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**BRIEF REPORT** 

# **TBM**

# Reach, acceptability, and perceived success of a telehealth diabetes prevention program among racially and ethnically diverse patients with gestational diabetes: the GEM cluster-randomized trial

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#### **Abstract**

Patients with gestational diabetes mellitus and from racial/ ethnic minority groups face disproportionate risk for type 2 diabetes. Lifestyle interventions, if accessible and acceptable to diverse patients, could advance diabetes prevention and mitigate racial/ethnic disparities. Here we describe overall and race/ethnicity-specific reach, acceptability, and perceived success from an effective telehealth diabetes prevention lifestyle program for patients with gestational diabetes mellitus, implemented in the Gestational Diabetes Effects on Moms (GEM) cluster-randomized controlled trial. GEM tested a program of 13 telephone sessions and behavior change techniques (BCTs, e.g., goal setting) in a healthcare system. We evaluated participation (completing ≥1 session), acceptability of BCTs, and perceived success reaching program goals. Among 1,087 patients (75.2% from minority groups), 50.3% participated. Participation rates were 61.7% among Black, 56.4% among Hispanic, 55.6% among multiracial/ other, 53.0% among White, and 43.7% among Asian/ Pacific Islander patients. Evaluation survey respondents (n = 433/547; 79.2%) largely rated BCTs as very helpful (range 40.9%-58.4%) or moderately helpful (27.3%-34.9%). Respondents from minority groups largely rated goal setting for weight management as very or moderately helpful, with fewer minority respondents rating it as only a little/not at all helpful than White respondents (p = .02). Black and White respondents reported more limited success reaching a healthy weight than Asian/Pacific Islander, Hispanic, and multiracial/other women (p = .005). A telehealth diabetes prevention lifestyle program demonstrated reach and acceptability across racial/ethnic groups. While perceived success can be improved among Black and White participants, such programs could promote access to preventive care and help mitigate disparities in diabetes risk.

#### **Keywords**

Gestational diabetes, Type 2 diabetes prevention, Lifestyle intervention, Implementation, Program evaluation

#### INTRODUCTION

Gestational diabetes mellitus (GDM) is a common pregnancy complication and significant risk factor for type 2 diabetes (T2DM). Rates of GDM are increasing in all racial and ethnic groups; at the

#### **Implications**

**Practice:** A telehealth diabetes prevention lifestyle program is acceptable and can be used to promote weight management among racially and ethnically diverse patients with gestational diabetes mellitus (GDM).

**Policy:** Health systems operational leaders and policymakers who want to reduce patients' risk factors for type 2 diabetes and eliminate diabetes health disparities should consider implementing preventive lifestyle programs at-scale.

**Research:** Future research should identify implementation strategies to enhance participation rates and participants' perceived success in meeting program goals.

same time, racial and ethnic disparities are evident with Asian Indian women at highest risk for GDM [1]. Disparities have also been found in the progression from GDM to T2DM after pregnancy. As compared with Black and Hispanic women without GDM, those with GDM face 9.9- and 7.7-fold greater risk for progression to T2DM, respectively. In contrast, as compared with Asian/Pacific Islander and White women without GDM, those with GDM face 6.3- and 6.5-fold greater risk, respectively [2]. Social determinants of health-including socioeconomic status, neighborhood, physical, and food environments, healthcare, and social factors-contribute to observed disparities in T2DM and its risk factors [3]. The rising rates of GDM overall, paired with the disproportionate risks borne by women from minority groups, highlight the urgency of advancing equitable diabetes prevention in diverse populations.

The Diabetes Prevention Program demonstrated that lifestyle intervention can prevent or delay T2DM, including among people with prior

GDM and from minority groups [4]. Yet scale-up and reach of effective interventions remains challenging, leaving minority groups vulnerable [3]. Implementing diabetes prevention programs could help mitigate racial/ethnic diabetes disparities, if such programs are accessible, acceptable, and able to engage diverse patients.

Here, we evaluate the Gestational Diabetes Effects on Moms (GEM) pragmatic cluster-randomized controlled trial, which demonstrated the effectiveness of a telehealth lifestyle program in reducing postpartum weight retention-a risk factor for progression to T2DM-at an estimated direct cost of <\$80 per patient [5, 6]. GEM included a large sample reflecting the underlying population with GDM, with 1,087 patients offered the lifestyle intervention (42% Asian, 25% White, 22% Hispanic, 4% African American, 3% multiracial, 1% Pacific Islander, and 1% other); comparable proportions comprised a usual care comparison group. Per Proctor et al.'s taxonomy of implementation outcomes, this analysis examined intervention penetration (i.e., reach) in the target population; patient acceptability, a key element for determining suitability for implementation into routine care [7]; and perceived success.

#### **METHODS**

GEM was set in Kaiser Permanente Northern California (KPNC), an integrated healthcare delivery system with >4 million members and  $^{\sim}2,500$  patients with GDM annually. The protocol is described elsewhere [8]. Briefly, eligible patients with GDM in KPNC's 44 facilities were identified through the electronic health record (EHR) over a 1-year period (2011–2012) and randomized to receive usual care alone or to be offered the GEM intervention (N=22 facilities per condition). The trial was registered at clinicaltrials.gov (NCT01344278) and approved by the Kaiser Foundation Research Institute Human Subjects Committee, which did not require informed consent for the intervention given the pragmatic trial design.

The lifestyle program was offered as an adjunct to usual care by trained lifestyle coaches located in the clinical setting [8]. The primary target was postpartum weight retention: losing the weight gained in pregnancy, for patients with a prepregnancy body mass index (BMI) <25.0 kg/m<sup>2</sup>; or losing an additional 5% of prepregnancy weight for patients with a BMI ≥25.0 kg/m<sup>2</sup>. The program consisted primarily of 13 one-on-one telephone sessions delivered ~6 weeks to 6 months postpartum, with an accompanying printed guidebook and self-monitoring booklets [8]. During pregnancy, patients also received one letter focused on gestational weight gain [6] and one "welcome call" to describe the sessions. Program content was designed to reflect the diversity of the target population. Program materials included images of racially/ethnically diverse women; coaches conducted sessions in English, Spanish, or other languages via interpreter; and coach training emphasized familiarity with foods from diverse cultures, for example, reflecting Resnicow et al.'s concepts of both surface and deep structure adaptations [9]. Program participants, defined as those completing ≥1 session (similar to Ely et al. [10]), were mailed a 2-page, 30-item evaluation survey (Supplemental file) at ~8 months postpartum, in English or Spanish. Research staff made reminder calls, if needed, after 2 weeks; participants could then complete the evaluation by phone or request another mailing. Respondents received a \$10 gift card.

#### Measures

Patient characteristics, assessed via EHR and supplemented by a study survey administered in pregnancy [8], included age, self-reported race or ethnicity, parity (number of births), and BMI. Postpartum depression was defined via physician diagnosis, use of antidepressant medication, or score ≥10 on the Patient Health Questionnaire-9 (PHO-9) or PHO-8, derived via EHR or survey [5, 11]. To examine reach, we assessed participation rates (the proportion completing ≥1 session), overall and across racial and ethnic groups. To examine acceptability and perceived success, the evaluation survey assessed four domains. First was overall acceptability: rating the program (excellent/very good, good, or fair/poor) and whether respondents would recommend it to others with GDM (definitely/probably yes or definitely/probably no). Second was acceptability of behavior change techniques (BCTs), that is, goal setting and self-monitoring for weight, healthy eating, and physical activity (very, moderately, or a little/not at all helpful). Third was acceptability of program components, for example, phone calls with a coach. We also assessed satisfaction with "service" features: amount of time and number of sessions, and ability to make appointments at convenient times. The fourth domain was perceived success reaching program goals, for example, progress reaching a healthy weight (a lot, moderate, or a little/none).

## Analyses

We examined descriptive frequencies and compared evaluation respondents and nonrespondents. Outcomes examined by race/ethnicity included reach; overall acceptability; and outcomes specific to the primary target of postpartum weight retention: weight-related goal setting, weight self-monitoring, and perceived success reaching a healthy weight (small cell sizes were combined). Chi-square or Fisher's exact tests for categorical variables, and *t*-tests for continuous variables, were conducted with a significance threshold of 0.05 using SAS 9.3 (Cary, NC) or R version 4.1.1 (R Foundation for Statistical Computing, Vienna, Austria, 2021).

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#### **RESULTS**

#### Reach

A total of 1,087 patients were offered the lifestyle program; as reported previously, 75.2% were from racial/ethnic minority groups [5]. Of 1,087 patients, 88.3% (n = 960) completed the welcome call and 10.1% (n = 110) delivered before it could be completed; 1.6% (n = 17) were unreachable. A total of 547 patients (50.3%) participated in  $\geq$ 1 session (Table 1). Across racial/ethnic groups, participation was highest among Black patients (61.7%, n = 29 of 47) followed by Hispanic (56.4%, n = 133 of 236); multiracial/other (55.6%, n = 35 of 63); White (53.0%, n = 142 of 268); and Asian/Pacific Islander patients (43.7%, n = 206 of 471; p = .004).

# Acceptability and perceived success

Of program participants, 433 (79.2%) responded to the evaluation. Respondents and nonrespondents did not differ by race/ethnicity, age, parity, BMI, postpartum depression, or preferred language, but respondents had completed more program sessions (Table 1). Overall, most respondents rated the program as excellent/very good (74.6%, n=323) or good (19.4%, n=84), with only 5.3% rating it as fair/poor (n=23); 95.4% (n=413) reported they would definitely or probably recommend it to others, while only 4.2% (n=18) definitely or probably would not. Most rated BCTs as very or moderately helpful, including goal setting (76.9%) and self-monitoring (75.5%) for weight; goal setting (85.7%) and self-monitoring (72.3%) for healthy eating; and goal

Table 1 | Characteristics of participants in the Gestational Diabetes' Effects on Moms (GEM) lifestyle program by response to the program evaluation survey

evaluation survey				
	Program evaluation survey			
	All program participants (N = 547)	Respondents $(n = 433)$	Nonrespondents (n = 114)	р
Race or ethnicity				.1
Asian	201 (36.7)	160 (37.0)	41 (36.0)	
Non-Hispanic White	142 (26.0)	116 (26.8)	26 (22.8)	
Hispanic	133 (24.3)	103 (23.8)	30 (26.3)	
Black	29 (5.3)	24 (5.5)	5 (4.4)	
Multiracial	25 (4.6)	20 (4.6)	5 (4.4)	
Pacific Islander	5 (0.9)	4 (0.9)	1 (0.9)	
Other	10 (1.8)	4 (0.9)	6 (5.3)	
Missing	2 (0.4)	2 (0.5)	0	
Age, years				.1
<25	26 (4.8)	18 (4.2)	8 (7.0)	
25–29	117 (21.4)	93 (21.5)	24 (21.1)	
30-34	215 (39.3)	162 (37.4)	53 (46.5)	
35–39	143 (26.1)	119 (27.5)	24 (21.1)	
≥40	46 (8.4)	41 (9.5)	5 (4.4)	
Parity				.2
0	220 (40.2)	177 (40.9)	43 (37.7)	
_ 1	179 (32.7)	141 (32.6)	38 (33.3)	
2	86 (15.7)	71 (16.4)	15 (13.2)	
≥3	57 (10.4)	42 (9.7)	15 (13.2)	
Missing	5 (0.9)	2 (0.5)	3 (2.6)	
Prepregnancy BMI, kg/m <sup>2</sup>	29.0 ± 6.9	28.8 ± 6.7	29.6 ± 7.8	.3
Postpartum depression				.4
Yes	113 (20.7)	86 (19.9)	27 (23.7)	
No	434 (79.3)	347 (80.1)	87 (76.3)	
Spanish language				1.0
Yes	33 (6.0)	26 (6.0)	7 (6.1)	
No	514 (94.0)	407 (94.0)	107 (93.9)	
Number sessions completed				<.0001
1-3	205 (37.5)	131 (30.3)	74 (64.9)	
4–12	176 (32.2)	147 (34.0)	29 (25.4)	
13	166 (30.4)	155 (35.8)	11 (9.7)	
Data are N (%) or mean ± SD. BMI body m	ass index.			

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setting (84.1%) and self-monitoring (76.6%) for physical activity (Table 2). Similarly, respondents rated as very or moderately helpful the phone calls with a lifestyle coach (80.2%) and gestational weight gain letter (62.8%); guidebook ratings were more evenly distributed (Table 2). Most respondents rated the amount of time and number of sessions as "about right" (85.2% and 82.4%, respectively; Table 2), and reported making appointments at convenient times (91.2%, n = 393).

significant differences by race/ethnicity emerged in overall acceptability (Table 3). Willingness to recommend the program exceeded 90% across groups but differed slightly, being highest among Black (100%), Hispanic (99.0%), and Asian/Pacific Islander patients (97.0%), followed by White (91.4%) and multiracial/other patients (91.7%; p = .03, Table 3). Across groups, of 23 respondents who rated acceptability of the program as fair/poor, 43.5% (n = 10) were still willing to recommend it. Regarding weight-related evaluation outcomes (Fig. 1), most minority respondents rated goal setting for weight management as very or moderately helpful, and they were less likely to rate it as a little/not at all helpful (range 8.3%-19.4%) than White respondents (29.6%; p = .02, Fig. 1a). A similar, nonsignificant pattern emerged for weight self-monitoring (p = .22, Fig. 1b). Black (41.7%) and White respondents (36.9%) more often reported limited success reaching a healthy weight than Asian/Pacific Islander (21.7%), Hispanic (25.5%), and multiracial/other respondents (30.4%; p = .005, Fig. 1c).

#### DISCUSSION

Equitable translation of behavioral interventions for diabetes prevention requires not only demonstrated effectiveness, but accessibility, convenience, and appropriateness for diverse communities [12]. We found that a telehealth lifestyle program reached racially and ethnically diverse patients at high risk for T2DM in a health system setting. Its BCTs of goal setting and self-monitoring for weight, healthy eating, and physical activity were acceptable, particularly by minority respondents. This notable finding has implications for implementing the GEM program at-scale. The individualized approach of one-on-one sessions, coupled with content designed to reflect population diversity, may have helped address concerns and preferences of participants from racial and ethnic minority groups. Remote, flexible intervention delivery may also have accommodated participants' caretaking and work obligations. Our findings reinforce recent calls to promote approaches such as these in intervention design [12].

**Table 2** | Acceptability of behavior change techniques, acceptability of program components, and perceived success in reaching program goals: the GEM lifestyle program

	Very helpful	Moderately helpful	A little/not at all helpfu
Acceptability of behavior change techniq	ues		
Weight			
Goal setting	182 (42.0)	151 (34.9)	81 (18.7)
Self-monitoring	188 (43.4)	139 (32.1)	82 (18.9)
Healthy eating			
Goal setting	253 (58.4)	118 (27.3)	51 (11.8)
Self-monitoring	177 (40.9)	136 (31.4)	79 (18.2)
Physical activity			
Goal setting	225 (52.0)	139 (32.1)	58 (13.4)
Self-monitoring	211 (48.7)	121 (27.9)	65 (15.0)
Acceptability of program components			
Phone calls with a lifestyle coach	242 (55.9)	105 (24.3)	76 (17.6)
Guidebook	145 (33.5)	112 (25.9)	104 (24.0)
Gestational weight gain letter	185 (42.7)	87 (20.1)	83 (19.2)
	About right	Not enough	Too much
Amount of time spent talking to a lifestyle coach	369 (85.2)	10 (2.3)	48 (11.1)
Number of sessions offered	357 (82.4)	37 (8.5)	34 (7.9)
	A lot of progress	Moderate progress	A little/no progress
Perceived success reaching program goa	ls		
Reaching a healthy weight	130 (30.0)	168 (38.8)	117 (27.0)
Eating healthier	175 (40.4)	173 (40.0)	72 (16.6)
Being more physically active	155 (35.8)	187 (43.2)	78 (18.0)

Data are *n* (%). Smaller proportions of participants reported not using behavior change techniques, program components, or working toward program goals; these ranged from 2.3% for phone calls with a lifestyle coach to 9.5% for self-monitoring eating (data not shown). Proportions who reported not using the guidebook or gestational weight gain letter were 16.6% and 18.0%, respectively. *GEM* Gestational Diabetes' Effects on Moms.

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Multiracial/Other 16 (66.7) 8 (33.3) 22 (91.7) 000 24 (100.0) 6 (25.0) 17 (70.8) 1 (4.2) Black (99.0%) 84 (82.4) 15 (14.7) 3 (2.9) Table 3 | Acceptability of the overall program and willingness to recommend it, by race or ethnicity: the GEM lifestyle program Non-Hispanic White 25 (21.7) 106 (91.4) 82 (71.3) 8 (7.0) Asian/Pacific Islander 122 (74.4) 31 (18.9) (97.0)11 (6.7) Millingness to recommend the program Acceptability of overall program Definitely/probably yes Excellent/very good Fair/poor Good

(8.3)

7

000

(%6:0)

10(8.6)

5 (3.1)

Data are n (%). GEM Gestational Diabetes' Effects on Moms

Definitely/probably no

Clinical and policy leaders may therefore consider adopting such programs in health systems serving diverse populations.

For patients with GDM, barriers to participation in postpartum diabetes prevention include time constraints, fatigue, and other demands of parenthood [13]. Yet recent research indicates strong interest in behavioral intervention for diabetes prevention [14], which can be further strengthened via theory-driven strategies [15]. In fact, a history of GDM has been linked with greater engagement in diabetes prevention activities [16]. Consistent with this, our data show robust overall participation, even in the early months of new parenthood. Participation may have been bolstered by high completion of the initial welcome call, which should be considered in future implementation efforts. Indeed, emerging empirical evidence suggests that such preintervention orientations may promote lifestyle program participation [17]. Of note, participation was highest among Black and lowest among Asian/Pacific Islander patients. Given the high rates of GDM in the latter group [1], more intensive or tailored outreach may be needed. Overall, findings still suggest that lifestyle programs would be well received by patients with GDM.

The GEM program's written materials and perceived success meeting goals could be improved, particularly for Black and White patients striving to reach a healthy weight. A theory-based strategy of providing more opportunities for mastery of behavioral goals could improve satisfaction and self-efficacy for weight management [18]. Also, while GEM was not designed to ensure racial/ethnic concordance of coaches and participants, future research could examine this.

Study strengths include the large sample; range of domains assessed in the evaluation survey; ability to examine key outcomes by race or ethnicity; and the pragmatic nature of the underlying cluster-randomized trial, which offers strong generalizability to real-world health system settings. Study limitations include the long duration between when the gestational weight gain letter was delivered (during pregnancy) and when it was evaluated (8 months postpartum). We also had limited opportunity to examine education or income. While important social determinants of health [3], recent research among patients with GDM indicates that interest in behavioral intervention for diabetes prevention did not differ across levels of education [14]. Finally, evaluation respondents were more likely than nonrespondents to have completed more intervention sessions, and therefore may have more positively evaluated the intervention. Innovative strategies are needed in future studies to solicit feedback from individuals with the lowest levels of intervention engagement. Still, the overall evaluation response rate

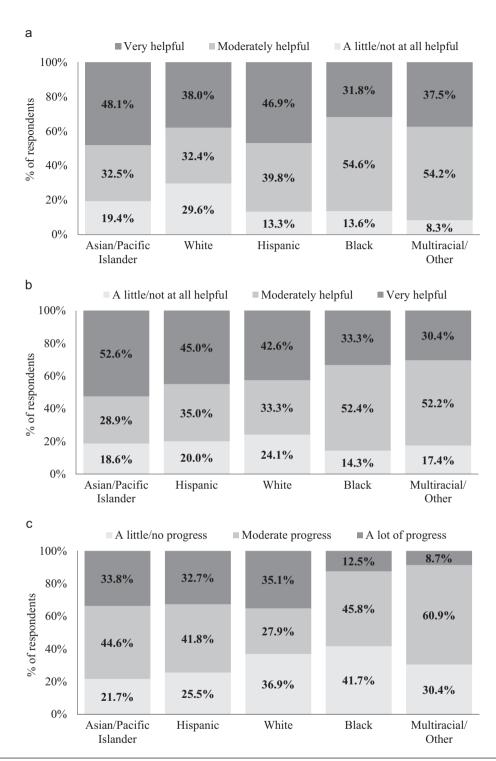


Fig 1 | Acceptability and perceived success for weight-related outcomes, by race or ethnicity: the GEM lifestyle program. GEM Gestational Diabetes' Effects on Moms.

was high with no other differences in participant characteristics.

In summary, an effective telehealth lifestyle program demonstrated reach and acceptability among diverse women at high risk for T2DM. In concert with interventions at community and policy levels, health system interventions such as this could promote convenient access to preventive care and help mitigate downstream diabetes health disparities.

#### **SUPPLEMENTARY MATERIAL**

Supplementary material is available at *Translational Behavioral Medicine* online.

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#### Compliance with Ethical Standards

Conflict of Interest: All authors declare that they have no conflicts of interest.

**Human Rights:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All study procedures were approved by the Kaiser Foundation Research Institute Human Subjects Committee.

**Informed Consent:** The Kaiser Foundation Research Institute Human Subjects Committee approved the trial and waived the requirement for informed consent for the intervention component of this pragmatic, cluster-randomized trial.

**Welfare of Animals:** This article does not contain any studies with animals performed by any of the authors.

#### Data Availability

The trial described here was preregistered at ClinicalTrials.gov (NCT01344278). The analysis plan for this manuscript was not formally preregistered. Deidentified data from this study are not available in a public archive. Deidentified data from this study can be made available to qualified researchers by emailing Dr. Ferrara and the corresponding author Dr. Brown, subject to approval by the Kaiser Foundation Research Institute Human Subjects Committee and by the Human Subjects Committee at the institution requesting the data, and a signed data sharing agreement. Analytic codes used to conduct the analyses presented in this study are not available in a public archive. They may be available by emailing the corresponding author. Materials used to conduct the study are not publicly available. The trial protocol is published at https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/1471-2393-14-21.

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