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Preventing Obesity during Infancy: A Pilot Study

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Abstract

More than 20% of US children between ages 2 and 5 years are overweight suggesting efforts to prevent obesity must begin earlier. This study tested the independent and combined effects of two behavioral interventions delivered to parents, designed to promote healthy infant growth in the first year. Mother–newborn dyads intending to breastfeed were recruited from a maternity ward. With a 2 × 2 design, 160 dyads were randomized into one of four treatment cells to receive both, one, or no interventions delivered at two nurse home visits. The first intervention ("Soothe/Sleep") instructed parents on discriminating between hunger and other sources of infant distress. Soothing strategies were taught to minimize feeding for non-hunger-related fussiness and to prolong sleep duration, particularly at night. The second intervention ("Introduction of Solids") taught parents about hunger and satiety cues, the timing for the introduction of solid foods, and how to overcome infants' initial rejection of healthy foods through repeated exposure. A total of 110 mother–infant dyads completed the year-long study. At 1 year, infants who received both interventions had lower weight-for-length percentiles ($P = 0.009$). Participants receiving both interventions had a mean weight-for-length in the 33rd percentile; in contrast, those in other study groups were higher first intervention only—50th percentile; second intervention only—56th percentile; control group—50th percentile).This suggests that multicomponent behavioral interventions may have potential for long-term obesity prevention (ClinicalTrials.gov number, NCT00359242).

INTRODUCTION

The obesity epidemic has affected children from all age groups including infants and toddlers (1). Data from the National Health and Nutrition Examination Survey demonstrate that the prevalence of obesity among infants <2 years of age has increased by >60% over the past three decades (2). These numbers are particularly troublesome because overweight infants and toddlers are at increased risk of staying overweight as they grow older (3–18), and attempts to prevent and treat obesity with older children have had limited success (19). In contrast, infancy may be an opportune time to begin obesity prevention (20,21); it is a critical period of rapid growth and developmental plasticity with long-lasting metabolic and behavioral consequences (22,23).

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SUPPLEMENTARY MATERIAL

Supplementary material is linked to the online version of the paper at http://www.nature.com/oby

DISCLOSURE

The authors declared no conflict of interest.

Two attractive behavioral intervention targets are the main components of infant lifestyle, sleeping and feeding. The link between short sleep duration and childhood obesity and higher body fat has been repeatedly demonstrated (11,24–29). Recently, Taveras *et al.* found that sleep duration of <12 h during infancy (age 6–24 months) is a risk factor for overweight and adiposity in preschoolers, leading Gillman *et al.* to propose infant sleep duration as a modifiable risk factor for obesity (30,31).

Regarding feeding, during the first year after birth, infants make a dramatic dietary transition from the initial exclusive milk diet of early infancy to the consumption of many foods of the adult diet of their culture. These early dietary experiences have powerful and persistent effects on growth and on the development of food preferences and the controls of food intake (32–35). Unfortunately, recent data from the Feeding Infants and Toddlers Study (FITS) revealed that unhealthy habits may be starting early; energy intakes among infants and toddlers exceeded requirements by 20–30% (36). In addition to consuming too much energy, young children (4–24 months old) consumed significant amounts of developmentally inappropriate foods, high in energy density and low in nutrients, while consuming too few of the foods that should form the basis of a healthy weaning diet (37).

Targeting these two major components of infant lifestyle, we conducted the SLeeping and Intake Methods Taught to Infants and Mothers Early in life (SLIMTIME) pilot study, a randomized trial using a 2 × 2 design testing the independent and combined effects of two interventions designed to promote healthy growth in the first year after birth. The first intervention, “Soothe/Sleep,” was implemented at 2–3 weeks after birth and was designed to increase sleep duration in early infancy by teaching parents alternate soothing and calming strategies to reduce feeding as a first response to fussiness. The second intervention, “Introduction of Solids,” taught parents at 2–3 weeks about hunger and satiety cues as well as the appropriate timing for the introduction of solid foods. The final portion of the second intervention began between 4 and 6 months after birth when parents reported that their infant was starting to consume solid foods, and taught parents how to use repeated exposure to new foods to overcome infant rejection of healthy foods such as vegetables. We hypothesized that infants receiving both interventions would have a lower weight-for-length percentile at 1 year compared with infants in the other three groups as well as lower conditional weight gain during the first year. We also hypothesized that infants in the “Soothe/Sleep” condition would have longer sleep duration and reduced feeding frequency relative to controls. Infants in the “Introduction of Solids” intervention were expected to begin solid foods later than controls and increase consumption of pureed vegetables following repeated exposure.

METHODS AND PROCEDURES

Participants, recruitment, and randomization

Following receipt of informed consent, 160 mother–newborn dyads were recruited from the maternity floor of a single, academic medical center in Hershey, Pennsylvania. Inclusion criteria specified that infants be singleton with a gestational age of 34 weeks or more without morbidities that would affect sleeping or feeding. Mothers of these infants were required to be primiparous and English speaking with intent to breastfeed after hospital discharge and intent to follow-up with a University-affiliated primary care provider. Dyads were excluded if either the newborn or mother had an extended hospital stay of 7 days or more after childbirth. Also, mothers were excluded if they had a major pre-existing condition or morbidity that would affect postpartum care or study participation (e.g., cancer, multiple sclerosis, lupus). Data were collected regarding the pregnancy, delivery, maternity/nursery hospital stay, maternal mental and physical health, and infant health through review of the medical record and from maternal interview. This study was approved by the Human

Subjects Protection Office of the Penn State College of Medicine and was registered at http://www.clinicaltrials.gov before the first subject's enrollment.

Study design and interventions

Following enrollment, mother–newborn dyads were randomized into one of four cells using a 2 × 2 design to receive both, one, or no interventions delivered at two nurse home visits (Table 1). One group received both the "Soothe/Sleep" and "Introduction of Solids" intervention while another received no interventions. The other two study groups received only one intervention or the other. Randomization included stratification for maternal prepregnancy BMI with two groups, BMI <25 and BMI ≥25. Regardless of study group, all participants received breastfeeding support and two nurse home visits during which interventions were delivered, and no interventions were delivered before the first home visit. Routine clinical care was given before and after that visit by primary care providers.

For all study participants, the first home visit occurred 2–3 weeks after birth, and the second home visit occurred within 2 weeks of the first introduction of complementary solid foods, typically between 4 and 6 months of age. Infants were assessed through age 1 year when a final study visit occurred at the General Clinical Research Center of The Penn State College of Medicine.

First home visit interventions. The "Soothe/Sleep" intervention was delivered by a research nurse at the first home visit that occurred between 2 and 3 weeks after birth. Parents randomized to the two "Soothe/Sleep" intervention cells were taught alternate strategies to feeding as an indiscriminate first response to infant distress. The goal of the intervention was to help both parents and infants learn to discriminate hunger from other distress causes (fear, anger, boredom, and other discomfort, including wet diapers) and not to use feeding for non-hunger-related fussiness. The use of alternative soothing techniques afforded the nonhungry infant opportunities to experience being soothed without being fed, and to learn to self-soothe and to return to sleep without a feeding. In addition to one-on-one instruction, participating mothers were given an instructional handout and a commercially produced video "The Happiest Baby on the Block" (38). The video details a process to help calm and soothe infants with strategies that can be applied during the day and at night when it is time for sleep. Briefly, the process includes instructions and demonstrations using five soothing techniques: (i) swaddling, (ii) side or stomach position while awake, (iii) shushing, (iv) swinging, and (v) sucking. Other instructions included in the "Soothe/Sleep" intervention taught parents to emphasize day/night environmental differences and to respond to nocturnal awakenings with other soothing and care-taking responses such as diaper changing before feeding the baby as has been done in a previous study (39). All study participants received a standard infant parenting book that included traditional advice on handling night awakenings including feeding, rocking, and checking for a dirty diaper, but control participants did not receive specific advice on soothing and calming their infants or guidance on prolonging infant sleep duration. For mothers in all four conditions, questions about general infant care and breastfeeding were answered. Infants were weighed and measured as described below. Finally, nurses reviewed diary cards and survey responses (described in more detail below) related to infant behavior, maternal mental health, and parenting that were completed before the visit to ensure adequate parental completion of surveys as well as to ensure that the results of the Edinburgh Postpartum Depression Scale (40) did not meet the threshold for referral.

At this same visit parents randomized to receive the second intervention, "Introduction of Solids," were instructed to delay the introduction of complementary foods until their infant was at least 4 months of age and to avoid putting infant cereal into a bottle of breast milk or formula. They were also given an instructional handout to help them recognize hunger and fullness cues. All mothers were instructed to call the research nurse when they were ready to introduce solids to their child.

Second home visit intervention. Once parents reported that their infant was ready to begin consuming solid foods, a second home nurse visit occurred within 2 weeks. At this visit, parents of infants randomized to receive the “Introduction of Solids” intervention were instructed on the importance of repeated exposure to solid foods to improve acceptance of unfamiliar foods. Developmental signs for solid food readiness such as good head control and sitting with support were reviewed. Intervention parents also received a hands-on demonstration on feeding their infant pureed solids as well as instructive handouts on infant feeding including guidance on recognizing hunger and fullness. They were also instructed to begin a feeding of pureed food when their infant was calm and alert, not crying or fussing. Control parents received the standard handout from the American Academy of Pediatrics on the introduction of solid foods that is often provided to parents at a 4-month well-child office visit. Similar to the first home visit, general infant care and breastfeeding guidance was given to all participating mothers in response to their questions and those from other family members, and all infants were weighed and measured. Again, nurses reviewed diary cards and survey responses. Additionally, though the details and outcomes of this portion of the study will not be presented in this article, all participating mother–infant dyads were videotaped during a feeding of infant cereal to assess maternal feeding style.

After the home visit for the intervention group only, as per instruction by study nurses at the second home visit, across 4 successive weeks, parents fed their infants one of four pureed vegetables each week for 6 consecutive days in the following order: green beans, peas, squash, carrots. They were asked to feed each week’s food at a similar time each day. If the infant refused the vegetable on three successive attempts at a meal or appeared hungry following consumption, the parents were instructed to offer infant cereal, breast milk, or formula. Foods used in the study were commercially available infant foods from Gerber (Gerber Products, Florham Park, NJ), and were delivered to the infants’ homes as part of the home visit with labels indicating the day on which they were to be presented to the infant.

Outcome measures and statistical analysis

The primary outcome of this study was weight-for-length percentile at age 1 year. To assess this outcome, at both home visits and the General Clinical Research Center visit, infant weights were measured by unblinded study nurses using a calibrated Medela BabyChecker scale (McHenry, IL). Lengths were measured using the Seca 210 Mobile Measuring Mat for Infants and Toddlers (Hanover, MD). Weight-for-length percentiles were calculated using Centers for Disease Control and Prevention growth charts (41). Weight-for-length percentile differences between study groups at age 1 year for those subjects who completed the research protocol (“completers”) were evaluated using ANOVA with adjustment for covariates. Maternal and infant physical and demographic variables were considered as potential covariates with only those that were significantly related to the outcome or clinically relevant remaining in the final model. The final covariate model was determined using a variable selection procedure in SAS (PROC GLMSELECT), which uses a hypothesis test-based stepwise selection approach, adding and removing variables from the model with a significance entry/stay level = 0.15. The final reported model is the most parsimonious model, having the largest adjusted R^2, the lowest PRESS statistic and Akaike’s Information Criterion values and with all variable significance levels <0.10. In addition to annual household income, the following maternal variables were examined as individual covariates: marital status, race, education level, intended breastfeeding duration, planned maternity leave duration, prepregnancy BMI, maternal height, gestational weight gain, and age at infant birth. Infant variables examined as individual covariates included birth weight adjusted for gestational age (both as a *z*-score and as a percentile), sex, gestational age, age at introduction of complementary foods, percent breast milk consumption at 16 weeks, total number of daily and nightly feeds at 3, 4, 8, and 16 weeks, total daily and night-time sleep at 3, 4, 8, and 16 weeks, and soothability at 16 weeks as defined by the Infant Behavior Questionnaire.

Because attrition occurred, in addition to the "completers" analysis, to account for potential bias caused by missing data we carried forward the weight-for-length percentile data for those "noncompleters" who had growth data from the second home visit as an estimate of weight-for-length percentile at 1 year. Dyads who did not receive the first and second home visit were not included in this analysis. Independent *t*-tests and χ^2-tests of independence were also used to compare demographic and anthropometric characteristics of the "completers" to the "noncompleters."

An additional growth outcome, conditional weight gain score, was examined using the approach of Griffiths *et al.* 42) Conditional weight gain *z*-scores were determined as the standardized residuals from the linear regression of 1 year weight-for-age *z*-score on weight-for-age *z*-scores at time of intervention delivery, adjusted for sex of the child. The standardized residuals were used as the conditional weight gain scores in an analysis of variance of the two interventions and their interaction, adjusted for covariates (see description of PROC GLMSELECT procedure and list of covariates examined in weight-for-length percentiles outcome analysis above). Positive conditional weight gain scores would be indicative of relatively faster weight gain, while negative scores would indicate relatively slower weight gain compared with the cohort mean.

To assess the impact of the "Soothe/Sleep" and "Introduction of Solids" interventions on infant sleeping and feeding, numerous behavioral outcomes were also evaluated. Regarding infant sleep, parents completed 96-h diary cards at 3, 4, 8, 16, 24, 36, and 48 weeks following phone call reminders to complete the diaries and other study forms. These diaries detailed at 15-min intervals whether the infant was sleeping, feeding, crying and fussy, or awake and content (43,44). Measures of total daily sleep, as well as nocturnal sleep defined *a priori* as between 9 PM and 6 AM, were calculated from the diary data. For feeding, in addition to notations on the diary cards regarding the timing and content of feeds (breast milk, formula, solids), parents also detailed the relative percentage of breast milk vs. formula that they were giving their infant using a visual analog scale anchored with 0% formula, 100% breast milk at one end and 100% formula, 0% breast milk at the other. An exclusively breastfed infant would therefore be noted as 100% breastfed by this assessment method. The age at which complementary foods were introduced was also recorded. Further, for those that received the "Introduction of Solids" instructions, each infant's gram intake of each vegetable on days 1 and 6 of the exposure series was measured by taking the difference in container pre- and postweights for each vegetable consumed using the method previously described by Sullivan and Birch (35). The postweights represented the unconsumed portion of the vegetables remaining in their original containers, which were returned to the investigators and weighed using an Ohaus Scout Pro scale (Ohaus, Pine Brook, NJ). Lastly, mothers completed surveys throughout the study assessing infant behavior, maternal mental health, and parenting.

All the participants in this study indicated that they intended to breastfeed during the childbirth hospitalization, but it was expected that there would be a steady decline in breastfeeding over the course of the study. To compare outcomes between breastfed and formula-fed infants, those infants consuming ≥80% breast milk were considered to be "predominantly breastfeeding" following the criteria used in the analyses of the recent Infant Feeding Practices Survey II (45).

Because behavioral interventions aimed at obesity prevention could theoretically cause infants to gain insufficient weight, this outcome was evaluated using two standard definitions, downward crossing of two major weight-for-age growth chart percentile lines between birth and age 1 year and weight less than the 5th percentile at age 1 year (46). Downward crossing of two major percentile lines was analyzed as weight change equivalent to 1.34 *z*-scores in order to provide a consistent measure across subjects. All were evaluated using Centers for Disease Control and Prevention growth charts (41). Finally, baseline characteristics were compared using χ^2 and Fisher's exact tests, and secondary outcomes related to sleep and feeding were analyzed using repeated measures ANOVA and χ^2-tests. All analyses were conducted using SAS statistical package, version 9.2 (Cary, NC).

RESULTS

Demographics

Of the 160 (Supplementary Table S1 online) participating mother–infant dyads, 110 (69%) completed the 1-year follow-up period (Table 2) with no significant difference in attrition by study group ($P = 0.07$). Mothers of infants not completing the study were significantly younger and less educated at baseline, and were more likely to be single, non-white, and Medicaid-insured compared with those who participated through the 1-year study visit. There were no differences in maternal prepregnancy BMI, maternal gestational weight gain, and infant's gestational age, birth weight, and birth length between those completing and not completing the study.

Among those infants that completed the study, 51% were female. The mean birth weight for these participants was 3.33 kg, equivalent to the 45th percentile for birth weight for gestational age (47). Mothers had a mean age of 27.1 years with 91% of them self-reporting to be white. The majority, 65%, had completed college, 90% were married, and 83% were privately insured. Among the 160 randomized dyads and the 110 "completers," none of the baseline infant or maternal demographic variables collected was significantly different when compared across the four study groups.

Infant growth

Analyses of variance including significant covariates revealed a significant interaction between the two interventions on weight-for-length percentile at age 1 year ($P = 0.03$, Figure 1). In this model using 110 participants who completed the study, those receiving both interventions had a lower mean weight-for-length percentile after adjusting for covariates with a mean at the 33rd percentile whereas those in other study groups were higher ($P = 0.009$; "Soothe/Sleep" intervention only—50th percentile; "Introduction of Solids" intervention only—56th percentile; control group—50th percentile). Model covariates included in the model were intended breastfeeding duration, total sleep duration at age 3 weeks, number of daily feeds at age 16 weeks, and maternal prepregnancy BMI.

Using data for those "noncompleters" who had growth data available from the second home visit as an estimate of weight-for-length percentile at 1 year increased the analyzable sample size to 124. Results are similar to the above results; participants receiving both interventions had lower mean weight-for-length percentiles than the other three study groups after adjusting for the same model covariates as above ($P < 0.05$).

As shown in Table 3conditional weight gain analyses of growth during the period from the first home visit and the final study visit at 1 year demonstrated a significant effect of the "Soothe/Sleep" intervention with those receiving this intervention gaining weight more slowly ($P = 0.02$). Neither the "Introduction of Solids" intervention nor the interaction between the two interventions was significant. Covariates retained in the model included length-for-age *z*-score at age 1 year ($P < 0.001$), intended duration of maternity leave ($P = 0.01$), and maternal prepregnancy BMI ($P = 0.08$).

In assessing the safety of the interventions on weight status in terms of sufficiency of weight gain, nine (8.2%) participants had weight-for-age <5th percentile at age 1 year, and 16 (14.6%) had downward crossing of two major percentile lines (Table 4). No significant differences were detected among treatment groups for either definition of insufficient weight gain.

Breastfeeding duration, exclusivity, and relationship to weight gain

Although the study sample included only mothers who indicated that they intended to breastfeed during the maternity stay, as expected, not all mothers continued to breastfeed. Among those that completed the study, by 3 weeks, 25% were no longer predominantly breastfeeding (defined as ≥80% of feeds), and by 16 weeks, 49% were not predominantly breastfeeding. These percentages did not differ by treatment group at any assessment during the first 16 weeks.

An additional conditional weight gain analysis examined the effect of infant feeding mode. Assessing this between birth and the 1 year study visit revealed that those predominantly breastfeeding at 16 weeks demonstrated a slower pattern of weight gain than those not predominantly breastfeeding ($P = 0.02$). Infant length for age *z*-score at 1 year was included in this model.

Sleeping and feeding frequency

To assess whether our intervention resulted in hypothesized behavioral differences that could influence 1 year weight-for-length differences between study groups, numerous secondary outcomes were examined. Those related to the "Soothe/Sleep" intervention were derived from sleep duration and infant feeding data obtained from diary cards. Because the study was intended to test the effect of interventions delivered to breast-feeding mother–baby dyads, the first models run for each variable were repeated measures models including Soothe/Sleep intervention group status, breastfeeding status at 16 weeks (predominantly breastfeeding vs. not predominantly breast-feeding), weeks (as the repeated factor), and the two- and three-way interactions among these factors. Breastfeeding status at 16 weeks was included in the models to test whether the effects of the intervention differed by feeding mode. The analyses indicated an interaction between breastfeeding status and nocturnal sleep ($P = 0.05$), total daily feeds ($P = 0.05$), and nocturnal feeds ($P = 0.04$). Therefore, the results related to infant sleep and breastfeeding status during the first 16 weeks after birth are presented separately for dyads who continued to predominantly breastfeed and those who were not predominantly breastfed.

A significant intervention effect was demonstrated on nocturnal sleep for predominantly breastfed infants, with breastfed dyads in the Soothe/Sleep groups showing significantly more sleep than controls ($P = 0.04$; Figure 2). An intervention effect was not seen for those that were not predominantly breastfed ($P = 0.40$).

The intervention also had effects on total daily feeds and nocturnal feeds for breastfed infants (Figure 3a). When compared with those not receiving the "Soothe/Sleep" intervention, breastfeeding infants in the treatment groups had significantly fewer feedings when analyzed over 24-h periods ($P = 0.008$) and when only nocturnal feedings were examined ($P = 0.003$; Figure 3b). Similar to the nocturnal sleep data, significant findings were not observed among infants that were not predominantly breastfed.

Introduction of solids and repeated exposure

The first behavioral outcome related to the "Introduction of Solids" intervention was the timing of the first introduction of solid foods. For the entire cohort, 22% of those surveyed introduced cereal before 4 months. Only 13% of mothers in the intervention group gave cereal before 4 months compared with 29% of control subjects ($P = 0.06$), providing evidence for effects of the intervention.

For the repeated exposure to vegetables component of this intervention, weighed intakes shown in Figure 4 revealed that infants who received the "Introduction of Solids" intervention showed significant increases in acceptance of new foods as indicated by increases in consumption of green beans ($P = 0.001$), peas ($P = 0.02$), and squash ($P = 0.04$) from day 1 to day 6.

DISCUSSION

The results of this pilot study provide initial evidence for effects of behavioral interventions delivered during the first year after birth on weight status at 1 year. As predicted, the behavioral interventions produced differences in sleep duration and feeding frequency among breastfed infants in the first months after birth and later in infancy affected the timing of introduction and acceptance of solid foods. The results at 1 year provide preliminary evidence that early-life differences among groups in sleeping and feeding may mediate differences in weight status at 1 year. These findings are potentially encouraging from an obesity prevention perspective because early-life growth patterns have increasingly been associated with both childhood and adult obesity (8,11,26,48–53) as well as risk for hypertension (54–57), coronary heart disease (58,59), and type 2 diabetes mellitus (60,61).

It is notable and not surprising that infants who received single interventions did not differ from the control group with regard to weight status at 1 year or growth over the study period. During the first year after birth the choice to breast or formula feed and the use of feeding to soothe, as well as later choices regarding the timing of the introduction of solids and the introduction of table foods all have been linked to differences in infant weight status (62–68). It is likely that multiple interventions and consistent reinforcement of their messages through the various stages of infant development are necessary to maintain long-term and sustained protection from obesity.

The interaction between feeding mode (predominantly breast milk or not predominantly breast milk) and the effect of the study interventions is also noteworthy. As found in this study, breastfeeding has been shown to have a modest protective effect against obesity development, but it has also been associated with shorter sleep duration when breastfed infants are compared with formula-fed infants (69–72). It is therefore paradoxical that shorter sleep duration has been associated with obesity, even among infants. The findings of this study for breastfed infants are provocative and hypothesis generating. Our findings, showing increased sleep duration among breastfed infants suggests that increasing sleep duration may confer additional protection against obesity for these infants. Alternatively, the inability to lengthen sleep duration among those not predominantly breastfeeding suggests that alternate strategies should be considered for this population already at risk for later obesity. The results for feeding frequency showing that the "Soothe/Sleep" intervention also reduced the number of nocturnal and total daily feedings for breastfed infants, suggest the possibility that reduced feeding frequency, rather than increased sleep duration may have contributed to the differences in growth noted among groups.

There are several limitations to this pilot study. First, our sample was limited to first-time mothers who intended to breastfeed, and was fairly homogeneous with limited minority participation making it difficult to generalize the findings to other populations, particularly those known to be at higher risk for obesity. Second, we obtained evidence of positive effects of our behavioral interventions designed to increase sleeping and reduce feeding frequency only among those dyads who continued to breastfeed. Because all mothers recruited originally intended to breastfeed, it is also possible that the mothers who discontinued breastfeeding differed in their ability to adhere to study interventions and/or requirements whether due to personal or environmental factors. The study population was also recruited from a single hospital with English speaking mothers who, as a group, were relatively well educated. Next, the duration of follow-up was relatively short. It will be important to follow infants longitudinally to see whether long-term obesity risk can be affected by interventions delivered during infancy. Fourth, the attrition rate for this study affects the interpretation of the findings particularly because the largest number of dropouts came from the dual intervention group. The birth of a first child and caring for the infant can be overwhelming for new parents, and although we noted effects of our interventions, the high participant burden and intensity of the interventions likely contributed to attrition. Alternatively, the added attention received by those receiving study interventions could have affected the outcomes compared with control participants who did not receive home visits of equal time duration or intensity. Finally, we do not have adequate data to assess the extent to which parents' implementation of the "Soothe/Sleep" intervention may have affected its impact. Future evaluations should better measure the adherence to intervention components.

Despite the limitations, these findings suggest that multi-component interventions may potentially be successful at helping infants achieve a healthy growth trajectory. The secondary outcomes related to each intervention (sleep duration, nocturnal feeding, acceptance of solid foods) reveal that behaviors previously associated with differences in weight gain in infancy and with long-term obesity risk can be influenced. Because infancy represents a critical period of rapid growth and developmental plasticity with long-lasting metabolic and behavioral consequences, successful interventions may have highly meaningful long-term effects for the prevention of obesity and its comorbidities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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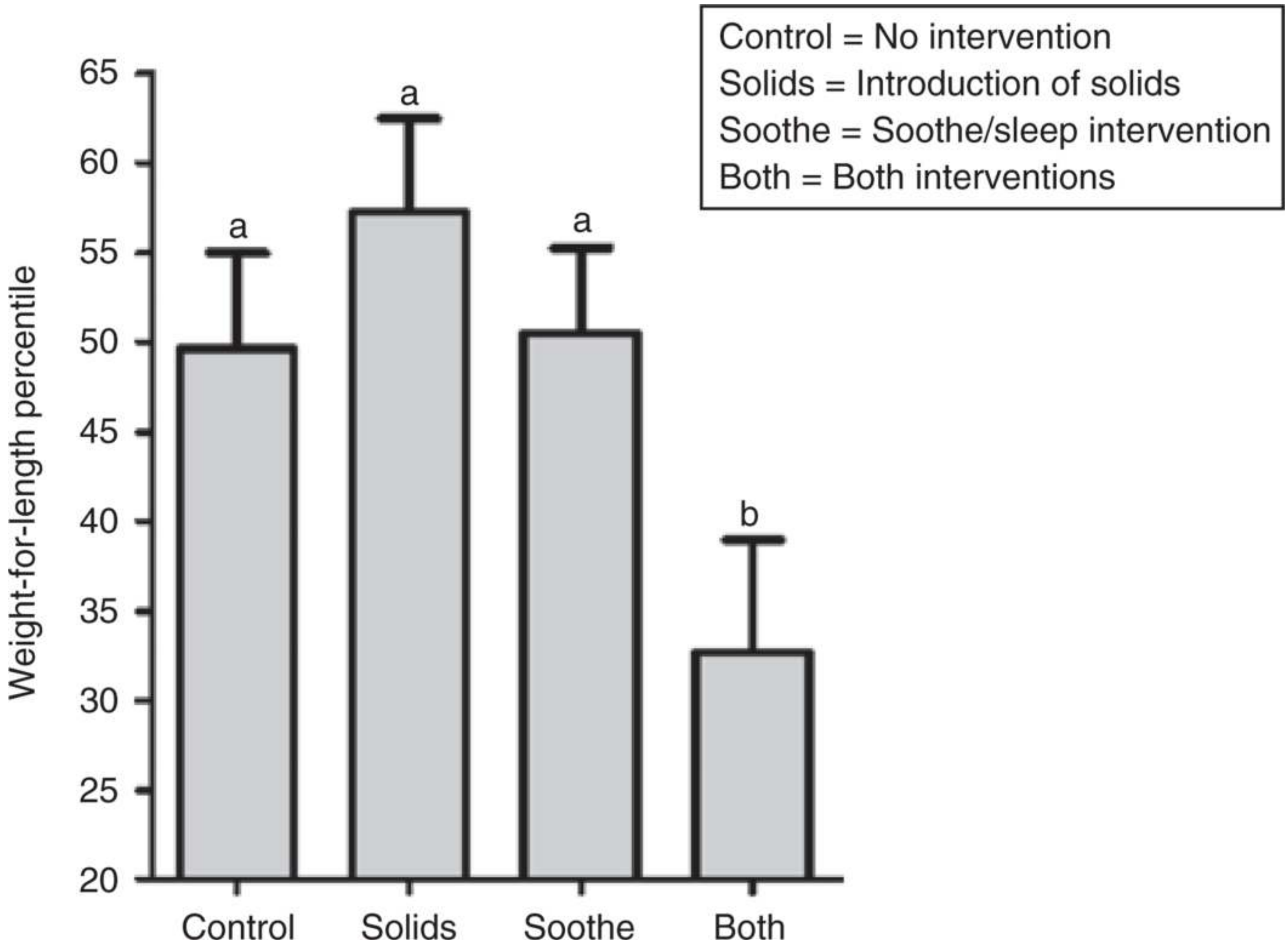

Figure 1.
Study group weight-for-length percentiles at 1 year (both interventions group vs. other three groups; $P = 0.009$).

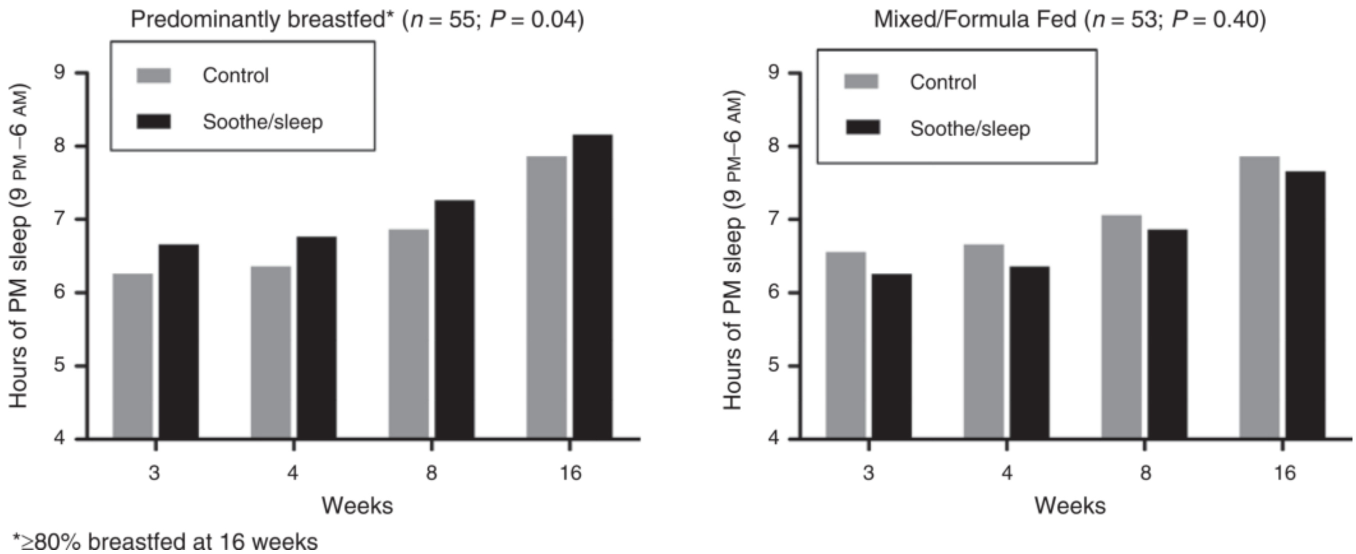

Figure 2.
Effect of “Soothe/Sleep” intervention on infant nocturnal sleep duration.

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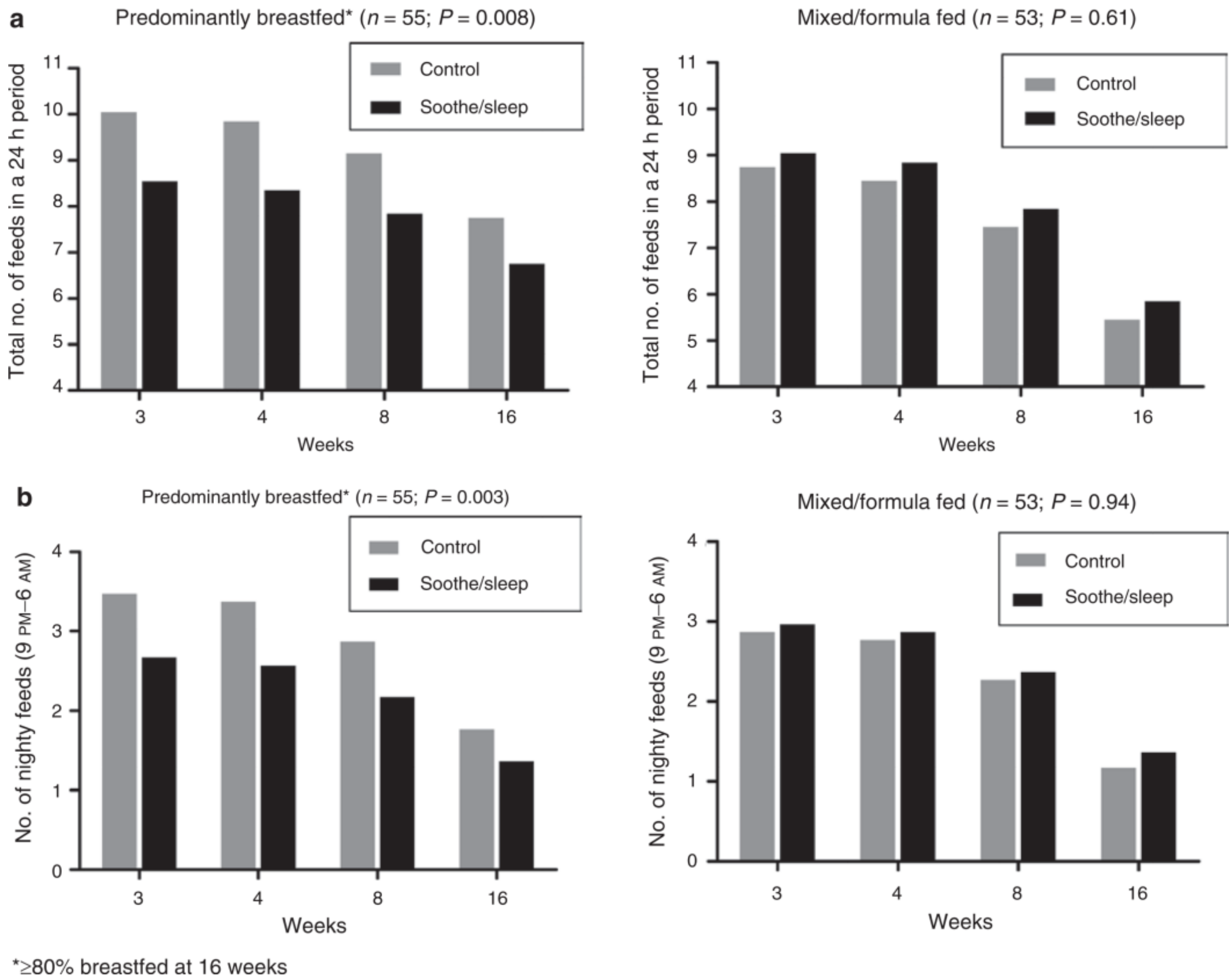

Figure 3.
Effect of “Soothe/Sleep” intervention on infant (a) total daily and (b) nocturnal feeds.

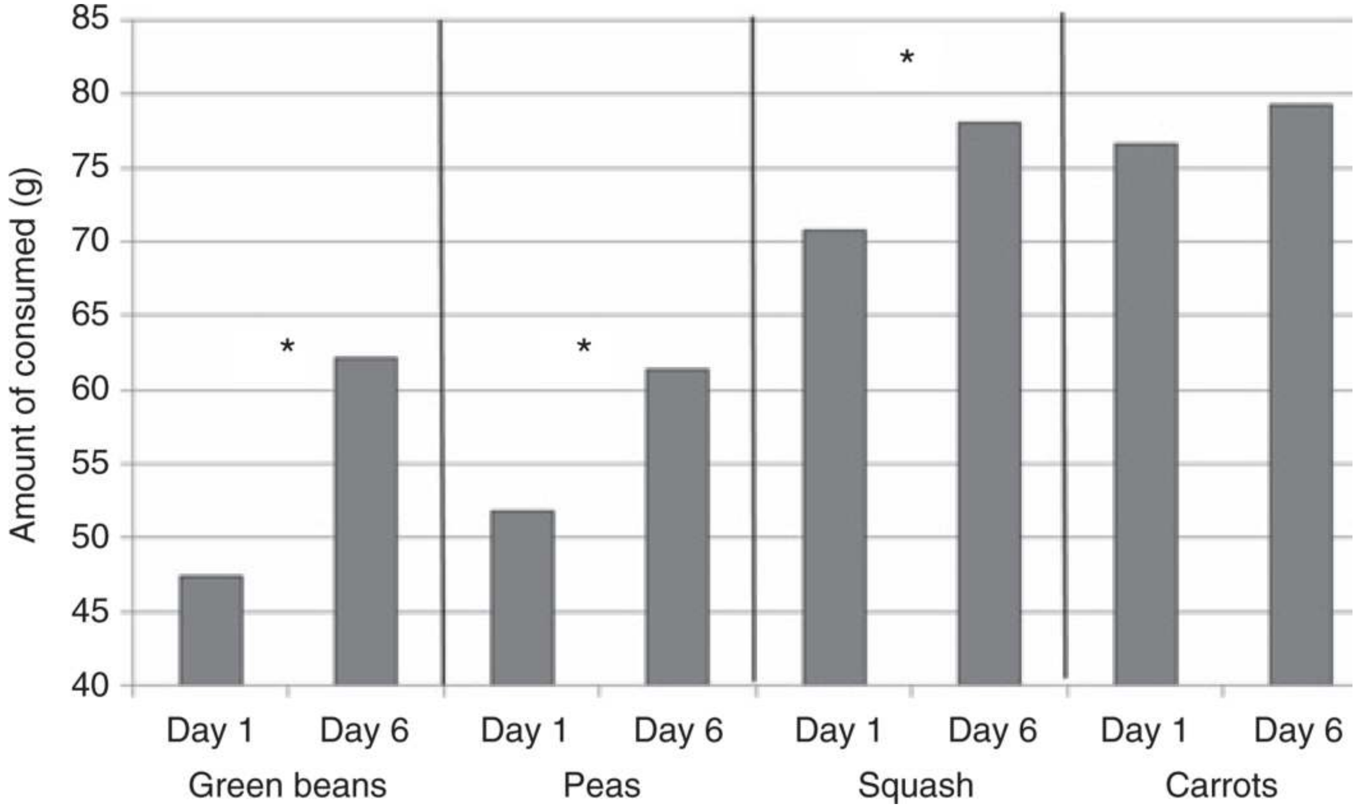

Figure 4.
Food intake after repeated exposure instructions ("Introduction of Solids" intervention group only, n = 52; *$P < 0.05$).

Table 1

Randomized 2 × 2 crossed design with two interventions (N = 160)

	Introduction of solids	**Control**
Soothe/sleep	N = 42; 2 interventions	N = 39; 1 intervention
Control	N = 38; 1 intervention	N = 41; 0 interventions

Table 2

Baseline demographics of participants completing the 1-year study by treatment group

	Study cohort (*N* = 110)	Soothe/Sleep + Introduction of Solids (*N*=22)	Soothe/Sleep + Control (*N* = 29)	Control + Introduction of Solids(*N* = 29)	Control + Control(*N* = 30)	*P*
Infant						
Sex, female (%)	56 (51)	10 (45)	11 (38)	15 (52)	20 (67)	0.16
Gestational age, weeks, mean (s.d.)	39.5 (1.3)	39.7 (1.1)	39.4 (1.4)	39.4 (1.3)	39.4 (1.5)	0.82
Birth weight, kg, mean (s.d.)	3.33 (0.48)	3.50 (0.5)	3.37 (0.5)	3.23 (0.6)	3.27 (0.3)	0.21
Birth weight for gestational age, percentile (s.d.)	45.0 (28.7)	53.5 (32.5)	47.2 (24.1)	37.3 (32.7)	44.2 (25.1)	0.24
Birth weight for gestational age, z-score (s.d.)	−0.17 (0.97)	0.10 (1.08)	−0.11 (0.77)	−0.39 (1.21)	−0.21 (0.77)	0.34
Birth length, cm, mean (s.d.)	49.6 (3.7)	51.0 (2.0)	48.5 (5.8)	49.3 (3.0)	49.8 (2.0)	0.12
Mother						
Age, years, mean (s.d.)	27.1 (4.7)	26.9 (5.1)	26.4 (4.3)	27.2 (5.2)	27.9 (4.6)	0.69
Race						0.33
White (%)	100 (91)	20 (91)	27 (93)	25 (86)	28 (93)	
Black (%)	6 (6)	0 (0)	2 (7)	3 (10)	1 (3)	
Asian (%)	3(3)	1(5)	0(0)	1(3)	1(3)	
Native American (%)	1(1)	1(5)	0(0)	0(0)	0(0)	
Hispanic ethnicity (%)	6(6)	2(9)	2(7)	2(7)	0(0)	0.41
Education						0.17
High school graduate or less education (%)	16 (15)	2 (9)	2 (7)	5 (17)	7 (23)	
Some college or technical school (%)	23 (21)	6 (27)	6 (21)	7 (24)	4 (13)	
College graduate or more education (%)	71 (65)	14(64)	21 (72)	17 (59)	19 (63)	
Marital status						0.74
Married or cohabitating	99 (90)	21 (95)	25 (86)	26 (90)	27 (90)	
Single	10 (9)	1 (5)	3 (10)	3 (10)	3 (10)	
Other	1 (1)	0 (0)	1 (3)	0 (0)	0 (0)	
Insurance						0.77
Private (%)	91 (83)	18 (82)	25 (89)	24 (83)	24 (80)	
Medicaid (%)	9 (8)	1(5)	1(4)	3(10)	4(13)	
Other	9 (8)	3 (14)	2 (7)	2 (7)	2 (7)	

	Study cohort (*N* = 110)	**Soothe/Sleep + Introduction of Solids (*N*=22)**	**Soothe/Sleep + Control (*N* = 29)**	**Control + Introduction of Solids(*N* = 29)**	**Control + Control(*N* = 30)**	***P***
Annual household income						0.68
<$25,000 (%)	11 (10)	3 (14)	1 (3)	5 (17)	2 (7)	
$25,000–$49,999 (%)	20 (18)	4(18)	5(17)	7(24)	4(13)	
$50,000–$99,999 (%)	46 (42)	8 (36)	16 (55)	10 (34)	12 (40)	
>100,000 (%)	25 (23)	5(23)	6(21)	6(21)	8(27)	
Refused/don't know	8 (7)	2 (9)	1 (3)	1 (3)	4 (13)	
Prepregnancy BMI, mean (s.d.)	24.8 (5.7)	27.2 (8.4)	24.8 (4.6)	23.7 (3.8)	25.2 (5.5)	0.21
Pregnancy weight gain, kg, mean (s.d.)	16.5 (6.0)	17.2 (6.6)	16.5 (6.7)	15.8 (5.0)	16.7 (5.9)	0.88
Tobacco use during pregnancy (%)	8 (7)	0 (0)	2 (7)	3 (10)	3 (10)	0.48
Diabetes during pregnancy (%)	4 (4)	1 (5)	1 (4)	2 (7)	0 (0)	0.56
Intended duration of breastfeeding, months (s.d.)	7.3 (3.8)	7.4 (5.5)	7.7 (3.7)	6.1 (3.1)	8.1 (3.1)	0.21
Intended duration of maternity leave, months (s.d.)	3.9 (3.4)	3.4 (5.1)	3.5 (2.6)	4.0 (2.8)	4.4 (3.4)	0.73

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Table 3

Conditional weight gain scores from 2 weeks to 1 year by study group for those completing the 1-year study ($N = 110$)

	Introduction of Solids	Control
Soothe/Sleep *	$N = 22$; −0.394	$N = 29$; −0.08
Control	$N = 29$; 0.25	$N = 30$; 0.08

Conditional weight gain scores are the standardized residuals from the linear regression of the weight-for-age z-scores between two time points. A positive score indicates a faster, and a negative score a slower, rate of weight gain in comparison with the overall study cohort.

* $P = 0.02$ for Soothe/Sleep vs. Control. Other comparisons and the interaction of the two interventions were nonsignificant.

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Table 4

Evaluation of potentially adverse effects on growth of study interventions (N= 110)

	Study Cohort (*N*= 110)	**Soothe/Sleep + Introduction of Solids (*N* = 22)**	**Soothe/Sleep + Control(*N* = 29)**	**Control + Introduction of Solids (*N* = 29)**	**Control +Control (*N* = 30)**	***P***
Weight <5th percentile at 1 year, *N*(%)	9 (8.2%)	1 (4.5)	1 (3.4)	5(17.2)	2 (6.7)	0.30
Downward crossing of two major centile lines between birth and 1 year, *N*(%)	16(14.6)	4(18.2)	3(10.3)	3(10.3)	6 (20.0)	0.62