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The effect of a general healthy lifestyle intervention delivered around pregnancy on gestational weight gain and infant growth.

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Abstract

Objectives: A life-course perspective emphasizes healthy behaviors before, during, and after pregnancy to support a multi-generational risk reduction in obesity for mothers and infants. Optimal timing, content, and dose of such interventions is not well defined.

Methods: We conducted a nested cohort within a randomized trial to evaluate whether a healthy lifestyle intervention around pregnancy led to a “spill-over effect,” including a healthier rate (kg/week) of maternal gestational weight gain, and infant growth during the first year. Study enrollment began in 2012, follow-up data collection completed in 2018, and the data were analyzed in 2019. The intervention focused on healthy maternal diet and physical activity but not pregnancy weight or infant feeding. Outcome data were abstracted from electronic medical records.

Results: Of the 165 women who became pregnant, 114 enrolled in the nested cohort. The average pre-pregnancy BMI was 29.6 (SD 5.1) kg/m². Mixed effects models suggested clinically insignificant differences in both the rate of gestational weight gain (−0.02 kg/week; 95% CI −0.09, 0.06) and the rate of infant growth (difference at 1 year: −0.002 kg/cm; 95% CI −0.009, 0.005).

Conclusions for Practice: A behavioral intervention that focused on overall maternal health delivered in the time around pregnancy did not result in a “spill-over effect” on healthy gestational weight gain or healthy infant growth during the first year of life.

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Keywords

Obesity; Behavioral Intervention; Pregnancy; Gestational Weight Gain; Infancy

Introduction

The peri-partum period is a key opportunity to intervene to prevent long-term obesity-related health outcomes in both mothers and their children (Oken & Gillman, 2003; Oken, Kleinman, Belfort, Hammitt, & Gillman, 2009; Oken, Taveras, Kleinman, Rich-Edwards, & Gillman, 2007; Oteng-Ntim, Varma, Croker, Poston, & Doyle, 2012; Wrotniak, Shults, Butts, & Stettler, 2008). For mothers, weight gain during pregnancy is adaptive, but excess weight gain during pregnancy and postpartum weight retention contribute to the development of obesity during a woman's childbearing years. For children, the notion of primordial childhood obesity prevention highlights the importance of the early weeks of pregnancy for influencing a child's weight status throughout life (Gillman, 2015). Furthermore, minority ethnic and low-income populations are disproportionately affected by pre-pregnancy obesity, excess gestational weight gain, inadequate postpartum weight loss, and subsequent childhood obesity (Hales, Fryar, Carroll, Freedman, Aoki, et al., 2018; Hales, Fryar, Carroll, Freedman, & Ogden, 2018; Krukowski, Bursac, McGehee, & West, 2013; Ogden et al., 2016; Walker et al., 2004). Thus, effective interventions for healthy behaviors to improve maternal and child weight before, during, and after pregnancy would have broad-reaching implications for reducing multi-generational obesity and potentially reducing health disparities.

Until recently, attempts to support appropriate gestational weight gain have met with limited success (Oteng-Ntim et al., 2012; Skouteris et al., 2010). The recent publication of data from the LIFE-Moms consortium demonstrated that lifestyle interventions can support healthy gestational weight gain (Peaceman et al., 2018). Gestational weight gain in the first trimester is most tightly linked to birthweight. Intervening before or during early pregnancy is thus viewed as an optimal time to prevent adverse long-term weight-related outcomes. However, enrolling women in behavioral interventions during this time is challenging, and gestational weight gain interventions that begin in the second trimester may be too late to have meaningful impact on infant growth parameters (Broskey et al., 2017; Catalano & Shankar, 2017). This leads to an unanswered question: could a general healthy-lifestyle intervention delivered before, during and/or after pregnancy potentially affect concurrent pregnancy health and infant health?

We conducted a nested cohort study within a randomized controlled trial (RCT) to determine if a general healthy-lifestyle intervention delivered before, during, and/or after pregnancy improved maternal gestational weight gain and subsequent infant growth during the first year of life. The Growing Right Onto Wellness (GROW) Trial targeted childhood obesity prevention and was delivered to parent-child pairs in local community centers (Barkin et al., 2018). The trial was not targeted at pregnancy or infant weight outcomes, but rather was focused on developing life-long patterns of healthy diet and physical activity for the

participating parent-preschool child pair. The control was a school-readiness educational program delivered to families at local community centers. We hypothesized that there would be improvement in both gestational weight gain and infant growth among mothers who became pregnant over the course of the study, comparing those mothers randomized to the intervention compared to the control group.

Methods

Study Design

We included women in this nested-cohort analysis who reported a live birth during the Growing Right Onto Wellness Trial ([clinicaltrials.gov: NCT01316653](https://clinicaltrials.gov/ct2/show/study/NCT01316653)) (Barkin et al., 2018). Study enrollment began in 2012, follow-up data collection completed in 2018, and the data were analyzed in 2019. The intervention was a healthy-lifestyle intervention directed at parents and preschool aged children in low-income minority families. Intervention content focused on parent-child skills building in health behaviors. Each session was designed to address specific skills related to key content areas (healthy diet, physical activity, sleep, and media use), and included activities like how to read a food label, how to use the local workout facilities, and how to use a schedule to help with sleep and media use at home. Sessions were built around the social cognitive theory and focused on building self-efficacy through goal-setting, self-monitoring, and problem solving. Intervention content did not address specific pregnancy behaviors or other behaviors known to influence healthy infant growth (e.g., breastfeeding, early introduction of solids). The active phase of the intervention was one year, consisting of a three-month period of weekly in-person sessions followed by nine months of monthly coaching calls; this was then followed by two years of passive intervention providing newsletters, texts, and phone calls to connect families to existing resources to support healthy family behaviors. Vanderbilt University Medical Center IRB approved the study protocol (IRB No. 120643). Participants signed informed consent for the original trial and the nested cohort.

Setting/Participants

Eligibility criteria for the original trial included: 1) index child ages 3–5 years old, 2) household qualifying for at least one governmental service for underserved populations, 3) living in Nashville, TN within five miles of a participating community center, 4) parent speaking English or Spanish, and 5) parent agreement to be in a three-year study. For the nested cohort, mothers had to report a live singleton birth during the three-year study period. Infants with known genetic conditions predisposing to abnormal growth (e.g., Down Syndrome) or prematurity (estimated gestational age <34 weeks) were excluded, as were their mothers.

Data Sources

Data were collected from multiple sources for this nested cohort analysis. As all mothers were originally enrolled in an RCT, prospectively collected data on height and weight were measured prior to pregnancy for the majority of women in the nested cohort. Demographic characteristics, including ethnicity and participation in SNAP or WIC, were reported from baseline data of the original trial. Outcome data for the nested cohort, including gestational

weight gain and infant growth, were abstracted from medical records of the participants' medical providers, including obstetric outpatient and inpatient records and pediatric outpatient and inpatient records.

Exposures and Outcomes

The primary exposure was randomization status (intervention vs. control) in the original RCT. Two co-primary outcomes were considered: maternal gestational weight gain and infant growth (reported as weight-for-length) over the first year of life. We also examined the secondary outcome of postpartum weight retention. We conducted exploratory analyses to determine whether the intervention effect differed according to the timing of the pregnancy with respect to exposure to specific phases of the GROW trial.

Gestational weight gain outcomes were reported continuously (kg) and also categorized based on 2009 guidelines from the Institute of Medicine (Institute of Medicine, 2009). A mother's pre-pregnancy weight was determined using an algorithm to select the highest quality data available, prioritizing as follows: 1) prospectively collected weight measured within 180 days before the estimated last menstrual period, 2) prospectively collected weight measured within 84 days after the estimated last menstrual period, 3) weight from the medical record measured within 84 days after the estimated last menstrual period, 4) the average of any prospectively collected weights measured more than 180 days before the estimated last menstrual period, and 5) self-reported pre-pregnancy weight. For participants with measurements in two or more of these categories, the values were highly correlated (Spearman's rho ranged from 0.95 to 0.98 for correlations with the prospectively collected weight measured within 180 days before the estimated last menstrual period).

Infant growth outcomes were reported as weight/length, and also converted to weight-for-length percentiles and z-scores based on the standardized World Health Organization growth curves ("World Health Organization Growth Charts," 2007).

Postpartum weight measurements from seven days through three months postpartum were collected from the medical record.

Statistical Methods

The unadjusted rate of gestational weight gain was calculated by subtracting the mother's first recorded pregnancy weight from the mother's final recorded pregnancy weight, then dividing by the elapsed time between the two measurements; this rate was then multiplied by the length of the pregnancy to obtain an estimated total gestational weight gain (Heerman, Bian, Shintani, & Barkin, 2014; Heerman et al., 2019). For infants, we calculated weight-for-length percentiles at 6 and 12 months ($\pm$ 30 days) using the WHO Anthro macros (<https://www.who.int/childgrowth/software/en/>). We first present the observed differences in 1) gestational weight gain (kg/week), and 2) child weight/length percentiles at 6- and 12-months of age between intervention and control groups.

To gain more accurate and precise estimates of the effect of the intervention, we analyzed the effects of the intervention on gestational weight gain and infant growth using adjusted mixed effects models. For gestational weight gain, we specified a linear relationship between

weeks of gestation and maternal weight (Singer & Willett, 2003). We allowed both the slope and the intercept of this relationship to vary by intervention status, pre-pregnancy BMI, gestational number, and participation in SNAP/WIC (no vs. yes or missing); we also allowed the intercept to vary by age at conception and race/ethnicity (Hispanic Mexican, Hispanic non-Mexican, Non-Hispanic). For infant growth, we specified a curvilinear relationship between infant age and weight-for-length, including terms for both age in weeks and its square root. We allowed both the curvature and the intercept of this relationship to vary by intervention status and mother's participation in SNAP/WIC (no vs. yes or missing); we also allowed the intercept to vary by the biological sex of the infant and the mother's race/ethnicity (Hispanic Mexican, Hispanic non-Mexican, Non-Hispanic). Models for both outcomes included random slopes/curvatures and random intercepts to account for within-subject correlation.

To test for the presence of a statistically significant relationship between intervention arm and gestational weight gain or infant growth, we conducted likelihood ratio tests in which we compared our analytical models to models that did not allow the slope/curvature to vary by intervention group but were otherwise identical to the main models. P-values below our pre-specified threshold of 0.05 would allow us to reject the hypothesis that the intervention had no effect on gestational weight gain or infant growth.

In our exploratory analysis of the relationship between intervention status and postpartum weight retention, we used a primarily cross-sectional model, because for most mothers we had only one postpartum weight measurement (if any) from the seven days to three months postpartum period. We used an ordinary least squares approach with clustered robust standard errors to account for the cases where we did have multiple observations per mother. We modeled the postpartum outcome as BMI. Our model adjusted for mother's pre-pregnancy BMI and age at the baby's birth, the gestational number, delivery type (Caesarean section vs. vaginal), study group, and time, allowing the effect of time to vary by pre-pregnancy BMI, delivery type, and study group. To test for the presence of a statistically significant relationship between intervention status and postpartum BMI across all timepoints, we conducted a 2-d.f. likelihood ratio test. We then calculated post-estimation contrasts to examine the relationship between study group and postpartum weight for mothers of average height at particular postpartum timepoints (including five weeks postpartum and eight weeks post-partum).

To explore how the timing of pregnancy relative to the start of the study was related to gestational weight gain and infant growth outcomes, we conducted exploratory interaction analyses where we allowed the intervention effect to vary according whether the pregnancy started before, during, or after the intervention. To further explore this relationship, we also conducted exploratory subgroup analyses within the group of mothers whose pregnancy started before or during the active phase of the intervention. For this group, we replaced the binary intervention indicator with the percentage of the pregnancy that overlapped the active phase of the intervention (set to zero for control participants). Within the group of mothers whose pregnancy started after the active phase of the intervention, we explored how the number of actual contact hours or "dose delivered" of the intervention was associated with gestational weight gain and infant growth outcomes by replacing the binary intervention

indicator with the total number of contact hours received during the intervention (set to zero for control participants).

Analyses were conducted using R statistical software, version 3.5.2 (R Core Team, 2017).

Results

Among 165 women who reported a pregnancy, 154 (93%) subsequently reported a live birth; of the remaining women, 114 (74%) agreed to participate in this secondary cohort analysis (Figure 1). At the 5% significance level, baseline demographic characteristics did not differ between participants and non-participants (data not shown). Gestational weight gain data were available on 111 of the 114 women, and infant growth data were available for all infants. Table 1 displays baseline characteristics of parent-child pairs, according to whether women were randomized to the intervention or control group. [Table 1] Among the 114 women in this nested cohort, the average age at last menstrual period was 30.9 (SD 4.5) years, the average pre-pregnancy BMI was 29.6 (SD 5.1) kg/m², 105 (92.1%) identified as Latino and 9 (7.9%) identified as African American. The majority of families received WIC or SNAP services (96/112; 85.7%). Among infants, the average birthweight was 3.4 (SD 0.5) kg, and the average estimated gestational age was 39.0 (SD 1.4) weeks, with eight infants born between 34 and 37 weeks gestation.

The distribution of start of pregnancy with respect to the timing of the intervention is as follows: 19 participants (16.7%) were already pregnant at the start of the intervention, 44 (38.6%) became pregnant during the active phase of the intervention, and 51 (44.7%) became pregnant after the active phase (Online Resource 1). Among the 34 intervention group participants whose pregnancy started before or during the active phase of the intervention, the median amount of overlap was 100% (that is, the entire pregnancy took place during the active phase of the intervention) (interquartile range (IQR) 69%, 100%). Among the 31 intervention group participants whose pregnancy started after the active phase of the intervention, the median number of contact hours was 23.5 (IQR 17.8, 26.0), out of a maximum of 26 hours.

Gestational Weight Gain

The mean unadjusted rate of gestational weight gain among the 65 mothers randomized to the intervention group was 0.3 (SD 0.2) kg/week compared to 0.3 (SD 0.3) kg/week among the 49 mothers randomized to the control group. Using the 2009 IOM guidelines for gestational weight gain, the distribution for the intervention group was: 17 (27.4%) inadequate, 13 (21.0%) appropriate, 32 (51.6%) excessive. Comparatively, the distribution for the control group was: 10 (20.8%) inadequate, 10 (20.8%) appropriate, 28 (58.3%) excessive. There were no statistically significant differences in the distribution of categorical weight gain comparing intervention vs. control ($p=0.7$). The covariate-adjusted mixed effects model demonstrated an intervention effect of -0.016 kg/week on gestational weight gain (95% CI $-0.094, 0.062$). That is, the rate of gestational weight gain was slightly lower in the intervention group; the confidence interval and the likelihood ratio test indicate that difference was not statistically significant at the 5% level ($p=0.69$). Figure 2 shows model-

based estimates for a typical covariate profile, and the full model results are provided in Online Resource 2.

Infant Growth

Among 114 infants included, the average weight-for-length percentile at six months was 56.9 (SD 27.8) in the intervention and 63.2 (SD 27.5) in the control group. The average weight-for-length percentile at 12 months was 59.0 (SD 28.4) in the intervention and 56.9 (SD 29.7) in the control group. The covariate-adjusted mixed effects model demonstrated essentially no difference in infant growth for the intervention group compared to the control group over the first year of life. Because we used two terms to model time in this model, we do not present individual coefficient estimates. Figure 3, which shows model-based estimates for a typical covariate profile, indicates that the estimated growth in the two groups were nearly identical. At one year, the estimated group difference (intervention minus control) was -0.002 kg/cm (95% CI -0.009 , 0.005). A likelihood ratio test indicated that the overall intervention effect was not statistically significant at the 5% level ($p=0.57$). The full model results are provided in Online Resource 3.

Exploratory Analyses

Of the 114 women enrolled, pre-pregnancy and postpartum weight data were available for 81 (43 intervention, 38 control). Among the intervention group, mean postpartum weight retention in the first 90 days postpartum was 1.2 (SD 4.6) kg, versus 1.8 (SD 5.0) kg in the control group; the mean measurement times in the two groups were 49 (SD 18) and 47 (SD 16) days postpartum, respectively (here we use only the second measurement for the 20 participants who had two postpartum weight measurements). The adjusted multivariable linear regression revealed a statistically significant intervention effect at five weeks postpartum, with women in the intervention group retaining an estimated 2.1 kilograms less than women of the same height in the control group (95% CI 0.1 , 4.1 ; $p = 0.039$). However, at eight weeks postpartum, the difference between groups was negligible. Neither timing of when mothers became pregnant during the intervention nor the total number of intervention contact hours received were significantly associated with differences in GWG or infant growth (p -values ranged between 0.5 and 0.7 for these tests).

Discussion

This nested cohort analysis did not detect a statistically significant effect of a healthy lifestyle intervention delivered before, during, or after pregnancy on either maternal gestational weight gain or subsequent infant growth over the first year of life. Because the precision of the effect estimates, as indicated by the 95% confidence intervals, suggested a clinically insignificant difference in both of the primary outcomes, we believe that the intervention had a negligible effect, at best.

Pregnancy continues to be a promising time for obesity interventions. A 2013 study found 73% of women exceeded the gestational weight gain recommendations set by the Institute of Medicine in 2009 (Johnson et al., 2013). Many women also retain weight beyond the immediate postpartum period, with around 75% of women weighing more at one year after

giving birth compared to pre-pregnancy (Endres et al., 2015). Postpartum weight retention is an important predictor of increased BMI, even up to at least a decade after giving birth (Rooney & Schauburger, 2002). The current study showed early improvements in post-partum weight change that were not sustained at eight weeks post-partum. With the current emphasis on developing multi-generational solutions to obesity, and the significant challenges related to improving gestational weight gain and supporting healthy infant growth, novel intervention strategies are needed. The data from the current study have important implications for the design and implementation of future obesity interventions delivered in the peri-pregnancy period. Specifically, these data would suggest that relying on a “spill-over” effect of a general healthy lifestyle intervention for women of child-bearing age is not sufficient to alter either gestational weight gain or infant growth. Thus, healthy lifestyle interventions delivered pre-pregnancy or early in pregnancy should specifically target behaviors known to affect pregnancy weight gain and infant growth.

Limitations

This study has several limitations. First, residual confounding is a potential problem in all cohort studies. The nested study design limits this, as randomization should account for unmeasured confounders. Second, because not all participants enrolled in the nested cohort, the possibility of selection bias must be considered. For example, mothers with the highest rates of gestational weight gain from the control group may have been less likely to enroll in this nested cohort. Third, there may have been measurement errors, as most outcome data were from chart review. Fourth, we elected to model gestational weight gain linearly, which may have obscured important trimester-specific differences in gestational weight gain between intervention and control groups. Finally, the effect size that was observed was smaller than expected. The analysis was adequately powered to detect clinically meaningful changes in the primary outcomes (i.e., kg/week), but the sample size was inadequate to evaluate additional exploratory questions of interest, including sub-group analyses or how timing of the health behavior intervention was associated with the outcomes.

Conclusions

A general healthy lifestyle intervention delivered around the timing of pregnancy did not result in statistically significant improvements in maternal gestational weight gain and subsequent infant growth during the first year of life.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Individual participant data from the original randomized controlled trial and data dictionaries will be made available via the NIH BioLINCC website (<https://biolincc.nhlbi.nih.gov/home/>), no later than 3 years after the end of the trial (final patient follow-up) or 2 years after the main paper of the trial has been published. The study protocol and statistical analysis plan for the original randomized trial have already been made available.

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Significance:

What is already known on this subject?

Excess weight gain during pregnancy and postpartum weight retention contribute to obesity development in women during childbearing years and disproportionately affect ethnic minority and low-income populations. Previous interventions to support healthy gestational weight gain have met with limited success, and enrolling women during the first trimester is challenging.

What this study adds

A general healthy lifestyle intervention delivered before, during, or after pregnancy did not improve gestational weight gain and subsequent infant growth during the first year of life. Future interventions should target behaviors that affect gestational weight gain and early infant growth.

Figure 1.
Cohort flow diagram

Figure 2.
Model-based estimates of gestational weight gain

Figure 3.
Model-based estimates of infant growth during the first year of life

Table 1:

Baseline characteristics of mothers enrolled in study by randomization status from the original RCT

	N	Control N=49	Intervention N=65	Combined N=114	Test Statistic
Race/ethnicity	114				$\chi^2_2=4.79$, $P=0.091^a$
Hispanic Mexican		69.4% (34)	61.5% (40)	64.9% (74)	
Hispanic non-Mexican		18.4% (9)	33.8% (22)	27.2% (31)	
Non-Hispanic		12.2% (6)	4.6% (3)	7.9% (9)	
Participation in SNAP or WIC	112	89.6% (43)	82.8% (53)	85.7% (96)	$\chi^2_1=1.03$, $P=0.311^a$
BMI (kg/m ²)	113	26.7 29.6 33.9	25.4 27.9 31.7	25.6 28.9 33.4	$F_{1,111}=2.46$, $P=0.12^b$
Years in USA	114	7.0 10.0 13.0	8.0 9.0 11.0	7.2 9.0 12.0	$F_{1,112}=0.97$, $P=0.326^b$
Employment	114				$\chi^2_2=0.18$, $P=0.915^a$
Working full time		16.3% (8)	13.8% (9)	14.9% (17)	
Working part time		16.3% (8)	15.4% (10)	15.8% (18)	
Not working for pay		67.3% (33)	70.8% (46)	69.3% (79)	
Married or living as married	114	77.6% (38)	81.5% (53)	79.8% (91)	$\chi^2_1=0.28$, $P=0.599^a$
Household income	113				$\chi^2_4=1.17$, $P=0.883^a$
\$14,999 or less		27.1% (13)	24.6% (16)	25.7% (29)	
\$15,000 - \$24,999		27.1% (13)	24.6% (16)	25.7% (29)	
\$25,000 - \$34,999		10.4% (5)	12.3% (8)	11.5% (13)	
\$35,000 or more		6.2% (3)	3.1% (2)	4.4% (5)	
Prefer not to answer		0.0% (0)	0.0% (0)	0.0% (0)	
Don't know		29.2% (14)	35.4% (23)	32.7% (37)	
High school education or above	114	40.8% (20)	36.9% (24)	38.6% (44)	$\chi^2_1=0.18$, $P=0.673^a$
Food insecurity level	114				$\chi^2_1=3.21$, $P=0.073^c$
Food secure		69.4% (34)	53.8% (35)	60.5% (69)	
Food insecure without hunger		18.4% (9)	23.1% (15)	21.1% (24)	
Food insecure with hunger		12.2% (6)	23.1% (15)	18.4% (21)	

a b c represent the lower quartile *a*, the median *b*, and the upper quartile *c* for continuous variables.

N is the number of non-missing values. Numbers after percentages are frequencies.

Tests used:

^a Pearson test;

^b Wilcoxon test;

^c Proportional odds likelihood ratio test.