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Lifestyle interventions limit gestational weight gain in women with overweight or obesity: LIFE-Moms prospective meta-analysis

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Abstract

Objective—To evaluate in pregnant women with overweight or obesity the effects of varied lifestyle intervention programs designed to ameliorate excess gestational weight gain (GWG) compared with standard care, and their effects on pregnancy outcomes.

Design and Methods—Seven clinical centers conducted separate randomized clinical trials to test different lifestyle intervention strategies to modify GWG in diverse populations. Eligibility criteria, specific outcome measures, and assessment procedures were standardized across trials. The results of the separate trials were combined using an individual participant data meta-analysis.

Results—For the 1150 women randomized, the percent with excess GWG/week was significantly lower in the intervention group compared with the standard care group (61.8% vs 75.0%, OR 0.52 [0.40, 0.67]). Total gestational weight gain from enrollment to 36 weeks' gestation was also lower in the intervention group (8.1 ± 5.2 v. 9.7 ± 5.4 kg [mean difference −1.59 kg {−2.18, −0.99 kg}]). The results from the individual trials were similar. The intervention and standard care groups did not differ in preeclampsia, gestational diabetes, cesarean delivery, or birth weight.

Conclusion—Behavioral lifestyle interventions focusing primarily on diet and physical activity among women with overweight and obesity resulted in a significantly lower proportion of women with excess GWG. This modest beneficial effect was consistent across diverse intervention modalities and in a large, racially and socioeconomically diverse US population of pregnant women.

Keywords

gestational weight gain; lifestyle modifications; clinical trials

Introduction

Maternal obesity during pregnancy increases health risks for both mother and child, including complications during gestation and delivery, and future obesity, diabetes, and cardiovascular risk.[1–3] In addition to pre-conception obesity, excess maternal weight gain has been associated with many of the same complications,[4] leading the Institute of Medicine (IOM) in 2009 to issue new guidelines focusing on the avoidance of excess gestational weight gain (GWG).[5] With more than half of U.S. women of child-bearing age now considered overweight or obese,[6] interventions designed to control or limit excess GWG and the associated metabolic risks in this population are timely. Pregnancy provides a unique opportunity to determine if relatively short-term lifestyle interventions to reduce excess GWG could have long-lasting benefits to the health of both mother and child.

Published trials over the past two decades testing different strategies for limiting GWG and promoting adherence to the IOM recommendations have produced mixed results in women with obesity.[1] Differences in the populations studied and the lack of standardized clinical outcome measures across trials might contribute to these mixed results. Women with overweight or obesity are an important group to target for lifestyle interventions given their higher incidence of excess GWG, and its association with higher rates of substantial maternal postpartum weight retention and childhood obesity.[7] Further research is needed to identify effective strategies in women with overweight or obesity for GWG control, and to evaluate the impact of such strategies on maternal and neonatal outcomes, and longer-term health outcomes in mothers and their offspring.

LIFE-Moms (Lifestyle Interventions for Expectant Moms) is a consortium of seven independent but collaborative clinical trials that sought to evaluate the efficacy of varied lifestyle intervention programs designed to ameliorate excess GWG compared with standard care. The centers shared common definitions, eligibility criteria, and measurements so that data could be combined to assess outcomes in a meaningful way in a racially, ethnically, and socioeconomically diverse population with greater power than would be possible for the individual studies. The primary hypothesis was that lifestyle interventions targeting diet, physical activity, and behavioral strategies in women with overweight and obesity would reduce excess GWG as defined by IOM recommendations. The primary outcome, excess gestational weight gain per week, and other pertinent maternal and neonatal outcomes are reported here.

Methods

Description of the Consortium

The Lifestyle Interventions for Expectant Moms (LIFE-Moms) consortium (NCT01545934, NCT01616147, NCT01771133, NCT01631747, NCT01768793, NCT01610752, NCT01812694) is a collaboration of seven clinical centers, a research coordinating unit, and the National Institutes of Health. As previously described,[8] each clinical center conducted a separate randomized clinical trial to test innovative strategies to modify GWG (e.g., meal replacements, modified DPP intervention,[9] the DASH diet,[10] smart-phone based intervention, parent educator intervention) in diverse populations, including under-represented racial/ethnic minority women and those of low socioeconomic status. More detail about the trials, their specific interventions, and individual results for four of the trials have been published.[8, 11–14]

Consortium Design

Selected eligibility criteria, measures, and procedures were standardized across all trials, thereby permitting pooling of the data and maximizing the value of the consortium. Standardized measures were collected throughout gestation: at baseline (9-15 weeks), 24-27 weeks, 35-36 weeks, and at delivery (within 7 days of birth). Institutional review boards for each site and the LIFE-Moms Data Safety Monitoring Board approved and monitored the conduct of the trials and consortium activities. Study participants provided written, informed consent prior to participation.

Study Population

Participants were pregnant women with a body mass index ≥ 25 kg/m^2 assessed by measured weight and height and a confirmed singleton pregnancy between 9 weeks 0 days and 15 weeks 6 days of gestation. Women were excluded for maternal age < 18 years, diagnosis of diabetes prior to pregnancy or study assessed HbA1c ≥ 6.5% prior to randomization, known fetal anomaly, history of three or more consecutive first trimester miscarriages, history of anorexia or bulimia, current eating disorder, active suicidal ideation, prior or planned bariatric surgery, current use of exclusionary medications, and contraindications to aerobic exercise in pregnancy. Some trials had additional exclusion criteria such as upper BMI cutoff or other study test results prior to randomization suggestive of diabetes (fasting plasma glucose ≥126 mg/dl, or 2-hour post-75g load plasma glucose ≥200 mg/dl). Eligible participants were randomized within their respective trial to the local site intervention or to a comparison group that received either standard practice from their prenatal care provider in one trial (Expecting Success, Pennington) or standard care and educational material/group sessions unrelated to GWG for the remaining trials.

Participant recruitment and screening

Participant recruitment occurred between November 2012 and December 2015. Individual sites developed their own recruitment plans, but most participants were approached with the opportunity to participate in the trial at a prenatal appointment or were referred by partnering obstetric provider groups.

Consortium Outcomes

Primary outcome—The primary outcome was excess GWG per week. GWG was defined as the difference between the study measured weight at 35-36 weeks gestation and baseline weight with GWG per week defined as GWG divided by the number of weeks (days/7) between the two visits. Women with baseline weights measured at 14 weeks had 0.45 kilograms (1 pound) subtracted and women at 15 weeks 0.91 kilograms (2 pounds) subtracted for an estimate of their first-trimester baseline weight.[8] Excess GWG was defined as GWG per week above the 2009 Institute of Medicine upper limit of second and third trimester weight gain for pregnant women with overweight (> 0.33 kg/week) or obesity (> 0.27 kg/week). If a weight measured between 35-36 weeks gestation was not available, the last weight measurement prior to 37 weeks gestation was used.

Secondary GWG outcomes—These include second trimester GWG per week (the difference between the baseline weight and 24-27 week measured weight divided by the number of weeks between the two visits with excess defined as greater than 0.33 kg/week for overweight and 0.27 kg/week for obese); and third trimester GWG per week (the difference between the 24-27 week measured weight and 35-36 week weight divided by the number of weeks between the two visits with excess defined as greater than 0.33 kg/week for overweight and 0.27 kg/week for obese). The lower limit of the IOM guidelines for second and third trimester GWG per week for pregnant women with overweight is 0.23 kg/week and for those with obesity is 0.17 kg/week; values below these limits defined GWG per week below IOM. As some women had their baseline weight measured in the first trimester, a *modified GWG* was also calculated, with participants whose weight was assessed in the first trimester being assigned to a starting gestational age of 13 weeks 6 days with no weight gain assumed in the first trimester. For those measured at 14 and 15 weeks gestation (i.e., the second trimester), unadjusted weights were used in the calculation of modified GWG.

Obstetric outcomes—Gestational hypertension and preeclampsia were based on clinical diagnoses abstracted from the medical record unless clearly incorrect as determined by the local study obstetrician. Gestational diabetes was diagnosed based on glucose testing conducted between 24 weeks 0 days and 31 weeks 6 days. Preterm delivery < 37 weeks 0 days, < 32 weeks 0 days and < 28 weeks 0 days were reported, as were miscarriages and abortions. Shoulder dystocia was defined by the use of documented maneuvers and centrally reviewed. Birth trauma also was centrally reviewed.

Neonatal outcomes—Birth weight was abstracted from the medical records. Small for gestational age was defined as a birth weight less than the 10^{th} percentile and large for gestational age as a birth weight at or above the 90^{th} percentile using the Alexander criteria specific for fetal sex and race.[15] Birth weight for length z-score was calculated using the WHO Child Growth Standards[16] and fetal and neonatal death included all fetal deaths and neonatal deaths within 28 days from birth. Neonatal respiratory morbidity was reported if any one of the following conditions were met: 1) cumulative use of supplemental oxygen for at least 6 hours in the first 72 hours of life; 2) continuous positive airway pressure or ventilator use within the first 72 hours of life, or; 3) extra-corporeal membrane oxygenation use. Neonatal hypoglycemia was defined as a newborn with sufficiently low blood sugar to require treatment with IV glucose therapy. Neonatal intensive care unit (NICU) or intermediate nursery admissions were defined as stays of 12 or more hours.

Statistical analyses

We performed an individual participant data meta-analysis combining the data from the seven randomized trials. All participants in the standard of care/enhanced standard of care groups were included as standard of care, and all participants in the interventions groups were included in the intervention group. Data from all women were analyzed according to the group to which they were randomly assigned, regardless of whether they adhered to the lifestyle intervention. The effect of the intervention on each outcome was analyzed by use of a generalized linear mixed model with a random effect included for trial. For outcomes related to GWG, including the primary outcome, overweight or obese status at baseline was included as a covariate in the model since the IOM guidelines differ by BMI category. In addition, we found a significant difference between groups for fetal sex and performed a sensitivity analysis that included this covariate in all models. All analyses including subgroups were pre-specified. Subgroups included baseline BMI category (overweight, obese), college education (yes, no), maternal age (18-24, 25-29, ≥30 years), nulliparous (yes, no), gestational age at randomization (< 13, ≥ 13 weeks) and race/ethnicity (Hispanic, Non-Hispanic Caucasian, Non-Hispanic African American). The race/ethnicity subgroup analysis excluded the three trials that contained a single racial/ethnic group (PEARLS, PreGO, and LIFE-Moms Phoenix).[8] Subgroups were initially assessed by including an interaction term between the group assignment and specified subgroup into the model. Subgroup analyses were only performed if the interaction term was significant (p<0.05). For all outcomes, nominal p-values of less than 0.05 were considered to indicate statistical significance; p-values have not been adjusted for multiple comparisons. Analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Results

A total of 32,860 women were screened for participation; 28,307 (86%) did not meet eligibility criteria, 3,403 (10%) declined to participate, and 1,150 women (4%) were randomized (Figure 1). The most common reason for exclusion was a BMI < 25 kg/m^2 (57%), followed by gestational age above 15 weeks, 6 days (19%). The distribution of participants across the 7 trials is as follows: 264 – California Polytechnic State University (n = 132) & Brown University (n = 132); 210 – St. Luke's – Roosevelt Hospital & Columbia University; 31 – University of Puerto Rico; 281 – Northwestern University; 267 – Washington University in St. Louis; 54 – Pennington Biomedical Research Center; 43 – NIDDK/Phoenix Indian Medical Center). Recruitment for 3 trials was stopped early by NIH on the recommendations of the LIFE-Moms Data Safety Monitoring Board, based upon low likelihood of accruing the target sample size within the study period. Nine women did not have a weight measured post randomization and were classified as lost to follow-up, leaving 1141 women available for the primary analysis (578 intervention, 563 standard of care; Figure 1). Pregnancy complications, obstetrical and neonatal outcomes were assessed among 1,139 women. Eleven women (5 intervention, 6 standard care) were missing these secondary outcomes due to study withdrawal or delivery at an outside hospital and inability to contact participant. Of the 1,150 women randomized, 35% were non-Hispanic Caucasian, 24% were Hispanic, 32% Non-Hispanic African American, and 9% other race/ethnicity; 50% had a college degree and 36% had a total family income less than $25,000. There were no differences between the intervention and standard care groups with respect to baseline BMI category, race/ethnicity, education, family income and marital status (Table 1). There was a significant difference in fetal sex between the intervention and standard care groups (male 44% intervention and 53% standard care, p=0.005).

The percentage of women with excess GWG per week was significantly lower in the intervention group than the standard care group (61.8% vs 75.0%, OR 0.52 [0.40, 0.67]), and mean total GWG was 1.6 kg less for the intervention group (Table 2). Results for the primary outcome of excess GWG per week for the individual trials is shown in Figure 2, showing similar results across the trials. The intra-class correlation coefficient, representing variation amongst the populations/trials for excess GWG per week was very low (3%). None of the pre-specified interactions between treatment groups and baseline BMI category, college education, maternal age, nulliparous, gestational age at randomization and race were significant. Using the *modified GWG* per week calculation, incidence of excess GWG remained significantly lower in the intervention group compared with the standard care group (61.8% vs 74.8%, OR 0.52 [0.40, 0.67]). Additional secondary outcomes that pertain to GWG are reported in Table 2. The percentage of women with GWG below IOM guidelines was significantly higher in the intervention group than the standard care group (20.6% vs 14.2%, OR 1.65 [1.20, 2.27], Table 2).

Pregnancy complications were infrequent: placental abruption occurred in 15 women (9 intervention, 6 standard care); severe anemia in 6 women (3 intervention, 3 standard care); postpartum hemorrhage in 6 women (6 intervention, 0 standard care); preterm premature rupture of membranes in 21 women (8 intervention, 13 standard care); wound separation in 3 women (1 intervention, 2 standard care); pulmonary embolism in 1 woman (intervention); and there were no reports of deep vein thrombosis or pyelonephritis. The combined outcomes of gestational hypertension and preeclampsia, preeclampsia alone, gestational diabetes, and cesarean delivery did not differ between the intervention and standard care groups (Table 3). Preterm birth prior to 37 and 32 weeks did not differ by group; however preterm birth prior to 28 weeks was significantly lower in the intervention group compared with standard care. Indicated preterm birth prior to 37 weeks did not differ by group assignment (5.1% intervention, 3.9% standard care, OR 1.32 [0.75, 2.34]). Among women with an indicated preterm birth, the most common indication for delivery was gestational hypertension/ preeclampsia (34/51=66.7%).

Among live born infants, birth weight, small and large for gestational age, and birth weight for length z-score were not significantly different between the intervention and standard care groups. Similarly, there was no difference in neonatal respiratory morbidity, neonatal hypoglycemia, and NICU admission. One neonate in the intervention group had confirmed seizures. There were no significant differences in major congenital malformations or perinatal death (Table 3). Overall there were 32 fetal deaths and 1,107 live born infants. Three neonatal deaths occurred within 28 days from birth, all in the intervention group. Two were due to congenital anomalies and 1 due to complications of prematurity. Shoulder dystocia was confirmed in 11 participants; 5 (0.9%) in the intervention group and 6 (1.1%) in standard care. Birth trauma was confirmed in 4 participants; 3 (0.5%) in the intervention group and 1 (0.2%) in standard care. Sensitivity analyses evaluating the imbalance of fetal sex between randomized groups did not change any of the findings.

Discussion

The LIFE-Moms Consortium found that varied lifestyle interventions designed to control gestational weight gain conducted in racially and socioeconomically diverse populations of pregnant women with overweight or obesity resulted in significantly less GWG and fewer women exceeding IOM recommendations. The primary outcome, incidence of excess GWG per week, was significantly lower in the intervention group compared with the standard care group (61.8% vs 75.0%). The intervention reduced the odds of exceeding IOM recommendations by 48%, but most women in the lifestyle intervention group still exceeded the recommended guideline for GWG. The improvement in the proportion of women within IOM guidelines is modest, but consistent with success rates of many weight control interventions. The difference in GWG between the groups did not result in differences in pregnancy outcomes or infant birth weight. The two groups were balanced at baseline for key factors that may impact GWG, including baseline BMI category (overweight vs obese), race/ethnicity, education, family income, and marital status.

The LIFE-Moms Consortium represents a collaborative study group with the goal of testing different behavioral/lifestyle interventions in pregnant women with overweight and obesity from diverse racial/ethnic and socioeconomic backgrounds. At the time of trial initiation, no single best clinically proven approach existed for the control of GWG using a multi-center randomized design. The consortium began with 7 separate trials, each independently powered to test a specific set of intervention strategies and ended with 4 of those trials successfully completing recruitment as per study protocols. All 4 completing studies individually found significant effects of the interventions on reducing excess GWG compared with the standard of care, thereby demonstrating the efficacy of these specific lifestyle interventions on controlling GWG during the second and third trimesters. That is, independent of study procedures, lifestyle interventions focusing on diet and physical activity resulted in a significantly lower percent of women with excess GWG. The centers where recruitment was stopped early also showed confidence intervals that included a positive impact on reducing excess GWG, although the power was too limited to be independently conclusive. This is a clinically important finding as it reaffirms that women can change behaviors to control the amount of weight gain in pregnancy. The withdrawal and loss to follow-up rate was low for randomized participants, and the studies were drawn from diverse populations, which increases generalizability of the findings.

In this analysis, the mean GWG was 1.6 kg (3.5 lb) higher in the standard care than in the intervention group, similar to that reported in a meta-analysis of prior studies performed among women with overweight and obesity.[1] We also found that weight gain per week (baseline to 35-36 weeks gestation) below the IOM guidelines was 20.6% vs. 14.2% (p=0.002), respectively for intervention and standard care, indicating that the interventions resulted in more women gaining less than the IOM recommended weight. Our primary outcome definition of gestational weight gain per week used the baseline measured weight and made minor weight adjustments to baseline weights measured at 14 and 15 weeks. Since that definition may not have represented actual weight gain for individual study participants, a *modified GWG* outcome, which used unadjusted weights at 14-15 weeks and a standardized gestational age for weights measured in the first trimester, was also calculated, with those results being similar to the primary outcome results. Prior studies have questioned whether reduced GWG or even weight loss in women with obesity is of concern;[17,18] this remains an avenue for future investigation.

Numerous prior observational studies have reported an association between excess GWG and adverse pregnancy outcomes, independent of maternal obesity.[19] This consortium analysis was not powered to detect a reduction in pregnancy or neonatal morbidities, which might explain the lack of observed effects on maternal or neonatal outcomes. A meta-analysis of randomized clinical trials included 49 published studies employing prenatal lifestyle interventions versus standard care found that interventions were effective overall in reducing excess GWG; however, there were no clear benefits on reducing the incidence of preeclampsia, preterm birth, or macrosomia (birth weight ≥ 4 kg).[4] A more recent meta-analysis using individual participant data from 36 randomized trials and 12,526 women concluded that prenatal lifestyle interventions were effective in reducing GWG and significantly reduced the odds of cesarean section but no other individual complications.[20] A significant limitation of these meta-analyses was the lack of standardization of outcome measures and definitions across studies, whereas the LIFE-Moms trials used standardized methods employed across all the trials making direct comparisons more feasible.

Additional factors could also have contributed to the absence of meaningful group differences in maternal and neonatal outcomes. Most notably, the intensity of the intervention and the level of adherence by the participants were not uniform across centers. It is also possible that interventions were applied too late, since recent data document that the causal relationship between excess GWG and adverse outcomes are established in the first trimester.[21] Further, the potential benefits of reduced weekly GWG among mothers with overweight or obesity and their offspring may not become evident until later, when the offspring are preschool age or older.[22,23] The effects of interventions improving the in utero milieu may not manifest until later in childhood because of the latency period between an environmental trigger and the onset or clinical detection of subsequent risk factors/disease.[24,25] In addition, modest reductions in gestational weight gain may have a favorable impact on postpartum weight retention and future risk of type 2 diabetes or cardiovascular disease in the mother. Longer-term follow up will provide further data documenting whether lifestyle interventions that successfully achieved modest reductions in gestational weight gain offer long term health benefits for both mother and child.

The growing body of evidence that reports on a lack of association between improved maternal weight gain with lifestyle interventions and reduced risk of adverse pregnancy and neonatal outcomes raises an important question: Is maternal weight the appropriate outcome metric? Weight is clearly an easy outcome to monitor in obstetrical practice; however, evaluating how lifestyle interventions in pregnancy modulate maternal body composition could be more informative. Prospective studies of body composition throughout pregnancy show that weight gained above the IOM guidelines is predominantly fat.[26] Infant adiposity at birth is associated with both maternal pre-pregnancy BMI[27] and improvements in gestational weight gain in the absence of an association with birth weight.[28] Therefore, before concluding that lifestyle interventions in pregnant women that result in modest effects on maternal weight and little impact on pregnancy and neonatal outcomes are clinically ineffective, it would be prudent to carefully investigate how such interventions impact dietary content and affect body composition, particularly fat mass of mothers and children.

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What is already known about this subject

- Excess gestational weight gain has been associated with increased rates of fetal macrosomia, gestational hypertension, and cesarean delivery, and long-term effects including increased maternal risks for weight retention and cardio metabolic diseases, as well as the development of obesity and diabetes in the offspring.
- The odds of excess gestational weight gain, and the negative long-term consequences, including postpartum maternal weight retention and childhood obesity, are greatest for mothers with preconception overweight and obesity.
- Previous individual studies have found inconsistent results for the effects of lifestyle interventions on gestational weight gain for women with overweight or obesity.

What this study adds

- Across 7 randomized trials, lifestyle behavioral interventions focusing on diet, physical activity, and weight control behaviors reduced excess gestational weight gain in women with overweight or obesity.
- The beneficial effect on reducing excess gestational weight gain was seen with different approaches to lifestyle intervention and in racially and socioeconomically diverse populations.
- This study examined the effects of prenatal lifestyle interventions using common definitions and measurements of gestational weight gain and other health outcomes that can be used in future research.

Figure 1.
Participant flowchart

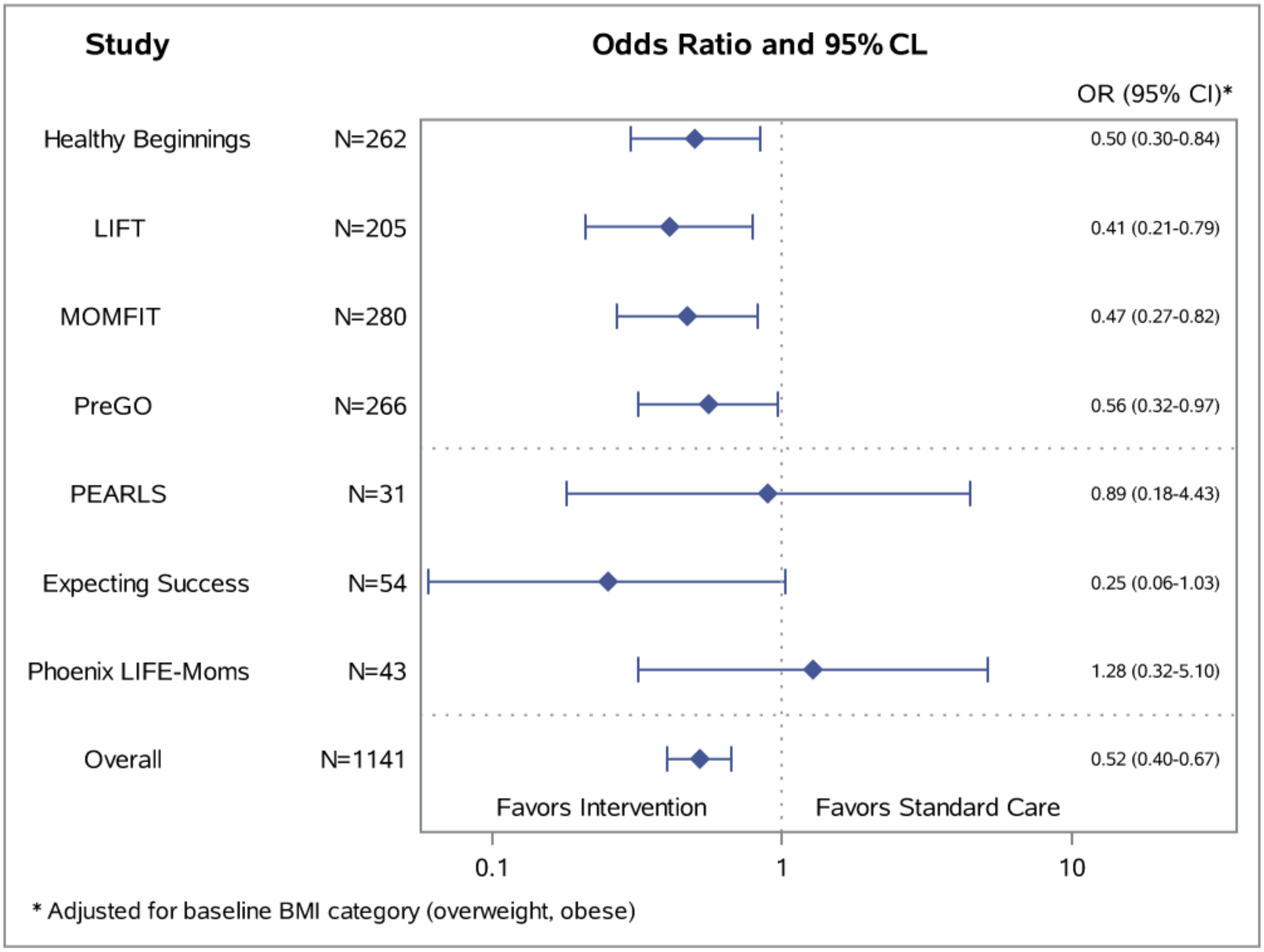

Figure 2.
Forest plot for primary outcome

Table 1

Baseline characteristics*

	Intervention (N=579)	Standard of care (N=571)
Gestational age at randomization (wk)	14.1 [12.7 – 15.1]	14.1 [12.6 – 15.3]
Maternal age (yr)	30.4 ± 5.6	30.5 ± 5.7
Adjusted BMI at baseline (kg/m^2)	30.6 [27.8 – 34.6]	30.7 [28.1 – 34.9]
Adjusted BMI at baseline category		
Overweight	261 (45.1%)	244 (42.7%)
Obese	318 (54.9%)	327 (57.3%)
Race/Ethnicity		
Non - Hispanic Caucasian	196 (33.9 %)	205 (35.9%)
Non - Hispanic African American	193 (33.3%)	180 (31.5%)
Hispanic	138 (23. 8 %)	133 (23.3%)
Other, more than one race	52 (9.0%)	53 (9.3%)
College education	291 (50.4%)	279 (48.9%)
Total family income		
< $25,000	198 (34.6%)	209 (36.8%)
$25,000 - $74,999	159 (27.8%)	151 (26.6%)
≥ $75,000	215 (37.6%)	208 (36.6%)
Married/living with significant other	435 (75.3%)	440 (77.1%)
Nulliparous	254 (43.9%)	219 (38.4%)
Neonatal sex		
Male	250/567 (44.1%)	289/550 (52.5%)
Female	317/567 (55.9%)	261/550 (47.5%)

*Data presented as N (percent), mean ± standard deviation, or median [inter-quartile range]

Table 2

Gestational Weight Gain Outcomes*

	Intervention (N=578)	Standard of care (N=563)	Intervention Effect**		P-value
			Odds Ratio [95% CI]	Mean difference [95% CI]	
Excess GWG per week	357/578 (61.8%)	422/563 (75.0%)	0.52 [0.40, 0.67]		<0.001
GWG per week (kg)	0.37 ± 0.24	0.44 ± 0.24		−0.07 [−0.09, −0.04]	<0.001
Total GWG (kg)#	8.1 ± 5.2	9.7 ± 5.4		−1.58 [−2.18, −0.99]	<0.001
Excess 2 nd trimester GWG	283/481 (58.8%)	340/470 (72.3%)	0.50 [0.38, 0.66]		<0.001
2nd trimester GWG per week (kg)	0.35 ± 0.24	0.43 ± 0.26		−0.09 [−0.12, −0.06]	<0.001
Excess 3rd trimester GWG	279/431 (64.7%)	303/428 (70.8%)	0.74 [0.56, 0.99]		0.045
3rd trimester GWG per week (kg)	0.41 ± 0.28	0.45 ± 0.28		−0.04 [−0.08, −0.00]	0.034
GWG per week below IOM	119/578 (20.6%)	8 0/563 (14.2%)	1.65 [1.20, 2.27]		0.002
GWG per week within IOM	102/578 (17.6%)	61/563 (10.8%)	1.78 [1.26, 2.50]		0.001

*Data presented as N (percent), or mean ± standard deviation; nine lost to follow-up excluded (1 intervention, 8 standard of care); GWG, gestational weight gain

**Adjusted for baseline BMI category (overweight, obese)

#Total GWG is defined as baseline to last weight before 37 weeks gestation

Table 3

Maternal & Neonatal Outcomes*

	Intervention (N=574)	Standard of care (N=565)	Intervention Effect		P-value
			Odds Ratio [95% CI]	Mean difference [95% CI]	
Maternal outcomes					
Gestational hypertension/ preeclampsia	88/573 (15.4%)	77/564 (13.7%)	1.15 [0.83, 1.61]		0.40
Preeclampsia	52/573 (9.1%)	36/564 (6.4%)	1.48 [0.95, 2.31]		0.09
Gestational diabetes	57/513 (11.1%)	59/494 (11.9%)	0.92 [0.61, 1.40]		0.71
Cesarean delivery	209/573 (36.5%)	179/565 (31.7%)	1.24 [0.97, 1.58]		0.09
Preterm delivery < 37 weeks	55/574 (9.6%)	64/565 (11.3%)	0.83 [0.56, 1.21]		0.33
Preterm delivery < 32 weeks	18/574 (3.1%)	23/565 (4.1%)	0.76 [0.41, 1.43]		0.40
Preterm delivery < 28 weeks	11/574 (1.9%)	23/565 (4.1%)	0.46 [0.22, 0.95]		0.037
Fetal/ Neonatal outcomes					
Major congenital malformation	9/573 (1.6%)	15/563 (2.7%)	0.58 [0.25, 1.34]		0.21
Fetal/neonatal death	13/574 (2.3%)	22/565 (3.9%)	0.57 [0.28, 1.15]		0.11
Fetal death < 24 weeks **	8/574 (1.4%)	18/565 (3.2%)	–		
Fetal death ≥ 24 weeks **	2/574 (0.3%)	4/565 (0.7%)	–		
Neonatal death **	3/573 (0.5%)	0/565 (0.0%)	–		
Birth weight (g)#	3306 ± 588	3268 ± 571		39.4 [−27.9, 106.8]	0.25
SGA < 10th percentile#	40/563 (7.1%)	51/543 (9.4%)	0.74 [0.48, 1.13]		0.16
LGA ≥ 90th percentile#	60/563 (10.7%)	48/543 (8.8%)	1.23 [0.83, 1.84]		0.31
Macrosomia (birth weight ≥ 4000 g)#	48/563 (8.5%)	43/543 (7.9%)	1.09 [0.71, 1.68]		0.69
Birth weight for length z-score#, †	−0.18 ± 1.29	−0.27 ± 1.29		0.09 [−0.06, 0.25]	0.24
Neonatal respiratory morbidity#	39/563 (6.9%)	30/542 (5.5%)	1.29 [0.79, 2.11]		0.31
Neonatal hypoglycemia#	16/563 (2.8%)	20/542 (3.7%)	0.78 [0.40, 1.53]		0.47
NICU/intermediate nursery stay#	71/564 (12.6%)	68/543 (12.5%)	1.02 [0.71, 1.45]		0.94

*Data presented as N (percent), mean ± standard deviation, or median [inter-quartile range]; eleven with unknown delivery outcome excluded (5 intervention, 6 standard of care)

** Odds ratios not reported due to small numbers

live born only (564 intervention, 543 standard care)

† 33 live born intervention neonates and 22 live born standard care neonates did not have this measure largely due to the WHO program's minimum length requirement of 45 cm