and weights, breastfeeding frequency, duration and intensity, quantity of formula consumed, pacifier use by the infant, and socio-demographic data. The RA also called the parent monthly until age 12 months to document breastfeeding status using the World Health Organization definitions¹⁴: 1=exclusive, 2=almost exclusive, 3=high partial, 4=medium partial, 5=low partial, 6=token, and 7=no breastfeeding.

Questionnaires

Items were used from the Edinburgh Postnatal Depression Scale,¹⁵ Infant Feeding Observation,¹⁶ Brief Acculturation Rating Scale for Mexican Americans,¹⁷ USDA 16-item Food Security Questionnaire,¹⁸ and Everyday Stressors Index.¹⁹

Child weight-for-height z-scores and weight-for-length categories

The statistician calculated infant weight for length z-scores using a SAS[®] macro from the U.S. Centers for Disease Control and Prevention (CDC) that draws on reference values from the World Health Organization growth data for healthy infants.¹³ The analysis used z-scores from the RA's 12-month home visits to classify infants into four weight-for-length categories: underweight ($z < -1.28$, $< 10^{\text{th}}$ percentile); normal weight ($-1.28 \leq z < 1.04$, 10^{th} to $< 85^{\text{th}}$ percentile); overweight ($1.04 \leq z < 1.64$, 85^{th} to $< 95^{\text{th}}$ percentile); and obese ($z \geq 1.64$, $\geq 95^{\text{th}}$ percentile). From these categories, the statistician created a dichotomous (normal or underweight = 0; overweight or obese = 1) indicator and a trichotomous

(underweight or normal weight = 0; overweight = 1; obese = 2) indicator of weight-for-length status.

Sample size

The sample size was based on power analyses of intervention effects on child growth using growth and home environmental data from a study previously conducted by the principal investigator.²⁰ Using the mean weights (expected $M = 1$, intervention group $M = 1.6$, $SD = 0.73$ versus control group $M = 1.19$, $SD = 0.66$, Cohen's $d = 0.59$) in the experimental and control groups (in the prior study) with power = 0.80 and alpha = 0.05 a minimum sample size of 36 subjects per group would be required to find similar differences in growth using a one-way ANOVA model. Fifty-six subjects per group would achieve 0.80 power at alpha = 0.05 to detect a medium effect ($d = 0.59$) in multiple regression models with three predictors (e.g., dietary intake, hours of sleep, and physical activity level) adjusted for 5 control variables ($R^2 = 0.20$). Recruitment of 70 women per group would account for 20% attrition. To account for subject attrition prior to delivery, the IRB approved enrollment of 175 mother-infant dyads ($n = 350$ total participants).

Data management and analysis

Breastfeeding was defined as including WHO categories one through five, but not six and seven. Regarding the relation between breastfeeding and weight-for-length outcomes, infants were coded as breastfeeding or not, at age two months, a categorical variable. Study data were managed using the REDCap (Research Electronic Data Capture) data entry and management platform hosted at Arizona State University.²¹ Data were downloaded from REDCap and analyzed using SAS[®] software. Data were examined for potential data transcription errors (e.g., checked for out-of-range values) and outliers (e.g., biologically implausible values, multivariate outliers/influential data points). Observations identified as being potentially problematic were then compared against values recorded on data collection forms and, as warranted, corrected in the dataset prior to analysis. Data analysis included all of the dyads (intervention and control) who attained the age of 12 months. To avoid bias, the analysis used only the measurements obtained by the RA. Bivariate analyses (chi-square, Fisher's exact, and t-tests) compared intervention and control, and breastfeeding versus formula feeding groups, on outcomes and potentially relevant covariates. Infant weight-for-length z-scores across all measurement ages were compared using the Pearson correlation coefficient. Multivariable logistic regression analyses were then used to assess unique associations between covariates and growth outcomes at age 12 months. A two-tailed $P < 0.05$ was considered to be statistically significant.

Results

Subjects enrolled, continuing, dropped, and/or lost to follow-up (Figure 1)

Of 807 pregnant women in the third trimester screened at WIC, 174 expressed interest in the study, qualified, signed consent, and were randomized. A total of 119 infants completed follow-up at age 12 months. The first mother was enrolled in March 2013. The first infant was born on 5/8/2013; the last mother delivered on 10/10/2014. Follow-up data collection

from birth to age three years was completed in October 2017; however, this paper reports only data obtained prior to and including the 12-month home visit (October 2015).

Descriptive statistics, primary outcome, and exploratory results by intervention group (Table 1)

All mothers were Latina and all but two were of Mexican ethnicity; 78% of mothers spoke Spanish at home "almost always". The cesarean section rate, 38% overall, was 20% higher in the intervention group than in the control group ($P=0.02$). Otherwise, randomization resulted in matching on all key variables. Two mothers smoked cigarettes. In the control and intervention groups, respectively, nine and 12 subjects either declined further participation or were lost to follow up after the infant's birth: regarding declined or lost, there were no differences between control and intervention when compared on Texas Temporary Assistance for Needy Families coverage, gender, delivery (cesarean section versus vaginal), language spoken at home, number of children in the family, mother's education, marital status, father living in the home at time of prenatal visit, father's or mother's employment status, mother's birth nation, use of a food bank, income, and financial stress. Regarding subjects who declined or were lost to follow up, subjects randomized to control were less likely to have received food stamps (1/9, 11%), as compared with intervention subjects (9/12, 75%, $P<0.008$). There were no differences between intervention and control infants on number of months breastfed, age at introduction of solids, weight-for-length z-scores or overweight/obese status at age 12 months.

A total of 63 infants were breastfed ≥ 2 months, and 56 were never breastfed or were breastfed initially but were consuming only formula at age two months (Table 2). Breastfeeding one week postpartum was more common in mothers born in Mexico (62/70, 89%) than mothers born in the U.S. (34/49, 69%, $P=0.01$), as was breastfeeding ≥ 2 months (43/63, 68% versus 25/56, 45% $P=0.02$, Mexican versus U.S. nativity, respectively). Infant birth weights and weight-for-length z-scores at the one-week visit were not different between the breastfed and formula-fed infants. Initial feeding status at the one-week visit verified mothers' early postpartum choices: the mean volumes of formula recorded at the one-week visit were 7 (range 0–9) and 19 (range 10–28) ounces for the breastfed ≥ 2 months versus formula-fed groups, respectively ($P<0.001$). Thirty-seven percent of breastfeeding mothers were giving their infants a bottle at age one week. Breastfeeding mothers used pacifiers somewhat less commonly. The mean duration of breastfeeding (WHO categories 1–5) was 7.95 months versus 0.24 months in breast versus formula groups, respectively. At age one week, 45/199=38% of mothers were exclusively breastfeeding. Regarding breastfeeding status at age two months, 38 were classified exclusive, six almost exclusive, nine high partial, six medium partial, and four low partial. Beyond age two months, the percentage of women exclusively breastfeeding was 30%, 22%, 15%, and 12% at three, six, nine and 12 months, respectively.

Overweight/obese status was more common in formula-fed infants at age six months (29/56=52% formula fed, 25/62=40% breastfed, $P<0.06$) and 12 months (29/56=52% formula-fed infants and 17/63=27% breastfed, $P=0.005$). At age 12 months, 17/118 infants (14.4%) were ≥ 2 standard deviations above normal weight-for-length ($z \geq 2$). Weight-for-

length z-scores at age one week and one month did not correlate with scores at 12 months ($r=0.05$, $P=0.58$; $r=0.05$, $P=0.62$ respectively), but weight-for-length z scores at age six months correlated with z-scores at age 12 months ($r=0.60$, $P<0.0001$).

Linear regression models predicting weight-for-length z-scores at age 12 months

A bivariate regression model (Model 1) was estimated examining the association between breastfeeding ≥ 2 months and weight-for-length z-score at 12 months. In this model, the association was negative and significant ($b = -0.459$, $SE = 0.211$, $P = 0.03$, $r^2 = .04$), indicating that, in terms of weight-for-length z-scores at 12 months, infants of mothers who breastfed ≥ 2 months were, on average, nearly one-half of a standard deviation below infants whose mothers formula fed or breastfed < 2 months. Next, the association between breastfeeding status and weight-for-length z-score at 12 months was estimated in a multiple regression model, adjusting for birth weight, gender, intervention group, father's unemployment status, mother's BMI and smoking status at 1 week postpartum, mother's nation of birth, annual household income, and age at which solid foods were introduced (Model 2). In Model 2, the negative association between breastfeeding status and weight-for-length percentile at 12 months was also statistically significant ($b = -0.497$, $SE = 0.229$, $P = 0.03$, partial $r^2 = .04$). In the multiple regression model, neither intervention group nor background covariates were related to weight-for-length percentile at 12 months.

Logistic regression models predicting overweight/obese status at age 12 months

Binomial logistic regression models paralleling linear regression Models 1 and 2 above were estimated for the prediction of overweight/obese status (vs. underweight or normal weight) at 12 months. In the bivariate logistic regression model (Model 3) breastfeeding ≥ 2 months was significantly related to overweight/obese status ($OR = 0.370$, 95% $CI = 0.169-0.786$, $P = 0.01$), indicating the odds of being overweight or obese at age 12 months were 2.7 times greater for infants who formula fed or breastfed < 2 months than those who breastfed ≥ 2 months. In the logistic regression model adjusting for covariates (Model 4), this association was also significant ($OR = 0.338$, 95% $CI = 0.141-0.780$, $P = 0.01$). As in Model 2, none of the background covariates was significantly related to the outcome.

Exploratory multinomial logistic regression models predicting weight status at age 12 months

A pair of exploratory multinomial logistic (generalized logit) regression models was also estimated. The first model (Model 5) examined the unadjusted association between the trichotomous weight status measure (underweight or normal weight, overweight, obese) and breastfeeding ≥ 2 months, with underweight/normal weight serving as the reference category. In this model, breastfeeding was significantly related to a lower likelihood of the infant being overweight (vs. normal or underweight, $OR = 0.304$, 95% $CI = 0.104-0.832$, $P = 0.02$) but not related to the likelihood of the child being obese (vs. normal or underweight, $OR = 0.435$, 95% $CI = 0.166-1.101$, $P = 0.08$). Likewise, in the multinomial model adjusting for covariates (Model 6), the association between breastfeeding and decreased likelihood of overweight (vs. normal or underweight) was also significant ($OR = 0.220$, 95% $CI = 0.065-0.673$, $P = 0.01$), and the association between breastfeeding and obesity (vs. normal or underweight) was not ($OR = 0.484$, 95% $CI = 0.164-1.396$, $P = 0.18$). As in the

linear model and binomial logistic models, none of the background covariates was significantly related to the outcome.

Stress factors and food insecurity by breastfeeding status at infant age 2 months

(Table 3) Parents described numerous stressors such as lack of family support, divorce and/or separation, lack of financial support from the father, spousal abuse, father's unemployment, inability to speak English, illiteracy in English and/or Spanish, household crowding, inability to take time off from work or school to care for the baby, lack of transportation, lack of medical/psychological care for self and/or family members, anxiety and depression. Mothers who were living with the infant's father at the prenatal visit were more likely to be breastfeeding at the two month visit (56/63, 89%, versus 37/56, 66%, $P<0.003$). Fathers of formula-fed infants were more likely to have experienced unemployment than those of infants in the breastfeeding group ($P<0.01$). Conversely, mothers who reported being employed at the six-month visit were more likely to have formula-fed their infants from birth or to have stopped breastfeeding before their infant attained the age of two months ($P<0.02$). Thirty-seven percent of families reported financial stress, 97% reported running out of money to buy food; nine percent used a food bank; 49% received Supplemental Nutrition Assistance Program support (food stamps). Five percent used water to extend the supply of food, 3% skipped meals or cut the size of the child's meals due to lack of money and reported child hunger. Seventy-three percent of parents planned and served meals, but only 49% reported meals being eaten on a regular schedule.

Secondary analysis, mothers' weight gain during pregnancy

Maternal weight gain during pregnancy correlated with infant birth weight ($r=0.24$, $P=0.01$) and weight-for-length z-score status at the one week RA visit ($r=0.18$, $P=<0.05$, Pearson) but not weight-for-length z-scores at infant age one, six or 12 months. Weight gain during pregnancy was grouped according to the 2009 Institute of Medicine guidelines for obese women, < 20 lb (9.1 kg) vs. ≥ 20 lb. Overweight/obese status of infants measured at age 12 months was less for infants of mothers who gained within the guidelines, but the comparisons did not reach statistical significance (8/46, 17%, vs. 22/71, 30%, respectively, $P=0.13$).

Adverse events

One child was hospitalized for treatment of bronchiolitis and one to rule out neonatal sepsis. Both recovered without complications. One child was found to be congenitally deaf. No other serious adverse events were encountered.

Discussion

This is the first study utilizing home visits by promotoras to prevent infant overweight in a high-risk Mexican-American population. Although the intervention measured at the one-year follow-up was not successful, the exploratory analysis highlighted the association of breastfeeding with healthy infant growth, even in this high-risk population. The preponderance of research supports the conclusion that breastfeeding is closely linked to healthy infant growth, while formula feeding is associated with infant overweight and

obesity,^{7, 22–26} but not all studies agree. Bell, et al, 2017,²⁷ described increased weight gain in formula-fed babies to age seven months, compared with breastfed babies, but the excess weight was found to be lean body mass, not fat mass. In retrospective studies, it may be difficult to assess the intensity and duration of breastfeeding and the possible negating effects of excessive calories consumed when the infant graduates to the family diet.²⁸

Our study focused on WIC, which provides breastfeeding and nutrition support for 53% of all infants in the U.S. WIC participation has been shown to reduce the incidence of low birth weight, improve the intake of critical nutrients, prevent iron deficiency, improve immunization rates, and improve the likelihood that children have a regular source of medical care. In addition, WIC food supplement represents a \$165 monthly benefit, in 2016 dollars. This amounts to 22% (\$165/739) of total monthly food expenditures for a WIC-enrolled family.²⁹

Twenty-four of 119 infants (20% overall, 25% in the formula fed group) were obese (≥ 95th percentile) at age 12 months, which is higher than described in the literature. Freedman, et al,³⁰ in a study of WIC-enrolled children ages 3–23 months, reported extreme overweight (weight-for-length z ≥ 2) in 12.3%, a decrease from 14.5% in 2010; by comparison, 14.4% of our study infants at age 12 months were extremely overweight (weight-for-length z ≥ 2). The prevalence of obesity for children in WIC, age 2–4 years, was 15.9% in 2010³¹, but by 2014, obesity (age 2–4 years) had decreased to 14.5%.

Studies report lower breastfeeding rates in WIC participants than in WIC-eligible participants who were not enrolled in WIC or non-WIC eligible participants.^{32,33} Enrollment in WIC during the first two trimesters of pregnancy has been associated with reduced initiation and duration of breastfeeding.³⁴ However, breastfeeding rates among WIC participants have increased concurrent with the widespread implementation of WIC's lactation initiatives.^{35,36}

Hispanic women more acculturated to US lifestyle breastfeed at lower rates than less acculturated Hispanic women.³⁷ Studies document that WIC-enrolled mothers lack confidence in exclusive breastfeeding. Of WIC-enrolled mothers who stopped breastfeeding within the first two weeks, 46% thought they did not have enough milk, and 40% said that breast milk alone did not satisfy the baby.³⁸ In our study, 37% of breastfeeding mothers, and 64% of mothers overall, were providing supplemental formula to their infants at the one-week visit. Mothers' employment status also affects breastfeeding decisions. Mothers employed six months postpartum were less likely to have been breastfeeding two months postpartum ($P=0.02$). Compared with mothers who were not breastfeeding, those who breastfed for two months were more likely to have been living with fathers at the time of the prenatal visit to WIC; this attests to the importance of paternal support, both emotional and financial. This paternal support seemed to translate into healthy weight outcomes for the infant at age one year, an outcome mediated by breastfeeding.

A limitation of the intervention was that all mothers in our study had access to WIC's breastfeeding peer counselor program. Our subjects' breastfeeding rates were somewhat better than reported in the most recent WIC survey and were comparable to rates reported

nationally, even given that our subjects were obese and experienced a high cesarean section rate.^{38,39} In our population, a pregnant woman enrolling in WIC would have received two classes on breastfeeding and one one-on-one session with the breastfeeding peer counselor. Another visit with the counselor would have occurred at 7 days postpartum, and every three months thereafter. Another limitation was our dependence on parent report of birth measurements and weight gain during pregnancy. Further, our sample size, limited by the expected differences between intervention and control, was not large enough to confirm findings from previous large retrospective studies that have associated infant overweight with gender, maternal smoking, maternal education, birth weight, weight gain during pregnancy, and age at introduction of solid foods.^{40–43} Results are not generalizable to the WIC population as a whole, because we studied only obese, Latina women.

Conclusions

While our study does not provide a cause-and-effect link between formula feeding and infant overweight, breastfeeding 2 months was a strong predictor of healthy infant growth in this high-risk group. Infants overweight at age six months were highly likely to be overweight at age 12 months. The study supports the need for early intervention and continued efforts by WIC personnel and clinicians to vigorously promote breastfeeding.

Acknowledgments

Funded by the National Institutes of Health. 5R01DK096488, 2012, PI Elizabeth Reifsnider, Co-PI David P. McCormick. The study sponsor had no role in the study design, collection, analysis and interpretation of data, the writing of the report, and the decision to submit the article for publication. The authors wish to thank promotora Irma Pecina for her valuable assistance in patient education and research assistant Maribell Guzman for her assistance in data collection. Kim Danielson helped prepare the manuscript; Lu Zheng assisted with data management.

References

1. McCormick DP, Sarpong K, Jordan L, et al. Infant obesity: are we ready to make this diagnosis? *J Pediatr*. 2010; 157:15–19. [PubMed: 20338575]
2. Dattilo AM, Birch L, Krebs NF, et al. Need for early interventions in the prevention of pediatric overweight: a review and upcoming directions. *J Obes*. 2012; 2012:123023. [PubMed: 22675610]
3. Lumeng JC, Taveras EM, Birch L, Yanovski SZ. Prevention of obesity in infancy and early childhood: a National Institutes of Health Workshop. *JAMA Pediatr*. 2015; 169:484–490. [PubMed: 25775180]
4. Salvy SJ, de la Haye K, Galama T, Goran MI. Home visitation programs: an untapped opportunity for the delivery of early childhood obesity prevention. *Obes Rev*. 2017; 18:149–163. [PubMed: 27911984]
5. Redsell SA, Edmonds B, Swift JA, et al. Systematic review of randomised controlled trials of interventions that aim to reduce the risk, either directly or indirectly, of overweight and obesity in infancy and early childhood. *Matern Child Nutr*. 2015; 12:24–38. [PubMed: 25894857]
6. Yavuz HM, van Ijzendoorn MH, Mesman J, van der Veek S. Interventions aimed at reducing obesity in early childhood: a meta-analysis of programs that involve parents. *J Child Psychol Psychiatry*. 2015; 56:677–692. [PubMed: 25292319]
7. Wen LM, Baur LA, Simpson JM, et al. Sustainability of effects of an early childhood obesity prevention trial over time: A Further 3-Year Follow-up of the Healthy Beginnings Trial. *JAMA Pediatr*. 2015; 169:543–551. [PubMed: 25893283]

8. Ochoa A, Berge JM. Home environmental influences on childhood obesity in the Latino population: A decade review of literature. *J Immigr Minor Health*. 2016; 19:430–447.
9. Reifsnider E, McCormick DP, Cullen KW, et al. A randomized controlled trial to prevent childhood obesity through early childhood feeding and parenting guidance: rationale and design of study. *BMC Public Health*. 2013; 13:880. [PubMed: 24063435]
10. American Academy of Pediatrics. [Accessed August 30, 2017] Bright Futures™. <https://brightfutures.aap.org/Pages/default.aspx>
11. UTMB Pediatrics Developmental Milestones Questionnaire. [Accessed August 30, 2017] https://www.utmb.edu/pedi_ed/Clerkship/pdf-files/well_child_worksheet_Milestones_Overview.pdf
12. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *Lancet*. 2001; 357:1191–1194. [PubMed: 11323066]
13. [Accessed May 17, 2016] US Centers for Disease Control and Prevention growth charts. (<http://www.cdc.gov/nccdphp/dnpao/growthcharts/resources/sas.htm>)
14. Labbok M, Krasovec K. Toward consistency in breastfeeding definitions. *Stud Fam Plann*. 1990; 21:226–230. [PubMed: 2219227]
15. Cox JL, Holden JM, Sagovsky R. Detection of Postnatal Depression. Development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry*. 1987; 150:782–786. [PubMed: 3651732]
16. Barnard, KE., Hammond, MA., Booth, CL., et al. Measurement and meaning of parent-child interaction. In: Morrison, F.Lord, C., Keating, D., editors. *Applied Developmental Psychology*. Vol. III. New York: Academic Press; 1989.
17. Bauman S. Reliability and validity of the Brief Acculturation Rating Scale for Mexican-Americans II for children and adolescents. *Hisp J Behav Sci*. 2005; 27:426–441.
18. [Accessed May 17, 2016] USDA 16-item Food Security Questionnaire. (<http://www.fns.usda.gov/guide-measuring-household-food-security-revised-2000>)
19. Gomez ML, Ashford K, Linares AM, Hall LA. A pilot test of the Everyday Stressors Index-Spanish Version in a sample of Hispanic women attending prenatal care. *J Nurs Meas*. 2015; 23:519–531. [PubMed: 26673774]
20. Reifsnider E, Shin CN, Todd M, et al. How did they grow: An intervention to reduce stunted growth in low-income Mexican-American children. *Res Nurs Health*. 2016; 39:105–120. [PubMed: 26915468]
21. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap) -- a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009; 42:377–381. [PubMed: 18929686]
22. Yan J, Liu L, Zhu Y, et al. The association between breastfeeding and childhood obesity: a meta-analysis. *BMC Public Health*. 2014; 14:1267. [PubMed: 25495402]
23. Kalies H, Heinrich J, Borte N, et al. The effect of breastfeeding on weight gain in infants: results of a birth cohort study. *Eur J Med Res*. 2005; 10:36–42. [PubMed: 15737952]
24. Jwa SC, Fujiwara T, Kondo N. Latent protective effects of breastfeeding on late childhood overweight and obesity: a nationwide prospective study. *Obesity (Silver Spring)*. 2014; 22:1527–1537. [PubMed: 24591416]
25. Wang CY, Gortmaker SL, Taveras EM. Trends and racial/ethnic disparities in severe obesity among US children and adolescents, 1976–2006. *Int J Pediatr Obes*. 2011; 6:12–20.
26. Whaley SE, Koleyat M, Leonard S, Whaley M. Breastfeeding is associated with reduced obesity in Hispanic 2- to 5-year-olds served by WIC. *J Nutr Educ Behav*. 2017; 49(7S2):S144–S150. e1. [PubMed: 28689551]
27. Bell KA, Wagner CL, Feldman HA, et al. Associations of infant feeding with trajectories of body composition and growth. *Am J Clin Nutr*. 2017; 106:491–498. [PubMed: 28659299]
28. Lefebvre CM, John RM. The effect of breastfeeding on childhood overweight and obesity: a systematic review of the literature. *J Am Assoc Nurse Pract*. 2014; 26:386–401. [PubMed: 24170411]
29. Fiscal Year 2010 WIC Food Cost Report. USDA Report Number: WIC-13-FCOST. Aug. 2013 <http://fns.usda.gov/research-and-analysis>. Monthly 2010 infant formula cost pre-rebate = \$114, or

\$125 in 2016 dollars. Monthly first six month post partum woman cost pre-rebate = \$36, or \$ 39 in 2016

30. Freedman DS, Sharma AJ, Hamner HC, et al. Trends in weight-for-length among infants in WIC from 2000 to 2014. *Pediatrics*. 2017;139. Pii: e20162034. Epub 2016 Dec 13.
31. Pan L, Freedman DS, Sharma AJ, et al. Trends in Obesity Among Participants Aged 2–4 Years in the Special Supplemental Nutrition Program for Women, Infants, and Children — United States, 2000–2014. *Morb Mort Wkly Rep*. 2016; 65:1256–1260.
32. Jacknowitz A, Novillo D, Tiehen L. Special Supplemental Nutrition Program for Women, Infants, and Children and infant feeding practices. *Pediatrics*. 2007 Feb.119:281–289. [PubMed: 17272617]
33. Ryan AS, Zhou W. Lower breastfeeding rates persist among the Special Supplemental Nutrition Program for Women, Infants, and Children participants, 1978–2003. *Pediatrics*. 2006; 117:1136–1146. [PubMed: 16585308]
34. Ziolo-Guest KM, Hernandez DC. First- and second-trimester WIC participation is associated with lower rates of breastfeeding and early introduction of cow's milk during infancy. *J Am Diet Assoc*. 2010; 110:702–709. [PubMed: 20430131]
35. Ahluwalia IB, Tessaro I, Grummer-Strawn LM, et al. Georgia's breastfeeding promotion program for low-income women. *Pediatrics*. 2000; 105:E85. [PubMed: 10835098]
36. Chiasson MA, Scheinmann R, Hartel D, et al. Predictors of obesity in a cohort of children enrolled in WIC as infants and retained to 3 years of age. *J Community Health*. 2016; 41:127–133. [PubMed: 26280211]
37. Rassin DK, Markides KS, Baranowski CJ, et al. Acculturation and the initiation of breastfeeding. *J Clin Epidemiol*. 1994 Jul.47:739–46. [PubMed: 7722587]
38. May, L., Christine Borger, C., Weinfield, N., et al. [Accessed Feb 8, 2017] WIC Infant and Toddler Feeding Practices Study – 2: Infant Year Report. Jan. 2017 <https://www.fns.usda.gov/wic/wic-infant-and-toddler-feeding-practices-study-2-infant-year-report>
39. [Accessed Aug 9, 2017] Breastfeeding among U.S. Children Born 2002–2014. CDC National Immunization Survey. https://www.cdc.gov/breastfeeding/data/nis_data/index.htm
40. Wallby T, Lagerberg D, Magnusson M. Relationship between breastfeeding and early childhood obesity; Results of a prospective longitudinal study from birth to 4 years. *Breastfeed Med*. 2017; 12:48–53. [PubMed: 27991826]
41. Mitchell EA, Steward AW, Braithwaite I, et al. Birth weight and subsequent body mass index in children: an international cross-sectional study. *Pediatr Obes*. 2016; 12:280–285. [PubMed: 27170099]
42. Oken E, Taveras EM, Kleinman KP, et al. Gestational weight gain and child adiposity at age 3 years. *Am J Obstet Gynecol*. 2007; 196:322e1–322.e8. [PubMed: 17403405]
43. Huh SY, Rifas-Shiman SL, Taveras EM, et al. Timing of solid food introduction and risk of obesity in preschool-aged children. *Pediatrics*. 2011; 127:e544–e551. [PubMed: 21300681]

What's new

In a high-stress, food insecure, low-income immigrant population, infant overweight, once established by age six months, tracked strongly to age 12 months. Breastfeeding two months predicted healthy infant growth. The study supports efforts by WIC to vigorously support breastfeeding.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Figure 1.
CONSORT Flow Diagram

Table 1

Descriptive statistics and *P*-values for comparisons of participant baseline characteristics by randomization status. Results for the primary outcome, infant weight-for-length z-scores, and secondary outcome, breastfeeding status (*n* = 119).

Participant	Control <i>n</i> (%) or <i>M</i> ± <i>SD</i>	Intervention <i>N</i> (%) or <i>M</i> ± <i>SD</i>	<i>P</i>
Mother speaks Spanish at home			.51
Not at all to very often	11 (19.0)	15 (24.6)	
Almost always	47 (81.0)	46 (75.4)	
Mother's nation of birth			1.0
Mexico	33 (56.9)	35 (57.4)	
United States	23 (39.7)	26 (42.6)	
Other	2 (3.5)	0	
Grandmother's nation of birth			.40
Mexico	46 (79.3)	55 (90.2)	
United States	9 (15.5)	6 (9.8)	
Other	3 (5.2)	0	
Mother's marital status			.16
Not currently married	45 (77.6)	40 (65.6)	
Married	13 (22.4)	21 (34.4)	
Father living with infant's mother at prenatal visit			0.56
No	14 (54.0)	12 (46.0)	
Yes	44 (47.0)	49 (53.0)	
Annual household income			.09
\$0–\$10,000	7 (12.1)	12 (19.7)	
\$10,001–\$20,000	4 (6.9)	8 (13.1)	
\$20,001–\$30,000	32 (55.2)	30 (49.2)	
\$30,000–\$40,000	15 (25.9)	9 (49.2)	
\$40,000–\$50,000	0	2 (3.3)	
Mother's highest education level			.85
Middle school	20 (34.5)	16 (26.2)	
Some high school	8 (13.8)	15 (24.6)	
At least some college	9 (15.5)	5 (8.2)	
Other	2 (3.5)	2 (3.3)	
Children in family (target child included)	2.7 ± 1.7	2.6 ± 1.2	.52
Range	1–7	1–6	
Weight gain during pregnancy (kg)	10.6 ± 4.5	12.5 ± 5.5	.20
Range	0 – 23.6	4.1 – 25.5	
Mother's post-partum BMI	33.1 ± 5.1	33.9 ± 5.3	.48
Range	24.6 – 44.4	24.0 – 46.2	
Mother's post-partum BMI category			1.0
Normal (10 BMI < 25)	2 (3.5)	1 (1.6)	

Participant	Control <i>n</i> (%) or <i>M</i> ± <i>SD</i>	Intervention <i>N</i> (%) or <i>M</i> ± <i>SD</i>	P
Overweight (25 ≤ BMI < 30)	13 (22.4)	13 (21.3)	1.0
Obese (BMI ≥ 30)	43 (74.1)	47 (77.1)	
Gender			
Female	24 (41.4)	26 (42.6)	.02
Male	34 (58.6)	35 (57.4)	
Gestational age (weeks)	39.2 ± 1.3	39.5 ± 1.1	
Delivery			.35
Vaginal birth	42 (72.4)	32 (52.5)	
Cesarean section	16 (27.6)	29 (47.5)	
Complications during pregnancy			.30
Gestational diabetes	7 (13.7)	5 (10.4)	
Preeclampsia	1 (2.0)	2 (4.2)	
Anemia	0	1 (2.1)	
Other	2 (3.9)	5 (10.4)	
None	41 (80.4)	35 (72.9)	.56
Birth weight (g)	3,453 ± 393	3,562 ± 467	
Range	2,500 – 4,232	2,672 – 4,800	
Weight-for-gestational age			.84
Large for gestational age	5 (8.6)	8 (13.1)	
Average for gestational age	51 (87.9)	50 (81.9)	
Small for gestational age	2 (3.5)	3 (4.9)	.84
Bottle use at age 1 week			
No	20 (34.5)	23 (37.7)	
Yes	38 (65.5)	38 (62.3)	.43
Pacifier use at age 1 week			
No	17 (29.3)	19 (31.2)	
Yes	41 (70.7)	42 (68.9)	.49
Mother employed at one week post-partum visit			
No	48 (82.7)	54 (88.5)	
Yes	10 (17.2)	7 (11.5)	.71
Beastfeeding at age one week			
No	45 (47.0)	51 (53.0)	
Yes	13 (57.0)	10 (43.0)	.91
Breastfeeding at age two months			
No	28 (51.0)	27 (49.0)	
Yes	30 (47.0)	34 (53.0)	.22
Months breastfed	4.43 ± 4.83	4.41 ± 4.71	
Age at introduction of solids (month)	4.79 ± 1.37	4.98 ± 1.21	
Weight-for-length z-score			.31
One week visit	−0.05 ± 1.02	0.16 ± 1.06	
12 month visit	0.84 ± 1.20	0.72 ± 1.13	.66

Participant	Control	Intervention	P
	<i>n (%) or M ± SD</i>	<i>N (%) or M ± SD</i>	
Weight classification at 12-mo assessment			.45
Underweight (< 10 th percentile)	1 (1.7)	2 (3.3)	
Normal weight (10 th - < 85 th percentile)	36 (63.2)	33 (54.0)	
Overweight (85 th - < 95 th percentile)	8 (14.0)	14 (23.0)	
Obese (95 th percentile and above)	12 (21)	12 (19.7)	

Table 2

Secondary analysis: descriptive statistics and *P*-values for infant outcomes at six and 12 months by breastfeeding status at infant age two months (*n* = 119).

Participant characteristic	Breastfed < 2 months <i>n</i> (%) or <i>M</i> ± <i>SD</i>	Breastfed 2 months <i>n</i> (%) or <i>M</i> ± <i>SD</i>	<i>P</i>
Mother born in Mexico			.02
Yes	25 (44.6)	43 (68.3)	
No	31 (55.4)	20 (31.7)	
Mother's weight gain during pregnancy (kg)	12.06 ± 5.38	11.20 ± 4.09	.40
Mother's post-partum BMI	34.43 ± 5.45	32.77 ± 4.79	.08
Infant weight-for-length z-score			
One week visit	−0.05 ± 0.82	0.15 ± 1.20	.38
Six month visit	0.88 ± 0.82	0.57 ± 1.27	.12
12 month visit	1.02 ± 1.12	0.56 ± 1.17	.03
Birth weight (gm)	3491 ± 450	3524 ± 422	.60
Range	2300–4800	1680–4459	
Bottle use at age 1 week			<.001
No	8 (18.6)	35 (81.4)	
Yes	48 (63.2)	28 (36.8)	
Pacifier use at age 1 week			.12
No	13 (36.1)	23 (63.9)	
Yes	43 (51.8)	40 (48.2)	
Infant weight status at age 12 months			.005
Underweight (< 10 th percentile)	0 (0)	3 (4.8)	
Normal weight (10 th – < 85 th percentile)	26 (47.3)	43 (68.3)	
Overweight (85 th – < 95 th percentile)	15 (27.2)	7 (11.1)	
Obese (95 th percentile and above)	14 (25.5)	10 (15.9)	

Table 3

Frequencies and P-values for comparison of factors contributing to stress, anxiety, and food insecurity in the household, by breastfeeding status at two months postpartum (n=119)

Variable	Breastfed< 2 months n (%)	Breastfed 2 months n (%)	P
Father living with infant's mother at prenatal visit			0.004
No	19 (73.0)	7 (7.0)	
Yes	37 (40.0)	56 (60.0)	
Father unemployed during past six months			<.01
No	17 (70.8)	7 (29.2)	
Yes	39 (41.0)	56 (59.0)	
Mother employed at one-week home visit			.18
No	45 (44.0)	57 (56.0)	
Yes	11 (65.0)	6 (35.0)	
Mother employed at six-month home visit			.02
Full time	13 (68.0)	6 (32.0)	
Part-time	6 (67.0)	3 (33.0)	
Not employed	36 (40.0)	54 (60.0)	
Family experienced financial stress			.91
No	35 (46.7)	40 (53.3)	
Yes	21 (47.7)	23 (52.3)	
Family moved			.64
No	35 (45.4)	42 (54.6)	
Yes	21 (50.0)	21 (50.0)	
Family member experienced injury/illness			1.0
No	51 (46.8)	58 (53.2)	
Yes	5 (50.0)	5 (50.0)	
Family member experienced drug/alcohol problem			
No	56 (47.1)	63 (52.0)	
Yes	0 (0.0)	0 (0.0)	
Family member felt depressed			.73
No	51 (46.4)	59 (53.6)	
Yes	5 (55.6)	4 (44.4)	
Family had arguments			.34
No	53 (46.1)	62 (53.9)	
Yes	3 (75.0)	1 (25.0)	
Family member experienced violence			1.0
No	56 (47.1)	63 (52.9)	
Yes	0 (0.0)	0 (0.0)	
Family member had trouble with the law			1.0
No	56 (47.1)	63 (52.9)	
Yes	0 (0.0)	0 (0.0)	

Variable	Breastfed< 2 months	Breastfed 2 months	P
Family runs out of money for food			.34
Weekly, Biweekly, or Monthly	52 (94.5)	61 (98.4)	
Occasionally or Never	3 (5.4)	1 (1.6)	
Uses food banks			.60
No	50 (46.3)	58 (53.7)	
Yes	6 (54.6)	5 (45.4)	
Receives SNAP (food stamps)			.91
No	29 (47.5)	32 (52.5)	
Yes	27 (46.6)	31 (53.4)	
Extends supply of food/formula with water, due to lack of money			.42
Never	52 (46.0)	61 (54.0)	
Ever (Occasionally-Weekly)	4 (66.7)	2 (33.3)	
Cuts size of child's meals, due to lack of money			.60
Never	54 (46.6)	62 (53.4)	
Ever (Occasionally-Weekly)	2 (66.7)	1 (33.3)	
Child is hungry			.60
Never	54 (46.6)	62 (53.4)	
Ever (Occasionally-Weekly)	2 (66.7)	1 (33.2)	
Mother skips meals, due to lack of money			.34
Never	53 (46.1)	62 (53.9)	
Ever (Occasionally-Weekly)	3 (75.0)	1 (25.0)	
How meals are planned			.77
Unplanned-Everyone gets his/her own meals	6 (60.0)	4 (40.0)	
Unplanned-Meals prepared when someone is hungry	11 (50.0)	11 (50.0)	
Planned-Food cooked but not served at a regular time	14 (48.3)	15 (51.7)	
Planned-Food cooked and served at a regular time	25 (43.1)	33 (56.9)	