A Cluster-Randomized Study of Technology-Assisted Health Coaching for Weight Management in Primary Care

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ABSTRACT

PURPOSE We undertook a trial to test the efficacy of a technology-assisted health coaching intervention for weight management, called Goals for Eating and Moving (GEM), within primary care.

METHODS This cluster-randomized controlled trial enrolled 19 primary care teams with 63 clinicians; 9 teams were randomized to GEM and 10 to enhanced usual care (EUC). The GEM intervention included 1 in-person and up to 12 telephone-delivered coaching sessions. Coaches supported goal setting and engagement with weight management programs, facilitated by a software tool. Patients in the EUC arm received educational handouts. We enrolled patients who spoke English or Spanish, were aged 18 to 69 years, and either were overweight (body mass index 25-29 kg/m^2) with a weight-related comorbidity or had obesity (body mass index ≥30 kg/m^2). The primary outcome (weight change at 12 months) and exploratory outcomes (eg, program attendance, diet, physical activity) were analyzed according to intention to treat.

RESULTS We enrolled 489 patients (220 in the GEM arm, 269 in the EUC arm). Their mean (SD) age was 49.8 (12.1) years; 44% were male, 41% Hispanic, and 44% non-Hispanic Black. At 12 months, the mean adjusted weight change (standard error) was −1.4 (0.8) kg in the GEM arm vs −0.8 (1.6) kg in the EUC arm, a nonsignificant difference (P = .48). There were no statistically significant differences in secondary outcomes. Exploratory analyses showed that the GEM arm had a greater change than the EUC arm in mean number of weekly minutes of moderate to vigorous physical activity other than walking, a finding that may warrant further exploration.

CONCLUSIONS The GEM intervention did not achieve clinically important weight loss in primary care. Although this was a negative study possibly affected by health system resource limitations and disruptions, its findings can guide the development of similar interventions. Future studies could explore the efficacy of higher-intensity interventions and interventions that include medication and bariatric surgery options, in addition to lifestyle modification.

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INTRODUCTION

Obesity is a serious global public health problem.[1,2] Veterans and racial and ethnic minority groups experience considerable disparities in obesity rates[2-4] and are thus at higher risk for comorbidities and other chronic diseases.[5,6] Primary care is an important venue to treat obesity, with more than 480 million visits taking place in this setting per year in the United States.[7,8] The patient-centered medical home (PCMH) model of primary care provides a patient-centered, team-based approach that can facilitate care for chronic diseases such as obesity.[9,10] There are several barriers to providing obesity care, however, including competing demands on time.[11,12]

The US Preventive Services Task Force (USPSTF) recommends that primary care clinicians refer patients with obesity to high-intensity (12-26 sessions per year),[13] "multicomponent behavioral" interventions such as the Diabetes Prevention Program (DPP) and the Veterans Health Administration's MOVE! weight management program.[14,15] But even when intensive programs are available, they are underused. For instance, only 3% to 7% of eligible patients attend even a single session of the MOVE! program.[16,17] Patients from low-income and minoritized communities experience even more barriers to controlling their weight, such as food insecurity and daily stress, and weight management interventions need to address these barriers.[18-20]

We created Goals for Eating and Moving (GEM) for high-risk patients[21] to facilitate 5As (assess, advise, agree, assist, arrange) counseling in primary care[22] and increase attendance of intensive interventions. A pilot study of GEM among 43 patients showed that it was feasible and acceptable among veterans, with a trend toward higher weight loss in the GEM arm vs an enhanced usual care (EUC) arm.[23] The objective of the current study was to test the efficacy of GEM vs EUC for achieving weight loss at 12 months in PCMH health care teams in 2 health care systems with patient populations having disproportionately elevated risks of obesity and related comorbidities. We hypothesized that patients in the GEM intervention arm would have greater weight loss compared with peers in the EUC arm at 12 months, as well as better clinical and behavioral outcomes including better attendance of weight management programs.

METHODS

Study Design and Aims

The complete design and methodology of the GEM study have been previously published.[21] Briefly, GEM was a 2-arm cluster-randomized controlled trial that compared the effects of the 12-month intervention (GEM tool + health coaching + clinician training) against those of EUC among patients who were overweight (body mass index 25-29 kg/m^2) with a weight-associated comorbidity or obese (body mass index ≥30 kg/m^2). PCMH health care teams were randomized to GEM vs EUC and patients from each cluster were invited to enroll in the study and receive the assigned intervention. The main outcome was weight change in kilograms at the end of the 12-month intervention, and 24-month outcomes were assessed to explore weight maintenance. All study procedures were approved by the institutional review boards of the New York University School of Medicine (#16-01445), VA New York Harbor (#01624), and Albert Einstein College of Medicine in collaboration with the Montefiore Health System (#2017-7603). The GEM study is registered on clinicaltrials.gov (NCT03006328).

Setting

The GEM study was conducted at the VA New York Harbor Healthcare System (Manhattan campus) and 4 Bronx, New York, primary care practices operated by the Montefiore Medical Group. Both systems use a PCMH model of care with interdisciplinary care teams that serve diverse patient populations. The VA patient population is 8% to 10% female, while the Montefiore sites are approximately 62% female. A total of 19 teams participated (11 from the VA and 8 from Montefiore).

Team Inclusion and Randomization

We included PCMH teams if they saw primary care patients and were willing to participate. We excluded teams with resident physicians, but did not exclude physicians who had participated in a pilot study of GEM.[23] Randomization was stratified by health care systems (VA or Montefiore) and the total number of care teams at each site. (See Supplemental Appendix for more detail.)

Patient Identification, Recruitment, and Enrollment

A full list of inclusion and exclusion criteria is given in the Supplemental Appendix. Enrollment started in November 2017 and ended before recruiting our target number of 512 patients in March 2020 because of the COVID-19 pandemic. Potentially eligible patients were identified via electronic health records. We sent participating primary care clinicians a list of potentially eligible patients, giving them the option to exclude the patients before outreach; clinicians excluded a total of 8 patients. Before calling patients to screen them for eligibility, we mailed them a letter describing the study, which included the contact information of the research team. We followed up with recruitment calls. The intervention design precluded blinding of patients and GEM health coaches to group assignment.

Sample Size and Power Analysis

The sample size calculation and power analysis were based on the primary outcome comparing within-person weight change in kilograms at 12-month follow-up. We anticipated recruiting 512 patients and assumed a dropout rate of 25%. We estimated that with 8 teams in each arm with an average of 2 clinicians per team, and 12 patients per clinician, having 384 evaluable patients at 12 months would provide 82% power to detect a 2.2-kg (SD = 6.0 kg) difference in weight between the intervention and control arms, using a 2-sided t test with a significance level of .05. See the Supplemental Appendix for more detail.

Study Arm Interventions

Patients in the GEM arm received the GEM intervention delivered by lay health coaches, which has been fully described elsewhere[21] and is summarized in the Supplemental Appendix. Briefly, GEM is a technology-assisted health coaching intervention designed to support 5A-based weight management counseling including connecting patients to weight management and other clinical services provided through PCMH models of care. The GEM intervention has 4 main components: (1) a tablet-delivered goal-setting tool; (2) one in-person health coach visit; (3) up to 12 telephone coaching calls over 12 months; and (4) brief counseling by the primary care clinician at primary care visits. Supplemental Table 1 shows a sample coaching call schedule.

Patients in the EUC control arm received an intervention that included weight management materials and general health education materials delivered by research assistants. These materials are described in the Supplemental Appendix.

Data Collection

Data collection occurred at the baseline and the 6-, 12-, and 24-month in-person or remote study visits. Before March 2020, research assistants blinded to the study arms collected biometric measures and administered survey instruments in

person. After March 2020, data were collected remotely. We describe the measurements, surveys, and measurement procedures in the Supplemental Appendix. Supplemental Table 2 shows the measurements collected at specific time points. Patient report and adverse events collected from electronic health records were reviewed at the 6-, 12-, and 24-month study visits. All data were entered into Research Electronic Data Capture (REDCap) 8.1.11 (REDCap Consortium), a secure, web-based software platform designed to support data capture for research studies. Study data were collected and managed using REDCap electronic data capture tools hosted at New York University Grossman School of Medicine.[24,25]

Statistical Analysis

To assess the efficacy of the GEM intervention compared with EUC, we performed univariate analyses using *t* tests for continuous outcomes and χ^2 tests for categorical outcomes. Unadjusted CIs were computed to compare the effects of GEM with the effects of EUC on each outcome. The primary outcome was weight change in kilograms at 12 months. Other exploratory clinical outcomes included changes in waist circumference and blood pressure and behavioral outcomes, as well as all outcomes at 6 and 24 months of follow-up. All exploratory outcomes are reported as point estimates of treatment effects along with 95% CIs for the difference between outcomes for GEM and EUC. Behavioral outcomes included follow-up program attendance and changes in physical activity.

The primary analysis was based on mixed effects modeling with clinician- and clinic-level random intercepts taking into account correlations among repeated measures and among patients within clinicians (ie, clustering). We adjusted for baseline characteristics (gender, age, race, employment status, food security, depression, year of enrollment). We used a multiple imputation procedure to account for missing data assuming that data were missing at random. Fifty data sets were imputed using a Monte Carlo approach with chained equations.[26] The number of imputed data sets was selected using a 2-stage approach based on the fraction of missing information.[27]

Because the 2 health care systems differed substantially, we conducted additional analyses adjusting for site. We adjusted for time effects to account for service discontinuation during the COVID-19 pandemic and conducted a sensitivity analysis (Supplemental Appendix). Finally, we adjusted for whether participants primarily spoke English at home to account for potential language barriers.

Univariate analyses were performed stratified by site. Each of the mixed effects models that were fit using data from the combined cohort were also fit using data from the 2 sites separately. These modeling choices allow the effect of the intervention and the covariates on the outcomes to vary across sites, increasing model flexibility at the expense of statistical power. All statistical tests were 2-tailed, with a .05 significance level. All analyses followed the intention-to-treat principle and were performed using SAS 9.4 (SAS Institute Inc) and R 3.14.0 (R Project for Statistical Computing).

RESULTS

Patient Characteristics

Figure 1 shows the Consolidated Standards of Reporting Trials diagram for the GEM trial. We recruited 19 PCMH teams with 63 clinicians and randomized 9 teams to GEM and 10 teams to EUC. We enrolled 489 patients: 220 in the GEM arm and 269 in the EUC arm (Table 1). The mean (SD) age was 49.8 (12.1) years and body mass index was 34.8 (6.2) kg/m^2. Overall, 44% of the patients were male, 51% were from the VA, 41% were Hispanic, and 44% were non-Hispanic Black. Roughly 13% of the cohort spoke primarily Spanish, 63% were unemployed, and 18% endorsed moderate to severe food insecurity.

Trial Outcomes

Table 2 details changes in weight and other physical outcomes from baseline to 12 months. Estimated means and standard errors (SEs) were drawn from the fit mixed effects models. At 12 months, weight outcomes were recorded for 418 participants (86%). The mean (SE) estimated weight change was −1.4 (0.8) kg in the GEM arm and −0.8 (1.6) kg in the EUC arm, a nonsignificant difference ($P = .48$). The estimated proportion of patients with weight loss of at least 5% was 22.8% in the GEM arm and 16.9% in the EUC arm (difference = 5.9%; 95% CI, −33.7% to 45.4%).

Table 3 provides estimated effects of the GEM intervention on behavioral outcomes at 12 months. There were no statistically significant differences in weight management program attendance and dietary change. Notably, the GEM arm had a larger increase in mean weekly minutes of moderate to vigorous nonwalking physical activity compared with the EUC arm (difference = 113.4 min/wk; 95% CI, 0.0-226.7). Subgroup analyses by site showed similar results. Additional subgroup analyses showed no difference in outcomes before vs after COVID-19 emergency declarations were issued and no difference between patients who did and did not speak Spanish at home. See Supplemental Table 3 and Supplemental Table 4 for 6- and 24-months outcomes.

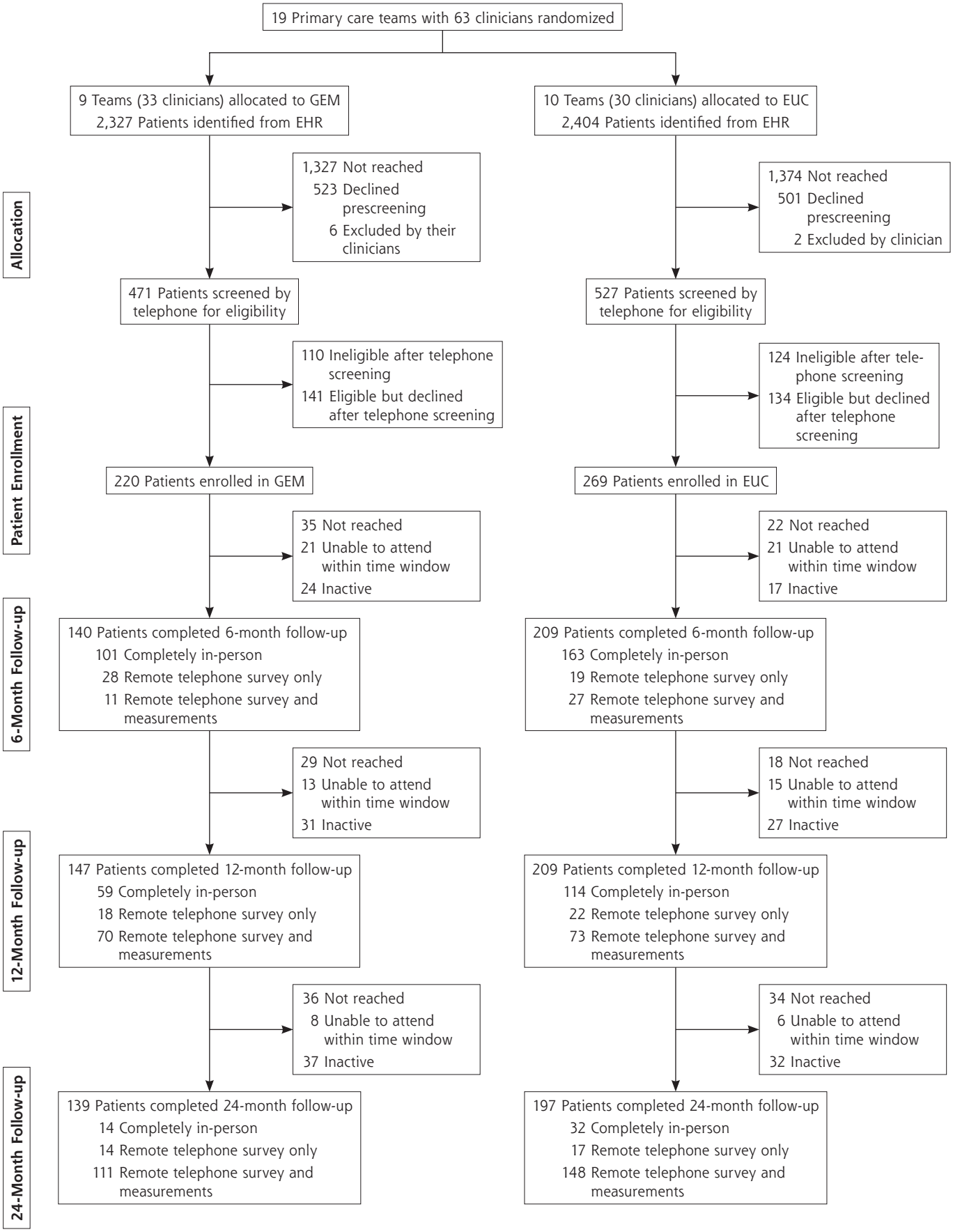
In both arms, attending a weight management program was associated with greater weight loss. Each 6-month period with self-reported regular (once-weekly) attendance of MOVE! or DPP was associated with an additional change (SE) in weight of −1.1% (0.5%) at 12 months (Supplemental Figure 1). In the GEM arm, the mean (SD) number of health coaching telephone calls was 5.4 (4.0) with a range from 0 to 13. On average, participants who completed 5 or more health coaching calls lost 2.0% (95% CI, 0.4%-3.7%) more weight at 12 months than did those who completed fewer than 5 calls (Supplemental Figure 2).

Adverse events did not differ between the study arms (Supplemental Appendix).

DISCUSSION

We showed that a technology-assisted weight management intervention delivered by lay health coaches in primary care

Figure 1. Trial CONSORT diagram.



CONSORT = Consolidated Standards of Reporting Trials; EHR = electronic health record; EUC = enhanced usual care; GEM = Goals for Eating and Moving.

Table 1. Characteristics of Study Patients

Characteristic	Overall (N = 489)	Study Arm		*P* Value	SMD
		GEM (n = 220)	EUC (n = 269)		
Age, mean (SD), y	49.8 (12.1)	49.2 (12.7)	50.2 (11.6)	.39	0.08
Height, mean (SD), in	167.4 (10.2)	167.9 (10.0)	167.0 (10.3)	.29	0.10
Weight, mean (SD), kg	97.6 (19.7)	98.0 (19.3)	97.3 (20.0)	.68	0.04
Body mass index, mean (SD), kg/m^2	34.8 (6.2)	34.7 (6.1)	34.8 (6.3)	.84	0.02
Waist circumference, mean (SD), in	43.0 (5.4)	43.2 (5.3)	42.8 (5.4)	.49	0.06
Diastolic blood pressure, mean (SD), mm Hg	79.3 (11.9)	80.2 (13.8)	78.6 (10.2)	.13	0.14
Systolic blood pressure, mean (SD), mm Hg	125.5 (16.6)	127.8 (18.1)	123.7 (15.0)	.01	0.25
Male, No. %	216 (44.2)	104 (47.3)	112 (41.6)	.25	0.11
CES-D-7 score, mean (SD)[a]	4.8 (4.7)	4.5 (4.7)	5.0 (4.7)	.24	0.11
Born in United States, No. (%)	365 (74.6)	162 (73.6)	203 (75.5)	.72	0.04
Food insecurity, No. (%)				.77	0.10
Mild	382 (78.1)	176 (80.0)	206 (76.6)		
Moderate	47 (9.6)	18 (8.2)	29 (10.8)		
Severe	42 (8.6)	18 (8.2)	24 (8.9)		
NA	18 (3.7)	8 (3.6)	10 (3.7)		
Unemployed, No. (%)	307 (62.8)	139 (63.2)	168 (62.5)	.94	0.02
Race, No. (%)				.15	0.21
Hispanic	199 (40.7)	99 (45.0)	100 (37.2)		
Non-Hispanic Black	213 (43.6)	84 (38.2)	129 (48.0)		
Non-Hispanic other	28 (5.7)	12 (5.5)	16 (5.9)		
Non-Hispanic White	49 (10.0)	25 (11.4)	24 (8.9)		
Spanish is primary language spoken at home, No. (%)				.51	0.10
No	426 (87.1)	190 (86.4)	236 (87.7)		
Yes	62 (12.7)	29 (13.2)	33 (12.3)		
NA	1 (0.2)	1 (0.5)	0 (0.0)		
Moderate or vigorous nonwalking physical activity, mean (SD), min/wk	681.8 (730.0)	663.3 (715.4)	697.2 (742.9)	.61	0.05
Fruits and/or vegetables eaten today, No. (%)				.20	0.29
½ cup	40 (8.2)	15 (6.8)	25 (0.3)		
1 cup	111 (22.7)	59 (26.8)	52 (19.3)		
1½ cups	64 (13.1)	27 (12.3)	37 (13.8)		
2 cups	77 (15.7)	33 (15.0)	44 (16.4)		
2½ cups	25 (5.1)	6 (2.7)	19 (7.1)		
3 cups	120 (24.5)	55 (25.0)	65 (24.2)		
None	51 (10.4)	25 (11.4)	26 (9.7)		
NA	1 (0.2)	0 (0.0)	1 (0.4)		
REAP-S score, mean (SD)[b]	4.4 (1.2)	4.5 (1.2)	4.4 (1.2)	.14	0.13
LDBQ score, mean (SD)[c]	12.4 (4.7)	12.4 (4.7)	12.5 (4.7)	.76	0.03
Regularly attended intensive program, No. (%)				.54	0.10
No	465 (95.1)	209 (95.0)	256 (95.2)		
Yes	23 (4.7)	10 (4.5)	13 (4.8)		
NA	1 (0.2)	1 (0.5)	0 (0.0)		
Site, No. (%)				.07	0.18
Veterans Affairs	248 (50.7)	101 (45.9)	147 (54.6)		
Montefiore Medical Group	241 (49.3)	119 (54.1)	122 (45.4)		

CES-D-7 = Brief Center for Epidemiologic Studies Depression Scale; EUC = enhanced usual care; GEM = Goals for Eating and Moving; LDBQ = Latino Dietary Behaviors Questionnaire; NA = not available; REAP-S = Rapid Eating Assessment for Participants; SMD = standardized mean difference.

[a] Possible scores range from 0 to 21. Higher score indicates higher level of depressive symptoms.

[b] Possible scores range from 2 to 6. Higher score indicates greater frequency of consuming sweets and salty snacks.

[c] Possible scores range from 6 to 30. Higher score indicates more healthful dietary behaviors.

Table 2. Adjusted Changes in Weight and Other Physical Outcomes Between Baseline and 12 Months

Outcome	GEM	EUC	Difference (GEM – EUC)	*P* Value	95% CI for Difference
Change in weight, kg	−1.4 (0.8)	−0.8 (1.6)	−0.7 (0.9)	.48	−2.4 to 1.1
Change in weight, %	−1.3 (0.8)	−0.6 (1.6)	−0.7 (0.9)	...	−2.4 to 1.1
Proportion with weight loss ≥5%, %	22.8 (17.3)	16.9 (36.1)	5.9 (20.2)	...	−33.7 to 45.4
Change in BMI, kg/m^2	−0.6 (0.4)	−0.3 (0.9)	−0.3 (0.5)	...	−1.3 to 0.7
Change in waist circumference, in	−0.4 (0.9)	0.2 (1.6)	−0.6 (0.6)	...	−1.8 to 0.6
Change in diastolic blood pressure, mm Hg	1.6 (1.4)	3.2 (2.5)	−1.7 (1.5)	...	−4.6 to 1.3
Change in systolic blood pressure, mm Hg	1.8 (1.7)	3.2 (2.7)	−1.4 (1.7)	...	−4.8 to 2.0

BMI = body mass index; EUC = enhanced usual care; GEM = Goals for Eating and Moving.

Note: Values are adjusted means (standard errors). *P* value is reported for the primary outcome (change in weight in kilograms) only.

Table 3. Adjusted Changes in Behavioral Outcomes Between Baseline and 12 Months

Outcome	GEM	EUC	Difference (GEM – EUC)	95% CI for Difference
Attended weekly MOVE! or DPP sessions, %	11.4 (29.0)	7.4 (14.0)	4.0 (16.9)	−29.1 to 37.1
Achieved >150 min/wk of moderate to vigorous nonwalking physical activity, %	54.4 (43.5)	48.0 (21.0)	6.5 (24.7)	−0.4 to 0.6
Change in consumption, cups/day				
Fruits and vegetables	−0.1 (0.8)	−0.1 (0.4)	0.0 (0.4)	−0.8 to 0.8
Fruits	−0.2 (0.6)	0.0 (0.3)	−0.1 (0.3)	−0.8 to 0.5
Vegetables	0.1 (0.6)	−0.1 (0.3)	0.2 (0.3)	−0.5 to 0.8
Change in REAP-S score	0.3 (0.7)	0.2 (0.4)	0.1 (0.4)	−0.7 to 0.9
Change in LDBQ score	3.8 (1.5)	2.6 (0.8)	1.1 (0.8)	−0.4 to 2.7
Change in moderate to vigorous nonwalking physical activity, min/wk	86.4 (144.5)	–27.0 (93.7)	113.4 (56.5)	0 to 226.7

DPP = Diabetes Prevention Program; EUC = enhanced usual care; GEM = Goals for Eating and Moving; LDBQ = Latino Dietary Behaviors Questionnaire; MOVE! = weight management program for veterans; REAP-S = Rapid Eating Assessment for Participants.

Note: Values for each study arm and for difference are adjusted means (standard errors).

did not promote weight loss. Although we saw a statistically and clinically significant increase in weekly minutes of moderate to physical nonwalking activity in the GEM arm at 12 months, this result should be considered exploratory as we did not control for multiple comparisons. Given the great need for increasing physical activity in primary care patients,[28] however, future studies should explore the use of health coaches for this purpose.

Several possibilities may account for our null findings. The GEM intervention was designed to increase enrollment and attendance in intensive, multicomponent weight management interventions; however, GEM did not increase attendance of the MOVE! and DPP programs. These programs experienced challenges during the study period. At the Manhattan VA, in-person MOVE! groups were discontinued, and patients were switched to telephone-delivered MOVE!, which caused delays in services. At the Montefiore sites, there was a long waiting list for DPP. During the COVID-19 pandemic, the DPP program was paused, and the MOVE! dietician had fewer appointments available. As GEM was a low- to moderate-intensity intervention—the mean number of telephone health coaching sessions received was fewer than one-half of the 12 offered—and did not increase program engagement, patients did not receive sufficient contact as per clinical guidelines that recommend 12 to 26 visits.[13] Indeed, our exploratory analyses indicated that those who attended weight management programs and received more coaching calls lost more weight. In contrast, in the Promoting Successful Weight Loss in Primary Care in Louisiana (PROPEL) study, health coaches delivered a 24-month program with 40 sessions over 18 months, and participants lost a mean of 5.0% (95% CI, 6.0%-4.0%) of their body weight at 24 months.[29] Unlike the PROPEL intervention, our GEM intervention was not designed to be intensive. Further, unlike PROPEL, GEM used lay health coaches, which is potentially cost-effective in low-resource settings. They may have provided insufficient expertise, however.

The GEM intervention may not have adequately addressed the needs of our diverse patient population. GEM health coaches used a toolkit to address barriers including food insecurity, mental health, and access to physical activity. They also facilitated communication with primary care clinicians. Despite these activities, barriers such as weight bias, pain, transportation, and other social determinants of health[12,30,31] may have been inadequately addressed, even though we recruited coaches from ethnically and socioeconomically diverse backgrounds. These barriers were likely worsened by the COVID-19 pandemic, whereby New York City residents and the minoritized patient populations in our

study were more likely to be affected.[32] A planned analysis of data on qualitative implementation of the GEM intervention based on the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework[33] will help to elucidate these challenges and how we can improve implementation in the future.

Importantly, the GEM health coaches supported only lifestyle-based obesity treatment. Even when patients engage in intensive lifestyle programs, only about one-half achieve a clinically important weight loss of at least 5%.[34,35] Anti-obesity medications have produced a 15% weight loss or more.[35-38] Bariatric surgery leads to a 25% to 35% weight loss on average.[39] Like lifestyle interventions, these treatments are also underused.[40,41] Future studies are warranted to explore the role of health coaches in supporting treatments that include lifestyle, medications, and bariatric surgery.

Strengths of this study include that it was conducted in 2 different health care systems serving diverse patient populations using a cluster-randomized design to test an innovative intervention. Although it was a negative study, findings can guide future intervention development.

A few study limitations need to be acknowledged. Both health systems were located in New York City, had PCMH models of care, and offered comprehensive weight management programs. It is possible, therefore, that these results may not be generalizable to other populations and settings. Because of the COVID-19 pandemic, we recruited fewer patients than we anticipated and had a higher dropout rate (27.2%). Although this may have affected our power to detect differences, having additional power would not change our conclusions given that estimated effects were smaller than expected.

Another limitation was the potential for contamination because of colocated teams randomized to different arms at both sites and participation of 3 VA clinicians in the EUC arm who had received brief 5As training when they participated in a pilot study of the GEM intervention 2 to 3 years prior. These 3 clinicians represented 10% of EUC clinicians, and they had 48 patients in the study (17.8% of patients in the EUC arm). Although the GEM pilot training may have improved outcomes in the EUC arm, the effects were probably minimal.

CONCLUSIONS

A low- to moderate-intensity technology-assisted health coaching intervention designed to increase engagement in intensive lifestyle programs and address weight management barriers did not lead to increased weight loss compared with enhanced usual care. Future studies are needed to determine how to best support weight management in primary care.

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Key words: obesity; overweight; comorbidity; health coaching; motivation; self-management; primary care; lifestyle; goal setting; diet; weight loss; physical activity; veterans; ethnic and racial minorities; vulnerable populations; barriers; practice-based research; health informatics

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Supplemental materials

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