Title

Efficacy of a group-based dietary intervention for limiting gestational weight gain among obese women: A randomized trial

Journal

Obesity, 22(9)

ISSN

1930-7381

Authors

Vesco, Kimberly K
Karanja, Njeri
King, Janet C
et al.

Publication Date

2014-09-01

DOI

10.1002/oby.20831

Peer reviewed

Published in final edited form as:

Obesity (Silver Spring). 2014 September ; 22(9): 1989–1996. doi:10.1002/oby.20831.

Efficacy of a group-based dietary intervention for limiting gestational weight gain among obese women: a randomized trial

Kimberly K. Vesco, MD, MPH[a,b], **Njeri Karanja, PhD**[a], **Janet C. King, PhD**[c], **Matthew W. Gillman, MD**[d], **Michael C. Leo, PhD**[a], **Nancy Perrin, PhD**[a], **Cindy T. McEvoy, MD, MCR**[e], **Cara L. Eckhardt, PhD**[f], **K. Sabina Smith, BS, CCRP**[a], and **Victor J. Stevens, PhD**[a]

[a]Center for Health Research, Kaiser Permanente, Northwest, 3800 N. Interstate Avenue, Portland, OR, 97227, USA

[b]Department of Obstetrics & Gynecology, Kaiser Permanente, Northwest, 500 NE Multnomah Street, Portland, OR 97232

[c]Children's Hospital Oakland Research Institute, 5700 Martin Luther King Jr Way, Oakland, CA, 94609, USA

[d]Obesity Prevention Program, Harvard Medical School/Harvard Pilgrim Health Care Institute, 133 Brookline Avenue, 6th Floor, Boston, MA, 02215, USA

[e]Oregon Health & Science University, 700 Southwest Campus Drive, Portland, OR, 97239, USA

Address correspondence and reprint requests to: Dr. Kimberly K. Vesco, Center for Health Research, 3800 N. Interstate Avenue, Portland OR 97227, USA. kimberly.k.vesco@kpchr.org. Phone: 503-335-2417; FAX: 503-335-2428.

Disclosure statement: The authors report no conflicts of interest.

Prior presentation of data: Dr. Vesco presented preliminary data from this study as oral abstracts at the Obesity Society Annual Meeting, San Antonio, Texas, September 20–24, 2012, and the Society for Maternal Fetal Medicine Annual Meeting, San Francisco, California, February 14–16, 2013, and as a poster presentation at The Obesity Society Annual Meeting, Atlanta, Georgia, November 11–16, 2013.

Conflicts of Interest

Competing interests: the authors have no competing interests.

Authors' Contributions:

Kimberly K. Vesco: Involvement in the conception and design of the study, overall lead of activities, review and interpretation of data, primary author of manuscript.

Njeri Karanja: Involvement in the conception and design of the study, led the dietary component of the intervention and infant feeding survey development, review and interpretation of data, critical revision and approval of the final manuscript.

Janet C. King: Involvement in the conception and design of the study, assisted with the dietary component of the intervention, review and interpretation of data, and critical revision and approval of the final manuscript.

Matthew W. Gillman: Involvement in the conception and design of the study and selection of outcome measures, review and interpretation of data, and critical revision and approval of the final manuscript.

Michael C. Leo: Assisted with data management, led completion of statistical analyses, assisted with interpretation of data, and with preparation, critical revision and approval of the final manuscript.

Nancy Perrin: Involvement in the conception and design of the study, assisted with statistical analyses, approval of the final submitted manuscript.

Cindy T. McEvoy: Involvement in the conception and design of the study, assisted with newborn outcome measurement training, review and interpretation of data, and approval of the final manuscript.

Cara L. Eckhardt: Involvement in the conception and design of the study, infant feeding survey development, review and interpretation of data, and critical revision and approval of the final manuscript.

K. Sabina Smith: Involvement in the conception and design of the study, review and interpretation of data, and assisted with preparation, critical revision, and approval of the final manuscript.

Victor J. Stevens: Involvement in the conception and design of the study, led the intervention team, review and interpretation of data, and assisted with preparation, critical revision, and approval of the final manuscript.

[f]School of Community Health, Portland State University, 506 SW Mill Street, Suite 450, Portland, OR, 97201, USA

Abstract

Objective—Observational studies suggest that minimal gestational weight gain (GWG) may optimize pregnancy outcomes for obese women. This trial tested the efficacy of a group-based weight management intervention for limiting GWG among obese women.

Methods—We randomized 114 obese women (BMI [mean±SD] 36.7±4.9 kg/m^2) between 7–21 weeks' (14.9±2.6) gestation to intervention (*n*=56) or usual care control conditions (*n*=58). The intervention included individualized calorie goals, advice to maintain weight within 3% of randomization and follow the Dietary Approaches to Stop Hypertension dietary pattern without sodium restriction, and attendance at weekly group meetings until delivery. Control participants received one-time dietary advice. Our three main outcomes were maternal weight change from randomization to 2 weeks postpartum and from randomization to 34 weeks gestation, and newborn large-for-gestational age (birth weight >90th percentile, LGA).

Results—Intervention participants gained less weight from randomization to 34 weeks gestation (5.0 vs 8.4 kg, mean difference=−3.4 kg, 95% CI [−5.1, −1.8]), and from randomization to 2 weeks postpartum (−2.6 vs +1.2 kg, mean difference=−3.8 kg, 95% CI [−5.9, −1.7]). They also had a lower proportion of LGA babies (9% vs. 26%, odds ratio=0.28, 95% CI [0.09, 0.84]).

Conclusions—The intervention resulted in lower GWG and lower prevalence of LGA newborns.

Keywords

obese; pregnancy; weight gain

Introduction

In the United States, about 30% of women of reproductive age are obese,[1, 2] and over 50% of obese women gain more weight during pregnancy than recommended by the Institute of Medicine (IOM).[1] Excessive gestational weight gain increases the risk of macrosomia (birth weight > 4000 grams),[3, 4] large for gestational age (birth weight >90th percentile),[3] higher child BMI z-scores,[5] and increased body fat and elevated systolic blood pressure in children at age 3 years.[5] Excessive gestational weight gain is also associated with both short- and long-term maternal weight retention.[6, 7]

How to reduce weight gain among obese pregnant women has been unclear. In nonpregnant adults, the most effective weight loss and weight maintenance interventions have employed dietary counseling and weekly participant contact.[8] Of weight management trials conducted among obese, nondiabetic, *pregnant* women,[9–14] most have used interventions with less frequent direct participant contact,[10–13] and few have been successful[9, 10, 14] in limiting gestational weight gain (GWG). The goal of our study was to determine whether the weight management model often used in nonpregnant adults, i.e., a weekly, group-based weight management intervention focused on diet and behavior change, would be effective among

obese women for limiting GWG and reducing the proportion of large-for-gestational age (LGA) infants.

Methods

We conducted a randomized controlled trial (parallel groups design with a 1:1 allocation ratio) among English-speaking, obese (BMI ≥30 kg/m^2) women aged 18 years or older who were receiving prenatal care at Kaiser Permanente, Northwest (KPNW). Women were excluded if they had diabetes mellitus or other medical conditions requiring specialized nutritional care (for example, a history of bariatric surgery), or had plans to leave the area during the expected follow up period (through 1 year postpartum). We aimed to randomize participants as early as possible in pregnancy, and included women up to 21 weeks gestational age. There was no lower limit of gestational age for inclusion, however, our outreach started after the first prenatal visit, which typically occurs in KPNW at 8 weeks gestation.

KPNW is a federally qualified, non-profit HMO that serves more than 470,000 members in northwest Oregon and southwest Washington. KPNW's membership is similar to the local insured community in terms of age, sex, race, and ethnicity. From October 2009 to June 2011, we used KPNW's electronic medical record and referrals (self or physician) to identify potentially eligible participants (n=2,279). We sent invitations to participate by mail and followed up by telephone (Figure). Interested women first attended an explanatory session, and those who wished to proceed returned in a week with completed baseline questionnaires and a five-day food record. Those who completed the questionnaires, food record, and provided informed consent, were informed of their randomization assignment by the study dietician, who used a computerized algorithm for random assignments stratified by age (<30 years, 30 years and older) and BMI (30 to 34.9 kg/m^2, 35 to 39.9 kg/m^2, and 40 or greater kg/m^2), in blocks of four. All randomizations were completed by July 2011. Of the 118 women randomized, 2 miscarried and 2 formally withdrew from the study within a week after randomization, leaving a final sample size of 114.

KPNW's Institutional Review Board and an independent data safety and monitoring board approved the study protocol and consent procedures. All participants provided written informed consent. Data collectors were unaware of treatment group assignment.

Intervention

Intervention goals—A detailed description of the intervention rationale, procedures and dietary recommendations has been published;[15] a brief outline is provided here. The intervention program included a combination of dietary and exercise recommendations, as well as the use of behavioral self-management techniques to help participants initiate and maintain behavior changes. This combination approach has been shown to be effective in adult weight management interventions, and has become the standard for high quality programs.[8] The intervention goal was to help participants maintain their weight during pregnancy to within 3% of their weight at randomization.[16] We chose this goal based on observational studies suggesting that limited weight gain or weight maintenance may result

in better pregnancy outcomes for obese women,[17, 18] and believed a 3% change was large enough to allow for fluctuations in weight due to edema

Intervention diet—The study dietician advised intervention participants to follow an energy reduced eating plan, based on Dietary Approaches to Stop Hypertension (DASH) dietary pattern[19] without sodium restriction. Energy-reduced versions of the DASH pattern have been used extensively for both initial weight loss interventions and also for long-term weight loss maintenance interventions.[20, 21] The DASH dietary pattern was selected because it is also consistent with the dietary recommendations for pregnant women.[22, 23] The study dietician used this formula for personalizing daily calorie goals: *Initial Caloric Needs = [(Pre-pregnant weight in kg) (30 Kcal/kg/day) (0.70)] + [(10 Kcal) (gestational age in weeks)]*.[15] The formula first calculates energy needs based on 30 kcal/kg/day of pre-pregnancy weight for non-obese women, then reduces calorie consumption by 30%.[24] The equation then adds 10 Kcal per week of gestation to accommodate rising basal metabolic rate during gestation. A woman with a pre-pregnancy weight of 91 kg who is ten weeks pregnant, for example, would be assigned an initial caloric intake of 2,011 Kcal/day, gradually rising to 2,311 by the time she delivers. A detailed rationale for this formula has been published.[15]

Physical activity—The intervention leaders encouraged participants to accumulate at least 30 minutes of moderate physical activity per day in the absence of medical or obstetrical complications, a goal consistent with the recommendations of the American College of Obstetricians and Gynecologists (ACOG).[25] They gave each intervention participant a pedometer, and encouraged them to record their physical activity in their daily food and activity records. The intervention did not involve an exercise component that was directly observed by the study team.

Intervention format and content—Intervention participants started by attending two individual counseling sessions, the first immediately after randomization and the second one week later. The study's dietician used the individual sessions to tailor the diet and physical activity guidelines to the participant's specific needs. Participants began attending weekly group sessions after their second individual session, and continued to attend group sessions throughout their pregnancy. We had rolling entry and exit from the group sessions, such that new participants would enter after randomization and leave after they delivered. There was one group session per week with 7–8 women in attendance per session (mean 7.4, standard deviation 3.3, maximum 15). The 16-session core curriculum was presented in a cyclical manner, so each woman would have the opportunity to experience the full curriculum. Interventionists used behavioral self-management principles[26] during the group intervention sessions to help participants set reasonable short-term goals, formulate action plans, and develop sources of reinforcement and social support to support behavior change.

Each 90-minute group session included a nutrition and/or exercise topic, a behavior change topic, and a goal-setting activity for the next week.[21] The meetings began with the check-in when participants reported on their experiences during the preceding week. The intervention team encouraged participants to discuss the behavior change challenges and encouraged questions, group discussions, and group problem solving focused on potential barriers and

facilitators for behavior change. They asked women to keep food and physical activity diaries and to monitor their progress weekly by charting their weight. Special attention was focused on identifying antecedents for both positive behaviors such as physical activity and healthful eating, and triggers for problematic behaviors such as eating inappropriate foods or eating large portions. Individual behavior change plans often included using this information to guide environmental changes (situational control techniques) designed to support behavior change.

Usual care control

Control participants received a one-time advice session from the study dietician that included general information about eating a healthy diet during pregnancy, without specific focus on the DASH dietary pattern or weight management. The session included feedback about their food diaries and a recommendation to follow their obstetrical care providers' advice. Our study did not provide any aspect of routine prenatal care for control or intervention participants. The information our participants received through the study was in addition to their routine medical care.

Measures

We asked participants in both conditions to return to the research clinic at 34 weeks gestation and at 2 weeks postpartum with their babies. The primary outcome measure for this study was total gestational weight gain, defined as weight measured at 2 weeks postpartum minus the weight measured at randomization (baseline). We chose weight at 2 weeks postpartum rather than the end of pregnancy to avoid including the weight of the products of conception, maternal edema, and increased maternal blood volume. In practice, the 34 week visit occurred at a mean±standard deviation (SD) of 33.7±1.7 weeks and the 2 week postpartum visit occurred at a mean of 3.2±1.0 weeks. For consistency, we will continue to call these visits 34 weeks gestation and 2 weeks (rather than 3 weeks) postpartum.

To compare with the 2009 IOM guidelines,[1] the rate of weight gain between baseline and 34 weeks gestation was stratified into three categories: above (>0.6 pounds [0.27 kg] per week), within (0.4 to 0.6 pounds [0.18 to 0.27 kg] per week), and below (<0.4 pounds [0.18 kg] per week) the guidelines.

Newborn weight outcomes included large-for-gestational-age (LGA, gender-specific birth weight greater than the 90th percentile), small-for-gestational-age (SGA, birth weight less than the 10th percentile), and weight-for-gestational-age z-score, which were calculated based on the 2000 US Natality data set,[27] and macrosomia (birth weight ≥4000 grams).

We used the study participants' medical records (ICD-9 codes, laboratory, and blood pressure measures) to identify additional key maternal and infant secondary outcomes: hypertensive disorders of pregnancy (gestational hypertension/preeclampsia); gestational diabetes; mode of delivery (cesarean section versus vaginal); preterm birth (<37 weeks, <34 weeks), neonatal hypoglycemia requiring treatment with IV glucose or supplemental feeds; hyperbilirubinemia requiring treatment within the first 8 days of life with phototherapy; respiratory morbidities requiring use of supplemental oxygen for >=6 hours total within first

72 hours of life, or any CPAP or ventilator use in first 72 hours of life; admissions to the special care nursery or neonatal intensive care unit; and perinatal mortality. Data about breastfeeding were obtained by maternal survey supplemented with medical record review.

There were 93 women who attended the 34 week and 93 women who attended the 2 week postpartum visit (81.6% attendance at each visit). In determining how to handle missing weight data, we discussed methods such as multiple imputation and direct maximum likelihood. However, because we had access to participant electronic medical record (EMR) weights measured during routine maternal care, we considered using EMR weights as a direct replacement for missing and out-of-window research visit weights. To determine whether the substitution of maternal EMR weights for research visit weights is valid (i.e., exchangeable), we obtained pairs of research and clinic weights collected within +/− 14 days of each other for 102 participants and examined the agreement between the weights. We found that the absolute agreement between the research and EMR weights was extremely high (Intraclass Correlation Coefficient [2,1]=0.999), providing strong support for exchangeability. Therefore, we chose to use EMR data to augment missing weight data for participants who did not attend the 34 week or 2 week postpartum research clinic visit or who did not attend the clinic visit within the specified collection windows (32 to 36 weeks gestation, and 10 to 42 days postpartum, respectively) (Figure). In these cases, we selected the medical record weight closest to the center of the window. Using this methodology we had complete weight data for 98% (N=112) of participants at 34 weeks' gestation and 98% (N=112) at 2 weeks' postpartum.

Statistical analyses

Prior to analysis, we examined the central tendency, variability, and distribution for all variables to ensure the assumptions for the analysis were met. We analyzed data from all participants as originally randomized (i.e., intent to treat). The primary endpoint was weight change from baseline to 2 weeks postpartum. To determine whether the intervention was efficacious, we used a 2×2 mixed-design ANOVA in which time was the within-subjects factor (baseline vs. 2 weeks postpartum), and arm was the between-subjects factor (intervention vs. control). We assessed weight change from baseline to 34 weeks with a similar analysis. We used t-tests to compare the intervention and control groups on rate of weight gain and birth weight (raw and z-score). We also repeated the analysis on birth weight controlling for gestational age with an ANCOVA. We assessed the categorical outcomes using chi-square or Fisher's exact test, depending on the distribution of the variable. Effect size measures for continuous outcomes are expressed as the standardized mean difference between groups (Cohen's d) and for categorical outcomes as Cramer's V. Because of the lack of published results of similar interventions, it is difficult to provide context regarding the magnitude of effects with standardized effect sizes. However, we provide the conventions for small, medium, and large effect sizes defined by Cohen for situations in which no other data is available. For Cohen's d, this corresponds to .20, .50, and .80 and for Cramer's V, this corresponds to .10, .30, and .50, respectively.[28, 29]

We used a two-tailed alpha level of .05 for all analyses. The original sample size target for this study was 160, and was based on the ability to detect a standardized effect size

difference of at least .39 in the weight change between the intervention and control groups from baseline to 2 weeks post-partum at a two-tailed alpha level of .05 with 80% power.

Results

The majority of participants were non-Hispanic White (86%), just under half were nulliparous (47%), and 56% had Class 2 or 3 Obesity (Table 1). Mean ±SD for maternal BMI at randomization was 36.7±4.9 kg/m^2 (range 30.2 to 51.6), weight was 99.7±15.3 kg (range 73.6 to 146.0), age was 31.8±4.9 years (range 19.1 to 45.2), and gestational age was 14.9±2.6 weeks (range 6.9 to 21.1).

Maternal weight change and pregnancy outcomes

Overall, mean weight decreased by 0.6±5.8 kg (range −18.3 to +13.7) from baseline to 2 weeks postpartum and increased by 6.8±4.7 kg (range −4.6 to +20.0) from baseline to 34 weeks gestation. The mean rate of weight gain during pregnancy was 0.36±0.25 kg/wk (range −0.27 to +1.00).

From baseline to 2 weeks postpartum, the mean weight declined by 2.6 kg in the intervention group, and increased by 1.2 kg in the control group (mean difference of change=−3.8, 95% CI [−5.9, −1.7], p<.001) (Table 2). Between baseline and 34 weeks gestation, intervention participants gained less weight (5.0 vs 8.4 kg, respectively; mean difference=−3.4 kg, 95% CI [−5.1, −1.8], p<.001), had a lower rate of weight gain (0.27 kg/wk vs 0.44 kg/wk; mean difference=−0.18, 95% CI [−0.26, −0.09]) and a lower prevalence of weight gain in excess of the 2009 IOM guidelines (44% vs 82% exceeding 0.27 kg/wk, p<.001). Based on Cohen's conventions, the magnitude of these effects were large (Cohen's d=.69–.77). We also performed a residualized change analysis (evaluation of change score adjusting for baseline weight), and the results are entirely consistent with the original analysis.

Breastfeeding was initiated by 109 participants. We did not detect differences between groups for gestational diabetes, hypertensive disorders of pregnancy, or cesarean delivery and the estimated effect sizes were small (Table 3).

Newborn outcomes

We did not detect differences between the intervention and control groups in mean birth weight (3484 vs 3678 grams, mean difference=−194; 95% CI for mean difference [−411,22]), birth weight adjusted for gestational age (3508 vs 3654 grams, mean difference= −146; 95% CI for mean difference [−331,39]), or weight for gestational age z-score (0.21 vs 0.52, mean difference=−0.31; 95% CI for mean difference [−0.67,0.05]) and had small effect sizes (Cramer's V ranged from .02 and .07) (Table 3). However, there was a difference in the prevalence of LGA within the intervention group compared to the control group (9% vs. 26%; odds ratio=0.28, 95% CI [0.09,0.84]; p=.02), a nonsignificant reduction in macrosomia (11% vs 22%; odds ratio=0.42, 95% CI [0.14,1.18]; p=.09), and no detectable difference in SGA (5% vs. 7%; odds ratio=0.76, 95% CI [0.11,4.76]; Fisher's exact p=1.00). The effect sizes for LGA and macrosomia were in between small and moderate (Cramer's V=.22 and .16, respectively), and the effect size was small for SGA

(Cramer's V=.03). We did not find differences between groups in preterm birth (<37 weeks, <34 weeks), neonatal hypoglycemia or hyperbilirubinemia, respiratory morbidity, or NICU admission (Table 3). All non-significant findings had small effect sizes (Cramer's V ranged from <.01 and .13).

Intervention adherence

The mean (±SD) interval between randomization and delivery was 24.7±3.0 weeks (range 18.7 to 34.3). Intervention participants attended an average of 20±7 (range 0 to 28) weekly sessions. When considering the number of intervention sessions participants attended normalized for number of the weekly sessions they could have attended, we found an average attendance of 79±25% (range 0 to 100%). Of the 56 women in the intervention group, 18% maintained their weight during pregnancy to within 3% of weight measured at randomization and 9% lost weight (maximum loss 3.0 kg).

Discussion

This intervention helped obese women minimize gestational weight gain and reduced prevalence of large for gestational age (LGA) newborns, with no apparent evidence for increasing the prevalence of small for gestational age (SGA) newborns. Given the low prevalence of SGA, larger studies with sufficient power to confirm the lack of impact of weight management on SGA are needed; as reducing the risk of LGA newborns through weight management during pregnancy without increasing the risk of SGA is of significant public health importance. LGA infants are at risk for neonatal hypoglycemia requiring medical intervention[30, 31] and in the long-term may be at increased risk for childhood obesity and metabolic syndrome.[32] LGA is also associated with an increased risk of cesarean delivery, postpartum hemorrhage, and shoulder dystocia, which can result in newborn clavicular fracture and brachial plexus injury.[31]

In nonpregnant adults, the most successful weight management interventions are comprehensive lifestyle modification programs that are 1) designed to modify eating and physical activity habits and 2) provided in weekly individual or group sessions.[8] Frequent contacts and self-monitoring (keeping food and activity records, weekly weigh-ins, and plotting weight gain), provide accountability and are among the most important components of behavioral weight management.[8] These components, which were included in our study, likely contributed to the intervention participants' success. The only prior randomized trials of dietary and lifestyle interventions conducted among obese, nondiabetic pregnant women that have been successful in limiting gestational weight gain are those that have included detailed dietary counseling and frequent participant contact.[9, 10, 14] Among these trials, ours was the first to use weekly group sessions, which may have the advantage of being less resource intensive than weekly individual contacts.

Prior observational studies suggest that for obese women, limited or no weight gain during pregnancy may lead to improved pregnancy outcomes such as reduced preterm birth and preeclampsia.[17, 18] In this trial, we found that having women aim for weight maintenance, actually resulted in an average weight gain within the IOM guidelines. Our study did not show an adverse effect of our intervention approach on pregnancy outcomes, however, our

study was not adequately powered to assure there were no differences between groups. A much larger sample size of obese women who were able to maintain their weight through healthy lifestyle changes would be required to truly understand the effects of limited weight gain or weight loss on outcomes such as SGA, GDM, or preeclampsia. Our next step will be to determine the longer term impact of the intervention on maternal and infant weight measures at one year postpartum. New studies of pregnancy weight gain should also include long-term follow up and measures of maternal and child health that we were unable to obtain such as measures of maternal and infant metabolism and body composition and infant development. A new group of ongoing trials [Lifestyle Interventions For Expectant Moms (LIFE-Moms) clinical trial consortium, https://lifemoms.bsc.gwu.edu] may overcome some of the limitations of our study and add information about longer term maternal and child health outcomes.

Our study is limited by minimal racial and ethnic diversity and inclusion of only insured women with access to routine prenatal care. As would be expected in most obstetrics clinical trials, our participants were highly motivated to have successful pregnancies. One of our main barriers to recruitment was that we only had a single time, day, and night of the week when the intervention was offered. Another reason for study refusal was concern that the intervention required too much time or effort. KPNW serves a large geographic region covering 6,000 square miles from Longview, Washington, to Salem, Oregon, thus geographically limiting weekly study participation for many women. Since our study and others show that frequent participant contact is necessary to achieve successful weight management during pregnancy among obese women, future studies among obese pregnant women should include interventions with a similar frequency of patient contact conducted on-line, by webinar, or by individual phone counseling to determine if these modalities are similarly effective as direct in-person contact. Another option, for health systems which utilize the group prenatal visit model or are considering its implementation, would be to incorporate weight management interventions into group prenatal visits. A recent retrospective study found that women in group prenatal care were less likely to have excessive gestational weight gain than those receiving individually delivered prenatal care.[33]

In summary, our comprehensive lifestyle modification intervention produced lower gestational weight gain and reduced the likelihood of large-for-gestational-age infants among obese women. Whether this or similar interventions can improve long-term maternal and child health is yet to be determined.

Acknowledgments

Financial source of the study:

This work was supported by a grant from the National Institute of Child Health and Human Development (RO1HD058061). Clinicaltrials.gov # NCT00950235

Reference List

1. Institute of Medicine and National Research Council. Weight gain during pregnancy: reexamining the guidelines. Washington, DC: The National Academies Press; 2009.

2. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. JAMA. 2010; 303(3):235–241. [PubMed: 20071471]
3. Vesco KK, Sharma AJ, Dietz PM, et al. Newborn size among obese women with weight gain outside the 2009 institute of medicine recommendation. Obstet Gynecol. 2011; 117(4):812–818. [PubMed: 21422851]
4. Hillier TA, Pedula KL, Vesco KK, et al. Excess gestational weight gain: Modifying fetal macrosomia risk associated with maternal glucose. Obstet Gynecol. 2008; 112(5):1007–1014. [PubMed: 18978099]
5. Oken E, Taveras EM, Kleinman KP, Rich-Edwards JW, Gillman MW. Gestational weight gain and child adiposity at age 3 years. Am J Obstet Gynecol. 2007; 196(4):322–328. [PubMed: 17403405]
6. Vesco KK, Dietz PM, Rizzo J, et al. Excessive gestational weight gain and postpartum weight retention among obese women. Obstet Gynecol. 2009; 114(5):1069–1075. [PubMed: 20168109]
7. Sarwer DB, Allison KC, Gibbons LM, Markowitz JT, Nelson DB. Pregnancy and obesity: a review and agenda for future research. J Womens Health (Larchmt). 2006; 15(6):720–733. [PubMed: 16910904]
8. Wadden TA, Webb VL, Moran CH, Bailer BA. Lifestyle modification for obesity: new developments in diet, physical activity, and behavior therapy. Circulation. 2012; 125(9):1157–1170. [PubMed: 22392863]
9. Wolff S, Legarth J, Vangsgaard K, Toubro S, Astrup A. A randomized trial of the effects of dietary counseling on gestational weight gain and glucose metabolism in obese pregnant women. International Journal of Obesity. 2008; 32(3):495–501. [PubMed: 18227847]
10. Thornton YS, Smarkola C, Kopacz SM, Ishoof SB. Perinatal outcomes in nutritionally monitored obese pregnant women: a randomized clinical trial. J Natl Med Assoc. 2009; 101(6):569–577. [PubMed: 19585925]
11. Jeffries K, Shub A, Walker SP, Hiscock R, Permezel M. Reducing excessive weight gain in pregnancy: a randomised controlled trial. Med J Aust. 2009; 191(8):429–433. [PubMed: 19835535]
12. Guelinckx I, Devlieger R, Mullie P, Vansant G. Effect of lifestyle intervention on dietary habits, physical activity, and gestational weight gain in obese pregnant women: a randomized controlled trial. Am J Clin Nutr. 2010; 91(2):373–380. [PubMed: 19955397]
13. Phelan S, Phipps MG, Abrams B, Darroch F, Schaffner A, Wing RR. Randomized trial of a behavioral intervention to prevent excessive gestational weight gain: the Fit for Delivery Study. Am J Clin Nutr. 2011; 93(4):772–779. [PubMed: 21310836]
14. Vinter CA, Beck-Nielsen H, Jensen DM, Jorgensen JS, Ovesen P. The LIP (Lifestyle in Pregnancy) study. Diabetes Care. 2011; 34(12):2502–2507. [PubMed: 21972411]
15. Vesco KK, Karanja N, King JC, et al. Healthy Moms, a randomized trial to promote and evaluate weight maintenance among obese pregnant women: Study design and rationale. Contemp Clin Trials. 2012; 33(4):777–785. [PubMed: 22465256]
16. Stevens J, Truesdale KP, McClain JE, Cai J. The definition of weight maintenance. Int J Obes. 2006; 30:391–399.
17. Cedergren MI. Optimal gestational weight gain for body mass index categories. Obstet Gynecol. 2007; 110(4):759–764. [PubMed: 17906006]
18. Kiel DW, Dodson EA, Artal R, Boehmer TK, Leet TL. Gestational weight gain and pregnancy outcomes in obese women: how much is enough? Obstet Gynecol. 2007; 110(4):752–758. [PubMed: 17906005]
19. Appel LJ, Moore TJ, Obarzanek E, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group. N Engl J Med. 1997; 336(16):1117–1124. [PubMed: 9099655]
20. Hollis JF, Gullion CM, Stevens VJ, et al. Weight loss during the intensive intervention phase of the weight-loss maintenance trial. American Journal of Preventive Medicine. 2008; 35(2):118–126. [PubMed: 18617080]
21. Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. JAMA. 2003; 289(16):2083–2093. [PubMed: 12709466]

22. ACOG Technical Bulletin. Nutrition during pregnancy. Int J Gynecol Obstet. 2007; 179:67–74.
23. United States Department of Agriculture. [Accessed May 9, 2013.] Health and Nutrition Information for Pregnant and Breastfeeding Women: Making Healthy Choices in Each Food Group. 2013. http://www.choosemyplate.gov/pregnancy-breastfeeding/making-healthy-food-choices.html
24. American Diabetes Association. Medical management of pregnancy complicated by diabetes. 3. Alexandria, Virginia: ADA; 2000. Nutritional management during pregnancy in preexisting diabetes; p. 70-86.
25. ACOG Committee Opinion. Exercise during pregnancy and the postpartum period. 2002 No. 267.)
26. Miltenberger, RG. Behavior modification: Principles and procedures. 4. Pacific Grove, CA: Homson/Wadsworth; 2008.
27. Oken E, Kleinman KP, Rich-Edwards J, Gillman MW. A nearly continuous measure of birth weight for gestational age using a United States national reference. BMC Pediatrics. 2003; 3:6. [PubMed: 12848901]
28. Cohen, J. Statistical Power Analysis for the Behavioral Sciences. 2. Lawrence Erlbaum Associates; 1988.
29. Ellis, PD. The Essential Guide to Effect Sizes: An Introduction to Statistical Power, Meta-Analysis and the Interpretation of Research Results. United Kingdom: Cambridge University Press; 2010.
30. ACOG practice bulletin No. 22. Fetal Macrosomia. The American College of Obstetricians and Gynecologists. 2000:1–11.
31. Weissmann-Brenner A, Simchen MJ, Zilberberg E, et al. Maternal and neonatal outcomes of large for gestational age pregnancies. Acta Obstetricia et Gynecologica Scandinavica. 2012; 91(7):844–849. [PubMed: 22471810]
32. Boney CM, Verma A, Tucker R, Vohr BR. Metabolic syndrome in childhood: association with birth weight, maternal obesity, and gestational diabetes mellitus. Pediatrics. 2005; 115(3):e290–e296. [PubMed: 15741354]
33. Tanner-Smith E, Steinka-Fry K, Gesell S. Comparative Effectiveness of Group and Individual Prenatal Care on Gestational Weight Gain. Matern Child Health J. 2013:1–10.

What is known

1. There has been a dramatic increase in the proportion of women who enter pregnancy as obese and approximately half of obese women gain excessive amounts of weight during pregnancy.
2. Observational studies have shown that pregnancy outcomes such as large-for-gestational age, preeclampsia, and preterm birth may be reduced with limited gestational weight gain among obese women.
3. Prior trials among obese pregnant women have shown that interventions with infrequent direct patient contact are not effective for limiting gestational weight gain.

What this study adds

1. This study shows that obese women can effectively manage their gestational weight gain using conventional behavioral weight loss techniques.
2. Weight management during pregnancy reduces the risk large-for-gestational-age without also increasing the risk of small-for-gestational-age newborns.

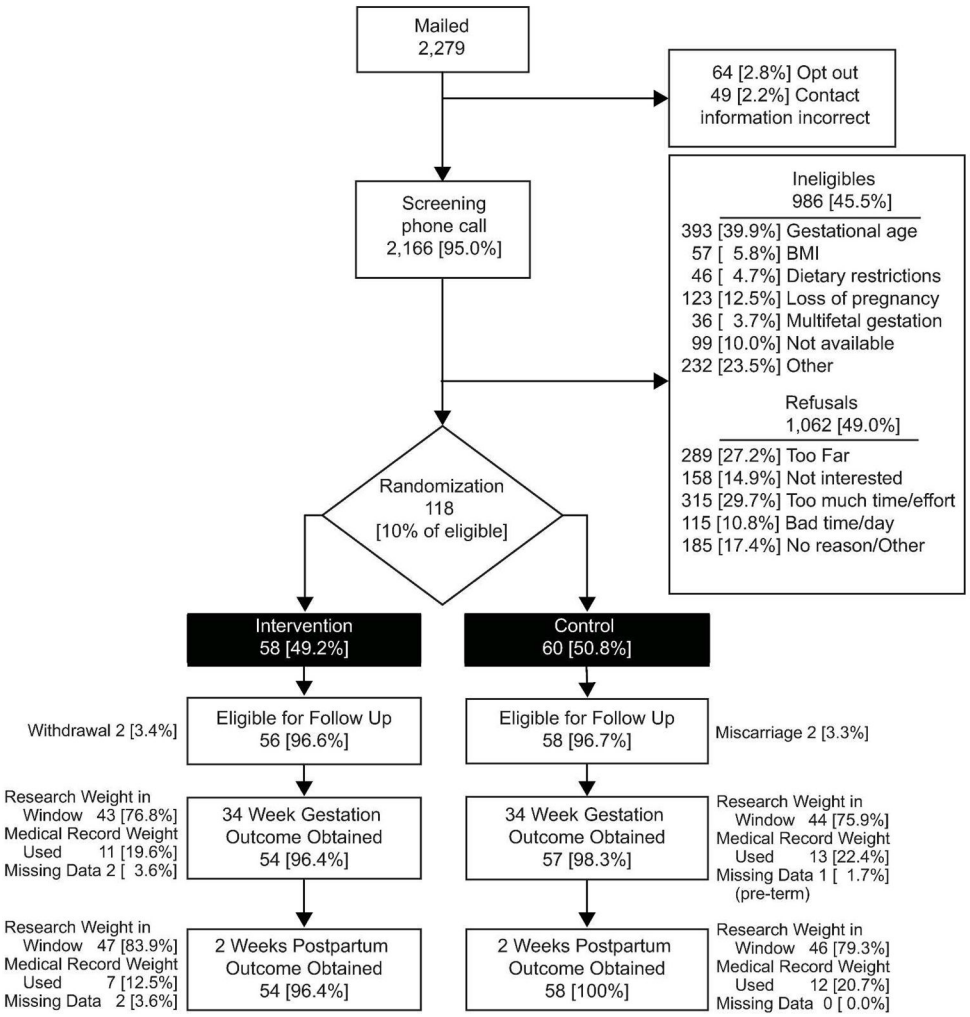

Figure. Healthy Moms CONSORT diagram

The figure shows the flow of participants in the Healthy Moms study.

Table 1

Maternal characteristics at randomization

	Control Group N = 58	Intervention Group N = 56	Overall[b] N=114
	Mean±SD or N(%)		
Maternal age (years)	31.2±4.6	32.4±5.1	31.8±4.8
Gestational age at randomization (weeks)	15.1±2.5	14.6±2.8	14.9±2.6
Weight (kg)	100.5±15.6	98.8±15.1	99.7±15.3
BMI (kg/m^2)	36.8±4.7	36.7±5.2	36.7±4.9
BMI category (kg/m^2)			
30–34.9	25 (43%)	25 (45%)	50 (44%)
35–39.9	21 (36%)	19 (34%)	40 (35%)
40+	12 (21%)	12 (21%)	24 (21%)
Nulliparous	27 (47%)	26 (46%)	53 (47%)
White race	49 (85%)	49 (88%)	98 (86%)
Household Income[a]			
Less_than_$14,999	3 (5%)	3 (5%)	6 (5%)
$15,000_to_$29,999	7 (12%)	3 (5%)	10 (9%)
$30,000_to_$44,999	5 (9%)	15 (27%)	20 (18%)
$45,000_to_$59,999	6 (10%)	13 (23%)	19 (17%)
$60,000_to_$74,999	12 (21%)	7 (13%)	19 (17%)
$75,000_to_$89,999	6 (10%)	5 (9%)	11 (10%)
90,000+	14 (24%)	10 (18%)	24 (21%)
Missing	5 (9%)	0 (0%)	5 (4%)
Education[a]			
High school graduate	20 (34%)	10 (18%)	30 (26%)
Technical school	5 (9%)	8 (14%)	13 (11%)
College graduate	29 (50%)	37 (66%)	66 (58%)
Missing	4 (7%)	1 (2%)	5 (4%)
Marital status[a]			

	Control Group N = 58	Intervention Group N = 56	Overall[b] N=114
	Mean±SD or N(%)		
Single	5 (9%)	2 (4%)	7 (6%)
Married	47 (81%)	45 (80%)	92 (81%)
Living together	5 (9%)	8 (14%)	13 (11%)
Divorced/Separated	1 (2%)	1 (2%)	2 (2%)
Tobacco use			
Prior to pregnancy	8 (14%)	7 (13%)	15 (13%)
At enrollment	0 (0%)	1 (2%)	1 (1%)

[a] Proportions do not total 100% due to rounding.

[b] There were no significant differences in characteristics between groups.

Table 2

Pregnancy weight gain

	Control	Intervention			
	MEAN±SD or N(%)	**MEAN±SD or N(%)**	**Mean Difference**	**95% CI of Difference**	**Effect size**
2 weeks postpartum – randomization (kg)	1.2±5.6	−2.6±5.5	−3.8[a]	[−5.9,−1.7]	.69[b]
34 weeks gestation – randomization (kg)	8.4±4.7	5.0±4.1	−3.4[a]	[−5.1,−1.8]	.77[b]
Rate of weight gain (kg/week)	0.4±0.2	0.3±0.2	−0.2[a]	[−0.3,−0.1]	.77[b]
Rate of weight gain according to 2009 IOM guidelines for obese women			N/A[a]	N/A	.40[c]
Below (<0.18 kg/week)	7 (12%)	21 (38%)			
Within (0.18 to 0.27 kg/week)	3 (5%)	10 (18%)			
Above (>0.27 kg/week)	47 (82%)	24 (44%)			

CI, confidence interval; N/A, Not Applicable

Note: N=112 for all analyses.

[a] p<.001;

[b] Standardized Mean Difference (Cohen's d);

[c] Cramer's V

Obesity (Silver Spring). Author manuscript; available in PMC 2015 September 01.

Table 3

Maternal and neonatal pregnancy outcomes

	N (%)		Odds Ratio	95% CI for Odds Ratio	Effect Size[a]
Maternal	**Control N=58**	**Intervention N=56**			
Gestational hypertension, preeclampsia	6 (10%)	5 (9%)	0.85	[0.24,2.96]	.02
Gestational diabetes	7 (12%)	6 (11%)	0.87	[0.28, 2.78]	.02
Cesarean delivery	26 (45%)	21 (38%)	0.74	[0.35,1.56]	.07
Primary cesarean delivery	12 (21%)	15 (27%)	1.40	[0.59,3.34]	.07
Neonatal					
LGA	15 (26%)	5 (9%)	0.28[b]	[0.09, 0.84]	.22
Macrosomia (>4000 grams)	13 (22%)	6 (11%)	0.42	[0.15, 1.18]	.16
SGA	4 (7%)	3 (5%)	0.76	[0.11, 4.76]	.03
Preterm birth (<37 weeks)	1 (2%)	4 (7%)	4.38	[0.41,219.64]	.13
Preterm birth (<34 weeks)	1 (2%)	0 (0%)	N/A[c]	N/A[c]	.09
NICU admission[d]	6 (11%)	2 (4%)	0.33	[0.03, 2.00]	.13
Hyperbilirubinemia[d]	7 (12%)	6 (11%)	0.91	[0.29, 2.91]	.02
Birth trauma[d]	2 (4%)	2 (4%)	1.08	[0.08, 15.38]	.01
Hypoglycemia[d]	1 (2%)	1 (2%)	1.08	[0.01,86.03]	<.01
Respiratory morbidity[d]	7 (12%)	3 (6%)	0.43	[0.07, 2.03]	.11
	Mean (SD)		Mean Difference	95% CI for Difference	Effect Size[e]
Birth weight (grams)					
Unadjusted	3678±583	3484±583	−194	[−411, 22]	.33
Adjusted for gestational age	3654±498	3508±498	−146	[−331, 39]	.29
z-score for gestational age	0.52 (1.0)	0.21 (1.0)	−0.31	[−0.67, 0.01]	.32

[a] Cramer's V,

[b] p<.05,

[c] N/A=Not applicable because cannot be computed,

[d] $N = 110$,

[e] Standardized Mean Difference (Cohen's d)