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Protocol for a cluster-randomized controlled trial of a technology-assisted health coaching intervention for weight management in primary care: The GEM (goals for eating and moving) study

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ABSTRACT

Introduction: Over one-third of American adults have obesity with increased risk of chronic disease. Primary care providers often do not counsel patients about weight management due to barriers such as lack of time and training. To address this problem, we developed a technology-assisted health coaching intervention called Goals for Eating and Moving (GEM) to facilitate obesity counseling within the patient-centered medical home (PCMH) model of primary care. The objective of this paper is to describe the rationale and design of a cluster-randomized controlled trial to test the GEM intervention when compared to Enhanced Usual Care (EUC).

Method: We have randomized 19 PCMH teams from two NYC healthcare systems (VA New York Harbor Healthcare System and Montefiore Medical Group practices) to either the GEM intervention or EUC. Eligible participants are English and Spanish-speaking primary care patients (ages 18–69 years) with obesity or who are overweight with comorbidity (e.g., arthritis, sleep apnea, hypertension). The GEM intervention consists of a tablet-delivered goal setting tool, a health coaching visit and twelve telephone calls for patients, and provider counseling training. Patients in the EUC arm receive health education materials. The primary outcome is mean weight loss at 1 year. Secondary outcomes include changes in waist circumference, diet, and physical activity. We will also examine the impact of GEM on obesity-related provider counseling competency and attitudes.

Conclusion: If GEM is found to be efficacious, it could provide a structured approach for improving weight management for diverse primary care patient populations with elevated cardiovascular disease risk.

1. Introduction

Approximately 40% of the US population has a body mass index (BMI) in the obese range ($\geq 30\ kg/m^2$), with even higher prevalence in Hispanic, non-Hispanic black, and Veteran populations [1,2]. Patients with obesity disproportionately suffer from hypertension, diabetes, and osteoarthritis, among other conditions treated in primary care [3]. Modest weight loss of 3–5% can produce clinically meaningful health

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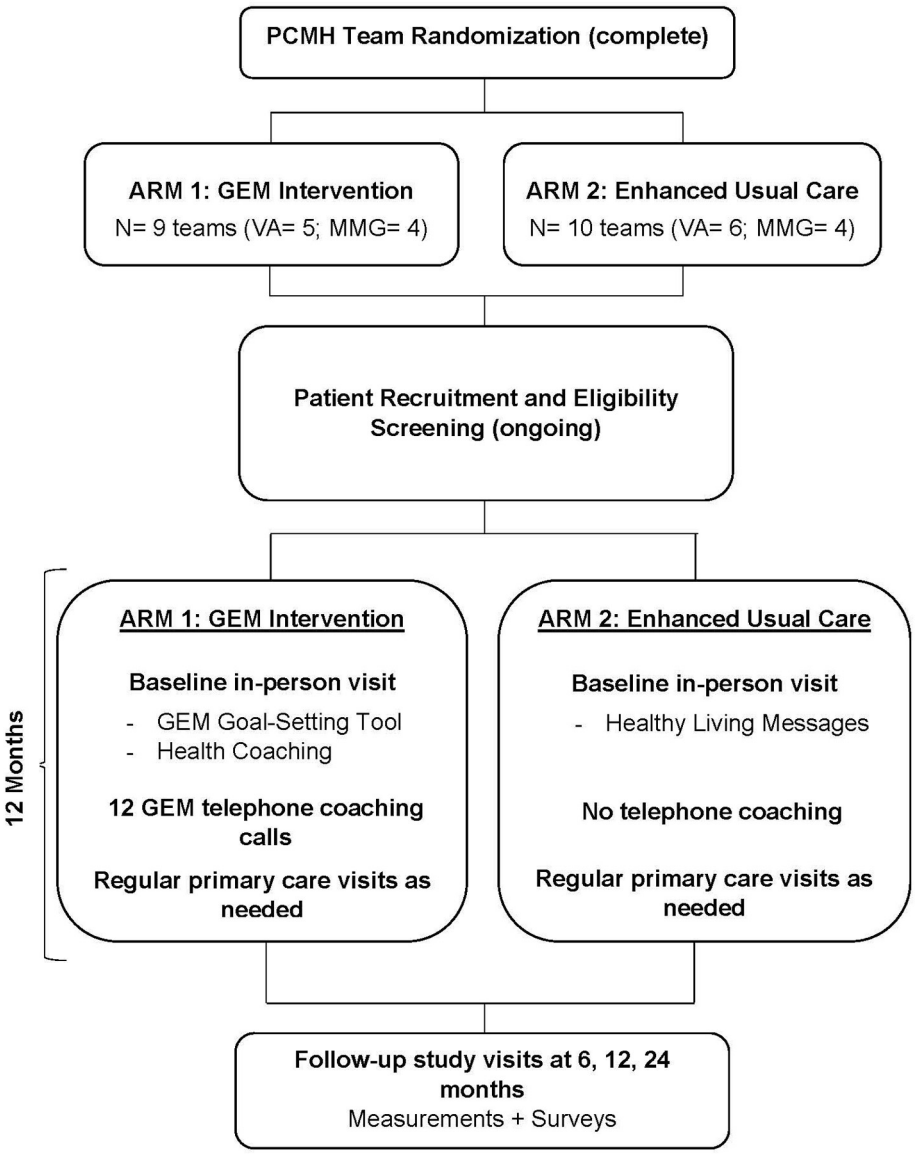

Fig. 1. Study design.

benefits [3].

Weight management practice recommendations are under-delivered in primary care [3]. Clinical guidelines recommend that providers systematically screen all patients for obesity and provide high-intensity, comprehensive weight management counseling (≥14 sessions over six months) [3]. Medicare reimburses clinicians to use the 5As framework for weight management counseling (Assess, Advise, Agree, Assist, Arrange) [4]. Providers face barriers adhering to this guideline, including lack of training, perceived lack of effectiveness, and competing demands on time [5–7].

The clinical guidelines also recommend referral of patients with obesity to intensive, multicomponent behavioral interventions [8]. Two examples of these programs are the MOVE! weight management program offered through the Veterans Health Administration (VHA) and the Diabetes Prevention Program (DPP). The DPP randomized control trial (16-session curriculum over 24 weeks) showed that it led to 5–7% weight loss and reduced risk of developing diabetes in patients by 58% [9]. In one study, patients who attended two or more MOVE! sessions were more likely to have ≥5% weight loss (19% vs. 12%) [10]. Unfortunately, only 5% of eligible patients attend at least one MOVE! session despite automatic referral alerts for the primary care provider [11]. Our formative work suggests that this may be due to patient-level barriers (e.g., time, transportation, low motivation) and inconsistent counseling by healthcare teams [5,12]. Similarly, at one urban medical center, fewer than 4% of eligible patients are referred to the affiliated DPP program and only 0.7% attend at least one session [13,14]. Thus, we need robust strategies to increase participation in these programs [15].

The Patient-Centered Medical Home (PCMH) model of care may provide more resources to help address challenges in providing both 5As counseling and improve utilization of local weight management programs. The PCMH model emphasizes patient-centered care delivered by inter-professional teams to integrate data-driven panel management and evidence-based approaches to improve health [16]. Few interventions are specifically designed to function within this model of care.

We designed a technology-assisted health coaching intervention called Goals for Eating and Moving (GEM) to help PCMH practices adhere to clinical guidelines for providing lifestyle-based weight management care. The goal of the GEM intervention is to provide 5As counseling to help patients lose weight and adopt healthier lifestyles by increasing attendance to comprehensive weight management programs.

GEM also provides support of weight management goals for those who choose not to attend programs. The GEM intervention was developed through rigorous formative work. A pilot study demonstrated that it was both feasible and acceptable to patients and providers [5,12,17]. This paper describes the protocol for a cluster-randomized controlled trial to test the GEM intervention's efficacy to reduce patients' weight when compared to Enhanced Usual Care (EUC). We randomized 19 healthcare teams at two urban healthcare systems that adhere to a PCMH model of care.

2. Methods and design

GEM is a cluster-randomized controlled trial of a 12-month weight management intervention for primary care patients who have obesity ($\geq 30\ kg/m^2$), or are overweight ($\geq 25\ kg/m^2$) with a weight associated co-morbidity at two urban healthcare systems in New York City: The VA New York Harbor Healthcare System (Manhattan campus) and four Montefiore Medical Group practices within Montefiore Health Systems (Bronx, NY). The trial has three aims. First, we will test the impact of the GEM intervention on weight loss, clinical and behavioral outcomes including attendance to multicomponent weight management programs (e.g., DPP or MOVE!). Second, we will identify predictors of weight loss related to a) goal-setting processes (e.g., self-efficacy and goal attainment) and b) specific intervention components. Third, we will determine the impact of the GEM intervention on provider obesity-related counseling competency and attitudes. Patients in both arms complete in-person assessments of body measurements (height, weight, waist circumference, and blood pressure) and survey measures at baseline, 6, 12, and 24 months (Fig. 1). The primary outcome is mean weight loss at 12 months. All study procedures were approved by the Institutional Review Boards at NYU School of Medicine (#i16–01445), VA New York Harbor (#01624), and Albert Einstein College of Medicine in collaboration with the Montefiore Health System (#2017-7603).

2.1. Setting

GEM is conducted at the VA New York Harbor Healthcare System Manhattan campus (VA) and four Montefiore Medical Group primary care practices with the patient-centered medical home. The VA Manhattan campus has 11 eligible Patient Aligned Care Teams (PACTs). Each PACT has 1–5 providers (23 providers total), a registered nurse (RN) care manager, a licensed practical nurse (LPN), and a clerical assistant. All PACTs share support from social workers, psychologists, pharmacists, dietitians, and other personnel.

The four Montefiore Medical Group (MMG) practices – Bronx East, Castle Hill, Grand Concourse, and University Avenue – are affiliated with the New York City Research and Improvement Networking Group. Similar to the PACT teams, the MMG sites are organized as pods. Each pod (8 total) is comprised of 2–6 providers (31 providers total), 1–2 RN care managers, an LPN, and a clerical assistant. A health educator, mental health provider, and social worker serve each pod.

Both healthcare systems serve diverse, urban populations. At the VA, approximately 21% of patients identify as Hispanic, and 53% as non-Hispanic black. At the MMG sites, approximately 55% of patients identify as Hispanic, and 37% as non-Hispanic black. Often, weight management studies include 70–80% women, while men are underrepresented. We anticipate that 52% of our sample will be women because the VA patient population is only 8–10% female, while the MMG sites are approximately 62% female [18]. Patients see their primary care provider approximately 2.5 times annually at the VA and 3.4 times annually at MMG.

2.2. Patient participants

Eligible patients are between the ages of 18–69 years, with either a body mass index of $\geq 30\ kg/m^2$ (obese) or $\geq 25\ kg/m^2$ (overweight) with a weight-associated co-morbidity (i.e., hypertension, high cholesterol, sleep apnea, osteoarthritis, metabolic syndrome, or pre-diabetes). Patients must have had at least one visit with their primary care provider in the prior 24 months, access to a telephone, and the ability to travel for in-person visits at baseline, 6, 12, and 24 months.

We do not enroll patients with a condition or medication for which weight-loss is contraindicated, that will likely impact their ability to fully participate, or may greatly impact weight change. Conditions include metastatic cancer in the last 6 months, current chemotherapy or cancer treatment, active psychosis, psychoactive substance use, Parkinson's disease, or a health condition that may prohibit the patient from walking or physical activity such as chest tightness, a heart condition, or severe arthritis. Excluded medications include those for weight-loss and antipsychotic medications. We also exclude patients who have a history of bariatric surgery or are currently being evaluated for bariatric surgery, who are pregnant, breastfeeding or become pregnant during the intervention period, or have participated in MOVE!, DPP, or another intensive weight management program (> 4 sessions) in the past year. Patients with diabetes are ineligible for the DPP program and therefore excluded from GEM. As the intervention includes telephone weight management counseling and reviewing of printed weight management materials, we are excluding patients who do not have a self-reported ability to read English or Spanish at the 5th-grade level or have profound cognitive limitations. We also exclude patients who do not want to lose weight and any patient whose primary care provider states that they should not participate.

2.3. Patient participant identifying and recruiting

Enrollment of patient participants began in November 2017 and is expected to conclude in December 2019. To identify eligible patients, we conduct queries of electronic health records through the Veterans Health Information Systems and Technology Architecture (VistA), and Clinical Looking Glass™ (CLG), for the VA and MMG, respectively. We repeat this process approximately every 6 months or as needed [19]. Primary care providers receive these lists and can exclude their patients based on medical or behavioral issues. Potential eligible patients are sent invitation letters and study flyers describing the GEM study, giving them the opportunity to call us if they either want to participate or opt out of receiving recruitment calls. After at least one week, we follow-up with a telephone call to assess interest in participation, screen for eligibility, and conduct a chart review if necessary. Eligible patients are then scheduled for the baseline visit. Patients complete the informed consent process at the beginning of the baseline visit before any study procedures commence.

2.4. Provider participants

To be eligible, primary care teams needed at least two providers per team to agree to participate. We enrolled all 19 eligible primary care teams (11 VA and 8 MMG). We are excluding providers who are residents. Individual providers can opt out of the study at any time. We do not anticipate that providers will drop out once enrolled, based on a recent panel management study in the same VA health care system, where all 18 eligible teams and 50/51 providers participated in the duration of the study [20]. However, we do expect some attrition due to clinicians leaving the team.

2.5. Randomization into intervention arms

The primary care teams were randomized using a random number generator in the statistical software R to either the GEM Intervention or Enhanced Usual Care arms. Randomization was stratified by healthcare systems (MMG and VA) in blocks of four. The intervention design precludes blinding of patients and GEM health coaches to intervention assignment. Blinding of research assistants is not possible because

patients in the intervention arms frequently reveal their condition by reporting about their interactions with the health coach.

2.6. Sample size and power analysis

We based our sample size calculation and power analysis on comparing the within-person weight change from baseline to 12-months follow-up in two arms. We assume an interclass correlation coefficient (ICC) of 0.05 for patients within each provider and an ICC of 0.01 for providers within each primary care team. We based our initial power calculations on the assumption to have at least eight teams in each arm with 2 providers each, and recruit 12 patients per provider (384 evaluable patients total at 12 months). This would provide at least 82% power to detect a 2.2-kg (SD = 6.0 kg) difference in weight between the intervention and control arms, using a two-sided *t*-test with a significance level of 5%. This amount of weight loss is consistent with findings from the ASPIRE VA study [21] and a systematic review of technology-assisted weight loss interventions in primary care [22]. We will also have at least 84% power to detect our hypothesized difference of 15% of GEM Intervention patients achieving 5% weight loss (clinically significant; 5% weight loss can reduce cardiovascular risk) [23],assuming 12% of patients in the EUC control arm achieve this amount of weight loss [24], using a two-sided chi-square with a significance level of 5%, as well as to detect a hypothesized difference of 2.9-cm change (SD = 7.7 cm) in waist circumference between two arms, using a two-sided t-test with significance level 5%. Assuming that the dropout rate at 12 months is about 25%, we plan to enroll approximately 512 patients to ensure that we have 384 evaluable patients at 12 months. This dropout rate is common for pragmatic studies of underserved populations where there is no run-in period to increase adherence [21,22].

Since we were able to enroll 9 teams in the GEM intervention arm and 10 teams in the EUC control arm (together 19 teams), with a current average of 3 providers in each team, this will provide additional power. For example, if we obtain data from 7 patients per provider (399 evaluable patients total at 12 months), we will have at least 89% power to detect a 2.2-kg (SD = 6.0 kg) difference in weight between the intervention and control arms. We will also have at least 90% power to detect our hypothesized difference of 15% of GEM Intervention patients achieving 5% weight loss (clinically significant; 5% weight loss can reduce cardiovascular risk), assuming 12% of patients in the EUC control arm achieve this amount of weight loss, as well as to detect a hypothesized difference of 2.9-cm change (SD = 7.7 cm) in waist circumference between two arms.

2.7. Intervention arms

2.7.1. GEM intervention arm

The GEM intervention leverages the patient-centered medical home model. This model emphasizes patient-centered care delivered by interprofessional teams. The GEM tool provides individually tailored, patient-centered care and promotes standardized weight management counseling by health coaches and primary team members. The GEM health coaches coordinate care between teams and the health system weight management service providers (e.g., registered dietitian nutritionists (RDNs), and health educators, who are Certified Health Education Specialists (CHES) and DPP lifestyle coaches), and provide feedback to the provider and primary care team about patients' weight management-related goals, progress, and care.

The GEM intervention uses the 5As model [4], motivational interviewing [25], and SMART goals [26] to help patients make behavior changes. The 5As model is incorporated into the GEM intervention design (further outlined in the following section). Motivational interviewing (MI) is a patient-centered counseling method that enhances a person's motivation and commitment to change by discussing ambivalence. The GEM health coaches use four techniques (open-ended questions, affirmations, summaries, and reflection statements) of MI to discuss behavior change with patients. The GEM health coaches utilize SMART (Specific, Measurable, Attainable, Relevant, and Timely) goals to help patients set detailed and realistic goals.

The GEM intervention is comprised of four components: 1) the GEM tool; 2) a GEM health coach visit; 3) twelve telephone coaching calls, and 4) brief counseling by the provider at primary care visits (items 1 and 2 will be completed at the baseline visit). Below we describe the intervention elements in more detail. The listed average times for patients to complete each component are based on our pilot study testing [17].

2.7.1.1. Complete GEM tool (20 min). The GEM tool is an online software program that is delivered on tablet computers. The tool is designed to support the GEM health coaches and the primary care teams in 5As (Assess, Advise, Agree, Assist, Arrange) counseling. It assesses current BMI (based on self-reported height and weight), health behaviors (e.g., dietary intake, physical activity), barriers to weight loss and physical activity (e.g., stress, lack of money, or pain), and interest in using self-monitoring options via a 16-item questionnaire (i.e., Assess). Based on a computer algorithm that considers the need to change each behavior, the tool provides tailored advice (i.e., Advice), and guides patients to set a (5–10%) weight loss goal, physical activity (PA) goal, and dietary goals (i.e., Agree). Patients choose between eight dietary goals (e.g., eating more fruits and vegetables, reducing soda consumption, or limiting portion size). The tool then generates an individualized comprehensive report, which guides the conversation with the GEM health coach. The tool also generates a patient report template for the primary care team, which the health coach enters into the electronic health record (EHR). Although initially developed for the VA with English speakers, we have since translated the GEM tool into Spanish and pilot tested it with Latina/o patients. If needed, GEM health coaches help patients use the GEM tool. The development of the tool is described elsewhere [17].

2.7.1.2. Meet with GEM health coach (30 min). After completing the GEM online tool, the patient meets with the GEM Health Coach (see below for more information on coach selection and training). Patients are assigned one primary health coach and a secondary health coach, who serves as a back-up, who stay with them for the duration of the study, if possible.

GEM health coaches use the individualized comprehensive report generated by the GEM tool and brief motivational interviewing to help patients: (1) transform initial lifestyle goals (originally facilitated by the GEM tool) into SMART goals [26]; (2) participate in MOVE!, DPP, or community-based weight management programs; (3) self-monitor weight, diet, and physical activity via pedometer, food log, and/or weight management apps (e.g., MyFitnessPal or Apple's Health app); and (4) determine strategies to overcome barriers (i.e., Agree and Assist) [17]. After the initial GEM visit, health coaches refer patients to extended healthcare team members (e.g., health educators, dietitians) and/or other resources if needed. For instance, for patients who report that they do not have enough money to buy food, the health coach will help them arrange a meeting with a social worker to determine their eligibility for benefits such as the Supplemental Nutrition Assistance Program (SNAP) (i.e., Assist and Arrange). To facilitate communication with the primary care teams, the health coach also completes the patient report template generated by the GEM tool and enters the report into the electronic health record. The purpose of this documentation is to communicate potential barriers or concerns and update the healthcare team on the goals set by patients throughout the intervention period. In addition to the health record, communication with healthcare teams occurs through a secure messaging system, telephone, written notes, or in-person meetings with the healthcare team members. To help motivate provider counseling, GEM health coaches attend primary care meetings to communicate the progress of enrolled

patients' adherence to weight management goals, MOVE! or DPP attendance, and individual barriers.

2.7.1.3. Telephone calls with GEM health coach (12 calls, 20–30 min each). To achieve sufficient coaching intensity according to USPSTF guidelines, GEM patients are offered 12 telephone coaching calls with a health coach over 12 months. Scheduled calls occur biweekly for month 1, monthly for months 2–10, and bimonthly for months 11–12. GEM Intervention arm patients receive a reminder call to self-monitor their weight, food intake, and physical activity 3 and 1 days prior to the scheduled coaching call. Studies suggest that episodes of short, consistent self-monitoring (for 3 days) may reduce weight and improve self-monitoring adherence in general [27]. Health coaches assess self-reported weight and self-monitoring data from pedometers, food logs, or smartphone apps. They also determine attainment of previous set SMART goals and use motivational interviewing techniques to help patients adapt previously set goals or create new goals, address barriers to behavior change, and provide resources. Health coaches document sessions in REDCap 8.1.11 (Research Electronic Data Capture). Health coaches also recommend to patients that they have continuous interaction with the PCMH team. Patients are able to contact health coaches via telephone for additional support as needed.

2.7.1.4. Training of health coaches. One full-time lead health coach works with a team of volunteer health coaches at each of the two sites (i.e., at the Manhatten VA and at MMG practices). Volunteers work 10–15 h per week for a year to receive school credit and/or relevant experience. The lead health coaches and volunteer health coaches have no formal clinical training. They receive approximately 40 h of training to deliver baseline and telephone-based health coaching (based on a prior 5As training intervention, adapted materials from the Centre for Collaboration, Motivation, and Innovation (CCMI)) [28]. Dr. Jay (PI) and lead health coaches provide the training for student health coaches and monitor fidelity. During this training, health coaches learn techniques based on motivational interviewing (e.g., open-ended questions, affirmations, summarizing, and reflections) review health coach protocols, and use role-playing and voice recordings to review and practice counseling skills. They are also trained to promote small lifestyle changes, provide empathic care to minimize perceived obesity stigma, interact with providers, and communicate weight management progress to the primary care teams. Finally, they are trained to identify red flags (e.g., suicide ideation) and barriers (e.g., pain, untreated depression), and communicate them to the primary care teams.

2.7.1.5. Meet with primary care providers. Health coaches recommend that patients discuss their weight management goals at primary care visits. Providers are trained and encouraged to provide brief counseling for 3–5 min and to document this counseling in the electronic health record (see provider training below).

2.7.1.5.1. Training of primary care providers. Primary care providers receive training sessions from Drs. Jay and Wylie-Rosett. Training includes a 30 min to 1-h initial session and annual follow-up sessions (15–30 min each) over the course of the study. The training occurs during staff meetings with the option for 1:1 training or academic detailing for those who could not attend the in-person sessions. Content includes an overview of the 5As, the intervention components, brief motivational interviewing to support patients' weight management goals and address barriers to change, and weight management resources available at their respective sites. We discuss the components of the GEM intervention and recommend providers to counsel patients for 3–5 min during regular primary care visits to support patients' weight management goals and address barriers. We demonstrate how to document this counseling in the electronic health record, Computerized Patient Record System (CPRS) at the VA and Epic Systems Corporation software at MMG practices. Providers also receive a biannual newsletter with updates on the progress of the GEM study in general and their patients. The newsletter includes information about recruitment numbers, patients enrolled in GEM per provider, and how to get additional weight management counseling training. It also includes reminders to do brief weight management counseling with each patient. Separately, providers receive individual updates on their patients' weight management progress, specific goals, and barriers.

2.7.1.5.2. Treatment fidelity. We randomly audiotape 10% of baseline health coaching visits and telephone coaching calls to be reviewed by the lead health coach. We use a health coach fidelity checklist that we adapted from the Aspiring to Lifelong Health in VA (ASPIRE-VA) study to monitor skill acquisition and quality of counseling [29]. During pilot studies, health coaches on average scored 92% on fidelity checks. Refresher training occurs biannually. Using the survey administered to patients at in-person follow-up visits, we will assess whether patients recall reviewing goals and receiving obesity-related counseling from their provider to evaluate treatment from the primary care teams. We will also monitor how often providers see patients and document goal setting discussions in the electronic health record during subsequent visits.

2.7.2. Control arm – enhanced usual care (EUC)

Patients in the EUC arm receive non-tailored general health and weight management education materials delivered by research assistants. During the control baseline visit, EUC patients receive nine healthy living messages developed by the VA, and adapted for MMG patients, that focus on general health, nutrition, and physical activity. The nine healthy living messages include: getting recommended screening test and immunizations, being involved in health care, managing stress, being tobacco-free, limiting alcohol, being safe, striving for a healthy weight, being physically active, and eating wisely. These handouts have a section where patients can write down goals related to each message. They also receive select MOVE! handouts on diet and physical activity, a pedometer, and information on the MOVE! program and MOVE! Telephone Lifestyle Coaching (VA), or DPP (MMG). Patients in the EUC arm are advised to follow-up with their healthcare teams as needed.

Providers in the EUC arm receive information about the GEM study aims but are not trained in weight management counseling. They also receive a biannual newsletter about the overall enrollment and retention in the GEM study.

2.7.3. Adaption of the GEM intervention for MMG sites

The GEM intervention was originally developed through rigorous formative work within the VA system [5,12,17]. We collaborated with local clinical champions, MMG site directors, and patients to adapt GEM for use within MMG sites. Given that MMG sites have large Hispanic populations, we used data from prior studies and Latina/o patient focus groups to make culturally and linguistically relevant modifications to the GEM tool. We tailored the GEM intervention for Latina/o patients because we recognize that Hispanic populations are culturally diverse and the GEM intervention facilitates tailored counseling at the individual level. We then tested the acceptability and usability in a pilot of the revised GEM tool health coaching protocols with 15 Spanish-speaking patients who have obesity or are overweight until data saturation was achieved using a “Think Aloud” protocol [30,31].

2.8. Data collection

2.8.1. Survey procedures and timing of visits

2.8.1.1. Patient participants. In-person visits occur at baseline, and then 6, 12, and 24 months after the baseline visit. At each study visit, a research assistant (RA) confirms contact information, collects biometric measures, and administers survey instruments (described below). Patients are assured that there are “no right or wrong answers” and advised to “answer as honestly as possible.” All biometric procedures

are adapted from the National Health and Nutrition Examination Survey (NHANES) [27]. Whenever possible, weight and waist circumference at follow-up visits will be collected by RAs who have not performed the baseline assessment and who are unaware of the patient's study arm assignment (unless disclosed by the patient) to limit measurement bias. Data is entered into REDCap 8.1.11.

2.8.1.2. Patient participant retention. We are using the following strategies to retain patients in both arms: pay honoraria for data collection visits (25 USD for baseline, 30 USD for 6-month visit, 40 USD for 12-month visit, and 50 USD for 24-month visit), ask patients to provide names of friends or relatives as back-up contacts, and use telephone and mail reminders for study visits.

2.8.1.3. Provider participants. Prior to randomization, providers were surveyed about their obesity-related counseling competency and attitudes (baseline survey). Twelve months after the start of patient recruitment, we administered a follow-up survey to providers. To enhance attendance and adherence, we provided beverages and food during the survey assessment.

2.8.2. Aim 1: weight change, clinical, and behavioral outcomes

2.8.2.1. Weight. RAs obtain patient weight measurements using a standardized protocol, which includes weighing twice without shoes or heavy garments to the nearest 0.1 pounds using a HealthOMeter 349KLX Digital Medical Weight Scale digital scale that is calibrated every 6 months. Patients stand still with both feet in the center of the scale, hands at sides, looking straight ahead. The average measure is used for analysis. If the first two weights differ by 0.5 pounds or more, we repeat the measurement. In this case, the average of the closest two out of the four measurements is used for analysis.

2.8.2.2. Height. RAs assess height once at baseline only. Patients' heights are rounded up to the nearest 0.5 cm, using a SECA 213 Portable Height. Patients remove shoes and extraneous clothing, and undo interfering hairstyles, if possible. Patients then stand upright looking straight ahead with heels, buttocks, shoulder blades, and back of head positioned against the ruler.

2.8.2.3. Waist circumference. RAs measure waist circumference twice, rounding down to the nearest 0.25 in. We take the measurement on bare skin if possible, at the high point of the iliac crests, drawing the tape measure snug at minimal respiration. The average measurement is used for analysis. If the first two values differ by 0.5 in. or more, we repeat the measure once and the two closest measurements are averaged.

2.8.2.4. Blood pressure. We obtain two resting blood pressure measures using the Omron HEM 907XL IntelliSense Professional Digital Blood Pressure Monitor, an automated sphygmomanometer. The patient remains seated without consuming caffeine or nicotine for 30 min prior to the measurement. We measure arm circumference first to determine the appropriate cuff size, then place the cuff snugly on the left upper arm with the bottom of the cuff approximately one inch above the inner elbow. The arm rests palm-up at heart level and the patient remains silent and still, with both feet on the floor, during the measurement. The average measurement is used for analysis. If the first two systolic or diastolic values differ by 5.0 mmHg or more, we remove and adjust the cuff, and repeat the two measures and the two closest measurements are averaged.

2.8.2.5. Attendance to intensive programs. We review the EHR to evaluate MOVE! (VA) or the DPP (MMG) attendance. We assess the self-reported use of community-based programs via survey items at 6, 12, and 24-month follow-ups.

2.8.2.6. Food behavior. We assess the consumption of fruits and vegetables using a 7-item subscale from the validated Food Behavior Checklist [32]. We evaluate sweets and salty snack intake using two items adapted from the Rapid Eating Assessment - Shortened Version (REAP-S) [33,34]. Healthy dietary changes in portion sizes and food choices such as fried food, fast food, and white bread, and consumption of and sugar-sweetened beverages are measured using the Latino Dietary Behaviors Questionnaire (LDBQ) [35]. The Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) [36] is used to assess the extent to which a patient is at risk for alcohol misuse based on DSM-V criteria.

2.8.2.7. Physical activity (PA). Walking and moderate-to-vigorous intensity physical activity are measured using the International Physical Activity Questionnaire short form (IPAQ-SF) [37]. The IPAQ is well-established in the public health literature as a valid and reliable physical activity assessment tool.

2.8.3. Aim 2: predictors of weight loss

2.8.3.1. Goal setting processes and motivation. We measure potential predictors of weight loss pertaining to goal setting processes in all patients. We use established instruments to assess changes in the following: 1) self-efficacy to resist overeating (Weight Efficacy Lifestyle Questionnaire short form) [38] and engage in regular physical activity [39] 2) outcome expectations for physical activity [40], 3) intrinsic motivation for self-monitoring (Treatment Self-Regulation Questionnaire) and weight loss (Behavioral Regulation in Exercise Questionnaire) [41], and 4) Stage of Change for eating [42,43] and physical activity [44].

2.8.3.2. Use of intervention components. Patients in the GEM intervention arm report attainment of behavioral goals by indicating if they have achieved each of their SMART goals as per the SCALE study [45]. For self-monitoring, we ask patients about their use of pedometers and food logs (paper or via smartphone apps) and collect their recorded data (similar to the ASPIRE VA study [21,29]) during telephone coaching. We record the number of telephone coaching calls received by patients within our research study database.

2.8.4. Aim 3: primary care provider outcomes

2.8.4.1. Obesity-related counseling competency and attitudes. We survey providers to measure 5As-related competency [7] and attitudes about obesity (including self-efficacy, outcome expectancy, discomfort, and bias) using validated survey items [46]. To measure the quality of counseling, patients report on their providers' use of 5As counseling practices (survey items that we have used previously) [47]. They also rate satisfaction with their treatment and willingness to follow their doctor's recommendations [48]. Frequency of counseling data comes from EHR reviews.

GEM Study Measures and Study Visit Time Points

Measures	Baseline	6-months	12-months	24-months
Aim 1: Weight/Clinical Outcomes				
Height	X			
Weight (BMI)	X	X	X	X
Waist circumference	X	X	X	X
Blood pressure	X	X	X	X
Aim 1: Behavioral Outcomes				
Intensive program attendance	X	X	X	X
Fruits and vegetables	X	X	X	X
Sweets and salty snacks	X	X	X	X
Healthy dietary changes	X	X	X	X
Sugar-sweetened beverages	X	X	X	X
Alcohol use	X		X	X
Physical activity	X	X	X	X

Aim 2: Predictors of Weight Loss				
Self-efficacy	X	X	X	X
Outcome expectations	X	X	X	X
Intrinsic motivation	X	X	X	X
Stage of change	X	X	X	X
Goal attainment		X	X	
Self-monitoring		X	X	
Number of phone coaching calls		X	X	
Aim 3: Primary Care Team Outcomes				
Quality of counseling	X	X	X	X
Satisfaction with treatment	X	X	X	X
Willingness to follow recommendations	X	X	X	X
Counseling competency and attitudes	X		X	
Counseling frequency	X		X	X
Other Measures				
Quality of life	X	X	X	X
Socio-demographics	X			
Depression	X	X	X	X
Food insecurity	X		X	X
Social support	X	X	X	X
Neighborhood environment	X			
Weight loss surgeries	X	X	X	X
Discrimination due to weight	X		X	
Discrimination due to race	X			
Technology use	X			
Health literacy	X			
Hospitalization and ER visits		X	X	X
Adverse events		X	X	X

2.9. Statistical analysis

Baseline demographic and clinical variables will be summarized (intention-to-treat approach) using mean (with standard deviation) and median (with interquartile range) for continuous variables and frequency table for categorical variables. All outcomes of interest will also be summarized by study visits and by study arms. Graphic displays, such as box plots and histograms, will be used to inspect the variable distributions and identify possible outliers. Mann-Whitney tests for continuous variables and Fisher's exact tests for categorical variables will be used to check if both providers' and patients' baseline characteristics are balanced between two intervention arms.

2.9.1. Aim 1: clinical and Behavioral outcomes

Our primary outcome for Aim 1 is mean weight change in kg at 12 months. To test the efficacy of the GEM intervention compared to the EUC arm on clinical (including weight loss, indicator of weight loss > 5%, waist circumference, and blood pressure) and behavioral outcomes (including the use of evidence-based weight management programs, food behavior, and physical activity, we will first conduct extensive descriptive and univariate analyses. For univariate analyses, we will use *t*-tests and Mann-Whitney tests for continuous outcomes (e.g., weight loss) and use chi-square tests and Fisher's exact tests for categorical outcomes (e.g., weight loss > 5%). In addition, unadjusted confidence intervals will be computed to compare the effects of GEM with the effects of EUC on outcomes.

After the above descriptive univariate analyses, we will use mixed effects modeling as the primary approach for multivariate analyses. Mixed effects modeling can (1) take into account the correlations among repeated measures at baseline and follow-up visits, assuming autoregressive covariance structure (i.e., AR(1)), (2) adjust for baseline characteristics (e.g., gender, age), and (3) take into account the correlations among patients within providers (i.e., clustering), assuming compound symmetry covariance structure (i.e., CS). Model-based adjusted confidence intervals will also be provided to measure the effects of the intervention on outcomes, including the primary aim of mean weight change in kg at 12 months between two arms. Although mixed effects modeling can address missing data automatically, assuming it is missing at random, we will use a multiple imputations procedure to conduct sensitivity analyses under the assumption of missing not at random. The sensitivity analyses will use pattern-mixture models to examine if the statistical findings are robust across several scenarios, including the least-favorable scenario where the missing data from the GEM intervention arm follows the same pattern as that of the observed data from the usual care arm.

2.9.2. Aim 2: predictors of weight loss

We will determine the predictors of weight loss related to goal setting processes and intervention components. To this aim, we will use visualization tools (such as scatterplots and bar graphs) and descriptive analyses (such as 5-number summary and Spearman correlation coefficient) to display the association between weight change and potential predictors. Multiple regression models, along with variable selection procedures, will be used to further explore the effects of those predictors that are suspected to be associated with weight loss.

2.9.3. Aim 3: provider outcomes

For Aim 3, we will determine the impact of the GEM Intervention on obesity-related counseling competency and attitudes in primary care providers. For this aim, we will use Mann-Whitney tests for continuous provider-level outcomes and Fisher's exact tests for categorical provider-level outcomes to compare the two arms. We will also use mixed models to analyze the provider outcomes, taking into account the correlations of providers within teams. Confidence intervals of the effects will also be obtained.

3. Discussion

Obesity is a major health crisis and primary care settings are important venues to engage patients in weight management. With over half a million visits per year in the United States [49], primary care settings are where patients seek care to treat and prevent chronic conditions. Unfortunately, primary care providers and practices have difficulty adhering to clinical guidelines recommending either intensive 5As counseling and/or referral to a multicomponent behavioral intervention. Further, even when multicomponent behavioral interventions are offered within primary care settings, they are often underutilized. The GEM intervention is a potentially innovative strategy to help providers and medical practices adhere to counseling and referral guidelines as well as increase attendance and adherence to evidence-based multicomponent behavioral interventions. This cluster-randomized controlled trial will determine the efficacy of GEM when compared to Enhanced Usual Care (EUC). If the GEM intervention is shown to be efficacious, it may warrant dissemination to many different practice environments.

Other studies have shown that weight management interventions can be effective in primary care settings [50–52]. For instance, the POWER-Hopkins study found that remote weight loss support (telephone, website, and email) led to more weight loss compared to self-directed support at 24 months (-4.6 ± 0.7 kg vs -0.8 ± 0.6 kg) [52]. Similar to these studies, GEM utilizes non-clinicians to help deliver weight management counseling and is assisted by technology. What makes GEM innovative is that it a) was designed specifically for the PCMH model of care, b) utilizes the 5As framework and c) is designed to increase utilization of existing multicomponent behavioral interventions while still providing counseling and support for those who do not attend.

Strengths of the study include that it is a cluster-randomized controlled trial that will test the efficacy of GEM at two different healthcare systems and in diverse patient populations. The Veterans Health Administration (VHA) is the only single-payer health system in the United States and serves a mostly male population of Veterans. At the VHA, approximately 21% of patients identify as Hispanic, and 53% as non-Hispanic black. The Montefiore Medical Group is a not-for-profit, privately run outpatient group affiliated with the Montefiore Health

System that serves patients in Bronx, NY and the Lower Hudson Valley. Most patients are insured by Medicaid or Medicare, 62% of patients are female and about 90% identify as either Hispanic or non-Hispanic black.

The anticipated diversity of our patient population will help make the study generalizable to other urban settings. While weight loss will be modest, the overall impact of the intervention could be substantial because this study will document how GEM can be incorporated with PCMH teams within primary care and reach a large number of patients. The GEM intervention itself was developed through rigorous formative work, and a pilot study at the VA Manhattan Campus showed that it was feasible and acceptable to patients and staff. This study will also add to scientific knowledge about the predictors of weight loss for patients based on which intervention components were most utilized and different demographics.

There are several limitations to this study as well. Practices that are not organized to support patient-centered medical home models may not find this study relevant as GEM was designed for team-based care. Even though multi-professional, team-based care is highly valued and increasingly being adopted, few studies have examined best weight management practices within medical homes [53]. This intervention could be tailored for non-medical home practices as well that do not have in-house weight management resources by partnering with community-based or commercial programs (e.g., DPP at the YMCA or Weight Watchers ©). Patients in the study may differ from the general population in primary care. As in many research studies, patients who volunteer to be part of this trial may be more motivated than the general population which may decrease generalizability. Recruitment bias toward patients with frequent primary care visits and more motivation may occur. We may not be powered to see statistically significant changes to diet or physical activity. Despite this, we believe that it is important to explore these clinical and behavioral outcomes. Finally, non-clinician health coach volunteers are often students who later graduate or find jobs and this can cause challenges with continuity. To address this, health coaches work in teams with a primary and secondary health coach. A lead health coach monitors teams for quality, fidelity, and continuity.

Despite these limitations, this study is of considerable public health importance. If the GEM intervention is found to be efficacious, it could help diverse healthcare systems meet clinical guidelines for obesity treatment in primary care, improve attendance to intensive programs and weight management outcomes for patients. We have designed the GEM intervention to be disseminated and adapted to other VHA and Non-VHA healthcare systems.

Authors' contributions

SW, AA, and MJ drafted the manuscript for publication. MJ initiated collaboration, conceived of, and obtained funding for the project. SW and SO designed data collection tools. SW, AA, and LV developed intervention materials and protocols. YF devised the statistical analysis plan. MJ and SW implement the trial at the VA New York Harbor Healthcare System (Manhattan campus) and JWR and LV implement the trial at four Montefiore Medical Group practices within Montefiore Health Systems (Bronx, NY). SW and LV are managing the project day-to-day and monitor data collection tools. All coauthors contributed to the conception and/or design of the work and read and approved the final manuscript.

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Clinical trial registration

ClinicalTrials.gov identifier: NCT03006328

Declaration of conflicts of interests

The other authors report no conflicts of interest.

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