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A Web-Based Lifestyle Intervention for Women With Recent Gestational Diabetes Mellitus: A Randomized Controlled Trial

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Abstract

Objective—To test the feasibility and effectiveness of a web-based lifestyle intervention based on the Diabetes Prevention Program modified for women with recent gestational diabetes mellitus (GDM) to reduce postpartum weight retention.

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Methods—We randomly allocated 75 women with recent GDM to either a web-based lifestyle program (Balance after Baby) delivered over the first postpartum year or to a control group. Primary outcomes were change in body weight at 12 months from 1) first postpartum measured weight, and 2) self-reported prepregnancy weight.

Results—There were no significant differences in baseline characteristics between groups including age, BMI, race and income status. Women assigned to the Balance after Baby program (n=36, 3 lost to follow-up) lost a mean of 2.8 kgs (95% CI −4.8 to −0.7) from 6 weeks to 12 months postpartum while the control group (n=39, 1 lost to follow-up) gained a mean of 0.5 kgs (−1.4 to +2.4) (p=0.022). Women in the intervention were closer to prepregnancy weight at 12 months postpartum (mean change −0.7 kgs; −3.5 to +2.2), compared to women in the control arm (+4.0 kgs; +1.3 to +6.8) (p=0.035).

Conclusion—A web-based lifestyle modification program for women with recent GDM decreased postpartum weight retention.

Introduction

Postpartum weight retention is a key risk factor for long-term maternal obesity. Cohort studies have demonstrated an association between postpartum weight retention at six months (1,2) and one year (3) postpartum with future overweight and obesity. Women with prior gestational diabetes mellitus (GDM) have a 7-fold increased risk of developing type 2 diabetes within 10 years postpartum, (4) and are therefore uniquely vulnerable to the impact of postpartum weight retention. (5–7) Although recommendations for women with a history of GDM include weight loss if overweight or obese, (8) women with prior GDM are no more likely to engage in healthy lifestyle behaviors (9,10) or return to pre-pregnancy weight (9) than women without a history of GDM. (8)

The Diabetes Prevention Program (DPP) demonstrated that an intensive, face-to-face lifestyle intervention could achieve weight loss and reduce incidence of type 2 diabetes in middle-aged adults at high risk, including women with a remote GDM history. (11) However, face-to-face lifestyle intervention studies in postpartum women have had limited success. (12,13) We and others have described barriers to lifestyle modification in women with GDM in the postpartum period, including lack of time and energy, competing work and family demands, and lack of childcare. (14,15) Given the multiple barriers to face-to-face interventions, and the widespread use of the internet (16), using web-based technology to deliver lifestyle change interventions for women with recent GDM may be more successful. (14)We therefore adapted the DPP into a web-based lifestyle intervention modified for postpartum women. We conducted a randomized trial of the web-based lifestyle intervention program (Balance after Baby) to decrease postpartum weight retention in women with recent GDM.

Materials and Methods

We recruited women aged 18–45, with GDM in their most recent pregnancy, from the Diabetes in Pregnancy Program at Brigham and Women's Hospital (BWH) (Boston, MA) from 5/2010–8/2011. We defined gestational diabetes by a 3-hour 100-gram oral glucose tolerance test (OGTT) meeting Carpenter-Coustan criteria, (17) or by medical record documented clinician diagnosis. We excluded women with a personal history of type 2 diabetes or bariatric surgery, women taking medications known to affect body weight, as well as women unable to read 8^{th} grade level English or planning to move out of the area. Additionally, we excluded women delivering before 32 weeks gestation and with net weight loss during pregnancy. We restricted participants to those whose BMI increased risk for diabetes using the same lower cut-offs as the DPP, (BMI ≤24 kg/m^2;≤22 kg/m^2 for Asian participants). We excluded women with a BMI >50 kg/m^2 since we felt they would require a more intensive program. At the time of recruitment, we gave all patients the National Diabetes Education Program's handout for women with prior GDM, "It's Never Too Early to Prevent Diabetes." The human subjects committee at BWH approved the study; all patients gave written informed consent.

At the initial study visit at 6 weeks postpartum, we randomized eligible patients into the Balance after Baby intervention or control group using a permuted block scheme with randomly varying block sizes. A statistician not otherwise involved in the study prepared sealed sequentially numbered envelopes containing group assignment, and clinical research staff opened these at the end of the first study visit. Women diagnosed with type 2 diabetes at the first study visit, (by two abnormal values on OGTT or by a single abnormal value that was repeated and again found to be abnormal), were not eligible to continue. We asked women in both arms to return for in-person visits at 6 and 12 months postpartum. Participants diagnosed with type 2 diabetes at the 6-month visit returned for the 12-month study visit, but did not undergo an OGTT.

The two primary outcomes were change in measured body weight at 12 months from 1) first postpartum measured weight, and 2) self-reported pre-pregnancy weight. We recorded self-reported pre-pregnancy weight at enrollment, either during pregnancy (63/75, 84%), or after delivery and before the randomization study visit (12/75, 16%). We reviewed medical records to ascertain insulin use during pregnancy, gestational age at delivery, and mode of delivery. We used the pregnancy weight recorded in the anesthesia record within two days before delivery (71/75, 95%), or the last recorded prenatal weight within 10 days of delivery (4/75, 5%), to calculate gestational weight gain. We used measured height with self-reported pre-pregnancy weight to calculate pre-pregnancy BMI. For participants who did not attend a follow-up study visit, we extracted clinically measured weights from the electronic medical record where available.

At each visit, trained staff measured body weight; the lifestyle coach and study physician did not conduct measurements so as to remain blinded. The protocol for study visits included a 2-hour 75-gram OGTT, during which women were asked to refrain from breastfeeding. Glucose, hemoglobin A1C (HbA1c) levels, and urine hCG were measured using standard assays. Patients completed socio-demographic, medical history, Edinburgh Postnatal Depression Scale (EPDS), (18) food-frequency (Harvard FFQ), (19) International Physical Activity (IPAQ), (20) and breastfeeding questionnaires at study visits. We collected data submitted by participants'on-line forms via Research Electronic Data Capture (REDCap). Participants submitted on-line forms after watching modules, and also reported modules watched to their lifestyle coach. We collected anonymous website traffic data to analyze trends in use.

Subjects allocated to the intervention were offered a web-based lifestyle modification program (Balance after Baby). We adapted the 16 core DPP modules to 12 core modules tailored for postpartum women with recent GDM. Adaptation included content review by a multidisciplinary team and by subject matter experts at the Massachusetts Department of Public Health, the Special Supplemental Nutrition Program for Women, Infants and Children, and the Centers for Disease Control and Prevention.

Women in the Balance after Baby program were given a goal to return to pre-pregnancy weight over the study period. If participants were still overweight once they had reached their pre-pregnancy weight, they were encouraged to continue to lose weight with a goal of total 7% weight loss from 6-week postpartum weight. The intervention program emphasized dietary choices that would transition readily from the pregnancy GDM diet, including lower glycemic index, higher fiber, and controlled portion sizes. The program recommended gradually increasing physical activity to ≥150 min/week, including resistance training. We suggested participants track diet and physical activity in logbooks, and participate in telephone or email sessions with their lifestyle coach, a licensed registered dietitian trained in patient-centered counseling. We encouraged women who were breastfeeding to continue.

We created the secure password-protected Balance after Baby website, including animated videos narrated by a study physician. We asked participants to watch one module each week for the first 12 weeks, and there were six optional “Balance after Core” modules available. The website provided secure communication with the lifestyle coach, forms to enter goals, weekly weight, and physical activity, shopping lists, recipes, menu planning tips, exchange lists, and physical activity education. The breastfeeding section contained four additional breastfeeding modules, and a mechanism to contact a lactation consultant.

We suggested participants connect with their lifestyle coach weekly for the first 12 weeks, every other week for the second 12 weeks, and monthly thereafter. A study physician reviewed recorded calls and emails to ensure adherence to patient-centered counseling techniques. We provided laptop computers for participants without regular computer access, and internet access for those without sufficient access to participate regularly. Intervention participants received body weight scales, measuring cups and spoons, pedometers, and complimentary membership to the Greater Boston YMCA for up to 10 months if interested.

Patients allocated to the control arm did not receive any additional information to support weight loss beyond the handout they received at recruitment.

We compared baseline characteristics with Pearson’s chi-squared or Fisher’s exact tests for categorical variables, and t-tests or Wilcoxon rank sum for continuous variables. Patients were categorized based on treatment allocation in an intent-to-treat fashion for analyses. We compared differences between groups over time for weight, BMI, fasting glucose, two-hour glucose, and HbA1c. Women who became pregnant, started assisted reproductive treatment, or had an infant death were censored at the time of these events. We accounted for missing values by estimating mixed-effects regression models using a random intercept and an unstructured covariance matrix, adjusting for baseline weight. Data after censoring events were considered missing at random, except that we carried forward glucose and HbA1c values for women diagnosed with type 2 diabetes at 6 months. We also estimated models that adjusted for gestational weight gain and breastfeeding. We developed linear regression models controlling for baseline kilocalorie intake and breastfeeding to assess changes in dietary intake. We conducted sensitivity analyses for the primary weight outcomes: one without 12 month values for two women diagnosed with type 2 diabetes at 6 months, one including self-reported weights when measured weights were not available, one using last value carried forward, and one imputing weight gain at the same rate as mean weight gain in the control group. For our primary outcome of weight change from postpartum to the 12 month study visit, we had 80% power with a sample size of 76 to detect a 3.2 kg mean difference in weight change between groups. We performed analyses using JMP 10 Pro and SAS 9 (SAS Institute Inc., 2012) and analysts were blinded to treatment assignment.

Results

Of 156 women assessed for study eligibility, 118 met eligibility criteria, and 107 (92%) of those consented to participate. Of 78 women who attended the baseline visit, 3 were diagnosed with type 2 diabetes and excluded, leaving 75 women randomized into the study. There were no significant differences in baseline characteristics between the two arms (Table 1). The study group was diverse, with 57% White, 29% African-American, and 15% Asian, and 20% identifying as Hispanic. Thirty-four percent of patients were low-income, and 59% had graduated from college. There were no significant differences between groups for number of women using hormonal forms of contraception or for the types of hormonal contraceptives being used at 6 or 12 months postpartum. We obtained weight for 82% of eligible participants at 6 months postpartum and 88% of eligible participants at 12 months postpartum (Figure 1).

At 6 months postpartum, women assigned to the Balance after Baby arm lost 2.6 (95% CI −4.4 to −0.8) kgs from baseline weight, whereas the control group gained 1.4 (95% CI −0.4 to +3.1) kgs (p=0.002). By 12 months postpartum, the intervention group lost 2.8 (95% CI −4.8 to −0.7) kgs, versus a gain of 0.5 (95% CI −1.4 to +2.4) kgs in the control arm, for a difference between groups of 3.3 kgs, adjusting for baseline weight (Figure 2a) (p=0.022 for difference between groups). Adjustment for gestational weight gain strengthened the association between the intervention and weight loss at both timepoints (Table 2).

In a separate model adjusting for gestational weight gain, women in the intervention were 0.7 kgs below pre-pregnancy weight (−3.5 to +2.2) at 12 months postpartum versus control arm women who were 4.0 kgs above pre-pregnancy weight (+1.3 to +6.8) (p=0.035), (Figure 2b). Further adjustment for breastfeeding did not substantially change the findings. Women in the intervention arm decreased their BMI at 12 months (−1.1 kg/m^2 95% CI −1.9 to −0.4) compared to controls (+0.2 kg/m^2, −0.5 to +0.9) (p=0.004) (Table 2). In three separate sensitivity analyses, using self-reported weights, last value carried forward, and missing weights imputed at the rate of weight gain in the control group, findings were similar in both arms. Exclusion of women diagnosed with type 2 diabetes during the study period also did not change the findings.

Of women who underwent an OGTT, 10/30 (33%) in the control group versus 6/27 (22%) in the intervention group had impaired glucose tolerance or type 2 diabetes at 12 months postpartum (p=NS). There were no significant differences in OGTT glucose values, HbA1c, type 2 diabetes, or EPDS scores (data not shown) between groups at any of the study visits. Three women in the control group were diagnosed with type 2 diabetes (two at 6 months and one at 12 months postpartum), versus none in the intervention group.

In linear regression models controlling for baseline kilocalorie intake and breastfeeding, lifestyle intervention was associated with total daily dietary intake of 177 ± 84 kcal less at 6 months (p=0.041) and 180 ± 101 kcal less at 12 months (p=0.079). There were no significant differences between groups in time spent walking or time engaged in moderate or heavy physical activity. There were no differences in breastfeeding prevalence between groups at six or twelve months postpartum.

Intervention participants reported watching a median of 9/12 modules, with 33% watching all 12 core modules at least once, and all participants watching at least one module. The median number of contacts with the lifestyle coach was 7 (range 0–12; only one participant had no contact) over the first 12 weeks of the program, 4 (range 0–9) over the second 12 weeks of the program, and 2 (range 0–10) over the last 6 months of the program. Four women contacted the lactation consultant. Participants accessed the website on all days of the week and at all times of day and night. Women accessed the website from home, work, and from mobile phones. We provided laptops and internet for three and two women, respectively. Sixty-one percent of participants logged dietary intake at least once and 67% used pedometers. One-third of participants used the YMCA at least once but only six used it for more than one month.

Discussion

This study demonstrates the feasibility and efficacy of the web-based Balance after Baby lifestyle modification program to decrease postpartum weight retention in the first postpartum year for women with recent GDM. Intervention participants returned to their pre-pregnancy weight at one year while control participants remained significantly above pre-pregnancy weight. Our study findings are important given that pregnancy weight retained at 6 months postpartum is highly predictive for future obesity, (1,2) and weight retention at one year postpartum is predictive of BMI greater than 25 kg/m^2 fifteen years later. (3) In contrast to many weight loss interventions in non-postpartum populations where maximal weight loss is typically reached around 6 months, (21) women in our study continued to lose weight from 6 to 12 months postpartum. Although we were not powered to detect a difference in glucose tolerance over the first 12 months, it is notable that all three cases of type 2 diabetes occurred in the control group.

This study was powered to detect differences in postpartum weight retention. Caloric intake and physical activity were examined as secondary outcomes. There was greater reduction in calorie intake in the intervention versus the control group, which may have contributed to the weight loss difference between groups. We did not detect significant differences in physical activity between groups, and the YMCA membership was underutilized. Other studies have shown that postpartum women did not increase exercise despite targeted interventions. (12,22,23)

Strengths of our study include the randomized controlled design in a diverse population. Unlike prior studies of weight loss in postpartum women, we achieved substantial engagement, by utilizing web-based delivery and lifestyle coaching by phone or email to decrease barriers to participation. There are several limitations to the study. As a single center trial, results may not be generalizable to other populations., Pre-pregnancy weight was based on self-report, which could result in recall bias; however mean weight changes from self-reported pre-pregnancy weight to 12 month measured weight were similar to that from measured 6 week weight. In addition, since these self-reported data were obtained prior to randomization, the effect of the bias on the primary outcome should be minimized. Other studies have demonstrated a strong correlation between self-reported and clinically measured pre-pregnancy weight. (24,25) Some participants were lost to follow up (5%), and we accounted for this using an intent-to-treat analysis. We were not able to measure cost-effectiveness in this study.

The successful weight loss in our study may translate to short-term benefits including decreased complications in future pregnancies (26–28) and long-term reduction in obesity and cardiometabolic disease. A post-hoc analysis of women with GDM in the DPP found a net weight loss of 1.6 kg on average was associated with a 53% decreased risk for type 2 diabetes at 3 years. (11) Since women with GDM tend to retain or gain weight postpartum (9), we believe our findings demonstrating a 3.3 kg difference between groups is of clinical significance. Given that obesity is the strongest modifiable risk factor for type 2 diabetes, (29) novel strategies to increase postpartum weight loss in women with recent GDM may decrease the incidence of type 2 diabetes. Since this program can be delivered remotely via website and lifestyle coach, we believe that it would be low-cost to implement and has potential for broad dissemination. A larger and longer study is needed to determine whether the web-based Balance after Baby lifestyle program would decrease progression to type 2 diabetes in women with recent GDM.

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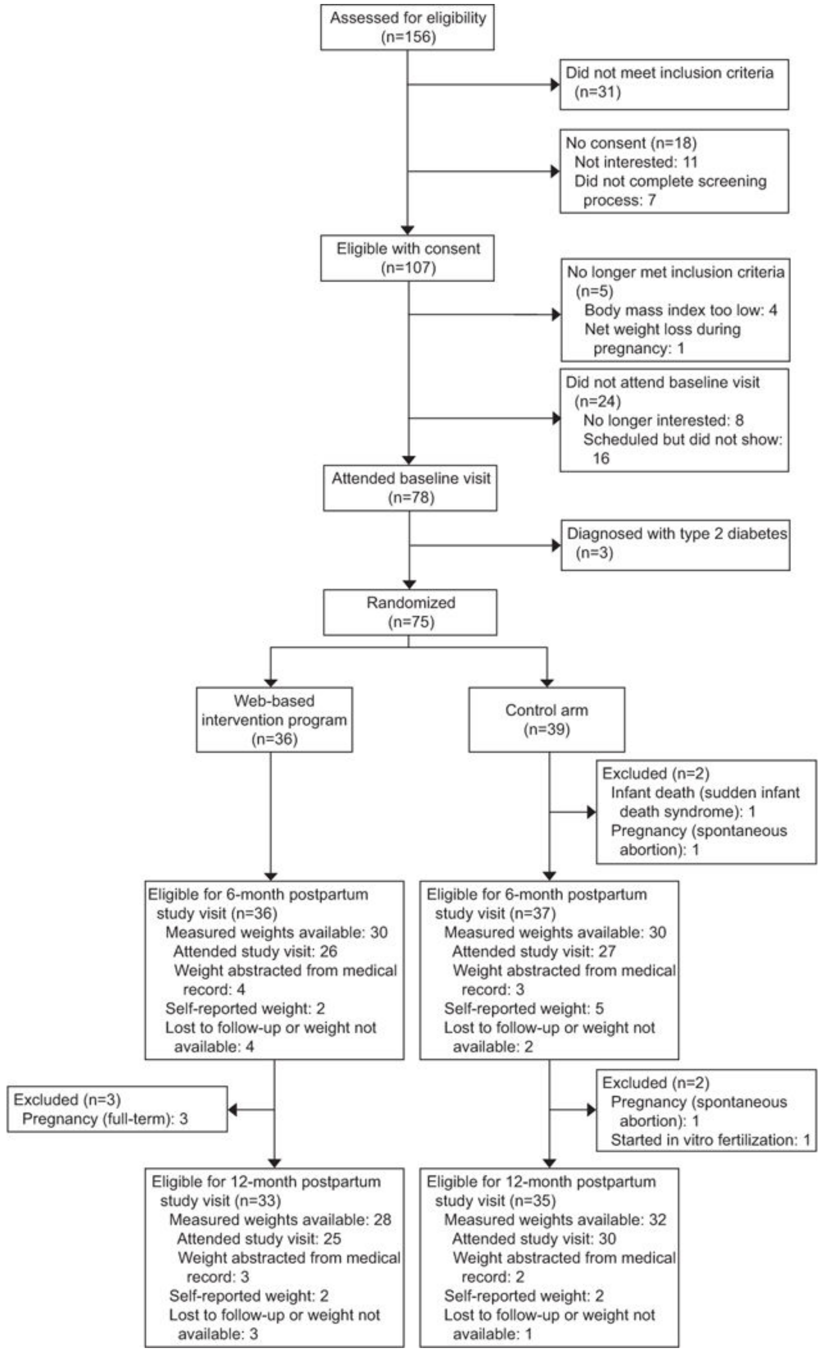

Figure 1.

Screening, recruitment, and follow up for the Balance after Baby study.

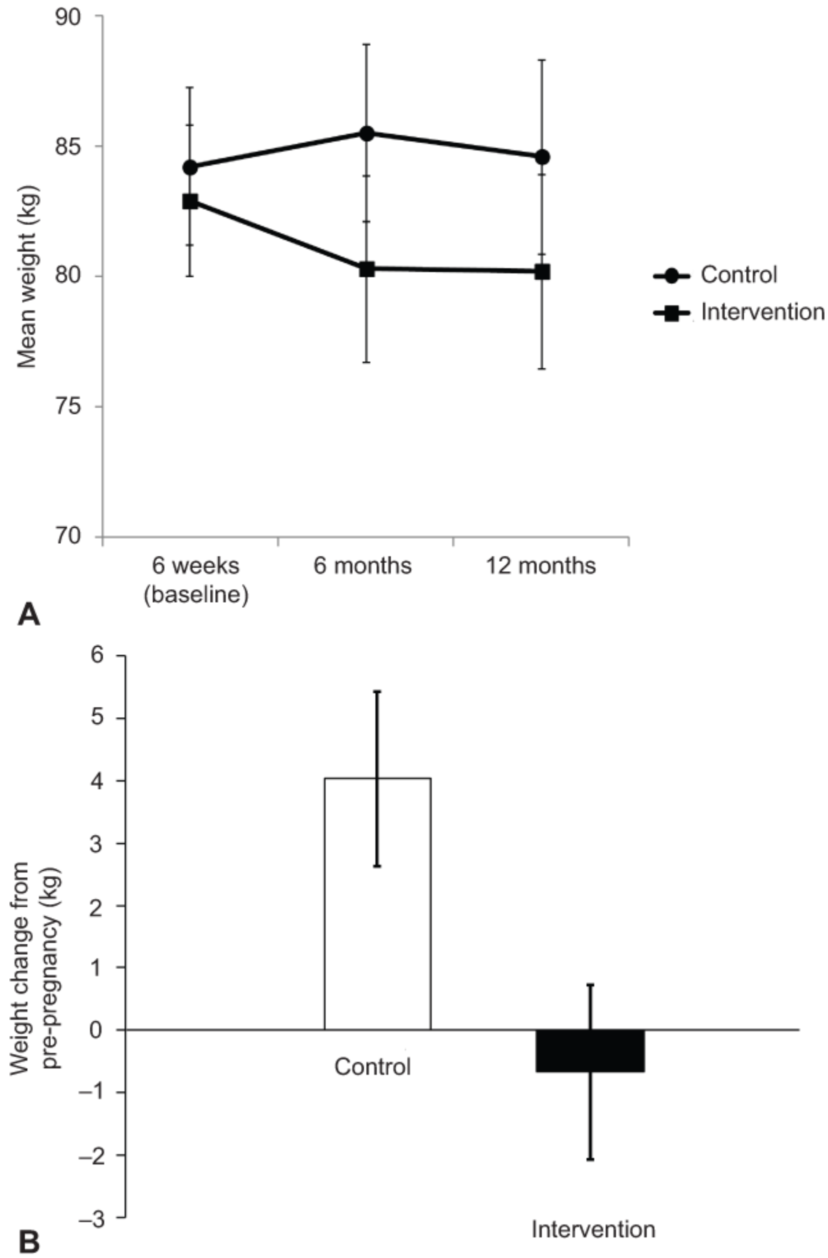

Figure 2.

A. Mean weight change (±SEM) from 6 weeks postpartum to 6 months and 12 months postpartum, in the intervention arm and control arm, controlling for baseline weight. **B.** Mean weight change (±SEM) at 12 months postpartum compared with pre-pregnancy weight, controlling for gestational weight gain.

Table 1

Baseline characteristics of the intervention and control groups

Characteristic*	Intervention arm n=36	Control arm n=39
Age, mean (SD)	33.6 (4.8)	33.3 (5.8)
Race:		
White, N (%)	23 (64%)	20 (51%)
African American, N (%)	9 (25%)	14 (36%)
Asian, N (%)	4 (11%)	5 (13%)
Hispanic/Latina N (%)	9 (25%)	6 (15%)
Education level attained:		
Some or all of high school	7 (20%)	6 (15%)
Some college	7 (20%)	11 (28%)
College graduate	21 (60%)	22 (56%)
Low-income (<≤175% Federal poverty level)	10 (29%)	14 (38%)
Has a partner, N (%)	28 (78%)	33 (85%)
Nulliparous, N (%)	18 (50%)	15 (38%)
Pre-pregnancy weight (kg), mean (SD)	80.6 (18.7)	81.1 (18.3)
Pre-pregnancy BMI (kg/m^2), mean (SD)	30.3 (6.3)	30.5 (5.7)
Used insulin during pregnancy, N (%)	24 (66%)	30 (77%)
Gestational weight gain (kg), mean (SD)	11.7 (8.2)	13.1 (7.7)
Cesarean delivery, N (%)	20 (56%)	16 (59%)
Weeks postpartum at baseline visit, weeks (SD)	7.3 (2.6)	7.0 (1.6)
6 week weight (kg), mean (SD)	82.9 (17.3)	84.2 (19.0)
6 wk BMI (kg/m2), mean (SD)	31.2 (5.8)	31.6 (5.5)
Impaired fasting glucose, n (%)	4 (11%)	8 (21%)
Impaired glucose tolerance, n (%)	8 (22%)	9 (23%)
IFG or IGT, n (%)	11 (31%)	13 (33%)
Current feeding:		
Exclusive breastfeeding	11 (31%)	13 (33%)
Formula only	9 (25%)	9 (23%)
Mixed	16 (44%)	17 (44%)
Depressive symptoms (EPDS ≥9)	12 (33%)	14 (36%)
Dietary data		
Total Kcal, median (IQR)	1889 (1627, 2193)	1973 (1324, 2727)

*Data are mean (standard deviation), n(%), or median (interquartile range).

Table 2

Baseline data and changes from baseline and from prepregnancy

Variable	Mean (SD) at baseline	Mean weight change from baseline Month 6*	Month 12*
		Mean weight change in kgs (95%CI)†	
Control weight (kg)	84.2 (19.0)	+1.4 (−0.4 to +3.1)	+0.5 (−1.4 to +2.4)
Intervention weight (kg)	82.9 (17.3)	−2.6 (−4.4 to −0.8)	−2.8 (−4.8 to −0.7)
Mean difference between groups(kg), (p value)		−3.9 (p=0.003)	−3.3 (p=0.022)
			Mean weight change in kgs (95%CI)‡
Control weight (kg)	84.2 (19.0)	+1.5 (−0.3 to +3.4)	+1.0 (−0.8 to +2.9)
Intervention weight (kg)	82.9 (17.3)	−2.6 (−4.4 to −0.8)	−3.0 (−4.9 to −1.0)
Difference between arms, mean (kg) (p value)		−3.9 (p=0.002)	−3.2 (p=0.004)
			BMI change, mean (95%CI)§
Control BMI (kg/m^2)	31.6 (5.5)	+0.5 (−0.2 to +1.2))	+0.2 (−0.5 to +0.9)
Intervention (kg/m^2)	31.2 (5.8)	−0.99 (−1.7 to −0.3)	−1.11 (−1.9 to −0.4)
Difference between arms, mean (p value)		−1.5 (p=0.004)	−1.3 (p=0.029)
			Weight change from prepregnancy weight (kgs), mean (95%CI)//
Control			+4.0 (+1.3 to +6.8)
Intervention			−0.7 (−3.5 to +2.2)
Difference between arms, mean (p value)			−4.7 (0.022)

*There were data from 60 participants at the 6- and 12-month time points, but that for the purposes of analysis, the model imputed data for all 75 women.

†Model controls for baseline weight.

‡Model controls for baseline weight and gestational weight gain.

§Model controls for baseline body mass index.

//Model controls for gestational weight gain.