A Pregnancy and Postpartum Lifestyle Intervention in Women With Gestational Diabetes Mellitus Reduces Diabetes Risk Factors

A feasibility randomized control trial

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OBJECTIVE—To pilot, among women with gestational diabetes mellitus (GDM), the feasibility of a prenatal/postpartum intervention to modify diet and physical activity similar to the Diabetes Prevention Program. The intervention was delivered by telephone, and support for breastfeeding was addressed.

RESEARCH DESIGN AND METHODS—The goal was to help women return to their prepregnancy weight, if it was normal, or achieve a 5% reduction from prepregnancy weight if overweight. Eligible participants were identified shortly after a GDM diagnosis; 83.8% consented to be randomly assigned to intervention or usual medical care (96 and 101 women, respectively). The retention was 85.2% at 12 months postpartum.

RESULTS—The proportion of women who reached the postpartum weight goal was higher, although not statistically significant, in the intervention condition than among usual care (37.5 vs. 21.4%, absolute difference 16.1%, $P = 0.07$). The intervention was more effective among women who did not exceed the recommended gestational weight gain (difference in the proportion of women meeting the weight goals: 22.5%, $P = 0.04$). The intervention condition decreased dietary fat intake more than the usual care (condition difference in the mean change in percent of calories from fat: −3.6%, $P = 0.002$) and increased breastfeeding, although not significantly (condition difference in proportion: 15.0%, $P = 0.09$). No differences in postpartum physical activity were observed between conditions.

CONCLUSIONS—This study suggests that a lifestyle intervention that starts during pregnancy and continues postpartum is feasible and may prevent pregnancy weight retention and help overweight women lose weight. Strategies to help postpartum women overcome barriers to increasing physical activity are needed.

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Gestational diabetes mellitus (GDM) is glucose intolerance with onset or first diagnosis during pregnancy (1). GDM complicates between 7–14% of pregnancies in the U.S. (1), and its incidence has increased 35–100% (2). A history of GDM is one of the strongest risk factors for type 2 diabetes (3). Among women with a history of GDM, the cumulative risk of developing type 2 diabetes at 10 years postpartum ranges from 20 to 50% (4,5). There is strong evidence from efficacy trials in at-risk individuals (6–8) that type 2 diabetes is preventable by lifestyle interventions focusing on weight management.

Despite this evidence, no lifestyle interventions for diabetes prevention starting during pregnancy and continuing postpartum have been translated for use in women with GDM. There are several reasons for starting an intervention soon after the diagnosis of GDM. First, women who exceed the Institute of Medicine (IOM) guidelines for gestational weight gain (GWG) retain twice as much weight compared with women who gain within the recommendations (9), and this is associated with an increased likelihood of long-term obesity (9–11). Second, a lifestyle intervention that starts soon after the diagnosis of GDM takes advantage of the "teachable moment" of pregnancy; women with GDM may be concerned about their children's increased risk of adverse health outcomes and their own increased risk of diabetes, which could motivate the adoption of preventive behaviors. Third, GDM patients' frequent interactions with the health care system during and after pregnancy present an opportunity for such an intervention to be adopted by the health care system. However, participation in such an intervention may not be feasible for women with young children who are also likely to work outside home.

The aim of this randomized pilot trial was to evaluate the feasibility of a lifestyle intervention initiated soon after the diagnosis of GDM and continuing postpartum. The primary goals of the intervention were to help women return to their pregravid weight if normal weight before pregnancy or achieve a 5% reduction from their pregravid weight if overweight or obese before pregnancy. The intervention curriculum was adapted from the Diabetes Prevention Program (DPP) (12) but delivered primarily by telephone (instead of individual, in-person counseling sessions) to make it more accessible to pregnant and postpartum

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women and feasible for the health care system.

RESEARCH DESIGN AND METHODS

—The setting was the Kaiser Permanente Medical Care Program of Northern California (KPNC), a large group practice prepaid health plan where GDM is diagnosed in accordance with the American Diabetes Association (ADA) guidelines (2,13). Recruitment for this feasibility study occurred between October 2005 and May 2008. Follow-up visits were conducted between January 2006 and June 2009. The study was conducted in collaboration with the KPNC Regional Perinatal Service Center, which provides supplemental prenatal care over the telephone to women with GDM.

Study design

Women with GDM according to the ADA criteria (13) were eligible to participate. Exclusion criteria included: age <18 years; multiple gestation; diagnosis of diabetic retinopathy; high-risk pregnancy (i.e., drug or alcohol abuse, chronic health problems, or pregnancy complications); thyroid diseases diagnosed in the last 30 days; and non-English speaker. Eligibility was assessed through the review of electronic medical records and telephone interviews (Fig. 1). Of the eligible women, 84% gave written informed consent and participated in a baseline visit. Women were randomly assigned to the lifestyle intervention condition or usual care control condition upon completion of their baseline clinic visit. A computer randomization program was used to ensure that the conditions remained balanced with regards to the following characteristics: age (<30 and ≥30 years), parity (≤1 and >1), and pregravid BMI (<27.0 and ≥27.0 kg/m^2). The institutional review board at KPNC approved the study protocol.

Intervention

The intervention was called Diet, Exercise and Breastfeeding Intervention (DEBI) for women with GDM. Two trained dietitians delivered the intervention, which was adapted from the DPP curriculum and incorporated behavioral constructs from social cognitive theory (14) and the transtheoretical model (15) of behavior change. DEBI was comprised of 3 intervention phases: prenatal, postpartum, and maintenance.

The prenatal phase started soon after the diagnosis of GDM and consisted of one in-person session and two individual telephone counseling contacts. The dietitians explained to the women their elevated risk of developing type 2 diabetes and advised the women to comply with the IOM guidelines (16) for GWG that were in place at the time. For obese women, the IOM guidelines did not provide an upper GWG limit, thus it was recommended that obese women not exceed a GWG of 11.4 kg, as advised for overweight women. They were encouraged to follow the ADA diet (17) and engage in moderate intensity physical activity for 150 min per week (18). Written intervention materials about portion size, foods with low glycemic index or low fat, and how to read food labels were discussed during telephone counseling contacts.

Toward the end of pregnancy, intervention women were referred to a lactation consultant who discussed the benefits of breastfeeding, offered a breast pump, and encouraged the women to exclusively breastfeed for 6 months (19). The lactation consultant then scheduled calls (1–4 calls, as needed) in the first 6 weeks after delivery to evaluate latch and feeding techniques and to review the maintenance of milk supply.

The early postpartum phase began 6 weeks after delivery and ended at

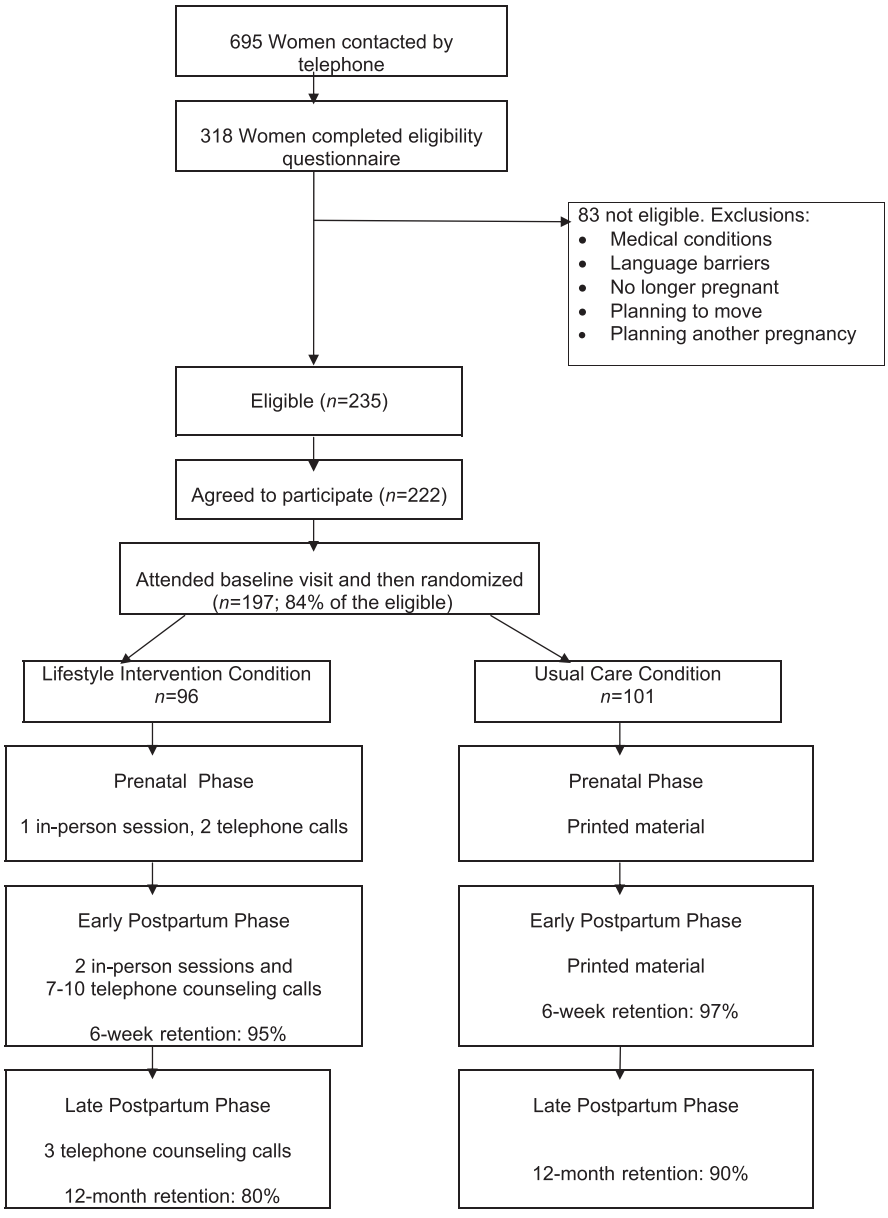

Figure 1—*Flow chart of participant recruitment and retention, Kaiser Permanente Northern California, 2005–2009.*

7 months postpartum. For women whose pregravid BMI was <25.0 kg/m^2, the postpartum weight goal was to reach prepregnancy weight. For women whose pregravid BMI was ≥25.0 kg/m^2, the postpartum weight goal was to lose an additional 5% of their prepregnancy weight. Women were asked to reach their weight goal during the first 12-months postpartum and were given the DPP handbook that contained written materials organized in 16 sessions (20). There was a core curriculum of 8 sessions with up to 8 additional sessions offered to those who desired more contact. The sessions were conducted over the telephone except for the first and the last, which were conducted in-person. Women were encouraged to perform 150 min of moderate or harder physical activity per week and to consume 25% or less of total calories from fat per day. Fat and calorie intake and physical activity goals were tailored based on dietary and physical activity assessments. Women were given self-monitoring diaries for recording the fat grams consumed and the minutes of physical activity and were asked to return these diaries weekly by mail. These diaries were used by the dietitians to help the women meet their goals. During counseling contacts, dietitians would review the previous week's diary and written material designated for that session.

The maintenance phase began soon after the early postpartum phase and ended at 12 months postpartum. It consisted of three telephone contacts that reinforced the positive behavioral changes achieved during the core curriculum and addressed relapse.

Women randomized to the usual care condition received printed educational materials that included publicly available information on GDM. In the postpartum period, they received two newsletters focusing on issues related to infant safety and general health.

Data collection

Participants were asked to attend four clinic visits for data collection: one during pregnancy soon after the diagnosis of GDM (baseline) and three follow-up visits at 6 weeks, 7 months, and 12 months postpartum. Baseline and follow-up data were collected by research assistants who were unaware of the condition assignment. Height was measured at baseline with a standard stadiometer, and weight was measured at each visit with a Tanita WB-110 digital electronic scale.

Table 1—*Baseline characteristics of women with GDM by randomization condition, KPNC, 2005–2008*

	Lifestyle intervention	Usual care	*P* value*
n	96	101	
Age (years)			0.88
21–24	3.1	4.0	
25–29	18.8	20.8	
30+	78.1	75.3	
Race/ethnicity			0.89
Non-Hispanic white	19.8	18.8	
Black/African American	5.2	4.0	
Asian or Pacific Islander	49.0	54.5	
Hispanic origin	18.8	18.8	
Other	4.2	2.0	
Missing	3.1	2.0	
Education			0.09
High school or less	16.7	6.9	
Some college	24.0	23.8	
College graduate	31.3	30.7	
Postgraduate	24.0	36.6	
Missing	4.2	2.0	
Marriage status			0.51
Married	86.5	84.2	
Not married, living with partner	7.3	6.9	
Never married	1.0	5.0	
Divorced/separated	1.0	2.0	
Missing	4.2	2.0	
Employment			0.14
Full time	40.6	55.4	
Part time	21.9	17.8	
Not employed	33.3	24.8	
Missing	4.2	2.0	
Parity			0.98
0	39.6	41.6	
1	41.7	40.6	
2	15.6	13.9	
3+	3.1	4.0	
First-degree family history of diabetes			0.67
Yes	47.3	48.3	
No	37.4	43.8	
Missing	15.4	7.9	
Smoking before pregnancy (≥7 cigarettes/week)			0.12
Yes	18.8	9.9	
No	7.3	5.0	
Never smoke	69.8	83.2	
Missing	4.2	2.0	
Alcohol consumption before pregnancy (≥1 drink/week)			0.51
Yes	24.0	28.7	
No	71.9	69.3	
Missing	4.2	2.0	
Prepregnancy BMI (kg/m^2)			0.90
17–24	40.6	43.6	
25–29	24.0	21.8	
30+	35.4	34.7	
BMI at baseline (kg/m^2)			
20–24	15.6	14.9	
25–29	27.1	32.7	
30+	57.3	52.5	

Table 1—*Continued*

	Lifestyle intervention	Usual care	*P* value*
Therapy during pregnancy after GDM diagnosis			0.50
Diet	66.7	60.4	
Glyburide	28.1	35.6	
Insulin	5.2	4.0	
Infant birth weight (g)			0.51
<2,500	4.6	4.2	
2,500–4,000	79.3	85.4	
>4,000	16.1	10.5	
	Mean (SD)	Mean (SD)	*P* value
Plasma glucose levels after 50-g glucose challenge (mg/dL)	165.5 (21.8)	166.1 (21.7)	0.85
Diagnostic test (100-g OGTT)			
Fasting plasma glucose	92.1 (12.2)	91.7 (13.6)	0.85
1-h plasma glucose	196.4 (22.6)	206.6 (22.7)	0.002
2-h plasma glucose	176.6 (18.9)	180.4 (26.2)	0.27
3-h plasma glucose	125.6 (35.0)	129.6 (34.4)	0.42
Gestation age at baseline (weeks)	31.8 (5.6)	31.0 (6.1)	0.34
Gestational weight gain at baseline (kg)	8.5 (5.4)	8.6 (5.4)	0.93
Percent of calories from dietary fat at baseline	37.3 (6.7)	37.6 (7.6)	0.81
Moderate or vigorous physical activity at baseline (min/week)	333.6 (295)	334.1 (326)	0.99
Number of visits to health care providers	11.1 (5.9)	11.0 (6.1)	0.86

Data are % unless otherwise indicated. OGTT, oral glucose tolerance test. *P values from χ^2 tests that exclude the missing category.

Information on diet during the previous month (assessed via a 120-item food frequency questionnaire [21]) and physical activity during the previous week (22) was collected at baseline, 6 weeks, and 7 months postpartum. Partial or exclusive breastfeeding was collected at 6 weeks and 7 months postpartum. Satisfaction with the intervention program was assessed by questionnaire at 12 months postpartum. Total GWG was calculated as the difference between the latest weight measured during pregnancy (obtained from medical records) and self-reported pregravid weight. The use of diabetes medications, number of perinatal clinic visits during pregnancy, and infant birthweight were obtained from the medical records.

Statistical analysis

All data analyses were by intention-to-treat. For the primary dichotomous outcome of meeting the postpartum weight goal and the secondary outcome of breastfeeding, we used repeated-measures logistic regression with estimation via generalized estimating equations to account for the within-person correlation in repeated binary responses. For continuous secondary outcomes (such as diet and physical activity), linear mixed-effects models were used to examine the overall average difference between the intervention and usual care conditions in the means at each visit. Condition difference in outcomes at each clinic visit were presented, with associated significance probabilities obtained from the longitudinal regression models that included condition-visit interaction terms. Heterogeneity in intervention effect over time was assessed via a test of the condition-clinic visit interaction terms.

RESULTS—Of the 710 women with GDM, 695 (97.9%) were contacted (Fig. 1). Of these, 318 completed the eligibility screening. There were no differences between these two groups with regard to age, race/ethnicity, and gestational age (data not shown). Among those who completed the eligibility screening, 83 (23.1%) were not eligible. Among the remaining 235 women, 222 (94.5%) agreed to participate and made a baseline visit appointment; 197 (83.8%) women attended the baseline visit, gave informed consent, and were randomized. Participant retention at each follow-up visit in the intervention and usual care conditions, respectively, were as follows: 95 and 97% at 6 weeks, 80 and 91% at 7 months, and 80 and 90% at 12 months postpartum (Fig. 1). No differences in baseline characteristics were observed between women in the intervention and usual care conditions except that the 1-h glucose value from the diagnostic 100-g oral glucose tolerance test was lower among women in the intervention condition compared with women in the usual care condition and small differences in smoking and employment status (Table 1).

Primary outcome

The proportion of women who reached their postpartum weight goal was higher in the intervention condition (Table 2). Although this difference was not statistically significant, the condition difference in absolute proportion was 16.1% (P = 0.07) at 12 months postpartum. Similar results were obtained after adjusting for 1-h glucose levels and in subgroup analyses where women were stratified by smoking or employment status (data not shown).

Because the postpartum weight goals differed between women with pregravid BMI <25.0 kg/m^2 and women with pregravid BMI ≥25.0 kg/m^2, the efficacy of the intervention within these two groups was examined (Table 2). The magnitude of the absolute condition difference in the proportion of women meeting the postpartum weight goal was similar in normal weight and overweight/obese women. Because the rationale for starting the intervention during pregnancy was that preventing excessive GWG would result in reduced postpartum weight retention, the efficacy of the intervention was assessed separately in those who did and did not exceed the recommended GWG (Table 2). The intervention appeared to be more effective among women who did not exceed the guidelines for GWG; the absolute difference between the intervention and the usual care conditions in the proportion of women reaching the weight goal at 12 months postpartum was 22.5% (P = 0.04).

In a sensitivity analysis where women who did not attend the postpartum visits were categorized as not having reached the weight goal at 12 months postpartum, the intervention condition remained more likely to reach the postpartum weight goal than usual care (absolute difference = 11%) despite a slightly greater loss to follow-up among women in the intervention condition.

Table 2—*Proportion of women with GDM meeting the postpartum weight goals by randomization group and time since delivery*

	Lifestyle intervention		Usual care		Group difference	
		Proportion		Proportion	Absolute proportion	
	n/N	%	*n/N*	%	%	*P* value
All women						
6 weeks postpartum	19/91	20.9	17/98	17.4	3.5	0.54
7 months postpartum	27/71	38.0	21/88	23.9	14.1	0.13
12 months postpartum	27/72	37.5	18/84	21.4	16.1	0.07
Women with pregavid BMI <25.0 kg/m^2						
6 weeks postpartum	8/38	21.1	5/43	11.6	9.5	0.25
7 months postpartum	14/31	45.2	10/38	26.3	18.9	0.19
12 months postpartum	15/32	46.9	11/36	30.6	16.3	0.26
Women with pregravid BMI ≥25.0 kg/m^2						
6 weeks postpartum	11/53	20.8	12/55	21.8	−1.0	0.89
7 months postpartum	13/40	32.5	11/50	22.0	10.5	0.41
12 months postpartum	12/40	30.0	7/48	14.6	15.4	0.15
Women not exceeding the IOM guidelines for gestational weight gain						
6 weeks postpartum	19/66	28.8	17/68	25.0	3.8	0.62
7 months postpartum	24/54	44.4	18/59	30.5	13.9	0.19
12 months postpartum	24/53	45.3	13/57	22.8	22.5	0.04
Women exceeding the IOM guidelines for gestation weight gain						
6 weeks postpartum	0/25	—	0/30	—	—	—
7 months postpartum	3/17	17.6	3/29	10.3	7.3	0.60
12 months postpartum	3/19	15.8	5/27	18.5	−2.7	0.81

All *P* values for treatment condition and follow-up visit interaction are >0.05.

Secondary outcomes

As compared with the usual care arm, the women in the intervention at 7 months postpartum showed a statistically significant decrease in dietary fat intake (condition difference in the mean change in percent of calories from fat: −3.55%, *P* = 0.002); a greater but nonsignificant increase in physical activity (condition difference in the mean change in minutes of moderate-to-vigorous physical activity per week: 25.3, *P* = 0.91); and a higher but not significant likelihood to partially or exclusively breastfeed (condition difference in proportion: 15.0%, *P* = 0.09) (Table 3).

Process measures of the intervention

Ninety-three percent of the women randomized to the intervention completed the first prenatal session, and 79% completed two or more. On average, the pregnancy telephone sessions lasted 31.2 ± 17.7 min, while the in-person sessions lasted approximately 1 h. For the early postpartum phase, 74% of the women completed the 8 core intervention sessions. Overall, women completed an average of 9.4 (SD 4.4) postpartum sessions. The telephone sessions lasted on average 32.6 ± 15.7 min each, while the in-person sessions lasted approximately 1 h. Women returned a median of 3 self-monitoring diaries, with 30.9% returning 6 or more. Overall, the women were very satisfied with the intervention (97%) and most (92%) would recommend the program

Table 3—*Breastfeeding and changes in dietary fat intake and physical activity by randomization condition and time since delivery*

	Lifestyle intervention		Usual care condition		Condition difference	
		Proportion		Proportion	Absolute proportion	
	n/N	%	*n/N*	%	%	*P* value
Partial or exclusive breastfeeding						
6 weeks postpartum	79/90	87.8	89/98	90.8	−3.0	0.50
7 months postpartum	47/75	62.7	41/86	47.7	15.0	0.09
	Mean	SD	Mean	SD	Mean difference	*P* value
Change in percent of calories from dietary fat						
6 weeks postpartum	−3.85	7.44	−3.27	8.02	−0.58	0.54
7 months postpartum	−6.39	8.04	−2.84	7.47	−3.55	0.002
Change in MVPA (min/week)						
6 weeks postpartum	−0.7	403.7	−22.0	430.8	21.3	0.92
7 months postpartum	29.0	541.9	3.7	452.9	25.3	0.91

All *P* values for treatment condition and follow-up visit interaction are >0.05 except for change in percent of calories from fat (*P* = 0.001). MVPA, moderate or vigorous physical activity.

to others with GDM. A majority (82%) said they were likely to continue to set weight goals.

Focus groups with intervention women

Two focus groups, each with 8 intervention participants, were conducted upon completion of the study. Women reported the desire for more information regarding health risks after GDM. For physical activity, the following themes emerged: *1*) the need for support for physical activity from family and others in their social network; *2*) the addition of a website to connect with other GDM women; and *3*) tips on how to exercise with a new infant. Reported barriers to physical activity were personal and child illnesses, returning to work, and bad weather. For diet, the following themes emerged: *1*) the need for information on the optimal type of carbohydrate for the transition from the pregnancy diet to the low-fat postpartum diet and *2*) the need for low-fat recipes.

CONCLUSIONS—This pilot study, which evaluated a DPP-based lifestyle intervention that aimed to reduce diabetes risk factors and started soon after the diagnosis of GDM and continued into the postpartum period, was shown to be feasible. Process data demonstrated satisfactory compliance with the intervention protocol. Thus, the DPP lifestyle intervention delivered by telephone was successfully adapted for women with GDM. The intervention appeared to reduce type 2 diabetes and GDM risk factors such as body weight and dietary fat intake (7,23) and increased breastfeeding. The intervention helped women meet their postpartum weight goals by reducing postpartum weight retention in normal-weight women and helping overweight or obese women to lose weight.

Only two randomized controlled trials have included women with a pregnancy complicated by GDM. In both trials, the affected pregnancies occurred several years prior to study initiation. In the Troglitazone in the Prevention of Diabetes (TRIPOD) trial (8), treatment with troglitazone reduced the incidence of diabetes by over 50%. Subgroup analyses (24) among DPP women with a history of GDM demonstrated that intensive lifestyle intervention and metformin both decreased the risk of type 2 diabetes by approximately 50%. Our study provides feasibility data suggesting that a DPP-based intervention delivered by telephone in pregnancy through the postpartum period is feasible and effective in women with GDM.

The higher proportion of women reaching their postpartum weight goal is mostly because of the postpartum intervention, however the short pregnancy intervention may have promoted some initial behavioral changes, making the postpartum intervention more effective as shown by our subgroup analyses according to GWG. Given the strong association between GWG and postpartum weight retention (9,11,25), it may be difficult to intervene and reduce postpartum weight without first preventing excessive GWG. In our stratified analyses, the intervention appeared to be more effective among women who met the guidelines for GWG, either because the postpartum intervention was easier for such women to adopt as they may be more adherent to health recommendations or because of the biological connection between GWG and postpartum weight retention.

The limitations are familiar to feasibility studies: a relatively small sample size and an intervention that needed additional refinement, specifically with input from the target population. Information learned from this feasibility trial will inform a future, adequately powered, randomized lifestyle intervention trial. There was also a small differential loss to follow-up between the intervention and the usual care conditions. This difference may be because of the translational nature of the study, which did not require participants to attend at least two baseline study visits before randomization, as is common practice in efficacy trials.

In conclusion, our study suggests that an adaptation of the DPP lifestyle intervention, delivered primarily by telephone, is feasible for women with GDM. It may also reduce pregnancy weight retention and may help overweight or obese women lose weight in the postpartum period. Although the intervention was effective in reducing dietary fat intake, strategies for helping postpartum women to overcome barriers and increase their physical activity are needed. Future randomized control trials should focus on developing such strategies, particularly for soliciting social support for increasing physical activity.

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