Perinatal Outcomes in Nutritionally Monitored Obese Pregnant Women: A Randomized Clinical Trial

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Background: Although obesity in pregnancy continues to be associated with ongoing health problems, many clinicians have been reluctant to place nondiabetic, obese, pregnant women on a monitored, calorie-appropriate nutritional regimen for fear of fetal growth restriction, low birth weight, or starvation ketosis.

Methods: A total of 257 patients were enrolled in the randomized study, with a loss-to-follow-up rate of 9.73%. Patients were assigned randomly to either the control (unmonitored) group (n = 116), consisting of conventional prenatal dietary management, or to the study (monitored) group (n = 116), which was prescribed a balanced nutritional regimen and were asked to record in a diary all of the foods eaten during each day. Women were eligible for the study if they were pregnant with a single fetus between 12 and 28 weeks of gestation and had a prepregnancy body mass index of more than 30 kg/m^2. The primary outcome was to compare perinatal outcomes in the control vs the study groups. The secondary measure was to compare outcomes in adherent and nonadherent patients in the study group.

Results: Omnibus MANOVA showed statistically significant differences between the study and control groups regarding 3 variables: (1) gestational hypertension, $p < .46$; (2) mother's last weight before delivery, $p < .001$; and (3) mother's 6-week postpartum weight, $p < .001$. Patients gaining 15 pounds or more during their pregnancy showed statistically significant differences between the groups for 8 variables.

Conclusion: Obese pregnant women may be placed on a healthy, well-balanced, monitored nutritional program during their antepartum course without adverse perinatal outcomes. (Clinicaltrials.gov identifier: NCT00740766)

Keywords: weight ■ obstetrics/gynecology ■ nutrition

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INTRODUCTION

Obesity has become endemic in the United States. More than 35% of adult women are considered to be obese[1]—obesity being defined as a body mass index (BMI) of 30 kg/m^2 or greater. African American women have the highest rates of being overweight or obese compared to other groups in the United States. About 4 out of 5 African-American women are overweight or obese. From 2001-2004, African American women were 70% more likely to be obese than non-Hispanic white women.[2]

Obesity was recognized as a risk factor in pregnancy more than 50 years ago.[3] Since then, numerous retrospective, observational, prospective, cohort, and case-control studies have demonstrated the association between maternal obesity and various pregnancy complications, including gestational diabetes, preeclampsia, shoulder dystocia, macrosomia, stillbirth, operative risks, wound infection/dehiscence, and higher rates of oxytocin induction, resulting in a 2-fold higher risk of primary cesarean delivery.[4-13]

For more than 20 years, the standard obstetric approach to maternal weight gain during pregnancy has been to follow the American College of Obstetricians and Gynecologists recommendation

> *Regardless of how much women weigh before they become pregnant, gaining between 26 to 35 pounds during pregnancy can improve the outcome of pregnancy and reduce their chances of having the pregnancy end in fetal death.*[14]

It is common for pregnant women to be given general prenatal dietary guidelines and to be told "to eat to appetite" with little other dietary direction. In 1990, The Institute of Medicine (IOM) recommended a minimum of 15 pounds weight gain for obese women.[15] This weight gain recommendation in an already obese patient seemed arbitrary and was criticized by some investigators because

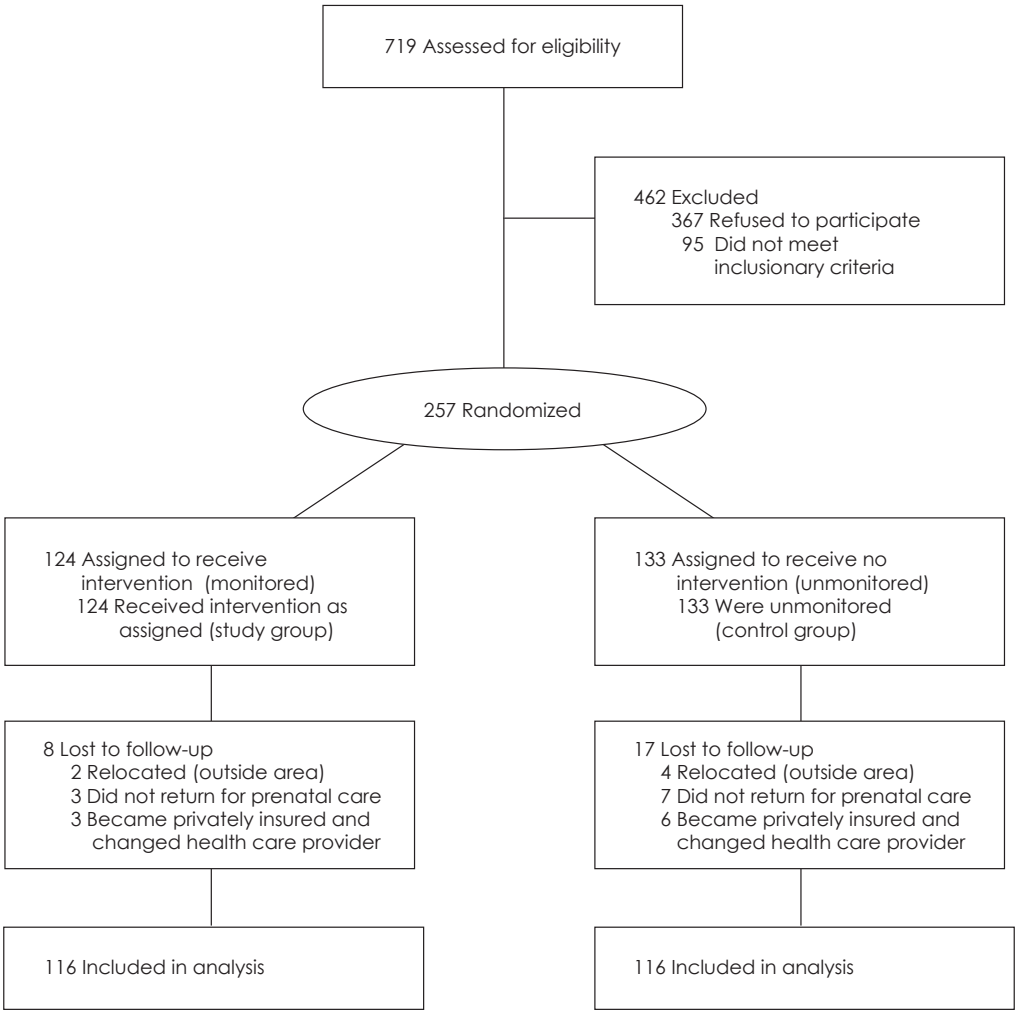
of concerns relating to the potential effects on accelerated fetal growth with trends toward fetal macrosomia.[16] Additionally, residual weight retention after pregnancy in those patients who had experienced a greater-than-recommended weight gain during pregnancy was given as 1 of the factors in the trend toward increasing obesity among American women of reproductive age.[17]

Recording daily food intake has been shown to be a significant factor in behavior modification associated with successful weight control.[18] Streit et al demonstrated a strong, linear relationship between recording food intake and weight loss. In spite of legitimate concerns about accuracy of a self-reported food intake, these records have considerable power as a predictor of success in achieving weight loss.[19] Although weight loss was not the aim of this study, the behavior involved in keeping a daily food diary proved to be most helpful in preventing excessive weight gain.

Although obesity in pregnancy continues to be associated with ongoing health problems, many clinicians have been reluctant to place nondiabetic, obese, pregnant women on a monitored, calorie-appropriate nutritional regimen for fear of fetal growth restriction, low birth weight, or starvation ketosis which, in older studies, was associated with neuropsychological deficits and lower IQ scores in diabetic mothers.[20] However, subsequent studies reported no ketonuria in obese pregnant women who were prescribed modest caloric restriction during pregnancy,[21] and in studies that did demonstrate ketonuria in pregnancy, the level of ketonuria did not correlate with lower IQ scores.[22]

The Food and Nutrition Board of the National Research Council under the aegis of the National Academy of Sciences established a subcommittee on Nutritional Status and Weight Gain During Pregnancy late in 1987 in order to address deficiencies regarding knowledge about maternal nutrition. In their 1990 report there was a reference to the caloric needs of obese healthy women and in their summary and recommendations it was suggested that *no more than 15 pounds* needed to be gained if the woman was obese.

Figure 1. Patient Participation



Moreover, a closer look at the outcome of pregnancies in morbidly obese women revealed that the subsequent infant birth weight was optimal if the maternal weight gain was minimized to less than 3 kilograms or if no weight was gained.[23]

To our knowledge, this is the first randomized clinical trial comparing active nutritional and behavioral intervention (study group) with conventional dietary prenatal management (control group) in obese pregnant women.[24]

METHODS

Objectives

The objectives of this study were (1) to compare perinatal outcomes of obese pregnant women treated in the conventional manner (control group) to outcomes of nutritionally monitored obese pregnant women (study group); (2) to determine the effects of weight stabilization during pregnancy in obese pregnant women between the control and study groups on perinatal morbidity and on birth weight of their newborns; (3) to determine perinatal differences in the study group's adherence vs non-adherence to a prescribed nutritional regimen applicable to the general practice of obstetrics; (4) to evaluate perinatal outcomes of obese pregnant women who had a gain of 15 pounds or more during their pregnancy compared to those who gained fewer than 15 pounds, irrespective of whether they were in the control or study group; and (5) to evaluate perinatal outcomes of obese pregnant women who had a gain of fewer than 10 pounds during their pregnancy compared to those who gained 10 pounds or more, irrespective of whether they were in the control or study group.

Study Design

The study was a randomized, parallel-group trial conducted sequentially in the ambulatory obstetric clinics of 3 tertiary care medical centers between June 1998 and May 2005—Morristown Memorial Hospital (1998-2000), St Luke's-Roosevelt Hospital Center (2001-2002), and Jamaica Hospital Medical Center (2002-2005). The study was conducted at the institutions of the principal investigator. Each study site was an urban, public clinic of a teaching hospital. All 3 human investigational review boards (IRBs) approved the study protocol as prepared by the principal investigator, and all patients in the study provided written, informed consent. The protocol was reviewed and approved annually by the IRB at each site during its participation in the study.

Study Participants

For this study, potential volunteers were approached by the principal investigator at their prenatal care visits for possible participation. Women were eligible for the study if they were pregnant with a single fetus between 12 and 28 weeks of gestation and had a BMI greater than or equal to 30 kg/m^2. Assessment of gestational age was based on the patient's last normal menstrual period (LNMP) with clinical examination and confirmed with a midtrimester sonographic study or, if the patient was uncertain of her LNMP, an earlier sonogram was performed. Exclusion criteria were patients with preexisting diabetes, hypertension, or chronic renal disease. A total of 257 patients were enrolled in the randomized study. A patient flow diagram outlines the progress of patients throughout the study (Figure 1).

After the study was explained, their BMI was calculated based on the women's prepregnancy weight as reported by patient and height as measured at the visit. Obese (BMI ≥30 kg/m^2) women were then invited to participate in the study before they knew to which group they would be assigned. After the participant signed a informed consent form, a randomization system was used to determine the group assignment. Envelopes were prepared and sequentially numbered. A card indicating the assigned group was placed in the envelope, and the envelope was sealed. A random-number table was used to assign each consecutively numbered envelope to either the study or control group in blocks of 10. The control group (unmonitored) was told to eat to appetite following general prenatal dietary guidelines. The study group (monitored) was prescribed a balanced nutritional regimen based on their weight at entry into the study and asked to record in a diary all of the foods and beverages consumed during each day. Demographic data for the randomized groups were comparable (Table 1).

Adherence was defined as recording daily food intake and bringing the logbook to her clinic visit for review by the physician. Nonadherence was defined as not recording food intake for more than a week and failing to bring the logbook to clinic for review. The sample size was based on the comparison of weight gain at delivery. For at least 80% power and a 5% significance level with an expected attrition rate of 20%, 100 patients were required for each group.

Study Protocol

Participants in both groups were counseled, at least once, by a registered dietician regarding conventional prenatal nutrition guidelines. However, patients in the study group were given a more detailed dietary intake protocol. The nutritional program for the monitored patients (study group) followed dietary guidelines similar to those used in patients with the diagnosis of gestational diabetes. The study group was placed on an 18 to 24 kcal/kg balanced nutritional regimen, consisting of 40% carbohydrates, 30% protein, and 30% fat. No patient received a diet of fewer than 2000 calories. All women in the study group were asked to record in a diary all of the foods and beverages consumed during each day. These records were reviewed at each prenatal visit by the physician. Six weeks after delivery, the patient was weighed during her postpartum visit and exited the study. The food diary notebooks were col-

lected from each patient at the end of the study.

Patients in both groups were weighed at each prenatal visit. The monitored patients were requested not to weigh themselves at home so as not to influence diet intake. Patients in both groups were asked to wear similar clothing at each visit. Participants in both groups were encouraged to engage in 30 minutes of walking per day. Blood pressure readings and urine for glucose, protein, and ketones were assessed for patients in both groups. During their prenatal care, if the ability to assess uterine fundal height was compromised in either group due to a large abdominal panniculus, serial sonographic examinations were requested monthly in order to assess fetal growth.

The weight of all participants was recorded at the time of entry into the study, before delivery, and at 6 weeks postpartum. In addition, the newborn was weighed by the delivery room nurse immediately after delivery. As is routine for all deliveries, neonatal outcome was assessed with Apgar scoring. Antepartum and intrapartum complications such as development of gestational diabetes, ketonuria, preeclampsia, and shoulder dystocia were identified from the medical record after the patient delivered. The type of delivery, macrosomia, anesthesia, intraoperative and postoperative complications such as wound dehiscence/infection, postpartum hemorrhage were also examined through review of the patients' medical records and recorded.

Statistical Analysis

All statistical analyses were performed using SPSS (SPSS Inc, Chicago, Illinois). The baseline pregnancy weight (in pounds) and BMI were used as baseline information in this study along with 16 perinatal outcome measured variables. Two *t* tests were performed to confirm there was no significant difference in baseline pregnancy weight, $t(230) = 1.49$, $p = .060$ and BMI $t(230) = 1.90$, $p = .134$, between the control and study groups (see Table 2 for mean comparisons).

For objectives 1, 3, 4, and 5, a multivariate analysis of variance (MANOVA) was used to compare the 5 continuous perinatal outcomes variables: maternal last weight before delivery, maternal 6-week postpartum weight, mean weight difference between the baseline pregnancy weight and weight before delivery, gestational age at birth, and infant birthweight. In addition, for objectives 1, 3, 4, and 5, χ^2 was used to compare the 11 categorical perinatal variables: gestational diabetes (0 = no, 1 = yes), preeclampsia, ketonuria, gestational hypertension, preterm delivery, postterm delivery, labor induction, macrosomic infant, Apgar score, cesarean delivery, and hemorrhage/infection postpartum (0 = no infection, 1 = infection, 2 = hemorrhage). For objective 2, a χ^2 test was used to compare the 2 categorical perinatal variables, macrosomic infant, and Apgar score. (Note: As the focus in objective 2 was on newborns, macrosomic infant and Apgar score were addressed in this objective, and a *t* test was performed for infant birth weight.) Levene's equality of error variance was used to test the homogeneity of variance assumption.

RESULTS

The analyses included 116 patients in the monitored (study) group and 116 patients in the unmonitored (con-

Table 1. Demographic Characteristics of Study Participants[a]

	Control Group (n = 116)	Study Group (n = 116)
Median age, y	27.3	26.8
Parity		
Nulliparous	20 (17.2)	19 (16.3)
Parous	96 (82.8)	97 (83.7)
Marital status		
Single	31 (26.7)	28 (24.1)
Married/de facto	85 (73.3)	88 (75.9)
Race/ethnicity		
African American	49 (42.2)	46 (39.7)
Caucasian	27 (23.3)	25 (21.6)
Latina	25 (21.6)	29 (25)
Indian	15 (12.9)	16 (13.7)

[a] Data are shown as n (%)

Table 2. Baseline Data of Study Participants[a]

	Control Group (n = 116)	Study Group (n = 116)	*P* Value
Baseline pregnancy weight, lbs	214.20 (50.71)	204.11 (51.80)	.060
Body mass index, kg/m^2	38.22 (7.48)	37.41 (7.01)	.134

[a] Data are shown as mean (standard deviation)

trol) group and were performed according to the intention-to-treat principle. Eight patients from the study (monitored) group were lost to follow-up, leaving 116 patients for analysis; 17 patients in the control (unmonitored) group were lost to follow-up, leaving 116 patients for analysis. Perinatal outcomes of the study participants are listed in Table 3.

Table 3. Perinatal Outcomes of Study Participants

	Control Group (n = 116)	95% CI	Study Group (n = 116)	95% CI	*P* Value
Maternal					
Last weight before delivery, lbs[a]	245.02 (50.27)	236-253	215.46 (47.41)	205-223	<.001
6-Week postpartum maternal weight, lbs[a]	226.86 (50.29)	218-236	199.76 (48.58)	191-209	<.001
Mean gain difference from baseline weight to last weight before delivery[a]	31 (16.31)	27.82-33.82	11 (14.96)	8.59-14.10	<.001
Mean loss difference from last weight before delivery to 6-week postpartums[a]	18 (32.71)	17.03-14.38	16 (7.21)	24.17-12.14	.431
Gestational diabetes[b]					
Yes	19 (16.4)		11 (9.5)		.118
No	97 (83.6)		105 (90.5)		
Preeclampsia[b]					
Yes	11 (9.5)		7 (6.0)		.326
No	105 (90.5)		109 (94)		
Ketonuria [b]					
Yes	0 (0)		0 (0)		NA
No	116 (100)		116 (100)		
Gestational hypertension[b]					
Yes	10 (8.6)		3 (2.6)		.046
No	106 (91.4)		113 (97.4)		
Hemorrhage/infection postpartum[b]					.729
Hemorrhage	5 (4.3)		3 (2.6)		
Infection	6 (5.2)		5 (4.3)		
No	105 (90.5)		108 (93.1)		
Preterm delivery (<37 weeks)[b]					
Yes	5 (4.3)		3 (2.6)		.472
No	111 (95.7)		113 (97.4)		
Postterm delivery (>41 weeks)[b]					
Yes	16 (13.8)		15 (12.9)		.847
No	100 (86.2)		101 (87.1)		
Labor induction[b]					
Yes	31 (26.7)		22 (19)		.159
No	85 (73.3)		94 (81)		
Cesarean delivery[b]					
Yes	83 (71.6)		91 (78.4)		.225
No	33 (28.4)		25 (21.6)		
Adherence with prescribed nutritional regimen[b]					
Yes	NA		90 (77.6)		NA
No			26 (22.4)		
Fetal					
Gestational age[a] at birth, w	39.35 (1.94)	38.95-39.77	39.41 (2.50)	38.99-39.84	.866
Infant birthweight, g[a]	3586 (560.81)	3478-3692	3526 (608.36)	3418-3632	.438
Macrosomic Infant (>4500 g/10 lbs)[b]					
Yes	4 (3.4)		9 (7.8)		.153
No	112 (96.6)		107 (92.2)		
Apgar score (<7 at 5 minutes)[b]					
Yes	0 (0)		1 (0.9)		.316
No	116 (100)		115 (99.1)		

Abbreviation: NA, not applicable

[a] Data are shown as mean (standard deviation); continuous data.

[b] Data are shown as n (%); categorical data.

[c] P value differences between groups were tested with an ANOVA for continuous variables and χ^2 for the categorical variable.

Objective 1: Perinatal Outcome Differences Between Control and Study Groups

The control group (unmonitored) had a BMI range between 30 and 64 kg/m^2, and the study group (monitored) had a BMI range between 30 and 69 kg/m^2. An Omnibus MANOVA showed statistically significant differences between the study and control groups for continuous variables previously stated in the statistical analysis section of this article (Wilks' $\lambda = 27.54$, $p < .001$, effect size = 0.327). A follow-up ANOVA indicated that there were statistically significant differences in the groups: (a) maternal last weight before delivery, $F(1, 232) = 21.22$, $p < .001$; (b) maternal 6-week postpartum weight, $F(1, 232) = 17.42$, $p < .001$; as well as (c) differences from maternal baseline weight to their last weight before delivery, $F(1, 232) = 89.76$, $p < .001$. Women in the control group weighed more before delivery than those in the study group. Mothers in the control group also weighed more at their 6-week postpartum visit than those in the study group. Mean differences from maternal baseline weight to their last weight before delivery confirmed that women in the control group gained significantly more weight during their pregnancy than mothers in the study group before birth. Weight loss differences from maternal last weight before delivery and their 6-week postpartum weight was not significantly different between the control and study groups (Table 3).

χ^2 Was used for the control and study groups to compare the following perinatal variables: gestational diabetes, preeclampsia, ketonuria, gestational hypertension, preterm delivery, postterm delivery, labor induction, cesarean delivery, and hemorrhage/infection postpartum. Expected cell count number standards were met for gestational hypertension and rendered a Pearson χ^2 of $p = .046$. Thus, women in the control group (9%) were more likely to experience gestational hypertension than women in the study group (3%), $\chi^2(1, N = 232) = 3.99$; $p = .046$ (Table 3). Ketonuria was not observed in any of the patients in the study. There were no adverse events in either group.

Objective 2: Effects of Weight Stabilization on Perinatal Morbidity and on Birthweight of Newborns

χ^2 Showed that there were no significant differences between the control and study groups on their newborns regarding fetal macrosomia $\chi^2(1, N = 232) = 1.30$; $p = .153$). The Apgar score between these groups was also not significant, $\chi^2(1, N = 232) = 1.004$; $p = .316$). However, raw numbers are too low for proper statistical computation. A t test showed no significant difference between the control and study groups and the infant birth weight, $t(230) = 0.778$, $p = 0.438$ (Table 3).

Objective 3: Differences in Perinatal Outcomes Regarding Adherence Versus Nonadherence With Prescribed Nutritional Regimen in the Study Group

Of the 116 women who participated in the study group, 90 mothers adhered to the nutritional program, and 26 did not adhere to the prescribed regimen. A MANOVA showed statistically significant differences for perinatal outcomes between the adherent and nonadherent groups (Wilks' $\lambda = 53.038$, $p < .001$, effect size = 0.707). A follow-up ANOVA indicated that there were statistically significant differences between the groups for (a) maternal last weight before delivery, $F(1, 114) = 4.13$, $p < .05$; (b) maternal 6-week postpartum weight, $F(1, 114) = 5.65$, $p < .05$, (c) weight difference between the baseline pregnancy weight and weight before delivery, $F(1, 114) = 4.13$, $p < .001$; and (d) infant birthweight, $F(1, 114) = 24.97$, $p < .001$ (Table 4).

In Table 4, a χ^2 test indicates that women in the study group who did not adhere to the nutritional regimen compared to those women in the study group who did

Table 4. Differences in Perinatal Outcomes Regarding Adherence vs Nonadherence With Prescribed Nutritional Regimen in Study Group

	Adherence (n = 90)	95% CI	Nonadherence (n = 26)	95% CI	*P* Value[c]
Infant birth weight, g[a]	3388 (418.10)	3272-3503	4004 (879.89)	3789-4219	<.001
Last weight before delivery, lbs[a]	211 (46.34)	201-221	232 (48.32)	214-250	<.05
6-Week postpartum maternal weight, lbs[a]	194 (46.84)	184-204	219 (50.33)	201-238	<.05
Mean gain difference from baseline weight to last weight before delivery[a]	5 (10.64)	3.5-7.9	31(10.74)	26.7-35.0	<.001
Gestational diabetes[b]	2 (2.2)		9 (34.6)		<.01
Preeclampsia[b]	2 (2.2)		5 (19.2)		<.01
Labor induction[b]	12 (13.3)		10 (38.5)		<.01
Cesarean delivery[b]	9 (10)		16 (61.5)		<.01
Macrosomic infant[b]	2 (2.2)		7 (27)		<.001

[a] Mean (standard deviation); continuous data.

[b] n (percentage); categorical data.

[c] *P* value differences between groups were tested with an ANOVA for continuous variables and χ^2 the categorical variables.

adhere were more likely to have gestational diabetes and preeclampsia. Women who did not adhere to the nutritional regimen compared to those who did adhere were also more likely to have labor induced, a cesarean delivery, give birth to macrosomic infants, and retain more weight during and after their pregnancy. (Note that minimal expected counts are low for gestational diabetes, preeclampsia, and macrosomic infants, and conclusions should be made with caution.)

Objective 4: Participants Who Gained 15 Pounds or More During Pregnancy

Obese pregnant women who gained 15 pounds or more during pregnancy compared to those who gained fewer than 15 pounds, irrespective of whether they were in the control or study group, were examined to determine the effect of abnormally high weight gain on perinatal outcomes. A MANOVA showed statistically significant differences between these 2 groups (Wilks' λ = 56.28, $p < .001$, effect size = 0.555) for 4 continuous perinatal variables. χ^2s showed statistical differences for 4 of the categorical perinatal variables. Results also showed that being in the control group vs the study group also made a difference in weight (Table 5).

Overall, during their pregnancy, women who gained 15 pounds or more compared to those women who gained fewer than 15 pounds were typically in the control group and had gained more weight during their pregnancy, gave birth to heavier babies and did not lose as much weight 6 weeks postpartum. Women who gained 15 pounds or more were also more likely to have gestational diabetes, preeclampsia, undergo cesarean delivery, and have labor induced.

Objective 5: Participants Who Gained Fewer Than 10 Pounds During Pregnancy

Patients who gained fewer than 10 pounds during pregnancy compared to those who gained 10 pounds or more, irrespective of whether they were in the control or study group, were initially examined to determine the effect of abnormally low weight gain in obese women on perinatal outcomes. A MANOVA showed statistically significant differences between these 2 groups (Wilks' λ = 37.49, $p < .001$, effect size = 0.453). A follow-up ANOVA indicated that there were statistically significant differences in the groups for maternal last weight before delivery, maternal 6-week postpartum weight, as well as mean weight difference between the baseline pregnancy weight and weight before delivery. There was no significant difference in infant birth weight between these 2 groups (Table 6).

In Table 6, χ^2 shows that women who gained fewer than 10 pounds were much more likely to be in the study group vs the control group. Women were also more likely to have a cesarean delivery and less likely to develop gestational diabetes. Those who gained fewer than 10 pounds and were in the study group (n = 53) all followed the nutritional prescribed diet. Interestingly, 40% of 57 women actually lost weight during their pregnancy. One patient who entered the study at a weight of 472 pounds (214.5 kg) with a BMI of 68.4 kg./m^2 weighed 446 pounds (202.7 kg) with a BMI of 65.6 kg/m^2 at term, delivering vaginally a 3510-g infant without complications.

DISCUSSION

According to Durnin, pregnancy requires a total energy intake of an additional 20 000 kcal.[25] In order to meet this increased energy demand, a caloric increase of 100 to 300 kcal per day is necessary during pregnancy. Yet, according to Cogswell and associates, utilizing the

Table 5. Participants Who Gained ≥15 lbs During Pregnancy With Those Who Gained Fewer Than 15 lbs

	Weight Gain <15 lbs (n = 92)	95% CI	Weight Gain ≥15 lbs (n = 140)	95% CI	*P* Value[c]
Last weight before delivery, lbs[a]	218 (54.75)	208-229	238 (46.85)	229-246	<.01
6-Week postpartum maternal weight, lbs[a]	201 (55)	190-211	221 (47)	212-230	<.01
Mean gain difference from baseline weight to last weight before delivery[a]	4.44 (9.32)	1.8-7.0	32 (14.24)	30-34	<.001
Infant birth weight, g[a]	3411 (468)	3292-3528	3651 (634)	3555-3746	<.01
Gestational diabetes[b]	4 (4)		26 (19)		<.01
Preeclampsia[b]	2 (2)		16 (11)		<.01
Labor induction[b]	12 (13)		41 (29)		<.05
Cesarean delivery[b]	13 (14)		45 (32)		<.01
Group type[b]					<.001
Study group	78 (67.2)		38 (32.8)		
Control group	14 (12.1)		102 (87.9)		

[a] Mean (standard deviation); continuous data.

[b] n (percentage); categorical data.

[c] *P* value differences between groups were tested with an ANOVA for continuous variables and χ^2 for the categorical variables.

Pregnancy Nutrition Surveillance System (PNSS) data (a national database based on information about low-income women from 25 states and 6 tribal agencies), there has been an increase of more than 50% in the percentage of women gaining weight above the Institute of Medicine (IOM) recommendations.[6,26]

In the 1940s and 1950s, it was standard practice in the United States to restrict weight gain during pregnancy to less than 9 kg (20 pounds) with the intent of reducing the risk of preeclampsia and of birth complications that were believed to occur more often with larger babies.[27] Following publication of the results for the Collaborative Perinatal Project by Eastman and Jackson in 1968,[28] there was increased awareness that mothers who gained less than 9 kg had smaller babies with poorer survival.

However, more than 40 years later, Catalano stated that poor maternal weight gain in pregnancy has not been found to be directly related to the risk of intrauterine fetal growth restriction.[29] Additionally, 2 more recent cohort studies concluded that a decreased risk of adverse obstetric and neonatal outcomes was associated with lower gestational weight gains than was earlier recommended, especially among obese women and that limited or no weight gain in obese pregnant women has favorable outcomes.[30,31]

Our randomized clinical trial has corroborated prior observations that obese pregnant women need not gain any extra weight during pregnancy.[32] This study has also demonstrated that weight loss resulting from a well-balanced, nutritionally sound calorie-appropriate regimen in obese women was not associated with ketonuria, increased perinatal morbidity, low birth weight, or fetal growth restriction. Statistically significant differences in the development of comorbidities in patients who were monitored (study group) compared to those who were not (control group) reinforce the benefits of good nutrition, as applied to obese pregnant women. It seems counterintuitive to recommend at least a 15-pound weight gain in an already obese woman who may have begun her pregnancy weighing 200, 300, or even 400 pounds, thus further contributing to the ubiquitous obesity continuum of risk. However, practitioners have been in accordance with the aforementioned weight gain recommendation in obese pregnant women for the past nineteen years. These 1990 IOM guidelines for recommended ranges of total weight gain for pregnant women by prepregnancy BMI for a singleton gestation are currently under review.[33]

Although this study had appropriate power, there are limitations. The study group (monitored patients) self-reported their nutritional regimen, which can be less reliable than objective measurements. Also, the conclusions regarding the development of gestational diabetes, preeclampsia, and fetal macrosomia in the adherent versus nonadherent group of patients should be made with caution due to the low sample numbers in these categories. Unlike past studies that have commented on the possibility of limiting weight gain in pregnancy for obese women,[34-37] this randomized clinical trial has designed a paradigm for obese pregnant women to minimize weight gain while improving perinatal outcomes. Hopefully, this will be the first of many studies that will further examine active intervention by nutritionally monitoring obese pregnant women and individualizing their course of prenatal management.

Rather than focusing on a numerical end point with respect to weight gain in obese pregnant women, perhaps policy-making bodies should consider recommendations that promote adherence to a monitored, well-balanced nutritional program. Based on the findings in this study, consideration should be made that the conventional, nonspecific, ad libitum, "eat to appetite" recommendations for obese pregnant women be replaced with an emphasis on instituting a monitored, healthy nutritional guideline, with the possibility of enlisting the support of a core nutri-

Table 6. Participants Who Gained Fewer Than 10 lbs During Pregnancy Compared to Those Who Gained 10 lbs or More

	Weight Gain <10 lbs (n = 57)	95% CI	Weight Gain ≥10 lbs (n = 175)	95% CI	*P* Value[c]
Last weight before delivery, lbs[a]	217 (54.04)	208 to 229	234 (49.32)	229 to 246	<.05
6-week postpartum maternal weight, lbs[a]	200 (54.81)	190 to 211	217 (49.41)	212 to 230	<.05
Mean difference from baseline weight to last weight before delivery[a]	–0.39 (8.79)	–3.98 to 3.19	28 (14.99)	26 to 30	<.05
Infant birthweight, g[a]	3437 (475)	3285-3589	3594 (612)	3507 to 3680	<.079
Gestational diabetes[b]	3 (5.3)		27 (15.4)		<.05
Cesarean delivery[b]	52 (91)		122 (70)		<.01
Group Type[b]					<.001
Study group	53 (54)		63 (46)		
Control group	4 (3)		112 (97)		

[a] Mean (standard deviation); continuous data.

[b] n (percentage); categorical data.

[c] P value differences between groups were tested with an ANOVA for continuous variables and χ^2 for the categorical variables.

tional program within a commercial weight management service adapted to the pregnant woman in order to attain the optimal benefits of a healthy pregnancy outcome.[38,39]

The results of this clinical trial have shown that obese pregnant women may be placed on a healthy, well-balanced, monitored nutritional program during their antepartum course without adverse perinatal outcomes. Moreover, those monitored patients who were adherent by following the prescribed nutritional program and maintaining a daily food diary demonstrated less perinatal morbidity compared to their nonadherent or unmonitored counterparts.

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