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Preventing excessive gestational weight gain among African American women: a randomized clinical trial

Sharon J. Herring^{1,2,3,4}, Jane F. Cruice², Gary G. Bennett^{5,6}, Marisa Z. Rose⁴, Adam Davey³, and Gary D. Foster^{2,7}

¹Department of Medicine, Temple University, Philadelphia, PA

²Center for Obesity Research and Education, Temple University, Philadelphia, PA

³College of Public Health, Temple University, Philadelphia, PA

⁴Department of Obstetrics, Gynecology, and Reproductive Sciences, Temple University, Philadelphia, PA

⁵Department of Psychology and Neuroscience, Duke University, Durham, NC

⁶Duke Obesity Prevention Program, Duke University, Durham, NC

⁷Weight Watchers International, New York, NY

Abstract

Objective—Evidence is lacking regarding effective weight control treatments in pregnancy for ethnic minority women with obesity. This study evaluated whether a technology-based, behavioral intervention could decrease the proportion of overweight or obese African American women who exceeded Institute of Medicine (IOM) guidelines for gestational weight gain.

Methods—We conducted a 2-arm pilot randomized clinical trial. Participants were 66 socioeconomically disadvantaged African American pregnant women (12.5 ± 3.7 weeks' gestation; 36% overweight, 64% obese) recruited from 2 outpatient obstetric practices at Temple University between 2013 and 2014. We randomized participants to usual care (n = 33) or a behavioral intervention (n = 33) that promoted weight control in pregnancy. The intervention included: 1) empirically-supported behavior change goals; 2) interactive self-monitoring text messages; 3) biweekly health coach calls; and 4) skills training and support through Facebook.

Results—The intervention reduced the proportion of women who exceeded IOM guidelines compared to usual care (37% vs. 66%, p = 0.033). Intervention participants gained less weight

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Address correspondence and reprint requests to: Sharon J. Herring, MD, MPH, Center for Obesity Research and Education, Temple University, 3223 N. Broad Street, Suite 175, Philadelphia, PA 19140, Phone: 215-707-2234, Fax: 215-707-6475, ; Email: Sharon.Herring@temple.edu

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during pregnancy (8.7 vs. 12.3 kg, adjusted mean difference -3.1 kg, 95% CI $-6.2, -0.1$). No group differences in neonatal or obstetric outcomes were found.

Conclusions—The intervention resulted in lower prevalence of excessive gestational weight gain.

Keywords

pregnancy; African American; behavior modifications; obesity; technology

Introduction

The puerperal period is a critical life stage for excess weight gain and obesity risk,¹ especially for African American women, who retain 2–3 times more weight after pregnancy than whites.^{2–5} Gestational weight gain is the strongest identified risk factor for retaining a substantial amount of weight postpartum,¹ yet few published interventions have been effective in reducing excessive weight gain in pregnancy, particularly among low-income African American mothers. These women may be especially disadvantaged, as they are the most likely to enter pregnancy overweight or obese,⁶ which is a strong risk factor for gaining in excess of Institute of Medicine (IOM) guidelines.¹ Moreover, higher weight gains are independently associated with additional adverse outcomes during and after pregnancy, including increased risk of maternal hyperglycemia, large-for-gestational-age infants, cesarean delivery, and childhood overweight.⁷ As a majority of African American women now overgain in pregnancy,^{8,10} interventions to prevent excessive gestational weight gain are of considerable public health importance.

Traditional, high-intensity, in-person weight control programs are unlikely to meet the needs of low-income African American mothers, whose competing demands (e.g., childcare, work, school) pose significant challenges to intervention adherence and efficacy.^{11,12} Face-to-face weight loss treatments can be costly and difficult to disseminate.^{13,14} Social media and text messaging are formats that may overcome these barriers. Preliminary data from our team support the utility of technology platforms (text messaging, Internet, Facebook, interactive voice response) for weight control intervention delivery.^{15–17} Users can interact frequently and at their convenience, a pattern likely to facilitate engagement, retention, and deliver a high intervention dose – all at low cost. Further, social networking sites (e.g., Facebook) allow for peer support through mentoring and modeling, components considered important for weight control success.¹⁸ Use of these technologies is widespread, especially among young, socioeconomically disadvantaged African American women on their mobile devices,¹⁹ and thus, any weight control interventions for this population should leverage technology to support behavior change.

The goal of this pilot study was to determine whether a technology-based, behavioral weight control intervention (using text messaging, Facebook, and telephonic counseling sessions with a health coach) would be effective among overweight or obese low-income African American women for decreasing the proportion who exceeded IOM guidelines for gestational weight gain.

Methods

Participants

Participants were 66 overweight or obese pregnant women recruited from 2 large outpatient obstetric practices at Temple University between 2013 and 2014. Study staff used Temple's electronic medical record to identify potential participants by body mass index (BMI) and age, and then approached them in waiting rooms to evaluate trial interest (Figure 1). Eligibility criteria included: 1) age ≥ 18 years; 2) self-identification as African American; 3) gestational age < 20 weeks; 4) first trimester BMI 25–45 kg/m²; 5) Medicaid recipient (income proxy); 6) cell phone ownership with unlimited text messaging; and 7) Facebook member. Women were excluded if they had conditions requiring specialized nutritional care (e.g., history of bariatric surgery), endorsed current tobacco use, or were carrying multiples. Obstetric provider consent was required for participation; however, providers and clinic staff were blinded to subject randomization to prevent contamination.

Women who were interested and eligible completed a baseline assessment at our research center (in a building separate from our obstetric practices) after which they were randomly assigned into the intervention (n=33) or usual care (n=33). Randomization was computer-generated (by study statistician) with a 1:1 allocation ratio; randomization status was concealed in opaque envelopes prepared by the statistician. Participants were assessed at study entry and 36 weeks' gestation and were compensated with \$30 at each assessment visit for time and travel. All participants gave written informed consent to join the study, which was approved by the Institutional Review Board at Temple University.

Treatment groups

Usual care—Women randomized to usual care received standard obstetrical care at Temple University, which included: 1) an initial visit in the first trimester, during which obstetric providers completed a comprehensive patient history, physical exam, ultrasound, and blood work; 2) follow-up visits monthly until week 24 and every 2 to 3 weeks until week 36, where providers assessed patient weight, blood pressure, urine protein, and fetal heart rate; and 3) weekly visits from week 36 until delivery. Information from the American College of Obstetricians and Gynecologists (ACOG) about optimal weight gain during pregnancy was also supplied.

Technology-based, behavioral intervention

Conceptual framework: Incorporating aspects of Social Cognitive Theory,^{20,21} which highlights self-efficacy and social support as drivers of behavior change, and the Social Ecological Model,²² that focuses on the influence of context, our intervention was designed to build participant motivation, support, and self-efficacy for weight-related behavior change, while at the same time remain responsive to low-income African American mothers' social context.

Intervention targets: We created behavior change goals around 3 evidence-based weight control targets (energy intake, physical activity, and self-weighing).^{1,23} During our formative work,^{24,25} we prioritized behavior change goals that were relevant to the patient population,

easily monitored through text messaging, and could be communicated simply so they would be understood by mothers with low literacy.

1. Energy intake. Plans for altering energy intake focused on changes in diet quality and quantity. Energy intake goals included (as provided to participants): “Limit sugar-sweetened beverages to 1 cup per day”; “Limit junk and high fat food to no more than 1 per day”; and “Stick to 1 plate of food at each meal”. Low-calorie beverages and nutrient-rich foods that were convenient, inexpensive, palatable, and consistent with mothers’ social norms were suggested as substitutions. This approach, rather than setting a specific caloric target, was consistent with IOM guidelines,¹ had fewer literacy/numeracy barriers, and was well suited for technology-based implementation.
2. Physical activity. Walking goals were consistent with ACOG recommendations: “Walk 5,000 steps daily”.²⁶ To permit adaptation to exercise and decrease chance for injury, mothers were encouraged to gradually increase their walking by 500 steps weekly (from their baseline to the 5,000 steps/day target). Pedometers and a walking DVD were provided to promote activity.
3. Self-weighing. Using study-supplied digital scales, participants were prompted to “Weigh yourself weekly” at home. Mothers were encouraged to meet weekly IOM weight gain targets in the second and third trimesters.¹

Intervention components: Skills training and support were delivered through 3 mechanisms.

1. Skills training and self-monitoring texts with personalized feedback. Participants received daily text messages tailored to each behavioral goal to build skills and self-efficacy (e.g., “One mom says, ‘Snacking at night will just give me heartburn. But if it’s yogurt, then I’ll be good. I don’t eat any junk late at night’”). Participants also received self-monitoring texts 3 to 4 times weekly to probe about behavioral adherence. Text message prompts in the morning (e.g., “Please text us total # junk and grease u had yesterday. Remember, 1 cookie = 1 junk food or 1 piece of fried chicken = 1 greasy food”) were followed by immediate personalized automatic feedback to reinforce successes and/or offer support (e.g., “U had 0 junk and grease foods. Ur really working toward growing a healthy baby! Keep eating fruits and veggies, they’re the healthiest! ☺”). As an incentive, participants received raffle entries for responding to self-monitoring text prompts; an automated computer program randomly chose monthly \$25 gift card winners.
2. Facebook. Participants were enrolled in a private Facebook group to provide a forum for support and additional behavioral skills training via links to websites and videos. Participants were encouraged to “like” weekly coach posts and provide updates. To ensure confidentiality, this group was by invitation only and had a generic name (e.g., “Pregnant Moms Temple”); information about privacy settings was also supplied.

3. Health coach calls. A bachelor's level health coach, trained in methods of behavioral weight control, delivered 15 to 20 minute counseling calls to participants weekly for the first two study weeks and then twice monthly thereafter. Counseling calls were designed to reinforce skills and provide the opportunity to problem-solve through barriers. To increase intervention fidelity, calls were scripted and audiotaped; 10% were reviewed at research meetings, with discussion and role-play retraining as needed. A web application was used for note taking and storage of process data (e.g., date/time of call, call attempts, disposition).

Implementation: Our intervention was designed to be an adjunct to clinical care, not formally integrated within it, as data suggest that healthcare providers consider weight control a lower priority than other clinical needs.^{27,28} This design, coupled with the use of technology to deliver content, was chosen for its potential ease of widespread dissemination.

Participants randomized to the intervention were oriented to the program at their baseline visit from the health coach, who provided an overview of the behavior change goals, explained the intervention components, and reviewed the schedule with participants. Each participant was assigned the same schedule for the first 12 program weeks (Figure 2) after which the health coach prioritized the order goals would be repeated until delivery (based on participant progress and preference). A binder with print versions of program content was also provided to offer tailored skills training if technology access was lost.

Measures

The primary outcome measure for this study was the proportion of women with excessive gestational weight gain based on the 2009 IOM guidelines for full term, singleton pregnancies.¹ These guidelines categorize total weight gains > 11.5 kg as excessive in overweight women and > 9 kg as excessive in obese women. We calculated total gestational weight gain as the difference between last measured weight recorded before delivery and first measured weight in early pregnancy, both extracted from clinical prenatal care records. Similar to other studies among pregnant women, we chose to use participants' earliest measured weight as the proxy for maternal weight at conception because measured maternal pre-pregnancy weight is seldom available, self-reported pre-pregnancy weight varies by BMI and sociodemographic factors, and the total weight gain in the first trimester is small (0.5–2 kg).^{29,31} As described in a prior publication, we found systematic differences in pre-pregnancy weight recall by BMI; underestimation of pre-pregnancy weight was significantly greater among women with obesity.¹⁰ Sixty-four participants (97%) had a first trimester measured weight available for this analysis (mean \pm standard deviation = 7.9 \pm 3.6 weeks' gestation). For the remaining 2 mothers, we used their initial weight measured at 18 weeks' gestation to calculate total gestational weight gain. Average gestational age of participants' last measured weight was 0.7 weeks (range 0–4) before delivery. Timing of weight measures did not significantly differ between treatment groups. We surveyed participants at study entry to collect data about demographics and again at 36 weeks' gestation to assess treatment acceptability. Heights were measured by trained research staff with a stadiometer at study entry, used with participants' earliest measured antenatal weight to calculate BMI. Neonatal weight outcomes (e.g., birth weight, small-for-gestational-age [SGA], birth weight

less than the 10th percentile], large-for-gestational-age [LGA, birth weight greater than the 90th percentile]) and maternal obstetric outcomes (e.g., mode of delivery, gestational diabetes) were abstracted from inpatient hospital records after delivery. We also examined intervention engagement by calculating the number of self-monitoring response texts received, number of participant comments or “likes” to posts on Facebook, and number of coach calls completed. Treatment fidelity was measured by monitoring the number of coach calls attempted and number of weekly coach posts to Facebook.

Statistical analyses

Based on the intent-to-treat principle, we analyzed data from all participants as originally randomized. Univariate analyses comparing baseline characteristics and outcome data between the intervention and usual care groups were performed for categorical variables using Pearson χ^2 tests, or Fisher’s exact tests in the case of expected cell frequencies of less than 5. We used t-tests or Mann-Whitney U tests for continuous variables, depending on the distribution of the variable. A multivariable logistic regression model was used to determine the effect of treatment group on the proportion of women who exceeded IOM gestational weight gain guidelines compared to those within and below the guidelines, controlling for early pregnancy BMI, parity, and maternal age. Women with miscarriages (n = 5) or elective termination (n = 1) were excluded from primary analyses; participants with preterm deliveries (< 37 weeks’ gestation, n = 4) were also excluded because IOM guidelines for pregnancy-related weight gains are based on full-term births. However, similar results were obtained with their inclusion, even after correcting for gestational age of final measurement. We used analysis of covariance to assess the effect of treatment group on total gestational weight gain, with adjustment for the same covariates along with length of gestation. We additionally used logistic regression analyses to examine group differences in neonatal and obstetric outcomes. Analyses were performed with SAS 9.4 software (SAS Institute, Cary, NC).

Results

The intervention and usual care groups did not differ significantly with respect to baseline characteristics (Table 1).

Weight change during pregnancy

Participants assigned to the intervention group were significantly less likely to exceed IOM guidelines compared to usual care (37% vs. 66%, p = 0.033; Table 2). Similar results were observed in analyses adjusted for early pregnancy BMI, parity, and maternal age (odds ratio: 0.3, 95% confidence interval [CI]: 0.10, 1.0, p = 0.0497). Intervention participants also gained less weight in pregnancy than controls (8.7 vs. 12.3 kg respectively, unadjusted mean difference: -3.6, 95% CI: -7.0 to -0.1, p = 0.046; adjusted mean difference: -3.1, 95% CI: -6.2 to -0.1, p = 0.045).

Stratification by weight status yielded analogous results. Intervention participants with obesity were less likely to exceed IOM guidelines (37% vs. 65%) and gained less weight in pregnancy (7.2 vs. 10.6 kg) than obese participants randomized to usual care; overweight

participants showed the same pattern (38% of overweight intervention participants exceeded IOM guidelines vs. 67% of usual care; mean weight gain in the two groups was 12.4 vs. 16.1 kg). However, neither comparison in our stratified analyses reached statistical significance.

Obstetric and neonatal outcomes

We did not detect differences between the intervention and usual care groups in mean birth weight (3147 vs. 3361 g, mean difference = -213; 95% CI: -431 to +3.7), birth weight adjusted for gestational age (3161 vs. 3349 g, mean difference = -188; 95% CI: -385 to +9.4), prevalence of SGA (8% vs. 7%, Fisher's exact $p = 1.00$), or prevalence of LGA (4% vs. 0%, Fisher's exact $p = 0.48$). There were also no significant effects of treatment group on prevalence of cesarean delivery (48% vs. 36%, $p = 0.35$) or gestational diabetes (4% vs. 4%, Fisher's exact $p = 1.00$), findings that persisted in multivariable logistic regression analyses.

Intervention engagement and treatment fidelity

The mean frequency of self-monitoring response texts per intervention participant was 65.2 ± 29.4 (expected texts = 114), with the majority of participants (70%) responding to 50% of the self-monitoring text prompts. Compared to participants who did not respond to 50% of the monitoring prompts, those who did respond were less likely to exceed IOM guidelines, although this association did not reach statistical significance (50% vs. 32%, Fisher's exact $p = 0.41$). Intervention participants also completed an average of 4 ± 1.5 coaching calls (expected calls = 7) during the first 12 program weeks and an average of 1 ± 0.5 additional calls until delivery; however, greater call frequency was not associated with greater weight control. More than 90% of calls were attempted. While few participants (11%) commented or "liked" posts on Facebook, average number of weekly coach posts was 1.7 ± 0.9 , which waned over time.

Treatment acceptability

Among intervention participants who completed the treatment acceptability questionnaire ($n = 22$; 81%), 96% reported that the skills they learned in the program were extremely helpful (at least an 8 on a 10-point scale); 96% found the text messages and 82% found the coach calls extremely useful; and 87% reported the program was extremely successful in changing eating habits. Qualitative feedback included: (i) *"I believe without this program my weight gain would have been out of control"* and (ii) *"I'm [now] watching what I eat and drink as well as monitoring my kids diets so we can stay healthy and fit throughout our lives."*

Discussion

In this pilot randomized clinical trial, we found that a technology-based, behavioral intervention reduced the prevalence of excessive gestational weight gain among overweight or obese African American women. The intervention additionally minimized mean gestational weight gain compared to usual care, without evidence of obstetric or neonatal complications. However, larger studies with sufficient power to evaluate clinical endpoints are needed to confirm our findings.

Our study is one of only two randomized trials involving at least 10% African Americans that resulted in a reduction in the proportion of women exceeding IOM weight gain guidelines. Thornton *et al.* randomized 257 obese women (41% African American) at 12–28 weeks' gestation to receive either 1) a dietary intervention focused on limiting caloric intake (18–24 kcals/kg/day) with food records reviewed by an obstetrician at prenatal visits, or 2) usual antenatal care.³² While the intervention lowered mean gestational weight gain and reduced the proportion of women exceeding IOM guidelines, dissemination of an obstetrician-delivered weight control intervention may be especially limited in busy, underresourced practices due to cost, inadequate provider training and time, and patient reliance on other sources of weight-related advice (e.g., Internet).^{24,27} The current data suggest that weight control programs run as adjuncts to clinical care (e.g., delivered through inexpensive digital health platforms with little required “manpower” [< 0.5 full time equivalents] for health coaching) may be equally as efficacious, with greater potential for widespread reach, accessibility, and scalability. The high rates of text message engagement signal that technology-based strategies can be effectively implemented in socioeconomically disadvantaged ethnic minority patient populations, populations that are increasingly “connected”.¹⁹ However, additional studies focusing on issues of implementation, dissemination, and cost are needed.

Our treatment approach focused exclusively on the modification of several simple and easily understood weight-related behaviors. Repeated conversations with mothers from our target population revealed that recommending strict caloric targets or specific diets were unappealing, due to the cognitive complexity and inherent resource assumptions (e.g., food access/availability, transportation, costs) associated with these strategies. Our intervention design, to be delivered via digital health platforms, offered a moderate to high intensity intervention with greater flexibility than repeated in-person visits for socioeconomically disadvantaged mothers – mothers who have proven difficult to treat in prior studies.^{33,34} Members of our team have tested a similar intervention approach (iOTA) in other populations of low-income ethnic minority adults with weight loss success.^{15–17} Our reliance on coach calls to deliver support and additional skills was met with high satisfaction, despite the lack of association with weight control. Human support is associated with better behavior change outcomes in clinical trials,³⁵ but whether this support needs to be in-person or can be remote for improving pregnancy outcomes is still up for debate.

While the intervention did not have adverse effects on obstetric or neonatal outcomes, we were not adequately powered to assure there were no group differences. A much larger sample would be required to examine outcomes such as SGA, LGA, and gestational diabetes. Our next step will be to determine the longer term effects of the intervention on 6-month and 1-year postpartum weights, following completion of a postpartum weight loss/weight maintenance phase.

The results of this study are encouraging; nonetheless, any conclusions drawn must be tempered by study limitations including the pilot nature and small sample size. We used clinic measured weights to calculate our primary outcome, and thus, cannot be certain these weights were collected with the same degree of quality (e.g., calibrated scales, no shoes) as weights collected by research staff. However, clinic staff were blind to randomization

assignment, so any measurement bias would likely be non-differential across treatment groups. Additionally, Vesco and colleagues found the absolute agreement between research and prenatal clinic measured weights to be extremely high, providing strong support for exchangeability.^{36,37} We may have misclassified participants as adhering to IOM guidelines by using the first measured weight in early pregnancy rather than self-reported pre-pregnancy weights or estimated pre-pregnancy weights using mathematical models, as described in other publications.^{38,39} Any misclassification, then again, should not differ between intervention and controls. Participant and coach activity on Facebook declined during the intervention making it difficult to fully appreciate Facebook's utility; future studies should test whether automating posts and/or establishing incentives for "likes" and comments leads to higher engagement. Further, our study design did not allow for isolation of the independent contribution of discrete intervention components, and thus, we were unable to determine which component attributed to the high degree of efficacy observed. While we suggested nutrient-rich foods as substitutions for obesogenic dietary behaviors, we did not perform a comprehensive assessment of diet to evaluate the quality of intervention participants' food choices. Larger, ongoing trials as part of the Lifestyle Interventions for Expectant Moms consortium may provide data that overcomes some of the limitations of this pilot study.⁴⁰

In summary, our findings show efficacy of a technology-based, behavioral intervention for controlling gestational weight gain in overweight or obese African American women. Whether minimizing excessive weight gain in pregnancy can successfully reduce disparities in obesity and improve child health among this high risk population is still unknown, but remains of great interest to further investigate.

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What is already known about this subject?

- Excessive weight gain in pregnancy is a major determinant of long-term obesity in women and linked to several other adverse maternal and fetal outcomes.
- Optimizing gestational weight gain is possible through intervention, although ethnic minority women have been underrepresented in clinical trials to date.
- In non-pregnant populations, digital health interfaces have been found to effectively deliver weight control interventions; however, limited data exist regarding the use of technology-based interventions in pregnancy.

What does this study add?

- This is the first randomized clinical trial to evaluate whether a technology-based, behavioural intervention could decrease the proportion of overweight or obese African American women who exceeded Institute of Medicine guidelines for gestational weight gain.
- The results suggest that digital health interfaces can reduce rates of excessive gestational weight gain, compared to usual care, among African American women during pregnancy.

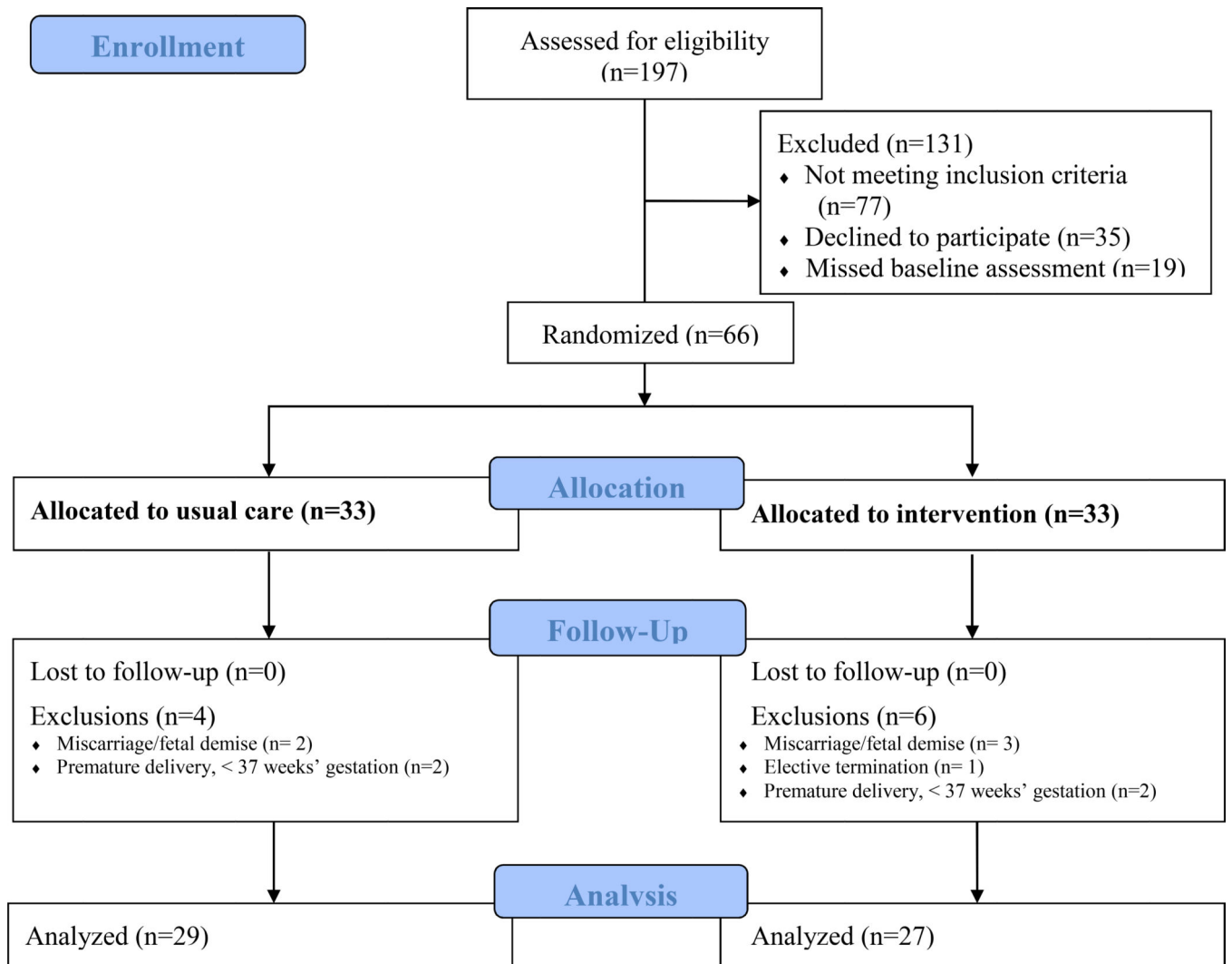


Figure 1.
CONSORT flow diagram

Study week	Location	Target	Behavioral goal
Baseline	In-person at Temple	Self-weighing	Weigh yourself weekly
Week 1	Telephone	Energy intake	Limit sugar-sweetened beverages to 1 cup per day
Week 2	Telephone	Energy intake	Limit junk and high fat food to no more than 1 per day
Week 4	Telephone		
Week 6	Telephone	Physical activity	Walk 5,000 steps daily
Week 8	Telephone	Energy intake	Stick to 1 plate of food at each meal
Week 10	Telephone		
Week 12	Telephone		

Figure 2.
Intervention schedule, first 12 weeks of the program

Table 1Maternal characteristics^a

Characteristic	Usual care (n=33)	Intervention (n=33)
Maternal age (years)	25.0 ± 5.7	25.9 ± 4.9
Early pregnancy weight (kg) ^b	87.2 ± 14.0	86.7 ± 15.6
Early pregnancy BMI (kg/m ²)	32.2 ± 5.4	33.5 ± 5.8
Early pregnancy BMI category (kg/m ²)		
25–29.9	13 (39%)	11 (33%)
30–45.0	20 (61%)	22 (67%)
Nulliparous	10 (30%)	9 (27%)
Single	22 (67%)	24 (73%)
Unemployed	17 (52%)	18 (55%)
Education		
Some high school or less	5 (15%)	7 (21%)
High school graduate	20 (61%)	16 (49%)
Technical school	4 (12%)	3 (9%)
Some college or more	4 (12%)	7 (21%)
Gestational age at baseline (weeks)	13.4 ± 4.1	11.5 ± 2.9

^aData are reported as mean ± standard deviation or n (%). There were no significant differences between groups.

^bEarly pregnancy weights were abstracted from participants' clinical prenatal care records, mean ± standard deviation = 7.9 ± 3.6 weeks' gestation.

Table 2Weight gain in pregnancy by treatment group^a

	Usual care (n=29)	Intervention (n=27)
Total weight gain, early pregnancy to delivery (kg) ^b	12.3 ± 6.4	8.7 ± 6.6
Guideline recommended weight gain ^c		
Exceeded IOM guidelines	19 (66%)	10 (37%)
Within IOM guidelines	5 (17%)	7 (26%)
Below IOM guidelines	5 (17%)	10 (37%)

^aData are reported as mean ± standard deviation or n (%).

^bUnadjusted mean difference: -3.6, 95% CI: -7.0 to -0.1, p = 0.046; adjusted mean difference (for early pregnancy BMI, parity, maternal age, and length of gestation): -3.1, 95% CI: -6.2 to -0.1, p = 0.045.

^cp = 0.033 for excessive weight gain versus all other Institute of Medicine (IOM) categories.