

# Effect of the INSIGHT Responsive Parenting Intervention on Rapid Infant Weight Gain and Overweight Status at Age 1 Year

## A Randomized Clinical Trial

Jennifer S. Savage, PhD; Leann L. Birch, PhD; Michele Marini, MS; Stephanie Anzman-Frasca, PhD; Ian M. Paul, MD, MSC

**IMPORTANCE** Rapid infant weight gain is associated with later obesity, but interventions to prevent rapid infant growth and reduce risk for overweight status in infancy are lacking.

**OBJECTIVE** To examine the effect of a responsive parenting (RP) intervention on infant weight gain between birth and 28 weeks and overweight status at age 1 year.

**DESIGN, SETTING, AND PARTICIPANTS** The Intervention Nurses Start Infants Growing on Healthy Trajectories (INSIGHT) study is an ongoing randomized clinical trial comparing an RP intervention designed to prevent childhood obesity with a safety control. The study includes primiparous mother-newborn dyads (n = 291) and was conducted at the Penn State Milton S. Hershey Medical Center, Hershey, Pennsylvania, in addition to home visits. Enrollment was initiated in January 2012, and evaluable population analyses for this study were conducted between April 2015 and November 2015.

**INTERVENTIONS** At 2 weeks post partum, initial intervention materials appropriate to the assigned treatment group were mailed to the participant's home. Research nurses conducted home visits at 3 weeks, 16 weeks, 28 weeks, and 40 weeks, and a research center visit occurred at 1 year. The Intervention Nurses Start Infants Growing on Healthy Trajectories curriculum included messages about infant feeding, sleep hygiene, active social play, emotion regulation, and growth record education. The control group received a developmentally appropriate home safety intervention also delivered by nurse home visitors.

**MAIN OUTCOMES AND MEASURES** Conditional weight gain from birth to 28 weeks was calculated. General linear models examined intervention effect on conditional weight gain. The intervention's effect on infant weight-for-length percentiles was tested using analysis of variance. Logistic regression compared the odds of overweight status (weight for length  $\geq$ 95th percentile) at 1 year as a function of conditional weight gain.

**RESULTS** Of the mothers included in the study, 246 were white (88%), 260 were non-Hispanic (93%), 210 were married (75%), and 201 were working full time (72%) at time of enrollment. The mean conditional weight gain score was lower among infants in the RP group compared with the control group ( $-0.18$ ; 95% CI,  $-0.36$  to  $-0.001$ ), reflecting that the RP infants gained weight more slowly than control group infants ( $0.18$ ; 95% CI,  $0.02$ - $0.34$ ); this effect did not differ by feeding mode (predominantly fed breast milk or not). Infants in the RP group also had lower mean weight-for-length percentiles at 1 year than infants in the control group (57.5%; 95% CI, 52.56%-62.37% vs 64.4%; 95% CI, 59.94%-69.26%;  $P = .04$ ) and were less likely to be overweight at age 1 year (5.5% vs 12.7%;  $P = .05$ ).

**CONCLUSIONS AND RELEVANCE** An RP intervention is associated with reduced rapid weight gain during the first 6 months after birth and overweight status at age 1 year.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: [NCT01167270](https://clinicaltrials.gov/ct2/show/study/NCT01167270).

JAMA Pediatr. 2016;170(8):742-749. doi:10.1001/jamapediatrics.2016.0445  
Published online June 6, 2016. Corrected on October 10, 2016.

**+** Journal Club Slides and Supplemental content at [jamapediatrics.com](http://jamapediatrics.com)

**+** CME Quiz at [jamanetworkcme.com](http://jamanetworkcme.com) and CME Questions page 815

**Author Affiliations:** Center for Childhood Obesity Research, The Pennsylvania State University, University Park (Savage, Marini); Nutritional Sciences, The Pennsylvania State University, University Park (Savage); Department of Foods and Nutrition, University of Georgia, Athens (Birch); Department of Pediatrics, State University of New York at Buffalo (Anzman-Frasca); Pediatrics and Public Health Sciences, Pennsylvania State College of Medicine, University Park (Paul).

**Corresponding Author:** Jennifer Savage, PhD, Center for Childhood Obesity Research, 129 Noll Laboratory, The Pennsylvania State University, University Park, PA 16802 ([jfs195@psu.edu](mailto:jfs195@psu.edu)).

Overweight status and rapid weight gain during infancy are associated with increased fat mass, later risk of being overweight,<sup>1-4</sup> and numerous comorbidities.<sup>5-7</sup> Infancy is a critical period of developmental plasticity with long-lasting metabolic and behavioral consequences,<sup>8,9</sup> and interventions developed for delivery during this period may alter long-term risk for obesity and associated comorbidities. Although modifiable factors that promote overweight status and rapid growth during infancy have been identified,<sup>10-12</sup> few preventive interventions addressing these factors have been tested.<sup>13</sup>

Based on our previous pilot randomized clinical trial demonstrating that an early responsive parenting (RP) intervention focused on infant soothing, sleeping, and feeding was associated with a significant decrease in infant weight gain and affected weight for length at age 1 year,<sup>14</sup> we developed the Intervention Nurses Start Infants Growing on Healthy Trajectories (INSIGHT), a randomized clinical trial, to evaluate an RP intervention designed for the primary prevention of obesity.<sup>15</sup> Mothers received guidance on RP, which is defined as developmentally appropriate, prompt, and contingent on their infant's needs.<sup>16</sup> The curriculum for INSIGHT includes messages about infant feeding, sleep hygiene, active social play, emotion regulation, and growth record education; these areas were selected based on the overarching RP framework, their potential to be modified, and evidence linking them to obesity risk.<sup>15</sup> Additionally, RP promotes a range of adaptive outcomes in children including secure attachment, emotion regulation, cognitive and language development, and aspects of self-regulation including inhibitory control and executive function.<sup>17-20</sup>

The aim of this study was to examine the effect of the RP intervention on infant weight gain and overweight status at 1 year compared with infants in the control condition, who received equal attention in a home safety intervention.<sup>15</sup> Based on prior research,<sup>21-23</sup> the interval between birth and age 6 months was chosen to evaluate infant weight gain, and we hypothesized that infants in the RP intervention would have slower weight gain than infants randomized to the control group, resulting in reduced overweight at age 1 year. Because formula feeding is a risk factor for excessive weight gain in infancy,<sup>24</sup> a second objective was to assess whether the effects of our intervention differed between breastfed and formula-fed infants.<sup>25</sup>

## Methods

### Participants

Primiparous mothers and their newborns were recruited in person by research staff shortly after delivery from 1 maternity ward (Penn State Milton S. Hershey Medical Center, Hershey, Pennsylvania) into the INSIGHT study (Figure 1). Participants were told that the purpose of the study was “to see if nurse visits to your home during your baby’s infancy can improve your ability to either respond to your child’s cues related to feeding and fussiness or improve your ability to provide safe environment for your child and prevent injuries.” Enrollment

### Key Points

**Question** Can rapid weight gain and overweight status at 1 year be prevented by a responsive parenting intervention that is delivered by nurse home visitors?

**Findings** In this randomized clinical trial that included 279 mother-infant dyads, the responsive parenting intervention was associated with reduced rapid weight gain, and fewer than 6% of infants in the responsive parenting group were overweight at age 1 year compared with 13% of control group infants, a significant difference.

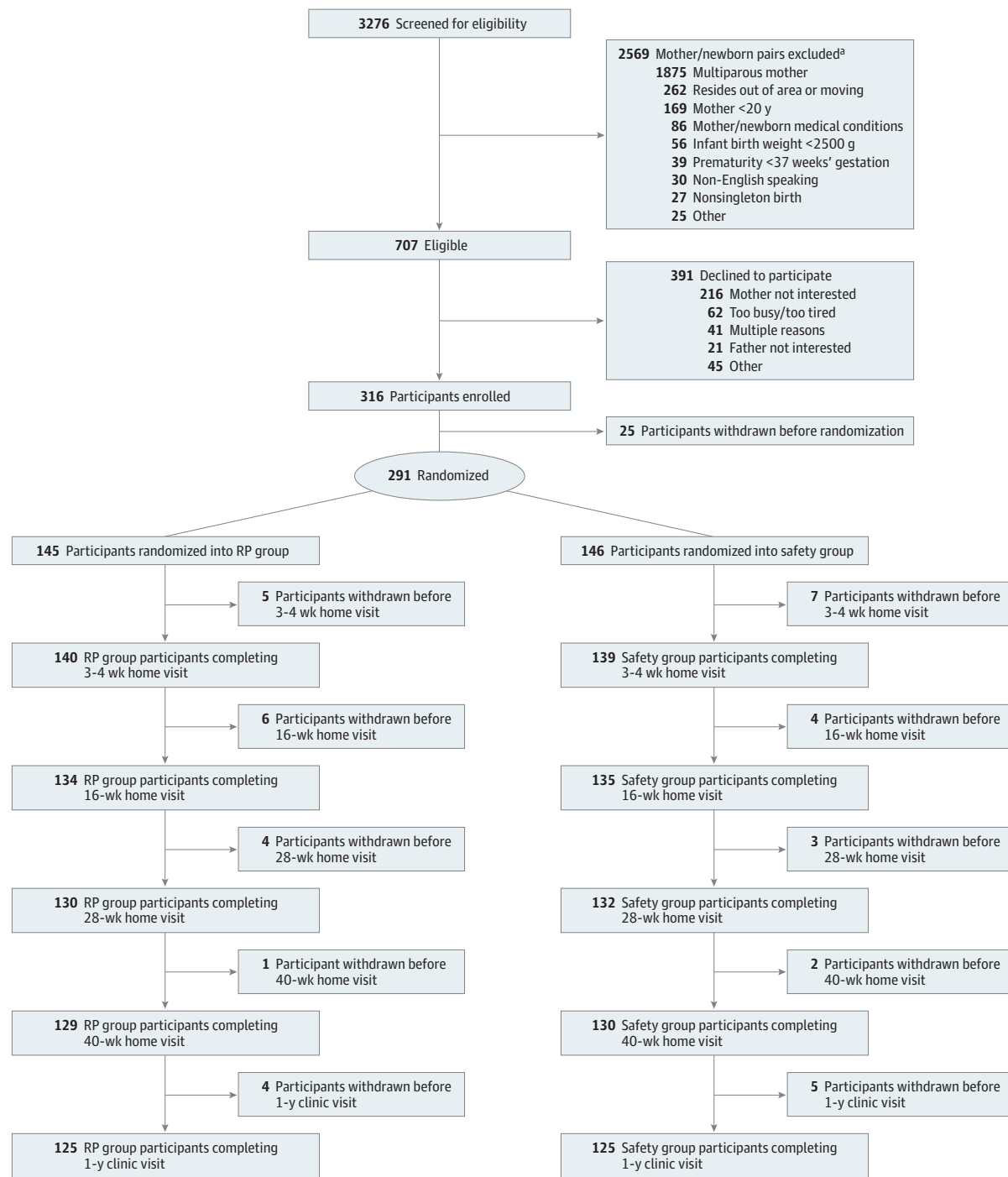
**Meaning** A multicomponent intervention that promotes responsive parenting behaviors is associated with healthy growth trajectories in infancy.

was initiated in January 2012, and analyses for this study were conducted between April 2015 and November 2015. Briefly, major eligibility criteria included full-term ( $\geq 37$  weeks' gestation), singleton newborns delivered to English-speaking, primiparous mothers at least 20 years of age residing within 80.5 km of the medical center. Infants born at less than 2500 g were excluded. More details have been published elsewhere.<sup>15</sup> Randomization was completed by the research nurse(s) during a telephone call 10 to 14 days post partum. The randomization scheme used permuted blocks (block size: 6) and stratified on birth weight for gestational age ( $< 50$ th percentile or  $\geq 50$ th percentile) and intended feeding mode (breastfeeding or formula feeding). Of 316 mother-newborn dyads who provided written consent to participate, 291 were randomized 2 weeks after birth, and 279 completed the first home visit at 3 to 4 weeks after birth. 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> prior to first participants' enrollment. The formal trial protocols can be found in the Supplement.

### Study Groups

The Intervention Nurses Start Infants Growing on Healthy Trajectories RP intervention addressed 4 infant behavioral states: drowsy, sleeping, fussy, and alert (eg, active social play and feeding) as previously described.<sup>15</sup> At each visit, intervention components were mapped to the 4 states. For example, age-appropriate sleep hygiene instructions promoted longer sleep duration and avoidance of feeding to sleep. The emotion regulation component encouraged parents to use alternative strategies besides feeding to calm a fussy infant. Parents were provided with a video, *The Happiest Baby on the Block*,<sup>26</sup> and received hands-on demonstrations of these strategies by visiting nurses. The feeding component taught parents to recognize hunger, satiety cues, and age-appropriate portion sizes and to use food for hunger only and not as a reward, punishment, or to soothe a distressed but not hungry child. Guidance included use of repeated exposure to promote acceptance of foods and beverages and the importance of modeling healthy eating behaviors, shared feeding responsibility, and establishing routines and limits. The active social play component focused on developmentally appropriate physical activities to engage infants, ranging from “tummy time” to

Figure 1. Study Consort Diagram



RP indicates Responsive Parenting.

<sup>a</sup> Potential participants may have had multiple exclusions.

outdoor play. Limit setting specific to screen time was also discussed. Last, growth chart education included instructing parents on typical patterns of infant growth and weight gain using color-coded growth charts that allowed nurses to provide feedback based on the individual child’s anthropometrics. The control group received a developmentally appropriate home safety

intervention also delivered by nurse home visitors.<sup>15</sup> The safety control intervention was dose-matched to ensure equivalent time and intensity.

Several efforts were made to maintain the integrity of these behavioral interventions including the use of scripted manuals for training and fidelity monitoring. Specifically, INSIGHT

RP and the safety control intervention included detailed manuals of intervention content, standardized training procedures, evaluation of the research nurse's delivery of the curriculum materials, and regular monitoring in the field. Random audio recordings of scheduled visits were reviewed, and feedback was provided to minimize drift in the research nurses' skills and ability to implement the curriculum as intended. Last, following each study visit, the nurse home visitors and study participants completed a checklist to monitor cross-contamination of the intervention groups.

Following randomization, a prestudy survey was administered to mothers electronically, and initial intervention materials appropriate to the assigned treatment group were mailed to the participant's home. Study data were collected and managed using Research Electronic Data Capture<sup>27</sup> tools hosted at the Penn State College of Medicine. If the mother lacked reliable internet access, the online survey was mailed with the intervention materials ( $n = 20$ ). Research nurses were trained in both RP and safety interventions, and generally, an individual nurse completed all study visits for each family. Home visits were conducted at infant ages 3 to 4 weeks, 16 weeks, 28 weeks, and 40 weeks, and a research center visit occurred at 1 year.

## Measures

### Background Characteristics

Family demographic information was collected at enrollment. Data extracted from medical records included maternal age, gestational weight gain, infant gestational age, birth weight, and length.

### Feeding Mode

A modified version of the Infant Feeding Practices Study 2 food frequency questionnaire from the US Centers for Disease Control and Prevention<sup>28</sup> was administered at 2 weeks, 16 weeks, and 28 weeks. Following the Infant Feeding Practices Study 2 study definition,<sup>28</sup> feeding mode at 16 and 28 weeks was defined as predominantly breastfed if 80% or more of milk feedings were breastmilk, either at the breast or by bottle; otherwise feeding mode was identified as not predominantly breastfed.<sup>29</sup>

### Anthropometrics

Maternal prepregnancy weight (kilograms) was extracted from medical records. Maternal height was measured in duplicate to the nearest 0.1 cm ( $n = 256$ ) using a portable stadiometer (Shorr Productions) or obtained from medical records ( $n = 23$ ). Maternal prepregnancy body mass index (BMI) was calculated as prepregnancy weight in kilograms divided by height in meters squared.

Infant birth weight and length were extracted from medical records. At each study visit, infant weight and recumbent length were measured by trained research nurses. Prior to age 1 year, these assessments were conducted by the research nurse completing the home visits for both groups. At the 1-year visit, anthropometrics were measured by research nurses blinded to study group. Weight was measured in duplicate to the nearest 0.1 kg using an electronic scale (Seca 354). Recumbent

length was measured in duplicate to the nearest 1 cm using a portable stadiometer (Shorr Productions). A third measurement was taken when weight and height differed by more than 0.05 kg and 1 cm, respectively. Multiple measures were averaged. Infant weight for age, length for age, and weight for length at birth, 28 weeks, and 1 year were converted to percentiles and  $z$  scores using World Health Organization data.<sup>30</sup>

### Conditional Weight Gain

Following the methods of Griffiths et al,<sup>31</sup> conditional weight gain (CWG) scores were calculated as standardized residuals from the linear regression of weight for age at 28 weeks on weight for age at birth, with length for age at birth and 28 weeks and infant age at the 28-week assessment entered as covariates. The CWG score represents the variation in child weight gain not explained by child age, birth length, or birth weight. A CWG score of zero represents the population mean.<sup>31</sup> Positive CWG scores (above the estimated regression) indicate more rapid or faster than average weight gain, while negative scores (below the estimated regression) indicate slower weight gain.

### Sample Size and Analysis Plan

The study was powered to detect a 0.67 difference in BMI  $z$  score at 3 years at 90% power, 5% type I error rate, with an anticipated attrition rate of 30%. Two hundred seventy-six participants were required for the study cohort a priori, defined as those completing the 3- to 4-week visit. The final cohort size of 279 resulted from additional participants who were in the "run-in" phase of the trial when the sample size goal was met and subsequently completed the 3- to 4-week visit.

Analysis of variance was used to examine the effect of the RP intervention on rapid weight gain. First, we examined the effect of study group on CWG scores from birth to 28 weeks (model 1). Next, feeding mode was included as a moderator to examine whether intervention effects differed for infants who were either predominantly breastfed at 16 weeks or not (model 2). These models were also tested after adjusting for covariates including marital status, maternal age at enrollment, maternal prepregnancy BMI, and estimated annual household income. Last, a Kolmogorov-Smirnov 2-sample test was used to determine whether there was a significant difference in the distribution of the CWG scores by intervention group. Weight for length at or higher than the 95th percentile at 1 year on the WHO growth charts<sup>30</sup> was defined as overweight per American Academy of Pediatrics guidelines.<sup>32</sup> Means and their 95% CIs were calculated in the general linear models program in SAS (SAS Institute). Logistic regression was used to compare intervention effects on the dichotomous outcome of overweight at age 1 year.

At 28 weeks and 52 weeks, 269 (96.4%) and 253 (90.7%) dyads remained in the study, respectively. Multiple imputation was used to account for the 10% of missing data at the 1-year weight outcome. To generate the multiple imputations, the following variables were included: infant weight at 3 weeks, maternal prepregnancy BMI, infant race/ethnicity (white vs other), gestational age, infant sex, marital status (married or not), mother age at recruitment, intent to breastfeed at 2 weeks, and study group. A Markov chain Monte Carlo imputation was used (Proc MI; SAS Institute). Parameter esti-

**Table 1. Demographic Characteristics of 279 Mother-Infant Dyads Who Were Randomized and Received the First Nurse Home Visit (n = 279)**

Characteristic	Responsive Parenting Group (n = 140)	Control Group (n = 139)
<b>Infant</b>		
Male sex, No. (%)	75 (54)	69 (50)
Gestational age, mean (SD), wk	39.6 (1.2)	39.5 (1.1)
Birth weight, mean (SD), kg	3.40 (0.43)	3.46 (0.43)
Birth length, mean (SD), cm	50.9 (2.4)	50.7 (4.5)
<b>Mother</b>		
Age, mean (SD), y	28.7 (4.6)	28.7 (4.9)
Prepregnancy BMI, mean (SD)	25.5 (5.0)	25.3 (5.6)
Gestational weight gain, mean (SD) kg	15.6 (6.4)	15.0 (6.0)
Diabetes during pregnancy, No. (%)	6 (4.3)	13 (9.4)
Smoked during pregnancy, No. (%)	12 (8.6)	9 (6.5)
<b>Race/ethnicity, No. (%)</b>		
Black	10 (7.1)	6 (4.3)
White	120 (85.7)	126 (90.7)
Native Hawaiian or Pacific Islander	1 (0.7)	0
Asian	5 (3.6)	4 (2.9)
Other	4 (2.9)	3 (2.1)
<b>Marital status, No. (%)</b>		
Married	102 (72.9)	108 (77.7)
Not married, living with partner	25 (17.9)	19 (13.7)
Single	12 (8.6)	12 (8.6)
Divorced/separated	1 (0.7)	0
<b>Annual household income, No. (%), \$</b>		
<10 000	6 (4.3)	5 (3.6)
10 000-24 999	10 (7.1)	10 (7.2)
25 000-49 999	5 (3.6)	23 (16.6)
50 000-74 999	46 (32.9)	26 (18.7)
75 000-99 999	32 (22.9)	23 (16.6)
≥100 000	32 (22.9)	43 (30.9)
Do not know or refuse to answer	9 (6.4)	9 (6.4)
<b>Education, No. (%)</b>		
High school graduate or less	16 (11.4)	16 (11.5)
Some college	37 (26.4)	36 (25.9)
College graduate	48 (34.3)	52 (37.4)
≥Graduate degree	39 (27.9)	35 (25.2)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

mates from imputation were virtually identical to full-data case analysis (Proc MIANALYZE; SAS Institute), and therefore, results are included for the full-data case analysis only. Data were analyzed using the SAS software, version 9.4 (SAS Institute).

## Results

There were no differences between RP and control groups on demographic characteristics (Table 1) or attrition. Two hundred forty-six mothers were white (88%), 260 were non-Hispanic (93%), 210 were married (75%), and 201 were working full time (72%) at time of enrollment. Mothers were also

predominately well educated and privately insured. Compared with those completing the 1-year visit, mothers of infants who elected to withdraw from the study (n = 26) were significantly younger, more likely to be single, had lower education levels, and reported lower annual household incomes (data not shown).

### Conditional Weight Gain From Birth to Age 6 Months by Study Group

During the first 6 months after birth, mean CWG score was negative for RP infants (mean, -0.18; 95% CI, -0.36 to 0), reflecting a slower than average pattern of weight gain. In contrast, mean CWG score was positive for control infants (mean, 0.18, 95% CI, 0.02-0.34), reflecting faster weight gain (model 1) as shown in Table 2 (P = .004). Figure 2 shows that the distribution of CWG scores for the control infants was shifted to the right relative to infants in the RP group, reflecting more rapid weight gain among control infants (Kolmogorov-Smirnov asymptotic test, 1.6; P = .01). The effect of the RP intervention on CWG from birth to 28 weeks did not vary by feeding mode (predominantly breastfed or not) at 16 weeks (Table 2, model 2). Results were similar when examining feeding mode at 28 weeks and when missing data were imputed (data not shown).

### Overweight Status at Age 1 Year by Study Group

At age 1 year, 7 infants in the RP group (5.5%) were overweight (weight for length ≥95th percentile) compared with 16 infants (12.7%) in the control group ( $\chi^2 = 4$ ; P = .05; Figure 3). Children in the control group had greater mean weight-for-length percentile values at 1 year (mean, 64.4%; 95% CI, 59.8%-69.0%) compared with children in the RP group (mean, 57.5%; 95% CI, 52.6-62.4) ( $F_{1,251} = 4.13$ ; P = .04). Similar results emerged when missing data were imputed (data not shown).

## Discussion

Infants in the INSIGHT RP intervention grew less rapidly (ie, lower CWG scores) during the first 6 months after birth, had a lower mean weight for length percentile at 1 year, and had lower prevalence of overweight status at 1 year than control infants. The effects of the intervention on growth and weight gain did not differ between breastfed and formula-fed infants. Although long-term data on the effects of the INSIGHT RP intervention are not yet available, results are promising: infants in the RP treatment had lower weight for length at 1 year, with 5.5% of RP group infants being overweight at 1 year compared with 12.7% of control group infants.

In addition to INSIGHT, 3 other trials focused on preventing obesity in infancy have reported beneficial effects on infant growth or weight status: Sleeping and Intake Methods Taught to Infants and Mothers,<sup>14</sup> which informed the design of INSIGHT, the Healthy Beginnings Trial,<sup>33</sup> and NOURISH-RCT.<sup>34</sup> Similarities and differences among these completed trials provide information on common features distinguishing the trials with positive effects on early growth from those multicomponent behavioral interventions reporting



**Table 2. Effect of Study Group (Model 1) and Feeding Mode<sup>a</sup> (Model 2) on CWG<sup>b</sup>**

Variable	Model 1 (n = 262)	P Value	Model 2: Study Group × Feeding Mode Interaction (n = 262)	P Value
	Mean CWG (95% CI)		Mean CWG (95% CI)	
Study group	NA	.04	NA	.002
Responsive parenting	-0.18 (-0.36 to 0)	NA	-0.21 (-0.38 to -0.03)	NA
Control	0.18 (0.02-0.34)		0.17 (0-0.34)	
Feeding mode at 16 wk × study group				
Responsive parenting	NA	NA	NA	NA
Breastfed <sup>4</sup>	NA	NA	-0.21 (-0.45 to 0.04)	.51
Formula-fed	NA	NA	-0.21 (-0.45 to 0.04)	
Control	NA	NA	NA	NA
Breastfed <sup>4</sup>	NA	NA	0.09 (-0.16 to 0.34)	
Formula-fed	NA	NA	0.25 (0.02 to 0.49)	

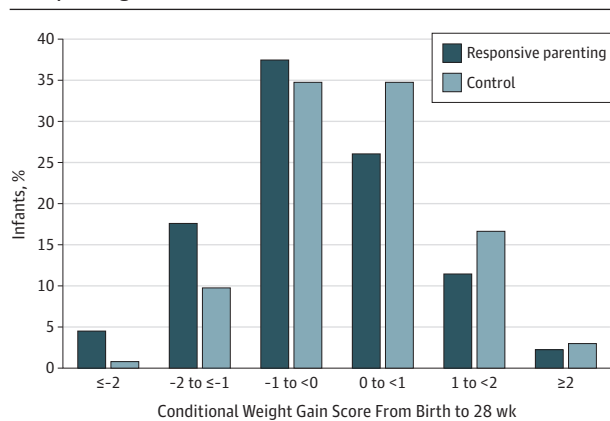
Abbreviations: CWG, conditional weight gain; NA, not applicable.

<sup>a</sup> Predominately breastfed at 16 weeks defined as 80% or more breastfeeding, either at the breast or by bottle. At 16 weeks, 48% of infants were predominately breastfed.

<sup>b</sup> Conditional weight gain scores are the studentized residuals from the model: weight for age at 28 weeks = weight for age at birth + length for age at birth + length for age at 28 weeks + infant age at 28 weeks + gestational age + intent

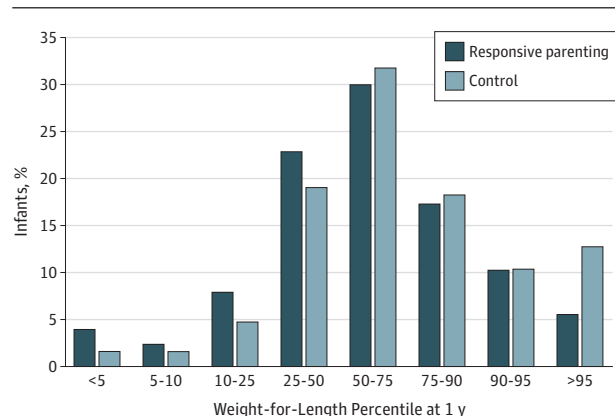
to breastfeed declared at 2 weeks. Similar results emerged after adjusting for the following covariates: maternal prepregnancy body mass index, income, marital status, and maternal age at recruitment. Income was ordinarily categorized as 6 levels from less than \$10 000, \$10 000 to \$24 999, \$25 000 to \$49 999, \$50 000 to \$74 999, \$75 000 to \$99 999, and \$100 000 and greater, but were treated as continuous data. These covariates were nonsignificant and not shown.

**Figure 2. Effect of Responsive Parenting Intervention on Rapid Weight Gain**



Responsive parenting group infants had lower conditional weight gain scores reflecting slower, less rapid weight gain. Conditional weight gain scores from birth to 28 weeks greater than 0 indicates faster weight gain.

**Figure 3. Study Group Weight-for-Length Percentiles at 1 Year**



Infants in the responsive parenting group have lower weight-for-length percentiles at age 1 year compared with control group infants (ANOVA *P* = .04). Among responsive parenting group infants, 5.5% were overweight at age 1 year compared with 12.7% of control group infants.

null findings for weight status.<sup>35</sup> One common feature of these trials is that only primiparous mothers and their full-term newborns were eligible to participate. Second, except for NOURISH, these interventions were delivered by nurses during home visits, allowing for somewhat tailored guidance. Third, the intervention dose was higher in the successful trials than most of those showing null effects.<sup>35</sup> Fourth, all provided guidance on aspects of RP, and 3 of the 4 interventions were implemented during early infancy.

Unique to INSIGHT, instead of explicitly focusing on nutrition, feeding, and obesity prevention in discussion with parents, INSIGHT used a “stealth” approach to preventing childhood obesity by promoting RP behaviors across infant behavioral domains (drowsy, sleeping, fussy, and alert). The focus on variables such as these is of more immediate inter-

est to most parents of infants than obesity prevention. We hypothesized that by promoting feeding, sleeping, and soothing within a RP framework, we could affect early growth and obesity risk. Self-regulatory skills begin to develop in late infancy, and infants need responsive caregiving to help them regulate distress. Teaching RP and effective soothing strategies and allowing infants opportunities to learn how to regulate their own distress, for example, by self-soothing during night waking, can scaffold children’s developing self-regulation abilities.<sup>36</sup> Parenting interventions that increase child self-regulation may also positively affect the development of empathy, cognitive and social competence, ability to delay gratification, compliance, and academic achievement.<sup>18,19,37</sup>

Given that development in infancy is rapid, the timing of intervention initiation and duration is likely to be critical. In INSIGHT, initial intervention materials were provided at 10 to 14 days post partum, with the first home visit occurring approximately 3 weeks after birth. For SLIMTIME, the first home visit occurred 2 to 3 weeks after birth. Healthy Beginnings started even earlier, beginning at 30 to 36 weeks' gestation. Interventions reporting null results on weight outcomes<sup>35</sup> began later, waiting until 2 to 4 months after childbirth to intervene. Although rapid growth in infancy has been measured at different times and defined multiple ways, a meta-analysis across 10 cohort studies<sup>38</sup> showed that rapid weight gain during the first year of life is positively associated with subsequent obesity. Further, birth weight and weight during the first weeks after birth explain substantial variance in later growth outcomes, another reason for focusing on early development.<sup>38</sup>

There are limitations to this study. First, the INSIGHT sample was fairly homogeneous, with limited minority participation. The study population was recruited from a single hospital with English-speaking mothers who, as a group, were well educated, and findings cannot be generalized to other populations. However, INSIGHT extends our previous work<sup>14</sup> by including women intending to formula feed and women intending to breastfeed. Second, because only first-time

mothers were recruited, it is unclear how effective the INSIGHT RP intervention would be for multiparous mothers. However, first-born infants are at increased risk of developing obesity<sup>39</sup> and symptoms of metabolic syndrome<sup>40</sup> compared with their younger siblings.

## Conclusions

The results of this study suggest that a multicomponent intervention promoting responsive parenting behaviors can be efficacious, promoting healthy growth trajectories in infancy that can reduce obesity risk. These findings, in combination with those of other trials,<sup>14,33,34</sup> reveal that interventions beginning early in infancy can have effects on growth and weight status, preventing rapid infant weight gain by providing RP guidance for first-time mothers. Future analyses will examine whether the INSIGHT RP intervention results in differences in parenting behaviors and in infant sleep, feeding, and emotion regulation, which may mediate effects on weight outcomes. We will continue to follow these infants longitudinally to examine the longer-term effects of the INSIGHT RP intervention on BMI at age 3 years and older.

### ARTICLE INFORMATION

**Accepted for Publication:** February 11, 2016.

**Correction:** There were errors in the Discussion section, the Conclusions section, and in the legend of Figure 3. In the first sentence of the second paragraph of the Discussion section, "Nourishing Our Understanding of Role-modeling to Increase Support and Health" should be replaced with "NOURISH-RCT." In the third sentence of the fourth paragraph of the Discussion section, "with the exception of NOURISH<sup>34</sup>" should be deleted. In the second sentence of the Conclusions section, reference 34 should be added following references 14 and 33. Finally, the legend of Figure 3 should be replaced with the following: "Infants in the responsive parenting group have lower weight-for-length percentiles at age 1 year compared with control group infants (ANOVA  $P = .04$ ). Among responsive parenting group infants, 5.5% were overweight at age 1 year compared with 12.7% of control group infants." This article was corrected on October 10, 2016.

**Published Online:** June 6, 2016.  
doi:10.1001/jamapediatrics.2016.0445.

**Author Contributions:** Dr Savage had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** All authors.

**Acquisition, analysis, or interpretation of data:** Savage, Birch, Marini, Paul.

**Drafting of the manuscript:** Savage, Marini, Paul.

**Critical revision of the manuscript for important intellectual content:** Savage, Birch, Anzman-Frasca, Paul.

**Statistical analysis:** Savage, Marini, Paul.

**Obtained funding:** Savage, Birch, Paul.

**Administrative, technical, or material support:** Marini, Anzman-Frasca, Paul.

**Study supervision:** Birch, Marini, Paul.

**Conflict of Interest Disclosures:** None reported.

**Funding/Support:** This research was supported by grant R01DK088244 from the National Institute of Diabetes and Digestive and Kidney Diseases. Additional support was received from the Children's Miracle Network at Penn State Children's Hospital. US Department of Agriculture grant 2011-67001-30117 supported graduate students. Research Electronic Data Capture support was received from The Penn State Clinical and Translational Research Institute, Pennsylvania State University Clinical and Translational Science Award, and National Institutes of Health/National Center for Advancing Translational Sciences grant number UL1 TR000127.

**Role of the Funder/Sponsor:** The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

**Additional Contributions:** We acknowledge Jodi Mindell, PhD, for contributing to the sleep curriculum development (Saint Joseph's University, Philadelphia, Pennsylvania), Jessica Beiler, MPH, Jennifer Stokes, RN, Patricia Carper, RN, Amy Shelly, LPN, Gabrielle Murray, RN, Heather Stokes, and Nicole Verdiglione for their assistance in recruiting and retaining participants, intervention delivery, and data collection (Pennsylvania State College of Health and Human Development), Susan Rzcudlo, MSN, RN, for contributing to the safety control curriculum development (Pennsylvania State College of Health and Human Development), Lindsey Hess, MS, Emily Hohman, PhD, Chelsea Rose, PhD, Katherine Balantekin, PhD, RD, and Julia Bleser, MS, for assisting with data collection and data management (The Center for Childhood Obesity Research, Pennsylvania State University), and Eric Loken, PhD, for statistical advising

(Pennsylvania State University). Drs Birch and Paul are principal investigators on the National Institutes of Health grant R01DK088244 that supported the study.

### REFERENCES

- Mei Z, Grummer-Strawn LM, Scanlon KS. Does overweight in infancy persist through the preschool years? an analysis of CDC Pediatric Nutrition Surveillance System data. *Soz Preventivmed*. 2003; 48(3):161-167.
- Stettler N, Zemel BS, Kumanyika S, Stallings VA. Infant weight gain and childhood overweight status in a multicenter, cohort study. *Pediatrics*. 2002; 109(2):194-199.
- 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(4):1177-1183.
- Leunissen RW, Kerkhof GF, Stijnen T, Hokken-Koelega A. Timing and tempo of first-year rapid growth in relation to cardiovascular and metabolic risk profile in early adulthood. *JAMA*. 2009;301(21):2234-2242.
- Barker DJ, Osmond C, Forsén TJ, Kajantie E, Eriksson JG. Trajectories of growth among children who have coronary events as adults. *N Engl J Med*. 2005;353(17):1802-1809.
- Bhargava SK, Sachdev HS, Fall CH, et al. Relation of serial changes in childhood body-mass index to impaired glucose tolerance in young adulthood. *N Engl J Med*. 2004;350(9):865-875.
- Paul IM, Camera L, Zeiger RS, et al; Childhood Asthma Research and Education (CARE) Network. Relationship between infant weight gain and later asthma. *Pediatr Allergy Immunol*. 2010;21(1 Pt 1): 82-89.

8. Gluckman PD, Hanson MA. Developmental and epigenetic pathways to obesity: an evolutionary-developmental perspective. *Int J Obes (Lond)*. 2008;32(suppl 7):S62-S71.
9. Gluckman PD, Hanson MA, Cooper C, Thornburg KL. Effect of in utero and early-life conditions on adult health and disease. *N Engl J Med*. 2008;359(1):61-73.
10. Paul IM, Bartok CJ, Downs DS, Stifter CA, Ventura AK, Birch LL. Opportunities for the primary prevention of obesity during infancy. *Adv Pediatr*. 2009;56(1):107-133.
11. Gillman MW, Rifas-Shiman SL, Kleinman K, Oken E, Rich-Edwards JW, Taveras EM. Developmental origins of childhood overweight: potential public health impact. *Obesity (Silver Spring)*. 2008;16(7):1651-1656.
12. Anderson SE, Whitaker RC. Household routines and obesity in US preschool-aged children. *Pediatrics*. 2010;125(3):420-428.
13. Hesketh KD, Campbell KJ. Interventions to prevent obesity in 0-5 year olds: an updated systematic review of the literature. *Obesity (Silver Spring)*. 2010;18(1s)(suppl 1):S27-S35.
14. Paul IM, Savage JS, Anzman SL, et al. Preventing obesity during infancy: a pilot study. *Obesity (Silver Spring)*. 2011;19(2):353-361.
15. Paul IM, Williams JS, Anzman-Frasca S, et al. The Intervention Nurses Start Infants Growing on Healthy Trajectories (INSIGHT) study. *BMC Pediatr*. 2014;14:184.
16. Eshel N, Daelmans B, de Mello MC, Martines J. Responsive parenting: interventions and outcomes. *Bull World Health Organ*. 2006;84(12):991-998.
17. Bernier A, Carlson SM, Deschênes M, Matte-Gagné C. Social factors in the development of early executive functioning: a closer look at the caregiving environment. *Dev Sci*. 2012;15(1):12-24.
18. Guttentag CL, Landry SH, Williams JM, et al. "My Baby & Me": effects of an early, comprehensive parenting intervention on at-risk mothers and their children. *Dev Psychol*. 2014;50(5):1482-1496.
19. Sulik MJ, Blair C, Mills-Koonce R, Berry D, Greenberg M; Family Life Project Investigators. Early parenting and the development of externalizing behavior problems: longitudinal mediation through children's executive function. *Child Dev*. 2015;86(5):1588-1603.
20. Dexter CA, Wong K, Stacks AM, Beehly M, Barnett D. Parenting and attachment among low-income African American and Caucasian preschoolers. *J Fam Psychol*. 2013;27(4):629-638.
21. Ong KK, Loos RJ. Rapid infancy weight gain and subsequent obesity: systematic reviews and hopeful suggestions. *Acta Paediatr*. 2006;95(8):904-908.
22. Young BE, Johnson SL, Krebs NF. Biological determinants linking infant weight gain and child obesity: current knowledge and future directions. *Adv Nutr*. 2012;3(5):675-686.
23. Monteiro PO, Victora CG, Barros FC, Monteiro LM. Birth size, early childhood growth, and adolescent obesity in a Brazilian birth cohort. *Int J Obes Relat Metab Disord*. 2003;27(10):1274-1282.
24. Butte NF, Wong WW, Hopkinson JM, Smith EO, Ellis KJ. Infant feeding mode affects early growth and body composition. *Pediatrics*. 2000;106(6):1355-1366.
25. van der Willik EM, Vrijkotte TGM, Altenburg TM, Gademan MGJ, Kist-van Holthe J. Exclusively breastfed overweight infants are at the same risk of childhood overweight as formula fed overweight infants. *Arch Dis Child*. 2015;100(10):932-937.
26. Karp H. *Happiest Baby on the Block: The New Way to Calm Crying and Help your Baby Sleep Longer* [DVD]. Los Angeles, CA: The Happiest Baby Inc; 2006.
27. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381.
28. Centers for Disease Control and Prevention. Infant Feeding Practices Study II and its year six follow up. <http://www.cdc.gov/breastfeeding/data/ifps/introduction.htm>. Accessed September 11, 2015.
29. Li R, Fein SB, Grummer-Strawn LM. Association of breastfeeding intensity and bottle-emptying behaviors at early infancy with infants' risk for excess weight at late infancy. *Pediatrics*. 2008;122(suppl 2):S77-S84.
30. World Health Organization. The WHO child growth standards. [http://www.who.int/childgrowth/standards/Technical\\_report.pdf](http://www.who.int/childgrowth/standards/Technical_report.pdf). Accessed April 2015.
31. Griffiths LJ, Smeeth L, Hawkins SS, Cole TJ, Dezateux C. Effects of infant feeding practice on weight gain from birth to 3 years. *Arch Dis Child*. 2009;94(8):577-582.
32. Daniels SR, Hassink SG; Committee on Nutrition. The role of the pediatrician in primary prevention of obesity. *Pediatrics*. 2015;136(1):e275-e292.
33. 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: randomised controlled trial. *BMJ*. 2012;344:e3732.
34. 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 (Lond)*. 2012;36(10):1292-1298.
35. 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*. 2016;12(1):24-38.
36. Jahromi LB, Stifter CA. Individual differences in the contribution of maternal soothing to infant distress reduction. *Infancy*. 2007;11:255-269. doi:10.1111/j.1532-7078.2007.tb00226.x.
37. Anzman SL, Birch LL. Low inhibitory control and restrictive feeding practices predict weight outcomes. *J Pediatr*. 2009;155(5):651-656.
38. Druet C, Stettler N, Sharp S, et al. Prediction of childhood obesity by infancy weight gain: an individual-level meta-analysis. *Paediatr Perinat Epidemiol*. 2012;26(1):19-26.
39. Ochiai H, Shirasawa T, Ohtsu T, et al. Number of siblings, birth order, and childhood overweight: a population-based cross-sectional study in Japan. *BMC Public Health*. 2012;12(1):766.
40. Siervo M, Horta BL, Stephan BC, Victora CG, Wells JC. First-borns carry a higher metabolic risk in early adulthood: evidence from a prospective cohort study. *PLoS One*. 2010;5(11):e13907.