

Supplementary Online Content

Paul IM, Savage JS, Anzman-Frasca S, et al. Effect of a responsive parenting educational intervention on childhood weight outcomes at 3 years of age: the INSIGHT randomized clinical trial. *JAMA*. doi:10.1001/jama.2018.9432.

eMethods.

eResults.

eTable 1. Breastfeeding Rates at Study Assessment Points

eTable 2. Study Attrition Through 3 Years By Demographic Group

eTable 3. Summary Statistics for BMI z Scores at 3 Years for the Complete Data Set (A) and the Imputed Data Sets (B)

eTable 4. Linear Model Estimates for Responsive Parenting Group vs Control From Both Completer and Imputed 3 Year BMI z Scores Data Sets

This supplementary material has been provided by the authors to give readers additional information about their work.

eMethods.

Intervention Fidelity and Maternal Acceptance of the Interventions. To monitor drift in intervention fidelity and contextual issues that may influence the implementation and receipt of the intervention, ongoing measures of adherence and competence were assessed. First, fidelity of message delivery was assessed at the end of each home visit by participating mothers. Mothers were given a list of 12 to 16 topics that addressed both RP and safety issues that were to be delivered during the home visit, and were asked to select which topics had been covered by their nurse during each visit. In addition, following every visit, research nurses completed a self-report checklist of intervention messages delivered. Research nurses also audio-recorded each of the home visits (e.g., 3, 16, 28, 40 weeks) every 6 months, after receiving verbal consent from the participant to record the session. Project managers and other trained observers provided ongoing coaching and supervision to the research nurses in a report.

Regarding maternal acceptance of the intervention, at 3, 16 and 28 weeks, mothers indicated their agreement with the following statement, “I think the lessons that I am learning in this program will work with my baby.” At 16 and 28 weeks mothers were also asked, “The information provided in the previous visit has helped me care for my baby.” Possible responses to these questions were: strongly agree, agree, neither agree nor disagree, disagree or strongly disagree.

Multiple Imputation Analyses of the Study Primary Outcome. The complete data analysis presented in the manuscript included 232 of the initial 279 participants (83% retention). Of the 47 missing cases due to attrition, 24 were from the RP group and 23 from the control group. Attrition is plausibly at worst missing at random (MAR), and so a multiple imputation analysis was performed. Missing data were imputed for predictor variables and the primary outcome variable, BMI z-score at age 3 years. The following variables were included as covariates in the imputation models: maternal pre-pregnancy BMI, maternal age, child sex, and child birthweight and weight-for-length at the 3-4 week study visit. Assuming a joint multivariate normal distribution, iterative Markov chain Monte Carlo (MCMC) imputation was used. Estimates of mean, minimum, maximum and variance are reported for both the imputed data sets and for the data set that resulted from the observation of the 232 participants who completed the study (referred to as ‘completers’).

Conditional Weight Gain During Infancy and Weight Outcomes at Age 3 Years. Conditional weight gain z-scores have a mean of zero; positive 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. Linear regression analysis examined the association between conditional weight gain between birth and 28 weeks with BMI z-score at 3 years. To further describe this association, scores were dichotomized to 2 groups (negative vs. positive), and chi-square tests were used to determine the association between early rapid growth and overweight and obese status at 3 years.

eResults.

Intervention Fidelity and Maternal Intervention Acceptance. For intervention fidelity, RP group mothers reported at 3, 16, 28 and 40 weeks that the research nurses delivered 96%, 88%, 91% and 97% of the outlined RP content, respectively. For maternal acceptance, $\geq 98\%$ of mothers in both study groups agreed or strongly agreed that the information they learned at 3-4, 16, and 28 weeks will work with their infant, and $\geq 97\%$ agreed or strongly agreed at 16 and 28 weeks that the previously delivered intervention content had been helpful for caring for their infant.

Primary Outcome Analyses Using Multiple Imputation. Using 10 imputations, we report the maximum, mean and variance for each variable (Supplemental Table 1). Estimating the treatment effect across the imputed datasets had high relative efficiency (97%), with a final estimated treatment effect for BMI z-score at age 3 years being slightly stronger than the complete data analysis reported in the manuscript (Supplemental Table 2).

Accelerated Infant Weight Gain Outcomes. The pre-specified intervals of birth to 4 months and birth to 1 year were analyzed to determine if there were study group differences for the prevalence of +0.67 z-score change in weight-for-age, which has been referred to as accelerated weight gain. For the interval of birth to 4 months, 12 of 134 (9.0%) infants in the RP group had accelerated weight gain compared with 16 of 135 (11.9%) controls ($P=0.44$). For the interval of birth to 1 year, 31 of 127 (32.3%) infants in the RP group had accelerated weight gain compared with 31 of 126 (34.1%) controls ($P=0.97$). The pre-specified intervals of birth to 3 years and 1 year to 3 years could not be analyzed as originally intended given that the standard growth references are different for children <2 years than those 2 years and older.

Conditional Weight Gain During Infancy and Weight Outcomes at Age 3 years. The mean conditional weight gain score from birth to 28 weeks for RP infants was -0.18 (95% CI, -0.36 to 0), reflecting a slower than average pattern of weight gain, but +0.18 for controls (95% CI, 0.02-0.34), reflecting faster weight gain ($P=.004$). Post-hoc analyses show that conditional weight gain from birth to 28 weeks was positively related to BMI z-score at 3 years ($P<.001$, $R^2=0.30$). Further, at age 3 years, compared with participants with negative conditional weight gain, those with a positive score were more likely to be overweight (25.9% vs. 6.5%; $P<.001$) or obese (8.3% vs. 1.6%; $P=.009$).

eTable 1. Breastfeeding Rates at Study Assessment Points

	Percent of mothers who predominantly breastfed (>80 %) at each time			
	Randomization N (%)	16 weeks N (%)	28 weeks N (%)	40 weeks N (%)
Responsive Parenting	84 of 140 (60.0%)	66 of 133 (49.6%)	45 of 129 (34.9%)	43 of 129 (33.3%)
Control	83 of 139 (59.7%)	62 of 134 (46.3%)	52 of 132 (39.4%)	42 of 130 (32.3%)
P^a	0.96	0.58	0.45	0.86

^aP values were determined using χ^2 tests.

eTable 2. Study Attrition Through 3 Years By Demographic Group

	Completed 3 Year Study Visit (n=232)	Withdrew from Study (n=47)	P Value ^a
Infant			
Male sex, No. (%)	121 (52.2)	23 (48.9)	.69
Gestational age, mean (SD), wk	39.5 (1.2)	39.5 (1.0)	.85
Birth weight, mean (SD), kg	3.4 (0.4)	3.4 (0.4)	.77
Birth length, mean (SD), cm	50.9 (2.4)	51.2 (1.8)	.34
Birth body mass index, mean (SD), kg/m ²	-0.41 (1.23)	-0.71 (1.24)	.13
Mother			
Age, mean (SD), y	29.3 (4.6)	25.7 (4.6)	<.001
Pre-pregnancy BMI, mean (SD), kg/m ²	25.7 (5.4)	24.3 (4.5)	.12
Gestational weight gain, mean (SD), kg	15.0 (6.2)	16.7 (6.2)	.10
Diabetes during pregnancy, No. (%)	15 (6.5%)	4 (8.5%)	.13
Smoked during pregnancy, No. (%)	15 (6.5%)	6 (12.8%)	.14
Hispanic Ethnicity No. (%)	12 (5.2%)	7 (14.9%)	.02
Race No. (%)			.002
Black	11 (4.7%)	9 (19.2%)	
White	207 (89.2%)	33 (70.2%)	
Native Hawaiian or Pacific Islander	1 (0.4%)	0 (0%)	
Asian	7 (3.0%)	2 (4.3%)	
Other	6 (2.6%)	3 (6.4%)	
Marital status No. (%)			<.001
Married	188 (81.0%)	22 (46.8%)	
Not married, living with partner	32 (13.8%)	12 (25.5%)	
Single	11 (4.7%)	13 (27.7%)	
Divorced/separated	1 (0.4%)	0 (0%)	
Education No. (%)			<.001
High school graduate or less	13 (5.6%)	19 (40.4%)	
Some college	54 (23.3%)	19 (40.4%)	
College graduate	97 (41.8%)	3 (6.4%)	
≥Graduate degree	68 (29.3%)	6 (12.8%)	

^aP values were determined using t tests for means or χ^2 tests for categorical variables.

eTable 3. Summary Statistics for BMI z Scores at 3 Years for the Complete Data Set (A) and the Imputed Data Sets (B)

A. Summary statistics for variables used in imputation process from completers (N=232)					
Variable	N	Mean	Minimum	Maximum	Variance
BMI z-score	232	0.01	-3.17	2.69	1.02
Birthweight (kg)	279	3.43	2.50	4.86	0.18
Weight-for-length z-score at 3-4 weeks	279	-0.33	-3.11	2.46	0.91
Mother pre-pregnancy BMI, kg/m²	278	25.43	16.37	47.80	28.07
Mother age, y	279	28.69	20.30	42.94	22.66
Child sex	279	---	1	2	---
B. Summary statistics for variables used in imputation process resulting from 10 imputed data sets					
Variable	N	Mean	Minimum	Maximum	Variance
BMI z-score	2790	0.01	-3.17	2.69	1.00
Birthweight (kg)	2790	3.43	2.50	4.86	0.18
Weight-for-length z-score at 3-4 weeks	2790	-0.33	-3.11	2.46	0.91
Mother pre-pregnancy BMI, kg/m²	2790	25.43	15.20	47.80	28.06
Mother age, y	2790	28.69	20.30	42.94	22.59
Child sex	2790	---	1	2	----

eTable 4. Linear Model Estimates for Responsive Parenting Group vs Control From Both Completer and Imputed 3 year BMI z Scores Data Sets

Estimates for Imputed Data Sets*					
Parameter	Effect Estimate	Standard Error	95% CI	# Imputations	P Value^a
RP Intervention	-0.30	0.14	-0.57, -0.03	10	0.03
*For 10 imputations: Relative efficiency: 0.97					
Estimates for Completer Data Set (N=232)					
Parameter	Effect Estimate	Standard Error	95% CI	# Imputations	P Value^a
RP Intervention	-0.27	0.13	-0.54, -0.01	---	0.04

^aP values were determined using ANOVA.