



A Tailored Letter Based on Electronic Health Record Data Improves Gestational Weight Gain Among Women With Gestational Diabetes Mellitus: The Gestational Diabetes' Effects on Moms (GEM) Cluster-Randomized Controlled Trial

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OBJECTIVE

Evaluate whether a tailored letter improved gestational weight gain (GWG) and whether GWG mediated a multicomponent intervention's effect on postpartum weight retention among women with gestational diabetes mellitus (GDM).

RESEARCH DESIGN AND METHODS

A cluster-randomized controlled trial of 44 medical facilities ($n = 2,014$ women) randomized to usual care or a multicomponent lifestyle intervention delivered during pregnancy (tailored letter) and postpartum (13 telephone sessions) to reduce postpartum weight retention. The tailored letter, using electronic health record (EHR) data, recommended an end-of-pregnancy weight goal tailored to prepregnancy BMI and GWG trajectory at GDM diagnosis: total GWG at the lower limit of the IOM range if BMI ≥ 18.5 kg/m² or the midpoint if < 18.5 kg/m² and weight maintenance if women had exceeded this. The outcomes for this study were the proportion of women meeting the Institute of Medicine (IOM) guidelines for weekly rate of GWG from GDM diagnosis to delivery and meeting the end-of-pregnancy weight goal.

RESULTS

The tailored letter significantly increased the proportion of women meeting the IOM guidelines (72.6% vs. 67.1%; relative risk 1.08 [95% CI 1.01–1.17]); results were similar among women with BMI < 25.0 kg/m² (1.07 [1.00–1.15]) and ≥ 25.0 kg/m² (1.08 [0.98–1.18]). Thirty-six percent in the intervention vs. 33.0% in usual care met the end-of-pregnancy weight goal (1.08 [0.99–1.18]); the difference was statistically significant among women with BMI < 25.0 kg/m² (1.28 [1.05–1.57]) but not ≥ 25.0 kg/m² (0.99 [0.87–1.13]). Meeting the IOM guidelines mediated the effect of the multicomponent intervention in reducing postpartum weight retention by 24.6% (11.3–37.8%).

CONCLUSIONS

A tailored EHR-based letter improved GWG, which mediated the effect of a multicomponent intervention in reducing postpartum weight retention.

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Gestational diabetes mellitus (GDM) is the most common complication of pregnancy. Women with GDM are at increased risk of perinatal complications and are seven times more likely to develop type 2 diabetes after pregnancy than women with normoglycemic pregnancies (1). Postpartum weight retention also increases the risk of progressing to diabetes after pregnancy (2), and the strongest predictor of postpartum weight retention is excessive gestational weight gain (GWG) (3,4). Promoting appropriate GWG (i.e., within the Institute of Medicine [IOM] guidelines for total or weekly rate of weight gain, which vary according to a woman's BMI prior to pregnancy) (5) may reduce postpartum weight retention and thus the incidence of diabetes in this high-risk population.

The Gestational Diabetes' Effects on Moms (GEM) trial (6) was a cluster-randomized controlled trial set within an integrated health care delivery system with the primary goal of reducing postpartum weight retention among women with GDM. The trial compared usual care to a multicomponent lifestyle intervention delivered at the health system level. The intervention was comprised of a pregnancy component (consisting of a single tailored letter using electronic health record [EHR] data to address GWG) and a postpartum component (consisting of 13 Diabetes Prevention Program [DPP]-based telephone sessions with a lifestyle coach offered between 6 weeks and 6 months postpartum). We previously reported the GEM trial main results, showing that women in medical facilities randomized to the multicomponent intervention had significantly less postpartum weight retention than women in facilities randomized to usual care (7). To help identify the influence of distinct components of this intervention, here we first evaluated whether the tailored letter improved GWG and then whether GWG mediated the effect of the multicomponent intervention on the trial's main outcome, postpartum weight retention. Outcomes for the evaluation of the tailored letter on GWG were the proportion of women meeting 1) the IOM guidelines for appropriate weekly rate of weight gain from GDM diagnosis until delivery and 2) a tailored weight goal for the end of pregnancy, specific to women's prepregnancy BMI and gestational weight trajectory at the time of GDM diagnosis (total GWG at the lower limit of the IOM range if prepregnancy BMI was ≥ 18.5 kg/m² or

the midpoint if < 18.5 kg/m², and weight maintenance if women had exceeded this).

RESEARCH DESIGN AND METHODS

The rationale and methods of the GEM trial have been described elsewhere (6). In brief, the setting, Kaiser Permanente Northern California (KPNC), is an integrated health care delivery system with 44 medical facilities managing $\sim 33,000$ births annually. KPNC membership closely approximates the surrounding population (8). All women with GDM at KPNC are offered telephone-based nurse case management during pregnancy from the Regional Perinatal Service Center (9). All 44 KPNC facilities were randomized to either usual care or intervention conditions ($n = 22$ each). Randomization was blocked on facility size, i.e., the expected annual number of women with GDM (three strata: < 25 , $25-74$, and ≥ 75). A restricted randomization scheme was used to ensure acceptable between-condition balance (i.e., maximum between-condition relative difference) in expected racial/ethnic distributions, both overall and within facility size stratum (6,10). All investigators, data collectors, and health care providers were blinded to condition assignment. The Kaiser Foundation Research Institute Human Subjects Committee approved the trial and waived the requirement for informed consent for the intervention.

Data Collection

We obtained prepregnancy weight and height as recorded in the EHR. Prepregnancy BMI was calculated from clinically measured prepregnancy weight (90.3%) or from self-reported prepregnancy weight at the time of the first prenatal clinic visit before 10 weeks gestation (9.7%). We also obtained weights during pregnancy as measured by clinical staff and recorded in the EHR, including weight at the time of GDM diagnosis (i.e., within 2 weeks of the diagnostic 100-g, 3-h oral glucose tolerance test). Gestational weight trajectory (i.e., cumulative amount of weight gained relative to week of gestation) from prepregnancy to the time of GDM diagnosis was categorized in relation to the IOM guidelines (5) for absolute GWG in the first trimester and weekly rate of GWG in the second and third trimesters. Total GWG was calculated as the last pregnancy weight (measured within 2 weeks of delivery, hereafter termed "delivery" for brevity) minus prepregnancy weight. Weight at

GDM diagnosis and the last pregnancy weight were used to calculate rate of weight gain per week from GDM diagnosis to delivery. Age, race/ethnicity, gestational age at GDM diagnosis and delivery, and parity were also obtained from the EHR.

Participants

Potentially eligible participants included pregnant women ≥ 18 years of age across all 44 KPNC medical facilities, diagnosed between March 2011 and March 2012 with GDM according to the Carpenter and Coustan criteria (as recommended by the American College of Obstetrics and Gynecologists [11] during this period; $n = 2,480$). We excluded 466 women from the current study, e.g., because they were not sent the tailored letter due to being pregnant with multiples (given a lack of IOM guidelines for such women), they were diagnosed with GDM at later than 34 weeks gestation, or they were missing essential data such as prepregnancy BMI (Fig. 1). An additional seven women were excluded from the primary analysis of GWG outcomes due to missing race/ethnicity or last weight before delivery, and 40 were excluded from the mediation analysis of postpartum weight retention due to missing a postpartum weight measured up to 12 months postpartum (7).

Usual Care

Supplementing care from their personal physician, all women with GDM at KPNC are provided telephone-based nurse case management from the Regional Perinatal Service Center to help maintain glycemic control during pregnancy (9). Women are sent a packet of health education materials shortly after their GDM diagnosis. Women then receive one to two calls per week to review self-monitored glucose data and to receive advice regarding nutrition and physical activity. Nurses are available by phone 7 days a week and dietitians 5 days a week. Neither the health education materials nor calls provide recommendations on GWG.

Intervention

In addition to usual care, women with GDM attending medical facilities randomized to the intervention received a separate, tailored letter after receiving the packet of health education materials from the Perinatal Center as part of usual care. The tailored letter was printed on Perinatal Center letterhead and personalized with the recipient's name in the salutation.

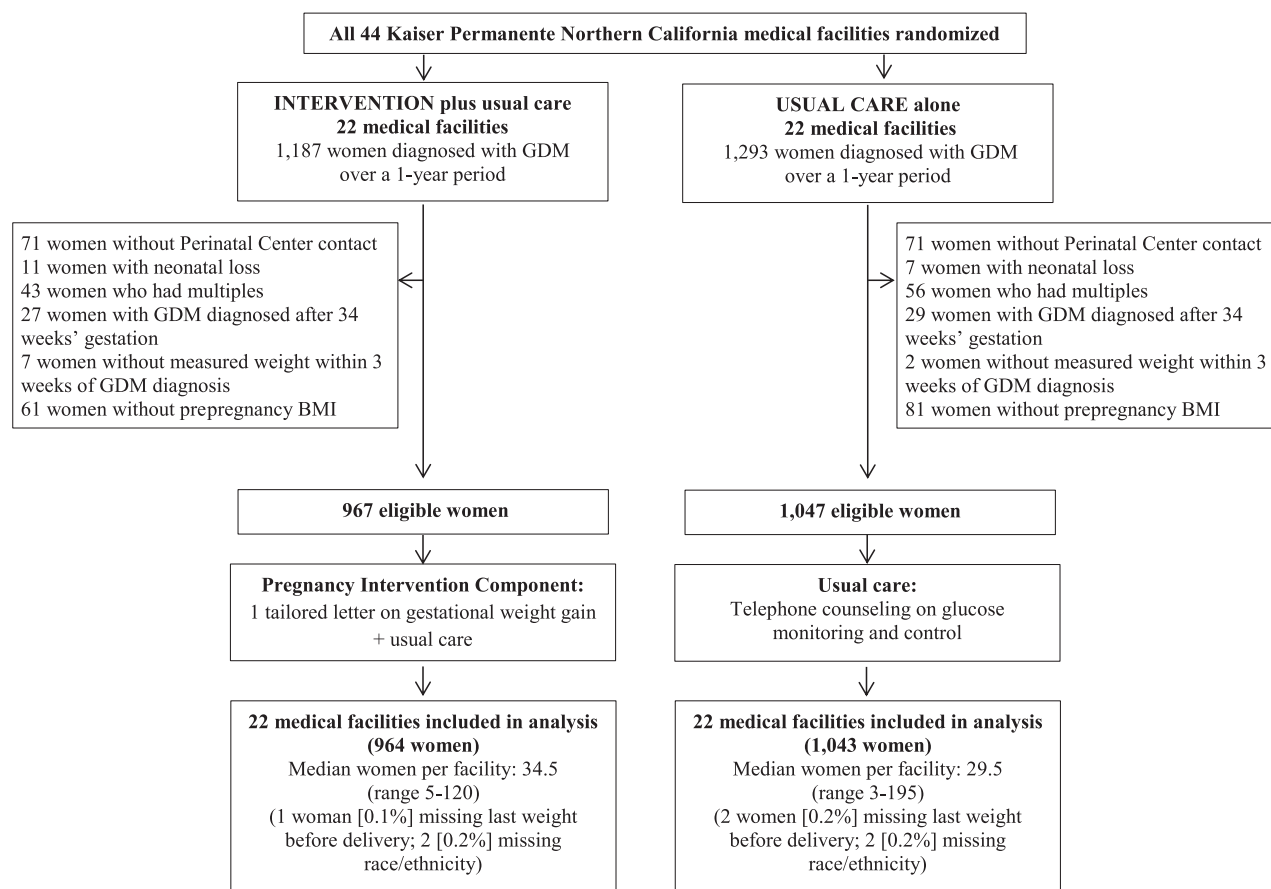


Figure 1—Overview of the pregnancy intervention component (from GDM diagnosis to delivery) of the GEM cluster-randomized trial.

Letters were written at less than an eighth grade reading level and sent in English or Spanish, according to the woman's preferred language recorded in the EHR.

Letters included six tailored messages regarding 1) weight history (i.e., the woman's prepregnancy weight, prepregnancy BMI, and current weight at the time of the GDM diagnosis); 2) a recommendation for total GWG specific to the woman's prepregnancy BMI; 3) a corresponding end-of-pregnancy weight goal; 4) a recommendation for weight management based on the woman's gestational weight trajectory; 5) lifestyle tips to help meet the end-of-pregnancy weight goal; and 6) information regarding GWG's impact on pregnancy and postpartum health (Table 1 and Supplementary Data).

Message elements 2 and 3 were tailored to the woman's prepregnancy BMI. Since women with GDM are at increased risk for complications, the recommendation for total GWG corresponded to the lower limit of the IOM range if a woman's prepregnancy BMI was ≥ 18.5 kg/m² (i.e., in the normal, overweight, or obese range)

or no more than the midpoint if prepregnancy BMI was < 18.5 kg/m² (i.e., in the underweight range). The end-of-pregnancy weight goal corresponded to 1) this total GWG recommendation or 2) the woman's current weight, if the total GWG recommendation had already been exceeded. Message elements 3–6 were tailored to the woman's gestational weight trajectory (i.e., cumulative amount of weight gained relative to week of gestation, from prepregnancy to the time of GDM diagnosis), which was based on the end-of-pregnancy weight goal and divided into four mutually exclusive categories: 1) gaining too slowly (> 3 lb under the target weight for current gestational age), 2) on track (within 3 lb of the target weight), 3) gaining too quickly (> 3 lb above the target weight), and 4) exceeded (already above the total GWG recommendation). All letters included a core set of lifestyle tips (e.g., choose produce, lean sources of protein, low- or nonfat dairy, and water instead of sugar-sweetened beverages, and take brisk 30-min walks daily unless advised otherwise by their physician) and a risk statement that

for women with GDM, gaining too much weight during pregnancy increases risks for poor glucose control during pregnancy and postpartum weight retention.

Implementation

All data needed to generate the tailored letters were electronically abstracted from the EHR in real time (i.e., as women were diagnosed with GDM and added to the study database). Given the four categories for prepregnancy BMI and four categories for gestational weight trajectory, there were 16 possible letter templates that were electronically populated with the patient-specific data derived from the EHR. Research staff generated the letters automatically using an ACCESS tracking system and mailed them on behalf of the Perinatal Center.

Outcomes

The outcomes for the evaluation of the tailored letter included the proportion of women meeting the IOM guidelines for second and third trimester appropriate weekly rate of weight gain from GDM diagnosis to delivery.

Table 1—Intervention elements of a tailored letter to promote appropriate GWG: the GEM trial

Tailored component	Description					Sample message
1) Weight history	Prepregnancy weight, prepregnancy BMI, and current weight at GDM diagnosis derived from the EHR					Our records show that before pregnancy, your weight was ___ lb; your BMI was _____. Our records also show that your current weight is about ___ lb.
2) Total GWG, specific to prepregnancy BMI			IOM guidelines		Recommendation	The IOM recommends that women with your BMI gain ___ lb to ___ lb by the end of pregnancy. However, because you have GDM and are at high risk of having a large baby, we recommend that you gain a total of ___ lb by the end of pregnancy.
	BMI (kg/m ²)	lb	kg	lb	kg	
	<18.5	28.0–40.0	12.5–18.0	34.0	15.3	
	18.5–24.9	25.0–35.0	11.5–16.0	25.0	11.5	
	25.0–29.9	15.0–25.0	7.0–11.5	15.0	7.0	
	≥30	11.0–20.0	5.0–9.0	11.0	5.0	
3) End-of-pregnancy weight goal	Amount to weigh at the end of pregnancy. Weight goal: a) the GWG recommendation above, or b) current weight, if the GWG recommendation had been exceeded.					a) Based on this information, we encourage you to weigh about ___ lb by the end of your pregnancy. b) You have met the weight gain recommendation for your pregnancy. We now encourage you to maintain your current weight.
4) Weight management recommendation, specific to weight trajectory from prepregnancy to GDM diagnosis	Trajectory		Recommendation			Stay on the right track. To ensure that you gain enough weight during pregnancy, follow [the subsequent lifestyle tips]. You're right on track! You're doing a great job gaining a healthy amount of weight during pregnancy. Keep it up with [the subsequent lifestyle tips]. In order to slow your weight gain and meet the recommendation, use [the subsequent lifestyle tips]. To maintain your current weight, follow [the subsequent lifestyle tips].
	Gaining too slowly		Gain enough weight			
	On track		Keep gaining at a similar rate			
	Gaining too quickly		Slow weight gain			
	Exceeded		Maintain weight			
5) Lifestyle tips	Trajectory		Tip			Eat enough whole grains, vegetables, fruits. . . Add small amounts of nuts, olive oil, or avocado. . . Add nonstarchy vegetables such as broccoli and leafy greens [to help you feel full longer and increase fiber intake]. . . Cut down on fats like butter. . . Olive [and canola] oil are healthy in small amounts. . .
	Gaining too slowly		Emphasis on increasing healthy dietary intake			
	On track, gaining too quickly, or exceeded		Emphasis on moderating dietary intake			
6) Risk information on weight gain	Trajectory		Risk information			. . . women who don't gain enough weight are at risk for having a premature baby. . . . women with GDM who gain too much weight during pregnancy are at risk for developing chronic diabetes later in life, high blood pressure, having a cesarean section, and having a premature or larger than average baby.
	Gaining too slowly		Insufficient GWG increases risk for premature birth			
	On track, gaining too quickly, or exceeded		Excess GWG increases risk for several pregnancy complications, macrosomia, and diabetes			

Women were classified as meeting the IOM guidelines for appropriate weekly rate of weight gain from GDM diagnosis until delivery if they did not exceed a weekly rate of 0.58, 0.50, 0.33, and 0.27 kg for prepregnancy BMI of <18.5, 18.5–24.9, 25.0–29.9, and ≥30.0 kg/m², respectively (5). Women were classified as meeting the end-of-pregnancy weight goal if they 1) did not exceed the recommendation for total GWG (i.e., the lower limit of the IOM range for total GWG if their prepregnancy BMI was ≥18.5 kg/m² or the midpoint if

it was <18.5 kg/m²) or 2) maintained their weight if they had already exceeded the recommendation for total GWG.

The main predefined outcome of the GEM trial was postpartum weight retention over a 12-month postpartum period, i.e., the proportion of women meeting the postpartum goal of 1) reaching prepregnancy weight if prepregnancy BMI was <25.0 kg/m² or 2) losing 5% of prepregnancy weight if BMI was ≥25.0 kg/m². Here, we evaluated whether appropriate GWG mediated the effect of the multi-

component intervention on postpartum weight retention.

Statistical Analysis

The sample size of 2,014 with GWG data allowed for robust estimation of the effect of the pregnancy intervention component on GWG, assessed through measured weights during pregnancy. This sample size was based on the main outcome of this cluster-randomized trial, which was postpartum weight retention (results previously published [7]).

Analyses were intent to treat. The population average intervention effects were estimated using log binomial regression in analyses of the proportions of women meeting the IOM guidelines for weekly rate of GWG from GDM diagnosis to delivery, meeting the end-of-pregnancy weight goal, and with adverse outcomes. Estimation of regression parameters via generalized estimating equations accounted for the within-medical facility (randomization unit) correlation between patients for valid estimation of treatment effects and associated SE. Subgroup analyses stratifying women by prepregnancy BMI were performed for meeting the IOM guidelines for weekly rate of weight gain and meeting the end-of-pregnancy weight goal (*P* values for the interaction of prepregnancy BMI with meeting the IOM guidelines for weekly rate of weight gain and meeting the end-of-pregnancy weight goal were 0.58 and 0.25, respectively). All models included race/ethnicity and facility size (three levels: <25, 25–75, and ≥ 75), given that these variables were used in the randomization procedure (12). In addition, we included prepregnancy BMI given that inclusion of covariates strongly related with the outcome can improve statistical power and precision (13,14).

We conducted mediation analyses (15) to examine the proportion of the multicomponent intervention's effect on postpartum weight retention that was mediated by appropriate GWG from GDM diagnosis to delivery, a measure that best reflects the time period during which the tailored letter could have had an effect. The mediation effect was assessed on a risk difference scale; the effect of GWG from GDM diagnosis to delivery on postpartum weight retention (i.e., the indirect effect) was divided by the effect of the multicomponent intervention on postpartum weight retention (i.e., the total effect) to estimate the proportion of the multicomponent intervention's total effect on postpartum weight retention that was mediated by appropriate GWG from GDM diagnosis to delivery. All analyses were conducted using SAS 9.3 (Cary, NC).

RESULTS

The usual care and intervention conditions were comparable on prerandomization characteristics. Among the 967 women from medical facilities randomized to the intervention and sent the letter, two

letters were returned due to wrong addresses. At the time of the GDM diagnosis, 17.2% of women in the intervention condition were classified as gaining too slowly, 27.9% were on track, 23.2% were gaining too quickly, and 31.7% had already exceeded the recommendation for total GWG; a similar distribution was observed among women from medical facilities randomized to usual care (Table 2).

Women in medical facilities randomized to the intervention had a statistically significant 8% increased likelihood of meeting the IOM guidelines for appropriate weekly rate of GWG from GDM diagnosis to delivery as compared with women in facilities randomized to usual care (relative risk [RR] 1.08 [95% CI 1.00–1.16]). The absolute difference between intervention and usual care conditions was 5.5% (72.6% vs. 67.1%) (Table 3). In stratified analyses, the effect was similar across prepregnancy BMI categories (RR 1.07 [1.00–1.15] among women with BMI <25.0 kg/m² and RR 1.08 [0.98–1.18] among women with BMI ≥ 25.0 kg/m²).

Women in medical facilities randomized to the intervention had only a slightly and not significantly increased likelihood of meeting the end-of-pregnancy weight goal as compared with usual care (RR 1.08 [95% CI 0.99–1.18]; 36.0% vs. 33.0%; absolute difference 3%). However, in stratified analyses, the effect was significant among women with prepregnancy BMI <25.0 kg/m². Specifically, women in facilities randomized to the intervention had a statistically significant 28% increased likelihood of meeting the end-of-pregnancy weight goal among those whose prepregnancy BMI was <25.0 kg/m² (RR 1.28 [1.05–1.57]) but not among those whose prepregnancy BMI was ≥ 25.0 kg/m² (RR 0.99 [0.87–1.13]) (Table 3).

We examined whether appropriate GWG influenced postpartum weight retention (the GEM trial's main outcome). The proportions of women meeting the multicomponent intervention's postpartum weight goal were 41.8% (393 of 939) among women in intervention facilities and 37.4% (384 of 1,028) among women in usual care facilities. Meeting the IOM guidelines for appropriate weekly rate of GWG from GDM diagnosis to delivery significantly mediated the multicomponent intervention's effect on postpartum weight retention by 24.6% (95% CI 11.3–37.8, *P* = 0.0003) (Supplementary Table 1).

Adverse Outcomes

There were no statistically significant differences between intervention and usual care in the proportions of women who had a preterm birth (95 [9.8%] vs. 117 [11.2%], *P* = 0.36), a cesarean delivery (292 [30.2%] vs. 347 [33.1%], *P* = 0.19), or a neonatal intensive care unit admission (134 [13.9%] vs. 173 [16.5%], *P* = 0.07) or women with small-for-gestational-age infants (82 [8.7%] vs. 79 [7.8%], *P* = 0.83). However, women in facilities randomized to the intervention were significantly less likely to have a large-for-gestational-age infant (92 [9.7%] vs. 129 [12.8%], *P* = 0.04).

CONCLUSIONS

Within the GEM cluster-randomized trial testing a multicomponent lifestyle intervention, a tailored letter efficiently utilizing clinical EHR data was effective in promoting appropriate GWG in women with GDM. The tailored letter, sent on behalf of the health care system shortly after GDM diagnosis, constituted the pregnancy component of the GEM intervention and was followed by a postpartum component of 13 telephone sessions to reduce postpartum weight retention (6,7). Lifestyle interventions are often complex and their components are difficult to evaluate (16). Here, we found that the tailored letter significantly increased by 8% the proportion of women who met the IOM guidelines for second and third trimester weekly rate of GWG from GDM diagnosis to delivery. In addition, meeting these IOM guidelines for appropriate GWG significantly mediated a substantial portion of the multicomponent intervention's effect on postpartum weight retention, highlighting the tailored letter as an important element of the GEM intervention. We found no evidence of adverse perinatal outcomes; in fact, women in intervention facilities were less likely to have a large-for-gestational-age infant.

Overall, the tailored letter did not have a statistically significant effect on meeting the end-of-pregnancy weight goal. However, it effectively increased the likelihood of meeting the end-of-pregnancy weight goal by 28% among women with a prepregnancy BMI in the normal weight range but not in women with a BMI in the overweight or obese range. This finding is consistent with several efficacy trials (17–20) in which lifestyle interventions were more effective in improving GWG among women in the normal weight range than those in the overweight and obese

Table 2—Baseline characteristics by treatment condition: the GEM trial

	Intervention, n = 967	Usual care, n = 1,047	Entire sample, n = 2,014
Age (years)			
18–24	45 (4.7)	48 (4.6)	93 (4.6)
25–29	213 (22.0)	260 (24.8)	473 (23.5)
30–34	380 (39.3)	370 (35.4)	750 (37.2)
35–39	255 (26.4)	287 (27.4)	542 (26.9)
40–50	74 (7.7)	82 (7.8)	156 (7.8)
Race/ethnicity			
Asian	420 (43.4)	423 (40.4)	843 (41.9)
Non-Hispanic white	231 (23.9)	269 (25.7)	500 (24.8)
Hispanic	215 (22.2)	235 (22.5)	450 (22.3)
African American	38 (3.9)	50 (4.8)	88 (4.4)
Multiracial	32 (3.3)	33 (3.2)	65 (3.2)
Other	18 (1.9)	13 (1.2)	31 (1.5)
Pacific Islander	11 (1.1)	22 (2.1)	33 (1.6)
Missing	2 (0.2)	2 (0.2)	4 (0.2)
Prepregnancy BMI (kg/m ²)			
15.9–18.4 (underweight)	13 (1.3)	14 (1.3)	27 (1.3)
18.5–24.9 (normal weight)	328 (33.9)	332 (31.7)	660 (32.8)
25.0–29.9 (overweight)	286 (29.6)	308 (29.4)	594 (29.5)
30.0–59.7 (obese)	340 (35.2)	393 (37.5)	733 (36.5)
Gestational weight trajectory at GDM diagnosis*			
Gaining too slowly	166 (17.2)	162 (15.6)	328 (16.4)
On track	270 (27.9)	281 (27.1)	551 (27.5)
Gaining too quickly	224 (23.2)	228 (22.0)	452 (22.6)
Exceeded	307 (31.8)	365 (35.2)	672 (33.6)
Parity			
0	406 (42.0)	427 (40.8)	833 (41.4)
1	321 (33.2)	357 (34.1)	678 (33.7)
2	153 (15.8)	133 (12.7)	286 (14.2)
3+	74 (7.7)	110 (10.5)	184 (9.1)
Missing	13 (1.3)	20 (1.9)	33 (1.6)
Gestational age at GDM diagnosis (weeks)			
<24	215 (22.2)	228 (21.8)	443 (22.0)
24–28	538 (55.6)	553 (52.8)	1,091 (54.2)
29–34	214 (22.1)	266 (25.4)	480 (23.8)

Data are n (%). *Weight at GDM diagnosis in relation to the end-of-pregnancy weight goal (see Table 1).

range (21); however, these previous studies were not restricted to women with GDM.

Providers and health systems have a key role to play in influencing patients' health outcomes. A recent review (22) found that

interventions delivered by health care providers resulted in a significantly greater reduction in GWG among overweight and obese women as compared with interventions delivered by non-health care

providers. Observational research supports the notion that women who report receiving GWG advice from their health care provider are more likely to gain appropriate weight compared with women whose

Table 3—Proportion of women meeting the IOM guidelines for weekly rate of GWG from GDM diagnosis to delivery or the end-of-pregnancy weight goal, with RRs estimating differences between conditions: the GEM trial*

	Meeting IOM guidelines for weekly rate of GWG from GDM diagnosis to delivery						Meeting the end-of-pregnancy weight goal					
	Intervention		Usual care		RR (95% CI)	P value	Intervention		Usual care		RR (95% CI)	P value
	n	% meeting guidelines	n	% meeting guidelines			n	% meeting goal	n	% meeting goal		
Entire sample	963	72.6	1,042	67.2	1.08 (1.00–1.16)	0.04	964	36.0	1,043	33.0	1.08 (0.99–1.18)	0.06
Women with BMI 15.9–24.9 kg/m ²	341	87.7	346	80.9	1.07 (1.00–1.15)	0.05	341	39.3	346	29.5	1.28 (1.05–1.57)	0.02
Women with BMI 25.0–59.7 kg/m ²	622	64.3	696	60.3	1.08 (0.98–1.18)	0.12	623	34.2	697	34.7	0.99 (0.87–1.13)	0.90

The BMI was assessed before pregnancy. *Models were adjusted for race/ethnicity, facility size (three levels: <25, 25–74, and ≥75), and prepregnancy BMI.

providers do not advise on GWG (23). In the GEM trial, sending a letter on behalf of a clinical center already caring for women with GDM may have increased the saliency of its message. Recent qualitative studies (including among women with a history of GDM) highlight women's views that health care providers are the most reliable and trustworthy source of information on GWG (24) and that tailored messages in particular should come from their health care provider (25).

In an era of increasingly prevalent EHRs, health systems have opportunities to leverage their data infrastructure to engage high-risk patients with tailored outreach (25). Indeed, since glucose screening in pregnancy is universal (26), women with GDM represent a group at high risk for diabetes that health systems routinely identify, who can thus be offered targeted prevention programs. The intervention tested here was unique in its use of weight data extracted in real time from the EHR to send a single tailored, electronically generated communication directly to women with GDM. This low-intensity approach may be easily scalable to other settings in which weight and diagnostic data are routinely available in an EHR. One prior study examined an EHR "best practice alert" intervention designed to improve provider communication regarding GWG recommendations. Although not a randomized trial, that intervention was associated with a 7% increase over time in the proportion of women who met IOM guidelines for total GWG, supporting our findings that health systems can leverage the EHR to promote healthy pregnancies (27).

The main predefined outcome of the GEM trial was postpartum weight retention, and we previously reported that the multicomponent intervention was effective in reducing it (7). Here we found that meeting the IOM recommendation for appropriate weekly rate of weight gain from GDM diagnosis to delivery mediated the intervention's effect on postpartum weight retention by 24.6%. This finding demonstrates the importance of GWG in impacting postpartum weight retention in this population.

Strengths of this study include the ability to evaluate the effect of the pregnancy intervention component on the proximal outcome of GWG, as well as the role of appropriate GWG in mediating the subsequent effect of the multicomponent intervention on postpartum weight retention.

In addition, the GEM trial included all women with GDM and was not restricted to a select group who consented to be part of a research study. In contrast to efficacy and effectiveness trials with carefully selected volunteers under ideal conditions (28), pragmatic trials such as this can evaluate the effectiveness of interventions in real-world clinical settings, thereby increasing generalizability and better informing health system adoption (29). Additional strengths include the racial/ethnic diversity of the sample, intent-to-treat analyses that included all medical facilities, blinding of investigators and health care providers, and analysis based on measured weight data obtained via EHR.

Study limitations include scant information about individual-level mechanisms by which the intervention may have impacted outcomes, e.g., whether women in the intervention were more likely to change their weight self-monitoring behaviors (30), change their diet and physical activity, or seek advice from their personal physician, other health system services, or community resources to manage GWG. In addition, the GWG outcomes evaluated here were neither primary nor secondary outcomes in the GEM trial; therefore, the study was not designed to detect a specific GWG effect size. As such, the present analyses can be considered an exploratory assessment of the effect of the tailored letter on GWG as well as of mediators that help explain the main results of the GEM trial. Finally, further work is needed to examine the generalizability of the results to settings outside of the KPNC health system and acceptability of the letter content across diverse groups of patients and providers. The latter may yield refinements to maximize the intervention's impact while applying suggested practices for effective patient-provider communication about weight (31).

In conclusion, the present evaluation of a tailored letter addressing GWG (the pregnancy component of the multicomponent GEM intervention) found that this low-intensity approach delivered at the health system level significantly increased the proportion of women with appropriate GWG from GDM diagnosis to delivery. Appropriate GWG also significantly mediated the multicomponent intervention's effect on postpartum weight retention. Thus, for women with GDM, pregnancy may offer a unique window of opportunity

to intervene to reduce postpartum weight retention when women are motivated to change lifestyle behaviors. Given the increased use of EHRs, system-level interventions using the EHR to provide tailored advice to large patient populations offers the potential to improve GWG and may be implementable across medical settings.

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Author Contributions. M.M.H., S.D.B., C.P.Q., Y.C., and A.F. conceived and designed the study; acquired, analyzed, and interpreted data; and drafted and critically revised the manuscript for important intellectual content. S.F.E. interpreted data and drafted and critically revised the manuscript for important intellectual content. A.-L.T. conducted the statistical analyses. Y.Z. interpreted data, assisted with the statistical analyses, and drafted and critically revised the manuscript for important intellectual content. M.M.H. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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References

- Bellamy L, Casas JP, Hingorani AD, Williams D. Type 2 diabetes mellitus after gestational diabetes: a systematic review and meta-analysis. *Lancet* 2009;373:1773–1779
- Peters RK, Kjos SL, Xiang A, Buchanan TA. Long-term diabetogenic effect of single pregnancy in women with previous gestational diabetes mellitus. *Lancet* 1996;347:227–230
- Mamun AA, Kinarivala M, O'Callaghan MJ, Williams GM, Najman JM, Callaway LK. Associations of excess weight gain during pregnancy with long-term maternal overweight and obesity: evidence from 21 y postpartum follow-up. *Am J Clin Nutr* 2010;91:1336–1341
- Amorim AR, Rössner S, Neovius M, Lourenço PM, Linné Y. Does excess pregnancy weight gain constitute a major risk for increasing long-term BMI? *Obesity (Silver Spring)* 2007;15:1278–1286

5. Rasmussen KM, Yaktine AL, Eds.; Institute of Medicine; National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines. *Weight Gain During Pregnancy: Reexamining the Guidelines*. Washington, DC, The National Academies Press, 2009
6. Ferrara A, Hedderson MM, Albright CL, et al. A pragmatic cluster randomized clinical trial of diabetes prevention strategies for women with gestational diabetes: design and rationale of the Gestational Diabetes' Effects on Moms (GEM) study. *BMC Pregnancy Childbirth* 2014;14:21
7. Ferrara A, Hedderson MM, Brown SD, et al. The comparative effectiveness of diabetes prevention strategies to reduce postpartum weight retention in women with gestational diabetes mellitus: the Gestational Diabetes' Effects on Moms (GEM) cluster randomized controlled trial. *Diabetes Care* 2016;39:65–74
8. Go AS, Hylek EM, Phillips KA, et al. Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. *JAMA* 2001;285:2370–2375
9. Ferrara A, Hedderson MM, Ching J, Kim C, Peng T, Crites YM. Referral to telephonic nurse management improves outcomes in women with gestational diabetes. *Am J Obstet Gynecol* 2012;206:491.e1–491.e5
10. Hayes RJ, Moulton LH. *Cluster Randomised Trials*. Boca Raton, FL, Chapman & Hall/CRC, 2009
11. Carpenter MW, Coustan DR. Criteria for screening tests for gestational diabetes. *Am J Obstet Gynecol* 1982;144:768–773
12. Raab GM, Day S, Sales J. How to select covariates to include in the analysis of a clinical trial. *Control Clin Trials* 2000;21:330–342
13. Roozenbeek B, Maas AJ, Lingsma HF, et al.; IMPACT Study Group. Baseline characteristics and statistical power in randomized controlled trials: selection, prognostic targeting, or covariate adjustment? *Crit Care Med* 2009;37:2683–2690
14. Hernández AV, Steyerberg EW, Habbema JD. Covariate adjustment in randomized controlled trials with dichotomous outcomes increases statistical power and reduces sample size requirements. *J Clin Epidemiol* 2004;57:454–460
15. Vanderweele TJ, Vansteelandt S. Odds ratios for mediation analysis for a dichotomous outcome. *Am J Epidemiol* 2010;172:1339–1348
16. Phelan S, Hagobian T, Brannen A, et al. Effect of an internet-based program on weight loss for low-income postpartum women: a randomized clinical trial. *JAMA* 2017;317:2381–2391
17. 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;93:772–779
18. Polley BA, Wing RR, Sims CJ. Randomized controlled trial to prevent excessive weight gain in pregnant women. *Int J Obes Relat Metab Disord* 2002;26:1494–1502
19. Asbee SM, Jenkins TR, Butler JR, White J, Elliot M, Rutledge A. Preventing excessive weight gain during pregnancy through dietary and lifestyle counseling: a randomized controlled trial. *Obstet Gynecol* 2009;113:305–312
20. Østbye T, Krause KM, Lovelady CA, et al. Active mothers postpartum: a randomized controlled weight-loss intervention trial. *Am J Prev Med* 2009;37:173–180
21. Brown MJ, Sinclair M, Liddle D, Hill AJ, Madden E, Stockdale J. A systematic review investigating healthy lifestyle interventions incorporating goal setting strategies for preventing excess gestational weight gain. *PLoS One* 2012;7:e39503
22. Yeo S, Walker JS, Caughey MC, Ferraro AM, Asafu-Adjei JK. What characteristics of nutrition and physical activity interventions are key to effectively reducing weight gain in obese or overweight pregnant women? A systematic review and meta-analysis. *Obes Rev* 2017;18:385–399
23. Strychar IM, Chabot C, Champagne F, et al. Psychosocial and lifestyle factors associated with insufficient and excessive maternal weight gain during pregnancy. *J Am Diet Assoc* 2000;100:353–356
24. Criss S, Oken E, Guthrie L, Hivert MF. A qualitative study of gestational weight gain goal setting. *BMC Pregnancy Childbirth* 2016;16:317
25. Brown SD, Grijalva CS, Ferrara A. Leveraging EHRs for patient engagement: perspectives on tailored program outreach. *Am J Manag Care* 2017;23:e223–e230
26. Hillier TA, Vesco KK, Whitlock EP, Pettitt DJ, Pedula KL, Beil TL. *Screening for Gestational Diabetes Mellitus*. Rockville, MD, Agency for Healthcare Research and Quality, 2008
27. Lindberg SM, DeBoth A, Anderson CK. Effect of a best practice alert on gestational weight gain, health services, and pregnancy outcomes. *Matern Child Health J* 2016;20:2169–2178
28. Ratner RE, Christophi CA, Metzger BE, et al.; Diabetes Prevention Program Research Group. Prevention of diabetes in women with a history of gestational diabetes: effects of metformin and lifestyle interventions. *J Clin Endocrinol Metab* 2008;93:4774–4779
29. Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. *JAMA* 2003;290:1624–1632
30. Phelan S, Jankovitz K, Hagobian T, Abrams B. Reducing excessive gestational weight gain: lessons from the weight control literature and avenues for future research. *Womens Health (Lond)* 2011;7:641–661
31. STOP Obesity Alliance. Why weight? A guide to discussing obesity & health with your patients [article online], 2014. Available from <http://stopobesityalliance.org/research-and-policy/alliance-initiatives/health-care-providers/>. Accessed 6 November 2014