



Published in final edited form as:

*Obesity (Silver Spring)*. 2019 May ; 27(5): 733–739. doi:10.1002/oby.22447.

## Ripple effect of lifestyle interventions during pregnancy on untreated partners' weight

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### Abstract

**Objective:** Weight loss interventions have a positive “ripple effect” on untreated partners weight, but ripple effects in pregnancy are unknown. The objective of this study is to determine whether prenatal lifestyle interventions that reduced gestational weight gain in pregnant women had a positive “ripple” effect on untreated partner weight.

**Methods:** Two clinical trials with the same outcome measures randomized pregnant women to lifestyle intervention or usual care. Untreated partners were randomized according to their pregnant partner's group allocation and assessed at study-entry (~13 weeks' gestation), 35 weeks' gestation, 6 and 12 months postpartum.

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**Author Contributions:**

TH had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. TH, SP, AG, and RW conceived and carried out the study. AS and TH conducted the analysis and interpretation of data. TH, SP, AS, AB, AM, RW, MAH, XPS, DG were responsible for data collection and management. TH drafted the manuscript. TH, SP, AS, AB, AM, RW, MAH, XPS, DG, AG provided critical revision of the manuscript for important intellectual content. TH, SP, RW, DG, XPS obtained funding. AB, AM, MAT, TH provided administrative, technical and material support. TH, SP, RW, DG provided study supervision.

**Disclosure:**

Suzanne Phelan received a grant from Weight Watchers International that was unrelated to this work. All other authors report no actual or potential conflicts of interest and no competing financial interests in relation to the work described.

Registered on [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier: NCT01770028

**Results:** 122 partners (100% male, 23% Hispanic, 82% married, 48% obese) were randomized to intervention (N=59) or usual care (N=63). There was no intervention or intervention by time interaction effect on partner weight ( $P = 0.795$ ). Partner weight changes were not statistically significant ( $P = 0.120$ ) from study-entry to 35 weeks' gestation (Mean 0.19 kg; 95% CI  $-0.73$  to 1.24) or to 12 months postpartum (Mean 0.82 kg; 95% CI:  $-0.26$  to 1.91 kg).

**Conclusions:** There was no evidence of a ripple effect on partner weight. In a self-selected sample, partners of pregnant women appear not to experience sympathy weight gain.

### Keywords

Ripple; Pregnancy; Weight; Fathers

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### Introduction

Behavioral interventions promote significant weight loss in individuals with obesity (1). Recently, randomized lifestyle interventions have shown a positive “ripple” effect on weight in untreated participants/spouses resulting in approximately 2 kg weight loss (2, 3). For example, the Look AHEAD trial showed that untreated spouses of participants randomized to the lifestyle intervention (vs. usual care) lost  $2.2 \pm 4.5$  kg over 1 year (2). Other non-randomized bariatric surgery treatments have shown positive ripple effects on weight loss of untreated family members with obesity (4, 5) with weight losses ranging from 1.3 to 5 kg. These data highlight the “indirect” reach of behavioral weight loss interventions to other members living in the home.

Potential intervention ripple effects on weight may result from the shared home environment where eating and activity habits of untreated participants may mimic behaviors of their spouse in the intervention. Previous studies have shown significant positive correlations between spouses in dietary fat intake and also in frequency of exercise (6, 7), suggesting that spouses mimic behaviors. The home food environment may also shape ripple effects. In Look AHEAD (2), intervention decreases in high-fat foods in the home were associated with reductions in energy intake (partial  $r = .24$ ,  $p < .001$ ) and weight loss (partial  $r = .12$ ,  $p = .049$ ) in untreated spouses. Thus, a behavioral intervention targeting eating, exercise habits, and the home food environment may extend to untreated participants.

Prenatal lifestyle interventions have been shown to reduce excessive gestational weight gain (GWG) in women (8, 9). While some research has examined the effects of prenatal interventions on offspring outcomes (8), the potential “ripple” effect of pregnancy weight gain interventions on partner weight has received little attention. This is of potential concern as observational studies have suggested that partners, like pregnant women, may experience unhealthy pregnancy weight gain and postpartum weight retention ( $\sim 1.5$  kg), although data are notably scant and self-reported (10). Our preliminary data suggested that a prenatal intervention targeting GWG resulted in weight loss in untreated partners with obesity (3). However, pregnant women self-reported their partner weight, which potentially biased partner results. To date, no published study has examined intervention-related maternal and partner weight changes during pregnancy using objective measured weights and long-term follow-up during the postpartum period.

The present study was ancillary to two phase III clinical trials in the Lifestyle Interventions for Expectant Moms (LIFE-Moms) consortium with a primary outcome to determine whether prenatal lifestyle interventions that effectively reduced excess GWG (11, 12) in pregnant women with overweight and obesity had a positive “ripple” effect on the weight of untreated partners living in the home through 12 months postpartum. We hypothesized that partners of pregnant women randomized to the lifestyle intervention, relative to those of usual care, would have greater weight loss at 35 weeks’ gestation, 6-months postpartum and 12-months postpartum. Secondary outcome examined whether maternal GWG and baseline partner characteristics would predict ripple effect weight loss in partners.

## Methods

### Overview

The purpose of this study was to determine whether prenatal lifestyle interventions to prevent excessive GWG in pregnant women with overweight and obesity had a positive “ripple” effect on the weight of partners living in the home. This ancillary study was part of the National Institutes of Health funded LIFE-Moms consortium (13), which was a collaborative of 7 studies with the goal of testing different lifestyle interventions in pregnant women with overweight and obesity in separate trials while providing the ability to combine data from the individual trials by harmonizing interventions, trial design elements, study procedures and data collection. During the LIFE-Moms consortium screening process, partners of pregnant women at 2 trials (Healthy Beginnings at California Polytechnic State University and The Miriam Hospital; and Lifestyle intervention for two at Columbia University) were asked to participate in this ancillary study. Untreated partners were categorized based on randomization status of their pregnant partner in the parent studies.

### Participants

The parent studies, Healthy Beginnings at California Polytechnic State University and Brown University and Lifestyle Intervention for Two (LIFT) at Columbia University, were part of the LIFE-Moms consortium (13) with recruitment of pregnant women and untreated partners conducted between November 2012 and May 2016. The study’s final postpartum assessment was conducted in June 2017. The two trials had the same eligibility criteria, and similar intervention content, duration, intensity, and timing; they also recruited diverse patient populations and utilized the same data collection methods. To be eligible for this study, untreated partners had to be 1) an adult ( ≥ 18 years old) who self-identified as sharing an intimate relationship and cohabitating in the home with the pregnant women (enrolled in the parent study) for at least the previous 3 months or recently (>2 weeks) been married and living in the home (2), 2) ≥ 18 years and, 3) willing to provide informed consent. Exclusion criteria included 1) medical comorbidities (cardiovascular disease, metabolic abnormalities) that may impact diet or ability to participate in physical activity and 2) medications that may influence eating or weight. Institutional Review Boards at each site approved the study, and all partners gave verbal and written informed consent. See Figure 1 for flow diagram of untreated partners.

## Conditions

Pregnant women with overweight and obesity were randomized within site (Cal Poly, Brown, Columbia) and ethnicity (Hispanic or non-Hispanic) to either Usual Care or a Lifestyle Intervention to reduce excessive GWG. In both parent studies, women in Usual Care received what is usual practice by their prenatal care provider during both the pregnancy and the postpartum period (11, 12). Participants also received study newsletters providing general information about pregnancy-related health (e.g., prenatal vitamins, smoking, breastfeeding) designed to improve retention in each study. In addition, women attended a brief (15–20 minute) visit conducted by study interventionists at the time of randomization to welcome and bond participants to the study (8, 11).

## Lifestyle Interventions

Women in Lifestyle Intervention received all aspects of Usual Care plus a behavioral lifestyle intervention designed to prevent excessive GWG. The interventions had many commonalities and a few differences. In both studies, the intervention was rooted in social learning theory (14) and conceptualized pregnancy as a “teachable moment” for behavior change (15). In the Cal Poly/Brown study, women attended individual counseling sessions every 2 weeks through 24 weeks gestation, and then monthly until delivery with an average of 7 face-to-face visits. In the LIFT study at Columbia University, participants had individual counseling every 2 weeks through delivery with an average of 9 face-to-face visits. Both programs were based on the Diabetes Prevention Program and Look Ahead Trial (16) tailored to pregnancy and prior interventions (17). Women were encouraged to gain approximately one-half pound per week, based on the 2009 IOM guidelines for healthy GWG during the 2<sup>nd</sup> and 3<sup>rd</sup> trimesters of pregnancy for women with overweight or obesity. In both studies, participants were provided meal plans and encouraged to aim for 30 minutes of activity on most days of the week (18). Behavioral strategies were introduced, including daily recording of food intake and activity, stimulus control techniques, problem-solving skills, goal-setting, self-reinforcement for goal attainment and self-monitoring of weight using a scale provided by the study (19). Additionally, the interventions included and targeted social support and provided ongoing contact with interventionists, promoted and encouraged pregnant woman to seek support from surroundings. Pregnant women were encouraged to practice assertiveness in ordering in restaurant settings, in handling pressures to eat from family and friends, and in engaging in non-sedentary social activities. However, no direct partner intervention was provided. Studies did not directly target smoking, but incidence of smoking was rare (<1%).

To promote adherence to the IOM recommendations, both studies encouraged healthy eating including the consumption of fruits and vegetables and reduced calorie intake. The prescribed meal plan was designed to meet the micronutrient and fluid needs recommended during pregnancy, took into consideration use of prenatal vitamins, and consisted of 20–30% of calories from fat, 15–20% from protein, and 50–55% from carbohydrates (20). However, in Healthy Beginnings, but not LIFT, women were provided with a partial meal replacement plan (21, 22). At each visit, participants received a free supply of organic meal replacement drinks and organic bars in the flavor of their choosing. Women were instructed to replace two meals with the provided meal replacement product and to consume at least one meal of

regular foods and two to four healthy snacks each day. Thus, both studies were adapted from DPP to pregnancy and stopped at delivery. The primary differences between the two studies were the number of face-to-face contacts (7 for Healthy Beginnings vs. 9 LIFT) and that Healthy Beginnings provided a free-supply of meal replacements whereas LIFT did not provide meal replacements.

In both studies the primary outcome manuscripts have been published elsewhere (11, 12). In Healthy Beginnings and LIFT, the interventions relative to Usual Care were effective in reducing total GWG from preconception to delivery (11.2 vs. 9.4 kg,  $P=0.029$ ; 9.67 vs. 7.89 kg;  $P = 0.003$ ), reducing rate of gestational weight gain per week of observation (0.39 vs. 0.33 kg/wk,  $P<0.001$ ; 0.29 vs. 0.25 kg/wk,  $P<0.05$ ) and reducing excessive GWG based on IOM recommendations (54% vs. 41%;  $P=0.039$ ; 38% vs. 19%;  $P = 0.03$ ). After intervention discontinuation after delivery, the Healthy Beginnings intervention no longer had an effect on postpartum weight retention at 12 months postpartum (23). The LIFT trial 12-month maternal postpartum results are forthcoming.

### Partner Outcome Assessments

Partners were assessed by research staff blinded to treatment allocation when their pregnant partners were 9 to 15.6 weeks' gestation (study entry), 35 weeks' gestation, 3 to 6 months postpartum (i.e., at 3 months for LIFT study only and at 6 months for Healthy Beginnings) and 12-month postpartum (both Healthy Beginnings and LIFT studies). Partners received \$25 for completing each assessment at study entry, 35-weeks' gestation, intermediate (3 or 6 months) postpartum, and \$50 for the 12-month assessment. Weight was measured to the nearest 0.1 kg using a calibrated and portable usual digital scale (Health-O-Meter Inc., Bridgeview, IL). Two measures were completed with participants in light clothing (without shoes). Scale calibration was checked weekly with known weights. Standing height was measured twice in patients without shoes in millimeters with a Harpenden stadiometer. Waist Circumference was measured at all assessment visits over bare skin or underwear using a tape measure (24). The primary outcome was partner weight over-time, and secondary outcomes examined whether maternal GWG and baseline partner characteristics would predict ripple effect weight loss in partners. There were no unintended harms or negative effects of the intervention on untreated partners.

### Statistical Methods

**Sample Size and Power**—The *a priori* sample size calculation for this study was based on the Look Ahead lifestyle intervention study that assessed untreated partner weight and found a significant ( $P<0.05$ ) weight difference in untreated partners of participants in the lifestyle intervention compared to control group (mean  $\pm$  SD;  $-2.4 \pm 4.5$  kg,  $-0.2 \pm 3.3$  kg weight loss, respectively) (2). With 122 total partners of pregnant women, we had 80.4% power to detect a  $-2.1$  kg weight difference between groups, using a two-tailed test and  $P<0.05$ .

**Statistical Analyses**—Pearson's chi-squared test and Analysis of Variance (ANOVA) was used to investigate baseline differences between groups for categorical and numeric responses, respectively. Linear mixed effects models including treatment/group (Intervention

vs. Usual Care) and group  $\times$  time interaction terms were used to test if partner weight changes over time differed significantly across the two study groups. *A priori* covariates included in the models were the fixed effects of maternal BMI at study entry and partner ethnicity, and random effects in the model were site (Cal Poly, Brown University and Columbia University) and subject. In secondary analysis we evaluated possible ripple effects on the subset of partners with overweight and obesity using a linear mixed model and the same covariates. Although missing or excluded data were rare in this study (see Figure 1), we chose a *priori* a linear mixed model that permitted missing data. An  $\alpha < 0.05$  was used to determine significance, and Tukey's HSD was used for post-hoc comparisons, if differences occurred.

## Results

Table 1 provides an overview of baseline participant characteristics by group. Partners were randomized by their pregnant partner's randomization allocation to intervention or usual care. Randomization resulted in well balanced groups with no significant differences between groups ( $P > 0.05$ ; Table 1). As shown in Table 1, all partners were male, 23% were Hispanic, 82% were married to their pregnant partner, and 19% were normal-weight, 32% were overweight, and 48% were obese. Partner retention at study visits was 90% at 35 weeks' gestation, 80% at 3 months postpartum, 80% at 6 months postpartum, and 80% at 12 months postpartum, with no difference between groups.

Partner weight change is summarized in Table 2. There was no evidence of a group or group by time interaction on partner weight ( $P = 0.795$ ). Partner weight trended higher over the study period, but the changes were not statistically significant ( $P = 0.12$ ). Overall, adjusted weight gain from study entry to 35 weeks was 0.19 kg (95% CI:  $-0.73$  to  $1.24$ ) and from study entry to 12 months postpartum was 0.82 kg (95% CI:  $-0.26$  to  $1.91$  kg). In secondary analysis, there was no group or group by time interaction on weight in partners with obesity ( $P > 0.05$ ; data not shown).

Examining demographic predictors of partner weight included in the model, study entry pregnant women's BMI was predictive of untreated partner study weight ( $P = 0.049$ ), but ethnicity was not ( $P = 0.522$ ). Also, adjusting for group assignment, pregnant women and their partners' weight changes were not correlated ( $P = 0.139$ ) from study entry to 35 weeks' gestation or 12 months postpartum.

## Discussion

The objective of this study was to determine whether prenatal lifestyle interventions compared to usual care in women with overweight or obesity had a positive "ripple" effect on untreated partner weight. The current study is the first to objectively measure weight in partners of pregnant women from early pregnancy through 12 months postpartum. There was no evidence of a "ripple" effect of the prenatal lifestyle interventions on partner weight. Partner weights did not change and were similar between intervention and usual care groups from early gestation through 12 months postpartum.



There are several potential reasons the intervention did not produce a ripple effect on untreated partners. It is quite possible that greater intervention-related weight changes are needed to produce ripple effects. The prenatal interventions produced only a modest ~1.8 kg gestational weight gain difference vs usual care (11, 12), which is significantly less than the 8 kg reduction seen in the intervention participants in Look Ahead that documented a ripple effect (2). Also, in the Look Ahead trial, the intervention goal was weight loss and participants were given low calorie goals which produced a ripple effect on untreated spouses. Even though the current prenatal interventions were adapted from DPP and Look Ahead, pregnant women were given goals to prevent *weight gain* and were given greater calorie allowance. Additionally, previous intervention studies that have shown positive ripple effects on untreated participant weight have included interventions that lasted 1 year in duration (2, 25). In the current study, interventions stopped at delivery and were relatively shorter in duration (5–6 months). Finally, the age of partners in the current study was on average 36 years, which is considerably younger than Look Ahead with a mean age of 59 years (2). It is possible that ripple effects are stronger in older adults who have had obesity longer and potentially experience comorbidities.

Future studies should consider continuing maternal interventions during the postpartum period when many new barriers emerge (26, 27), including reduced time for healthy lifestyle and increased responsibilities with newborn. It is possible that continued maternal intervention beyond pregnancy and into the postpartum period would have greater effects on partners' weight. We recently showed that a lifestyle intervention that reduced maternal weight during the 12 months postpartum period also reduced infant zBMI in the first 6 months of the intervention (25) suggesting that ripple effects may extend to others in the home. Thus, future research should examine whether continuing and intensifying maternal postpartum interventions or initiating them before pregnancy have effects on partner weight.

It is generally thought that partners of pregnant women gain a large amount of weight during pregnancy, a phenomenon called Couvade syndrome in which expectant fathers experience somatic symptoms of pregnant women (28). However, empirical data supporting Couvade syndrome and father/partner weight gain in the time surrounding pregnancy are noticeably scant and this study offers no statistical support for this phenomenon. Epidemiological data suggest that entrance into fatherhood is associated an increased BMI trajectory, whereas nonfathers have a decreased BMI trajectory (29). Condon et al. (10) prospectively showed that self-reported weight gain in men was ~1.5 kg from 23 weeks' gestation to 12 months postpartum. To our knowledge, the current investigation is the first to recruit partners of pregnant women early in pregnancy (~13 weeks' gestation) and follow them through 12 months postpartum with repeated assessment of objectively measured weight. Results indicated that partners did not gain weight during pregnancy on average (+0.19 kg), and pregnant women's weight changes were not predictive of partner weight changes ( $P=0.139$ ). During 12 months postpartum, a nonsignificant average of 0.82 kg gain was observed, consistent with average annual weight gain in the general population (30, 31). Thus, based on the current investigation it appears that partners may not experience "sympathy" weight gain during pregnancy and the postpartum period, and if they do, the mean gain is at most 1.91 kg (95% upper confidence bound). These results are contrary to what would be expected from Couvade Syndrome.

Strengths of the study include randomized assessor-blinded design, consistent with CONSORT guidelines (32), on objectively measured partner weight from early pregnancy through 12 months postpartum and evaluation of predictors of partner weight changes. The study has limitations, which are common to multisite collaborative work. Pregnant women randomization (and thus partner randomization) was conducted within two studies and the intervention treatment arms were both adapted from the DPP and stopped at delivery, but slightly differed in frequency of contact (9 vs. 7 face-to-face contacts with pregnant women), meal replacements, lesson plans, and one postpartum assessment time (LIFT at 3 months and Healthy Beginnings at 6 months), which may have influenced potential partner ripple effects. The current study tested ripple effects of interventions that occurred in pregnancy but there was no intervention in the postpartum period. Also, the refusal partner rate was higher than anticipated, as only ~60% of partners enrolled in the study. Thus, this study recruited a sample of self-selected partners, and results may not be generalizable to other partners of pregnant women. Finally, future studies will examine shared home environment where eating and activity habits of untreated participants may mimic behaviors of their spouse in the intervention.

## Conclusion

In summary, there was no evidence of a ripple effect of a pregnancy intervention on untreated partner weight. Partner weight gain from early gestation through 12 months postpartum was on average 0.82, consistent with annual weight gain patterns (30, 31) and suggesting that fathers/partners did not experience “sympathy” weight gain. Future intervention studies should consider whether intensified and/or continued maternal interventions through the postpartum period has ripple effect on partners and other family members to optimize weight outcomes in both mothers and fathers.

## Acknowledgements

We thank all partners for participating in this ancillary study, and all research staff at each site for aiding in data collection. Data is deposited in Digital Commons at California Polytechnic State University data repository and freely available for download once the original paper is published.

### Funding:

Research reported in this publication was supported by the National Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number R01HL118208. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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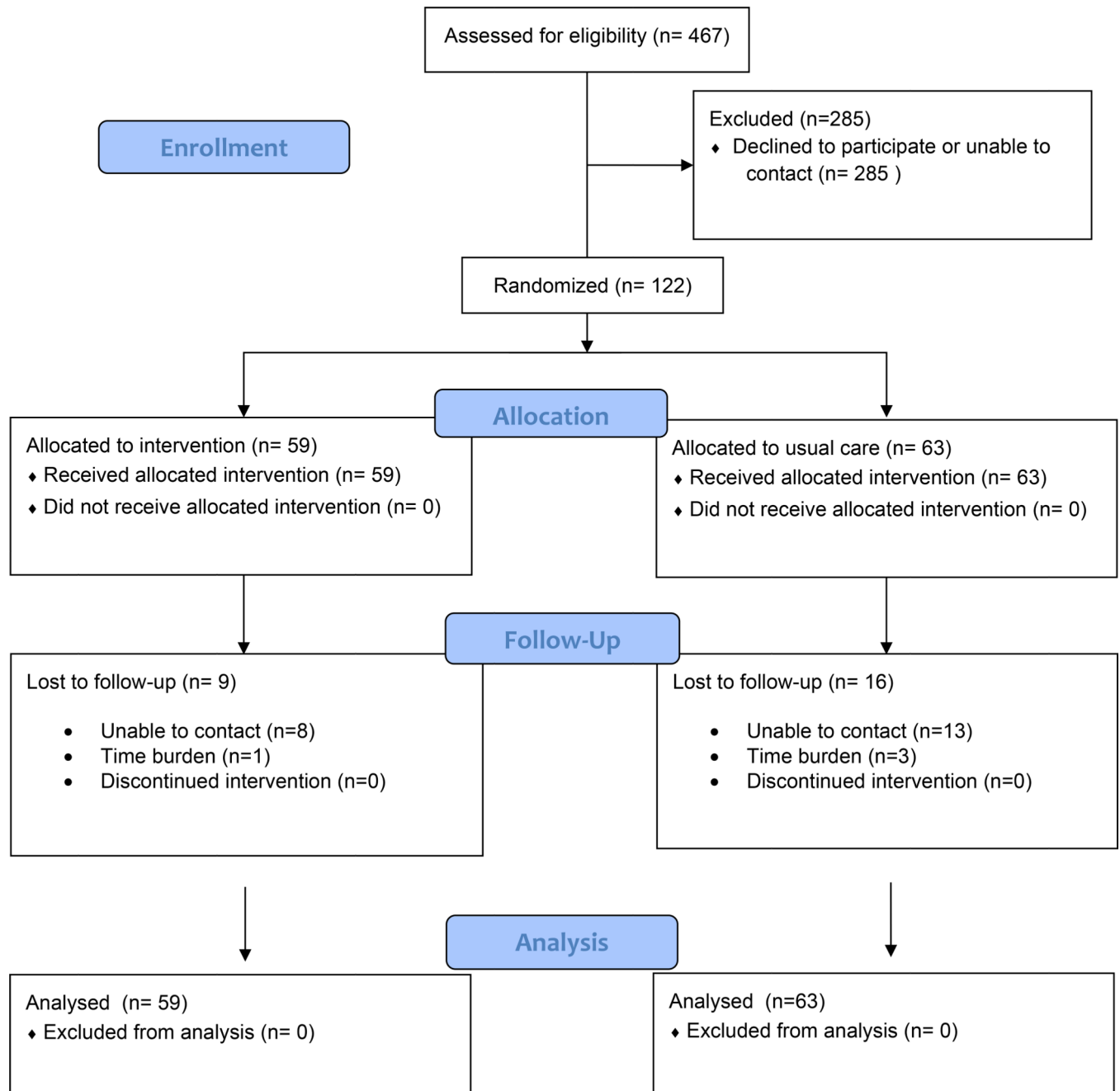
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**What is already known about this subject?**

- Lifestyle interventions have a direct effect on weight loss in individuals with obesity.
- Weight loss interventions produce a ripple effect on weight in non-pregnant untreated spouses/partners.

**What does your study add?**

- There was no evidence of a ripple effect of a prenatal intervention on untreated partner weight.
- On average, partner (fathers) weight gain was 0.82 kg through 12 months postpartum (95% CI: -0.26 to 1.91 kg).
- There was no evidence of sympathetic weight gain in a self-selected sample of partners of pregnant women in the time surrounding pregnancy.



**Figure 1. Flow Diagram of Untreated Partners.**

122 untreated partners were randomized to intervention (n=59) or usual care (n=63) based on their pregnant partners randomization. After randomization, 25 partners were lost to follow-up. All participants were included in statistical analyses using a linear mixed model adjusting for study entry maternal BMI and partner ethnicity.

**Table 1.**

## Untreated Partner Study Entry Characteristics

Characteristic	Total	Usual Care	Intervention
N	122	63	59
Sex, n (%)			
Male	122 (100%)	63 (100%)	59 (100%)
Female	0 (0%)	0 (0%)	0 (0%)
Hispanic/Latino, n (%)			
Yes	28 (23.0)	16 (25.4)	12 (20.3)
No	92 (75.4)	46 (73.0)	46 (78)
Not reported	2 (1.6)	1 (1.6)	1 (1.7)
Race/ethnicity (participants could select multiple), n (%)			
American Indian or Alaskan Native	8 (6.6)	3 (4.8)	5 (8.5)
Asian	3 (2.5)	2 (3.2)	1 (1.7)
Black or African American	12 (9.8)	7 (11.1)	5 (8.5)
Native Hawaiian or Pacific Islander	0	0	0
White	84 (68.9)	43 (68.3)	41 (69.5)
Other	18 (14.8)	10 (15.9)	8 (13.6)
Marital status, n (%)	100 (82)	47 (74.6)	53 (89.8)
Biological Father of partner's baby, n (%)			
Yes	116 (95.1)	60 (95.2)	56 (94.9)
Not reported	6 (4.9)	3 (4.8)	3 (5.1)
Annual household income, n (%)			
<\$24,999	15 (12.3)	7 (11.1)	8 (13.6)
\$25,000-\$49,999	19 (15.6)	9 (14.3)	10 (16.9)
\$50,000-\$99,000	39 (31.9)	23 (36.5)	16 (27.1)
>\$99,000	42 (34.4)	21 (33.3)	21 (35.6)
Not reported	7 (5.7)	4 (6.3)	3 (5.1)
Education, n (%)			
High school or less	32 (26.2)	17 (27)	15 (25.4)
Some college/completed college	64 (52.5)	28 (44.4)	37 (62.7)
Postgraduate work	20 (16.4)	14 (22.2)	6 (10.2)
Not reported	7 (5.7)	4 (6.3)	3 (5.1)
Employment			
35 hours per week	92 (75.4)	47 (74.6)	45 (76.3)
<35 hours per week	12 (9.8)	7 (11.1)	5 (8.5)
Unemployed	10 (8.2)	4 (6.3)	6 (10.2)
Medical disability	2 (1.6)	2 (3.2)	0
Not reported	6 (4.9)	3 (4.8)	3 (5.1)
Age, yrs, mean $\pm$ SD	35.9 $\pm$ 4.8	36.4 $\pm$ 5.1	35.6 $\pm$ 4.7
Weight, kg, mean $\pm$ SD	92.0 $\pm$ 16.7	92.4 $\pm$ 16.7	92.2 $\pm$ 16.7
Ht, m, mean $\pm$ SD	1.77 $\pm$ 0.73	1.77 $\pm$ 0.73	1.77 $\pm$ 0.69



Characteristic	Total	Usual Care	Intervention
BMI (kg/m <sup>2</sup> ), mean ± SD	29.6 ± 4.8	29.7 ± 4.7	29.6 ± 4.9
Weight status, n (%)			
Normal weight	24 (19.4)	14 (22.2)	10 (16.9)
Overweight	39 (32.0)	20 (31.7)	19 (32.2)
Obese	59 (48.4)	29 (46.0)	30 (50.8)

There was no significant difference between groups in any study entry characteristic.

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**Table 2.**

Untreated partner weight change by group at study-entry, 35 weeks' gestation, 6 months and 12 months postpartum.

	Usual Care (N=63)	Intervention (N=59)	Total (N=122)
Study-entry weight, kg	92.41 ± 2.41	91.96 ± 2.60	92.18 ± 1.95
35 weeks' gestation weight, kg	92.98 ± 2.41	91.76 ± 2.61	92.37 ± 1.95
Weight change from study-entry, kg	0.58 ± 0.55	-0.20 ± 0.58	0.19 ± 0.40
6 months postpartum weight, kg	93.19 ± 2.42	92.75 ± 2.62	92.97 ± 1.95
Weight change from study-entry, kg	0.79 ± 0.58	0.79 ± 0.60	0.79 ± 0.42
12 months postpartum weight, kg	93.14 ± 2.43	92.88 ± 2.61	93.01 ± 1.95
Weight change from study-entry, kg	0.73 ± 0.60	0.92 ± 0.59	0.82 ± 0.42

Values are least-squares mean ± SEM. Linear mixed effects model including treatment/group (Intervention vs. Usual Care) and group × time interaction terms over time found no significant time main effect or group × time interaction effect ( $P > 0.05$ ) adjusting for study entry maternal BMI and partner ethnicity.