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The GEM Intervention: Goals for Eating and Moving

A technology-assisted 5As-based intervention for Medical Homes to promote weight loss, behavior change, and participation in intensive weight management programs.

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I. Purpose of the Study

Brief Background and Rationale

Over 35% of adults in the United States are obese, with increased risk of diabetes, hypertension, and hyperlipidemia.[1,2] However, there are few primary care (PC)-based weight management interventions for this population. Modest weight loss improves health and prevents chronic disease, but healthcare teams often fail to counsel patients about their weight due to barriers such as competing demands and poor competency. Thus, PC-based weight management interventions are needed to address the needs of adults with obesity and support healthcare teams to improve care.

With funding from a Career Development Award from the Veteran's Affairs (VA) and rigorous formative research, we developed a technology-assisted weight management intervention, called Goals for Eating and Moving (GEM). This intervention is based on the 5As framework (assess, advise, agree, assist, arrange) as recommended by the United States Preventive Services Task Force and reimbursed by the Centers for Medicare and Medicaid Services. The GEM intervention uses a tablet-delivered online tool to facilitate in-person and telephone-delivered health coaching by non-clinical staff, provide tailored patient education materials, and activate patients to set behavior change goals and discuss weight management treatments with their healthcare teams. Preliminary data suggests that the GEM intervention is feasible and acceptable to Veterans and VA staff and facilitates 5As counseling. An ongoing RCT will determine if it promotes weight loss.

The Patient-Centered Medical Home model is an expanded care model emphasizing patient-centered care delivered by inter-professional teams of individuals working to integrate evidence based approaches to improve individual and population health.[14,15] However, it is unclear how the Patient-Centered Medical Home model can be used to address barriers to 5As implementation, improve weight management counseling, and increase participation in intensive weight management programs. We developed GEM (Goals for Eating and Moving), an innovative, technology-assisted 5As-based intervention for Medical Homes to promote weight loss, behavior change, and participation in intensive weight management programs. To establish the efficacy of the GEM intervention, we will conduct a cluster randomized controlled 12-month intervention of 16 primary care teams at two urban healthcare systems with Medical Home models of care to compare the GEM intervention (intervention arm) with Enhanced Usual Care (educational materials; control arm).

Specific Aims

1. Test the impact of the GEM intervention on weight change, and clinical and behavioral outcomes.

2. Identify predictors of weight loss in the GEM intervention arm related to: a) goal-setting processes and b) intervention components

3. Determine the impact of the GEM intervention on obesity-related counseling practices and attitudes in primary care providers.

Hypothesis

The patients within primary care teams randomized to the Goals for Eating and Moving (GEM) intervention will have greater weight loss than those who receive Enhanced Usual Care.

Research Design

a. We will conduct a cluster-randomized controlled trial of the GEM intervention at two healthcare systems in New York City: The VA New York Harbor Healthcare System (Manhattan campuse) and Montefiore Medical Groups (4 sites affiliated with New York City Research and Improvement Networking practice-based research network).

b. We will conduct a RE-AIM (reach, efficacy, adoption, implementation, and maintenance) evaluation of the GEM intervention. [20]

c. We will explore potential effects of secondary measures such as perceived procedural fairness or experiences of discrimination on health outcomes and weight-loss behaviors including but not limited to dietary behaviors, physical activity, and quality of life measures.

Background

Modest weight loss (7%) via the Diabetes Prevention Program (DPP) can reduce the risk of diabetes in high-risk patients by 58%. [3] Similarly, all Veterans Affairs (VA) Medical Centers offer the MOVE! program, a lifestyle-based program delivered in small group sessions. [4, 26, 27] One report found that patients who attended two or more MOVE! sessions were more likely than matched controls to have clinically significant (>5%) weight loss ad less likely to gain weight. [28] Unfortunately, intensive lifestyle programs like this are not available to most primary care patients and very few studies have looked at interventions to treat obesity in the primary care setting,[29-30] despite the obvious need for improving delivery of obesity care. We need to test more robust strategies to increase participation in these effective programs.

The primary care setting is critical to reducing the burden of obesity. Primary care (PC) is an important venue to promote weight loss through lifestyle behavior change, and effective PC-based interventions can potentially have a significant public health impact,

since the majority of the 1 billion yearly ambulatory visits are made to primary care physicians. [9] Moreover, physicians' and other providers' counseling is associated with positive behavioral and weight-loss outcomes.[31-34] The United States Preventive Services Task Force endorses the use of the 5As framework (Assess, Advise, Agree, Assist, Arrange) to deliver obesity counseling within primary care.[35] While Medicare reimburses providers for 5As weight management counseling, providers frequently fail to effectively counsel obese patients to lose weight.[33, 36] This has been attributed to lack of training,[34,37] poor competency,[38] perceived lack of effectiveness,[39] and competing demands on time during the medical visit.[40] Thus, more studies are needed to determine the best way to integrate weight management into primary care practice.

With funding from a Career Development Award (CDA) from the Veterans Affairs, we recently developed a technology-assisted, weight management intervention called Goals for Eating and Moving (GEM) to deliver 5As weight management counseling within a patient centered medical home model of care (PCMH). Figure 1 illustrates how the intervention is delivered within PCMH and promotes goal setting and weight loss. Patients arrive early to their PC appointment to use an online goal setting tool (GEM tool) delivered on a tablet computer that generates a personalized binder of tailored materials. The patient then meets with a health coach to further refine weight loss and lifestyle goals, address barriers, and suggest other weight management resources. PC teams then endorse goals and provide brief motivational interviewing as needed. They can use a clinical reminder within the electronic health record to document 5As counseling conversations. Patients receive follow-up phone coaching calls from their health coach to document progress, adjust goals, and facilitate communication with the heath care team and weight management-related services.

The GEM intervention has great potential to improve the delivery of obesity counseling within the PCMH model of primary care. Initial findings from an ongoing pilot study of this intervention among Veterans and PC staff at a VA medical center demonstrated that it was feasible and acceptable to Veterans and staff and facilitated goal-setting conversations (see Preliminary Studies). However, there is no standard by which to leverage the Patient-Centered Medical Home model to provide weight management care. There is a need to test weight management interventions within patient-centered medical homes that integrate and/or partner with effective, intensive programs such as MOVE! and DPP.

Judith Wylie-Rosett, EdD, RD (Co-I) has over three decades of experience leading multicenter and investigator-initiated lifestyle trials for diet, obesity, and exercise whose work in Diabetes Prevention Program (DPP), DDP-Outcomes Study and Women's Health Initiative has shaped national health guidelines. [52-56]

Study Design

We will conduct this study using 3 steps:

1. Test the impact of the GEM Intervention on weight change, and clinical and behavioral outcomes.
    a. We will obtain weight and height measurements, waist circumference measurements, , and blood pressure measurements from patients at multiple time points throughout the study. We will also use questionnaires to measure dietary outcomes and physical activity outcomes. Finally, electronic health records (EHR) and surveys will be utilized to evaluate attendance to intensive weight management programs. [85, 96, 86, 97, 98. 99, 100, 101, 102]

2. Identify predictors of weight loss in the GEM intervention arm related to: a) goal-setting processes and b) intervention components.
    a. We will measure attainment of behavioral goals by asking patients to report on how many days in the past week they achieved each of their SMART goals. [88] We will record the number of telephone coaching calls received by patients within the research study database and measure the frequency of counseling by running a clinical reminder report and conducting electronic chart reviews.

3. Determine the impact of the GEM intervention on obesity-related counseling practices and attitudes in primary care providers.
    a. We will survey providers to measure 5As-related competency and attitudes about weight loss using validated survey items. [13] The feasibility and acceptability of the intervention will be evaluated using RE-AIM analysis.

II. Characteristics of the Research Population

Number of Subjects
With an expected 20% participation rate (based on pilot data) and a 75% retention rate (based on rates from another VA study and other technology-based interventions)[49,69], we will need to screen 2,615 eligible patients to enroll a baseline sample of 512 patients and end with 384 patients completing the study.

Gender of Subjects
Both male and female patients will be recruited as part of the weight management study being tested, and the study is not intended to be gender specific. Often, weight management studies include 70-80% women,[96] and men are often under-represented. However, we anticipate that 52% of our sample will be women since the VA has only 8-10% women.

Age of Subjects
Subjects between the ages of 18 and 69 years of age are eligible to participate in the study. The research study is not being conducted with children and thus subjects must

be at least 18 years of age. We are not including individuals older than 69 years of age as the published evidence is unclear whether weight loss should be a treatment strategy for obese older adults and also whether obesity might be protective against mortality in seniors. [109]

Racial and Ethnic Origin
We will not exclude any human subject based on race or ethnicity.

The following list the inclusion and exclusion criteria for our study population.

Inclusion Criteria
- Between the ages of 18-69 years of age,
- Body mass index of ≥30kg/m^2 **OR**
- Body mass index of ≥25 kg/m^2 with an obesity associated co-morbidity[67,68]
  - Hypertension
  - High Cholesterol
  - Sleep Apnea
  - Osteoarthritis
  - Metabolic Syndrome
- Under primary care team care with at least one prior visit with their provider in the past 24 months
- Access to a telephone, and ability to travel for in-person evaluations at baseline, 6, 12, and 24 months (optional for follow-up)

The BMI inclusion criteria aim to include participants with overweight/obesity. Those patients who are overweight should have obesity co-morbidity as this is an at-risk population for negative health conditions, similar to those with obesity.

Exclusion Criteria
- Patients who do not speak English or Spanish,
- Have active psychosis or require antipsychotic medication, psychoactive substance use, chronic rheumatic heart disease, other diseases of endocardium and cardiac dysrhythmia, Parkinson's disease, diabetes, or other cognitive issues
- Participated in MOVE!, DPP, or another intensive weight management program (>4 sessions) in the past year,
- Have a history of bariatric surgery,
- Are pregnant, breastfeeding or become pregnant during the intervention period,
- Have a provider who states they should not participate,
- Have self-reported inability to read at 5th grade level.
- Currently take weight-loss medications or diabetes medication that may impact weight change
- Receive chemotherapy or cancer treatment
- Had metastatic cancer in the last 6 months
- Does not want to lose weight

We are excluding individuals with any of the above listed conditions as this will likely impact their ability to fully participate in this study. Additionally, some of these listed health conditions may limit physical activity. As this intervention includes telephone weight management counseling and reviewing of printed weight management materials, we are excluding participants without a telephone or participants who cannot read material written at the 5th grade level or above.

We will use phone screen and EHR information to verify inclusion and exclusion criteria.

Vulnerable Subjects
No vulnerable populations will be included as part of this weight management intervention study.

III. Methods and Procedures

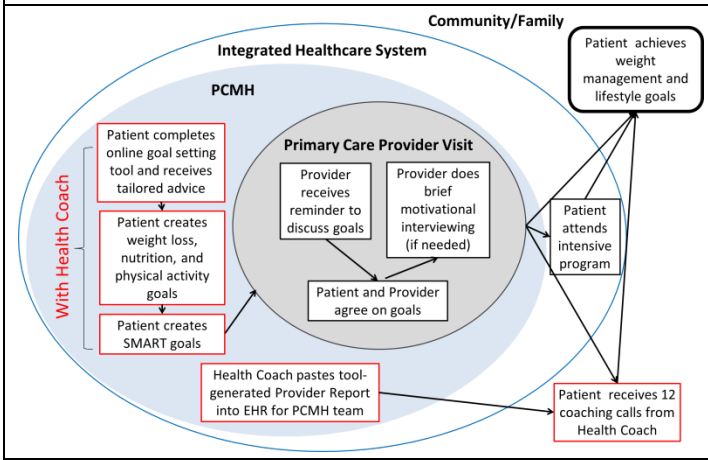
We will conduct a cluster-randomized controlled trial of the GEM intervention at two healthcare systems in New York City: The VA New York Harbor Healthcare System (Manhattan campus) and Montefiore Medical Group (4 sites affiliated with New York City Research and Improvement Networking (NYC RING) practice-based research network. Participants will be randomized at the team level (19 teams with approximately 28 providers and 512 patients to achieve a sample size of 384 patients at 12 month follow-up for the primary outcome assessment). The primary care teams will be randomized using a random number generator (block randomization with block size of four) to either the GEM Intervention or Enhanced Usual Care arms. Randomization will be stratified by healthcare system (MMG and VA).

Intervention Arm – GEM

The GEM intervention leverages the patient-centered medical home model (see Figure 1 below) by using the GEM tool to provide individually tailored, patient-centered care at the time of the primary care visit, promote standardized weight management counseling by health coaches and primary team members, coordinate care between teams and other weight management service providers/programs (e.g., dietitians, health educators, DPP), and provide feedback to the provider and primary care team about patients' weight management-related goals, progress, and care. Patients in the GEM intervention will complete the following (items 1–2 will be completed at the baseline visit). Average times to complete are included below based on pilot testing.

1. Complete the GEM tool (20 minutes)
2. Meet with a health coach and review tailored patient report and educational materials (30 minutes)
3. Meet with their primary care team for regularly scheduled visit (varies 15–45 minutes, 1–8 times/year)
4. Receive 12 telephone coaching calls from health coach (20–30 minutes each)
5. Follow up as needed with primary care teams (varies)

Figure 1: How GEM intervention fits within PCMH



❖ <u>GEM Tool:</u> If needed, health coaches will help patients to use the GEM tool. The online program is optimized for use on tablet computers and designed to support health coach and primary care team counseling. It assesses current behaviors, barriers, and facilitators to weight loss via a 16-item questionnaire, provides tailored advice, and guides patients to set weight loss (5–10%)[10], diet, and physical activity (PA) goals. It identifies intensive weight management programs and self-monitoring options, allowing patients to choose which to discuss with the health coach and primary care team. This tool also generates an individualized patient report, provides tailored educational materials, and produces a report for the primary care team through the EHR. Although developed initially for the VA, it can be customized for other healthcare systems with minimal programming.

❖ <u>Baseline Health Coach Visit:</u> After completing the GEM tool, a Health Coach meets with the patient for 30 minutes (based on our pilot study). Sessions will be audio-recorded for fidelity checks and health coach training. The Health Coaches will perform the following tasks:

- Make initial goals into SMART (Specific, Measurable, Attainable, Relevant, Timely) goals[63]
- Encourage participation (using MI) in MOVE, DPP, or community-based programs/gyms
- Teach how to self-monitor weight, diet, and PA behaviors via pedometer, food log, and/or weight management apps (e.g. MOVE! Coach mobile[70,71] on iPhones, My Fitness Pal[72] on Androids)

- Provide brief MI and Brief Action Planning[73] to address barriers and increase patient self-efficacy
- Facilitate meetings with extended team members (e.g. health educators, dietitians, primary care physicians) if needed
- Enter a report for primary care teams into EHR from the GEM tool
- Communicate potential barriers/concerns to the team at baseline visit and as needed throughout the intervention period (e.g., via EHR notes, secure messaging system, telephone, and/or team meetings)

❖ Telephone Coaching: To achieve sufficient intensity according to USPSTF guidelines,[10] we will incorporate 12 telephone coaching calls by a health coach over 12 months. Scheduled calls will occur every 2 weeks (biweekly) for months 1–3, monthly for months 4–6, and every other month (bimonthly) for months 7–12. GEM Intervention arm patients will receive a reminder call or an electronic reminder via MyHealtheVet or VA's Annie texting service to self-monitor their weight, food intake, and PA for at least 3 days prior to the coaching call. Studies suggest that episodes of short, consistent self-monitoring (for 3 days) reduce weight and may improve adherence.[74] Health coaches will use self-reported self-monitoring data (from pedometers, food logs, and smart phone apps) to determine goal adherence and counsel patients to encourage small changes.[49] Health coaches will document sessions in REDCap, help patients create new goals when appropriate, and use MI techniques to address barriers to behavior change. Patients will be able to contact health coaches via telephone for additional support. Patients will be reminded to discuss their goals during their next primary care visit (if scheduled).

❖ Provider Role: Providers in the GEM arm will provide 3–5 minutes of counseling, use clinical reminders to document this counseling, provide brief MI to address barriers (depending on time and patient needs), and discuss GEM-generated weight management goals during future visits. The GEM tool creates a report to communicate data to the participant's primary care team and generates a clinical reminder which facilitates documentation of primary team goal setting conversations and counseling.

Control Arm – Enhanced Usual Care (EUC)

Patients in the EUC arm will receive non-tailored weight management handouts by health coaches (Health Bulletins from the NYC DOHMH).[79–81] Patients will follow-up with their primary care teams as needed.

Data Collection

Patients: Assessment will occur at the following time points:

❖ At Baseline, 6, 12, and 24 months, patients will meet in-person or over the phone (for follow-up) with a research assistant (RA) to complete surveys; measure weight, height, blood pressure, and waist circumference. Baseline surveys will include a pre-survey (completed before receiving GEM Intervention/Enhanced Usual Care). Electronic chart review will also occur at these time points. The RA will administer all surveys and enter the data directly into our REDCap database. To compensate for

travel and time spent completing study measurements, patients will be given $25 dollars for the baseline study visit, $30 dollars for the 6-month study visit, $40 dollars for the 12-month study visit, and $50 for the follow-up 24-month visit and $20 dollars for the optional one hour opinion session and 2 follow-up phone calls. During the baseline visit we will encourage patients to sign-up for MyHealtheVet, if they haven't done. In addition, we will inform patients about the VA's secure Annie texting service and help them to sign up, if requested, as another option to receive reminder text messages for appointmentsIf patients are signed-up for MyHealtheVet, they can choose to receive reminders for their upcoming study visits or health coach phone calls electronically via myHealtheVet. Alternatively, patients can choose receive reminder phone calls from secure VA phones lines or via the secure Cisco Jabber application.. Before upcoming phone coaching calls and study visits, we will send reminders via the secure messaging system MyhealtheVet, VA's Annie texting service or make phone calls via secure VA phone lines or via the secure Cisco Jabber application.

- When performing telephone Coaching Calls (patients in GEM Intervention arm only), Health coaches will use a counseling tool that also facilitates data collection into REDCap database.
- Chart reviews 12 and 24 months post-baseline visit to explore maintenance of counseling post-intervention

Primary Care Teams: At 12 months, we will give surveys to providers, which will be administered in paper and then entered into our REDCap database. Alternatively, we will administer the provider survey online via REDCap. Furthermore, we will conduct qualitative interviews, and audiotape select visits.

Future Directions: In future versions of the GEM intervention we would like to add a visualization technique called Mental Contrasting with Implementation Intentions (MCII) that is utilized through an exercise called WOOP (Wish, Outcome, Obstacle, Plan). MCII is a novel, practical strategy that was developed and tested through 20+ years of research to promote motivation and behavior change, particularly for challenging behaviors.[110-115] In order to obtain data on feasibility and acceptability among Veterans without introducing the burden of an additional visit, we will invite up to 20 participants in either arm at the Manhattan VA site to participate in an optional one hour session at their 24 month visit for an additional $20. Veterans that agree to this additional session will be reconsented with the revised consent form describing this session. During this session they will receive training on WOOP and will be shown how to use the free downloadable WOOP app.[24] We will then ask them to share their opinions on WOOP and the app. We will not collect any information from the WOOP app and discussed this piece of the protocol with the Privacy Officers (Lindsay Dean and Chrissie Palividas). In addition to this training, we will ask each participant a few brief questions related to goal commitment and stage of change before and after the WOOP training. We will also ask permission to follow up via telephone at 3 days and 1 month after the training to see if they have used the technique to make any changes related to weight, diet or physical activity. The materials for this session can be found in Appendix F.

Data Analysis and Data Monitoring

First, all the 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) overall and by interventions arms, respectively. Then, 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 the interventions arms.

Impact of the GEM intervention on weight change, and clinical and behavioral outcomes: The primary outcome is mean weight loss at 12 months. Mann-Whitney tests for continuous outcomes (e.g., weight loss) and Fisher's exact tests for categorical outcomes (e.g., whether or not patients achieve ≥5% weight loss) will be used to compare the two intervention arms at 12 months. Unadjusted confidence intervals will be computed to compare the effects of the GEM intervention on outcomes with the effects of enhanced usual care on outcomes. Moreover, we will use repeated measures modeling, based on mixed models, to compare outcome variables between intervention arms, using all the data at baseline and three follow-up visits. Such modeling can adjust for baseline characteristics (e.g. diabetes, gender), taking into account: a) the correlation among patients within providers, and b) the correlation among repeated measures within patients. Model-based adjusted confidence intervals will be provided to also measure the effects of the intervention on outcomes. Although the repeated measures modeling can address missing data automatically, assuming it is missing at random, we will further use a multiple imputation procedure to conduct sensitivity analyses under the assumption of missing data not at 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.

Predictors of weight loss in the GEM intervention arm related to: a) goal setting processes and b) intervention components: We will use visualization tools, such as scatterplots and descriptive analyses (e.g., Spearman correlation coefficients) to display the association between weight change and potential predictors. Multivariate regression models will be used to examine the effects of those predictors, which we suspect will be associated with weight loss in the intervention arm. Multivariate linear regression models will be considered for continuous outcomes and multiple logistic regression models will be considered for binary outcomes. Missing data will be dealt with using inverse-probability-weighted methods.

Impact of the GEM Intervention on obesity-related counseling practices and attitudes in primary care providers: 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 intervention arms at each survey. Confidence intervals of the effects will also be computed.

Data Monitoring: There will be no formal data and safety monitoring board for this

protocol as there is only minimal risk associated with participation in the current study. The PI will monitor data and safety. Should unanticipated reportable events occur, defined as internal or external events (such as deaths, life-threatening experiences, injuries, breaches of confidentiality, or other problems) any time during or after the research study, which in the opinion of the PI are unanticipated, the PI will report them immediately to the NYU IRB. Any new information indicating a change to the risks or potential benefits of the research, any deviation from the protocol, and any possible serious or continued non-compliance will be reported to the NYU IRB by the principal investigator immediately.

Data Storage and Confidentiality

Storage of Subject Data: All subject data collected from the GEM online tool including survey responses and recording of responses while using the tool, interviews, focus groups, pre/post surveys, and measurements will be kept confidential and anonymous through de-identification. This signifies that subject names, dates of birth, and primary care provider names will be de-identified both in audio and written script during the transcription, segmentation, and coding process. Study session data will be entered into REDCap, which is a password-protected database. Subjects will each be given a study identification number, which will be stored in the password-protected database. Patient identifying information (e.g. subject name and date of birth) will be maintained REDCap, which is a password-protected database. All paper data will be kept in a locked, fire-proof file cabinet dedicated to the study that is kept in one of the study team's locked offices (15028BN, 15028AN 15028CN, or 15161N at the Manhattan VA).

Access to Subject Data: Only IRB-approved study personnel, including the Principal Investigator, Co-Investigators, Research Coordinator, and other research staff, will have access to the data for entry and analysis. Healthcare providers who are not key personnel will not be informed of any responses given by subjects during the study visit.

Retention of Subject Data: Subject data will be kept throughout the duration of the study and after the study has concluded to continue with data analysis. When data is no longer needed it will be disposed of appropriately via shredder in order to continue protecting subject confidentiality and anonymity.

IV. Risk/Benefit Assessment

Risk

Any research study has possible risks and discomfort and on a rare occasion, unknown and unforeseeable (unanticipated) risks may also occur. Participation in the study poses no more than minimal risks to the subject's physical and mental health as well as personally identifiable information. Subjects may experience frustration that is often experienced when completing surveys. Some questions may be of a sensitive nature, and subjects may therefore become distressed as a result. If, however, subjects become distressed by a question, subjects have the right to stop at any time or choose not to answer a question or certain questions.

The research team understands that discussing topics related to weight, diet, physical activity, and/or an individual's experiences with these topics can be emotional given the stigma surrounding obesity and its associated medical problems within society.

Protection against Risks

All members of the research team have been extensively trained in order to effectively facilitate conversations and minimize the level of discomfort that individuals may face when dealing with sensitive topics throughout the duration of the study. In addition, any potential behavioral changes related to diet or physical activity will be assessed and approved beforehand by properly trained individuals, which include the Principal Investigator, Co-Investigators, Research Coordinator, and other research staff.

To assure the minimization of any risks all aspects of the research study will be conducted in a private and safe setting. Subjects may withdraw from the study at any given point without having their regular care impacted at the VA or MMG. Protection against the loss of confidentiality will occur through securing all subject data in a locked study office and in a database that is on password-protected computer. As for employees who are participating, this research involves minimal risk for physical, psychological, social, and economic harm.

Potential Benefits to the Subjects

- ***Patients***: The patients who participate in the study will have the opportunity to receive weight management information and set lifestyle behavior change goals to improve their diet and increase physical activity, which may lead to weight loss and improved health outcomes. Even for patients who do not change their health behaviors, talking about these topics with trained researchers could serve as support or motivation to move them closer to doing so in the future.
- ***Providers, , and other VA or Montefiore employees***: Employees who participate in the study may gain improved obesity-related knowledge and patient counseling skills, which could enhance their career, job performance, and satisfaction. Specifically, employees may have the opportunity to receive (additional) training in 5As weight management counseling and practice brief motivational interviewing. Training in these could help to facilitate and/or improve discussions around weight management and health behavior change with patients, as well as encourage the use of individualized techniques to improve diet and exercise and setting health behavior change goals with patients.

V. Investigator's Qualifications and Experience

The CV for each key personnel involved in the study is included in the IRB submission. Modifications will be made when Research Assistants and Health Coaches are on-boarded. All key personnel have (or will have) completed online training in the protection of human subjects.

Summary of Research Personnel and Main Roles:

- Principal Investigator/Project Coordinator: oversees project implementation
  - Dr. Melanie Jay (PI)
  - Sandra Wittleder (Project Manager)
  - Victoria Sweat (Program Manager)
- Co-Investigators/Other significant contributors
  - Dr. Judith Wylie-Rosett: Health behavior Intervention expertise
- Research Staff
  - Research Assistants: Consenting, data management, protocol fidelity
  - Health Coaches: Health coaching patients and data collection

VI. Subject Identification, Recruitment, and Consent/Assent

Method of Subject Identification and Recruitment

- **Primary Care Teams –** Primary care teams at each site that meet the eligibility criteria below will be separately assigned a number using a random number generator, and the first seven teams selected at each site will enroll in the study for a total of 19 primary care teams (11 VA and 8 MMG). Individual providers will be allowed to opt out of the study. We do not anticipate that providers will drop out once enrolled, based on the VA PROVE study where all 18 eligible teams and 51/52 providers participated for the duration of the study.[65] While pods (at MMG) and PACTs (at VA) have variable numbers of providers and patients, we will recruit 2-3 providers from each team prior to randomization to ensure similar numbers of teams, providers, and patients in each arm. **Table 2** (below) provides an overview of the staffing/patient population for each site.

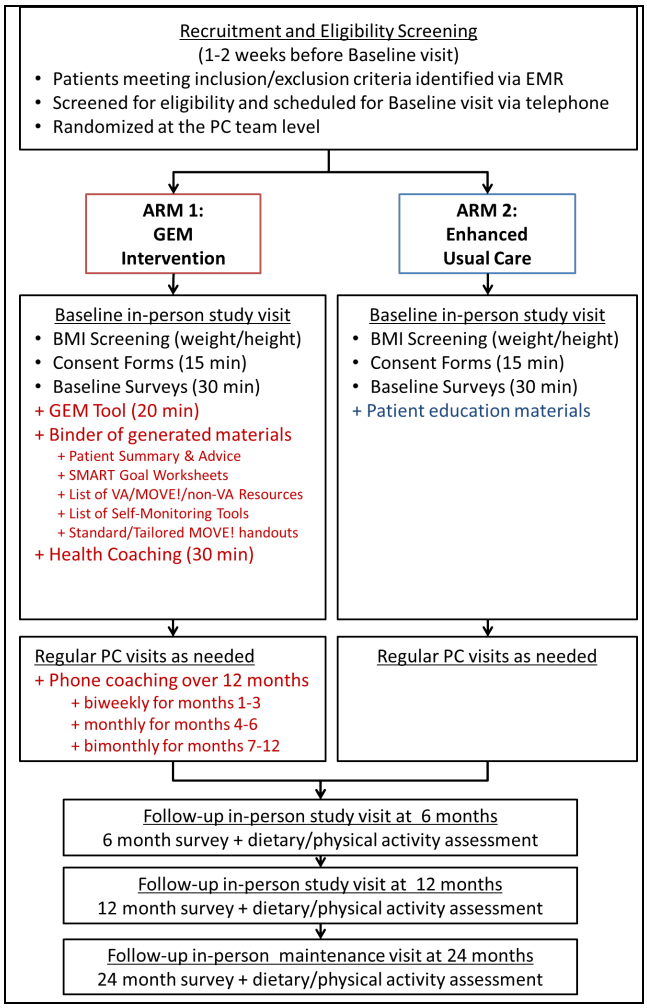
Table 2: Description of PC staffing and patient populations at each of the VA and MMG sites (Data from the VA PC Almanac as of May 2015 or from MMG site director budget reports)

Site	#Teams (Pods or PACTs)	# Providers	Total # Patients in PC	% Obese	% Female	% Hispanic or Latino
VA Brooklyn	12	24	13,219	32.7	11%	21%
VA Manhattan	11	28	13,813	26.7	8%	
MMG Bronx East	3	17	24,917	47.0	62%	38%
MMG Grand Concourse	2	11	17,841	41.0	67%	40%
MMG University Avenue	2	9	3,679	42.0	58%	79%
MMG Castle Hill	1	7	6,079	45.6	59%	58%

❖ **Patient Recruitment (Figure 2 below) –** Using the Patients Health Information Systems and Technology Architecture (VistA), the VA's Health Information Technology system, and the Montefiore EPIC and Clinical Looking Glass systems, we will identify patients with upcoming primary care appointments who meet the eligibility criteria. A Research Assistant (RA) will confirm eligibility by EHR and provider review. One to two weeks before their baseline visit, eligible participants will be sent a letter signed by both the Principal Investigator (PI) and giving them the opportunity to opt out (i.e., request to not be contacted). The RA will call patients to recruit, screen for eligibility, and schedule the baseline. This allows enough time for all intervention components to be completed, and is responsive to patient scheduling preferences expressed in a similar recruitment strategy used in the VA PROVE study[65] and our pilot studies.

Eligibility will be based on the inclusion and exclusion criteria established for the study. Participation in the study is completely voluntary and all prospective subjects may refuse to participate or withdraw from the study at any given time.

Figure 2: Recruitment and Eligibility Screening



Process of Consent

Consent will be obtained by a research assistant trained in consenting protocols. Once subjects have been identified as eligible, the study will be described in detail and informed consent will be obtained from subjects who wish to participate. An audio-video consent form will also be described in detail for subjects who agree to have their study session audio recorded.

Subject Capacity

In order for subjects to be eligible to participate in the study, subjects must have the capacity to give informed consent. Capacity will be assessed with the set of inclusion and exclusion criteria that has been established specifically for this study. In short, participants must be at least 18 years of age, have access to a telephone, be able to travel for in-person evaluations, and not currently have functional impairments that limit

physical activity.

Subject/Representative Comprehension
Research Assistants will be intensively trained in consenting protocols. RAs will assess comprehension by asking the subject whether the explanation of the information presented was understandable. The research assistant will be prepared to clearly summarize each section and will answer questions the subject may have about the consent forms. A copy of the consent form will be available for the patient to take home with them or will be sent to them.

Debriefing Procedures
For this particular weight management intervention study, no information will be purposely withheld from any of the subjects who are recruited and/or are actively enrolled in the study.

Consent Forms
For the patient participants, two consent forms will be used: the research subject informed consent and audio-video consent forms. For provider participants, completion of the survey will serve as implied consent. On the first page of the survey, it will explicitly state that participation is voluntary and that completion serves as consent. A waiver of documentation of informed consent was requested for the provider survey For provider participants, who chose to participate in qualitative interviews, we have a separate research subject informed consent form.

Documentation of Consent
Written consent will be obtained from all patient subjects who are eligible and agree to participate in the study and for provider subjects who chose to participate in qualitative interviews. Documentation of consent will be securely stored in the research team's locked office on 15 North (15028CN) at the Manhattan VA Hospital.

Costs to the Subject
There will be no costs to the subjects for participating in this study. However, medical care and services provided by subjects' current health care facility that are not part of the study, which includes normal visits and prescription expenses, may require payment.

Payment for Participation
To compensate for travel and time spent completing survey measures and basic measurements, study participants will be given cash or a ClinCard in the amount of 25 dollars for the Baseline study visit, 30 dollars for the 6 month visit, 40 for the 12 month visit, and 50 dollars for the 24 month study visit and 20 dollars for the optional opinion session at the same 24 month study visit for up to a subset of 20 participants. This proposed payment is reasonable and commensurate with the expected contributions of participants and is meant to provide additional incentives for participants to complete all 4 study visits. This amount of payment and the terms of the payment are included in the informed consent form. This payment is fair and appropriate and does not constitute

undue pressure or influence, or coercion of, the prospective research participant to volunteer for or continue participation in the research study.

VII. List of Appendices

1. Appendix A - Recruitment Protocols and Materials*
2. Appendix B – Data Collection Surveys*
3. Appendix C - GEM Online Tool Screenshots*
4. Appendix D – GEM Personalized Binder Materials
5. Appendix E - Health Coaching Training Materials and Protocols*
6. Appendix F – WOOP Materials

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