**TITLE: Improving Weight Management at the VA: Using the MOVE! Toward Your Goals tool in Primary Care (Awardee/ PI: Melanie Jay, MD MS)**

**SPECIFIC AIMS**

Veterans shoulder a disproportionate burden of obesity and its co-morbidities, including diabetes, hypertension, and hyperlipidemia. Modest weight loss in obese patients through diet and exercise improves health and prevents chronic disease, but primary care providers (PCPs) often fail to adequately counsel patients about their weight due to lack of time and training. Thus, tools and brief interventions are needed to support providers' behavior change counseling. The VA currently offers the MOVE! program to treat overweight and obese patients, but only 9% of eligible patients attend. At the same time, Veterans on average see their PCPs 3.6 times per year, which supports the importance of developing primary care (PC)-based interventions. The United States Preventive Services Task force (USPSTF) recommends the use of the 5As framework (Assess, Advise, Agree, Assist, Arrange) for counseling patients about weight.

Interactive behavior change technologies utilizing expert system software programs are an innovative way to facilitate 5As counseling to promote behavior change in primary care. These programs perform computerized risk, lifestyle, and theory- based, behavioral assessment to provide computer-generated, tailored advice to patients. They also can provide information to healthcare teams. The MOVE!11 software is an expert system program for VA patients referred to MOVE!, but is not currently used in primary care by Patient-Aligned Care Teams (PACT).

Collaborative goal setting can be used to achieve behavior change in this intervention. This construct, a critical component of several behavior change theories and models and corresponding to "agree" in the 5As model, has been widely recommended for health promotion in primary care. Our formative work (MIRB #01333) using key informant interviews with PACT teamlets and MOVE! staff and focus groups with Veterans demonstrated that goal setting is feasible and acceptable to patients and PACT teamlets and provided insight on barriers to goal setting, and ways to facilitate goal-setting conversations.

During the development phase of this project, we developed a primary care-based intervention called MOVE! Toward Your Goals (MTG) to facilitate weight management within primary care and increase adoption of intensive VA programs such as MOVE!. The MTG intervention uses a new MTG software tool (that we developed) delivered on tablets to facilitate 5As-based weight management counseling with a health coach and healthcare team to promote goal-setting, behavior change, and weight loss in the primary care setting. The Veteran also receives follow up with 10-15 health coaching calls over 1 year.

As part of a pilot study for a larger, multicenter trial, we will randomize 160 subjects to receive either Enhanced Usual Care or the MTG Intervention.

**Primary Aim:** To explore differences in feasibility, acceptability, and intermediate, behavioral, and weight loss outcomes at 3, 6 and 12 months pre- and post-intervention between the MTG intervention and Enhanced Usual Care. We will explore differences within each arm and compare the 2 intervention arms.

**Hypothesis:** Among obese VA PC patients in an urban primary care practice, a brief, interactive computer- assisted intervention will result in significant improvements in intermediate (self-efficacy, intention, and motivation to change lifestyle behaviors), behavioral (diet and physical activity improvements, adherence to MOVE!), and weight loss outcomes at 3, 6 and 12 months.

**Exploratory Aim:** To compare the intervention arm to a third study arm of non-enrolled PC patients matched for age, gender, and BMI ("Usual Care").

**RESEARCH PLAN**

## A. BACKGROUND/SIGNIFICANCE

- ### VETERANS/OBESITY

    The burden of obesity among Veterans is substantial, and modest weight loss can have significant benefit. The majority of Americans are either overweight or obese[1] and obesity is associated with higher mortality.[2] Approximately 36-37% of patients seen at the VA are obese,[3,4] and obese patients have a high degree of chronic disease. For instance, 84% of obese Veterans have hypertension, 78% have hyperlipidemia, and 45% have diabetes.[4] Modest weight loss (7%) via a 16-session program can reduce the risk of diabetes in high-risk patients by 58%.[5] Thus, the United States Preventive Services Task Force recommends that all patients are screened for obesity and offered intensive lifestyle counseling.[6]

    The VA offers the MOVE! program, an intensive lifestyle behavior change program, nationally. Patients who attended 2 or more MOVE! sessions lost 2.6 pounds more over 6 months than matched controls.[7] They were also more likely to have clinically significant (>5%) weight loss (19% vs. 12%) and less likely to gain weight (29% vs. 38%).[7] Another study of MOVE! demonstrated improved weight loss trajectories (-1.6kg/yr) compared to weight gain (+2kg/yr) prior to enrollment.[8] Unfortunately, many obese patients are either unwilling or unable to attend intensive weight management programs, and barriers are poorly understood. Only 8% of eligible patients attend at least 1 MOVE! visit[9]. While this is partly due to poor patient adherence to the MOVE! program, another reason is variable implementation of MOVE! across VA sites. In addition, while one of the goals of the MOVE! program was to integrate weight management into primary care (PC), in practice, this program often operates more like a specialty service where treatment is provided outside of the PC visit or setting where patients receive frequent care.
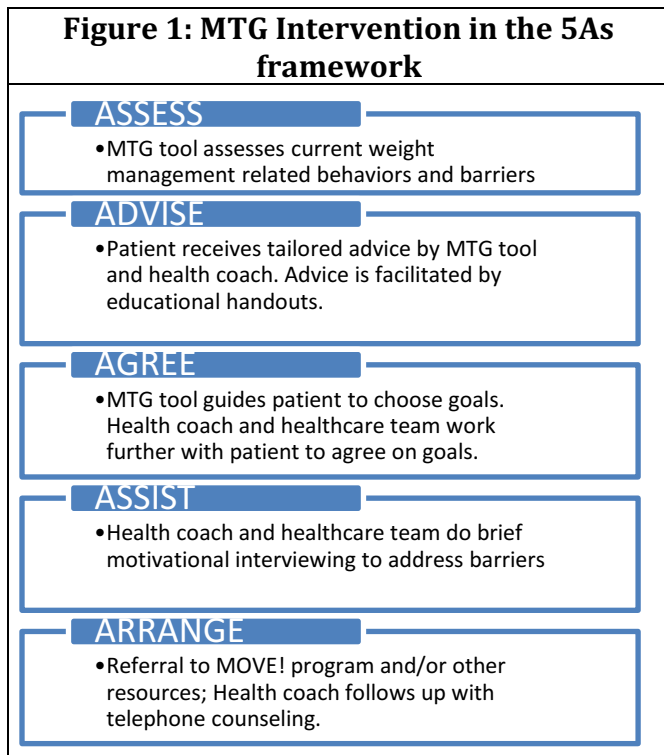
- ### PACT

    The PC setting is critical to reducing the burden of obesity; primary care-based interventions have a broad potential reach. The VA/Department of Defense (DOD) guidelines for screening and management of overweight and obesity recommend that providers treat all patients with obesity.[10] Veterans in the VA system see a primary care provider (PCP) an average of 3.6 times per year,[11] providing multiple opportunities for weight management counseling and referral to MOVE!. PC is an important venue to promote weight loss, and effective PC-based interventions can have a significant public health impact. Physicians' and other providers' counseling is associated with positive behavioral and weight-loss outcomes.[12,13] However, PCPs frequently fail to effectively counsel obese patients to lose weight.[14,15] This is due to lack of training,[16] poor competency,[17] perceived lack of effectiveness,[18] and competing demands on time during the medical visit.[19] PCPs may fail to recognize that a patient is obese. In a recent study, only 53.5% of obese patients at the VA had an obesity diagnosis in their electronic medical record.[4] Those that had a diagnosis of obesity were much more likely to receive counseling.[4] Thus, interventions are needed to support physicians' and other providers' obesity identification and counseling.

    To improve counseling opportunities and enhance care coordination during a primary care visit, the VA adopted a patient centered medical home model called Patient Aligned Care Teams (PACT) in 2010. The PACT model provides a team-based, patient-centered approach to health care that utilizes a multidisciplinary practice team that includes a RN Care Manager, a Clinical Associate (LPN), and Administrative Associate, and the primary care provider (the "teamlet") as well as social workers, dietitians, and specialists (other team members) to deliver patient-centered care.[9,20] This recent implementation of PACT provides the opportunity for longitudinal, team-based care that is integrated with the MOVE! program. However, in the 2013 MOVE! progress report, the majority (55%) of VA sites surveyed reported that MOVE! programs were separate from PACT.[21] Improving weight management counseling by PACT teamlets could increase patient motivation to attend the MOVE! program and facilitate weight loss for those who do not attend.

- ### THE 5As

    The United States Preventive Services Task Force (USPSTF) recommends that providers use the 5As framework to counsel patients for weight management. This model, which has been shown to promote weight loss and smoking cessation,[22,23] guides the provider to Assess risk and stage of change, Advise weight loss and behavior change, Agree on goals, Assist via addressing barriers (motivational interviewing), and Arrange to follow-up or refer patient for further

treatment.[24] Our previous work has allowed us to determine which aspects of the 5As framework need to involve the healthcare team (e.g. agree and assist) and also identified which are particularly time-consuming (assessing multiple behaviors and providing advice).

### Figure 1: MTG Intervention in the 5As framework

**ASSESS**
- MTG tool assesses current weight management related behaviors and barriers

**ADVISE**
- Patient receives tailored advice by MTG tool and health coach. Advice is facilitated by educational handouts.

**AGREE**
- MTG tool guides patient to choose goals. Health coach and healthcare team work further with patient to agree on goals.

**ASSIST**
- Health coach and healthcare team do brief motivational interviewing to address barriers

**ARRANGE**
- Referral to MOVE! program and/or other resources; Health coach follows up with telephone counseling.

Computerized interventions may be effective in helping deliver 5As-based obesity counseling in the primary care setting. Interactive behavior change technologies use expert system computer software to evaluate patients' risk and current behaviors (assess), and then generate personalized, tailored behavior change advice (advise).[25] They have the potential to help providers counsel obese patients[25] and have been shown to facilitate goal setting (agree) and lifestyle behavior change in primary care settings,[26,27] but have been criticized for not including active provider counseling.[26,27] Patients want and expect their primary care providers to deliver lifestyle and weight-loss counseling[28] and may be more likely to change their lifestyle behavior when counseled by their own provider.[16] Further, patient-provider communication has been directly linked to adherence and health outcomes.[29] **Figure 1** shows how the MTG intervention corresponds to the 5As framework.

- **GOAL-SETTING**

Goal setting is a critical component of the MTG intervention , corresponds to the "Agree" component of the 5As framework[24] and is associated with effective weight management.[26,30] Effective weight loss interventions need to include the patients' perspective, and having them set individualized goals is a strategy supported by many behavior change theories including the Theory of Planned Behavior.[31] Based on this theory, having an intention to change a behavior predicts behavior change. Thus, forming specific goals or "goal intentions" increases the likelihood of behavior chage.[32,33] Goal setting is also commonly used to promote behavior change in primary care settings[34] and fits well into other behavior change theories and models including the chronic care model,[35] chronic disease self-management programs,[36,37] and social cognitive theory.[38] A systematic review of goal setting for lifestyle behavior change in primary care showed that it was effective in promoting diet and physical activity changes.[38] Another systematic review showed that technology-assisted interventions combined with counseling promoted weight loss.[39] Thus, technology-assisted goal setting has the potential to overcome barriers and facilitate weight management.

Health-related goals can be general (losing weight, exercising more) or specific (substituting water for soda, attending a weekly aerobics class).[34] Goals can be assigned by a health care provider or set collaboratively. [34] Current goal setting theory, much of which is derived from occupational psychology literature, states that to maximize goal attainment, behavior change goals should be specific, difficult, proximal, and set collaboratively with the provider.[34,37,40,41] However, less is known about how to best apply goal setting to the primary care setting at the VA or the specific socioeconomic,[42] environmental, nutrition knowledge and behavior,[43,44] and health literacy factors[45] that may affect goal setting processes and outcomes. Prior to our own qualitative studies (see below), a review of the literature revealed no studies examining the barriers, preferences, and facilitators to goal setting in obese VA patients. We used this information to optimize the goal setting process for the intervention.

- **RELEVANCE OF PROPOSED RESEARCH TO VA**

The VA is a national leader in providing comprehensive obesity screening and treatment programs. The VA currently screens all patients for obesity, and high-risk overweight and obese patients are referred by their provider to the MOVE! program to receive comprehensive obesity counseling. Performance measures from the Office of Healthcare Transformation (OHT) stipulate that screening for BMI and offer of referral to MOVE! occur for all eligible patients ( the average screening and referral rate is 94%) . The MOVE!11 questionnaire is currently used primarily by the small subset of patients who attend MOVE! programs (use varies by institution). However, this tool is not currently used for PC patients outside of the MOVE! program, and our own formative research showed that it needed increased
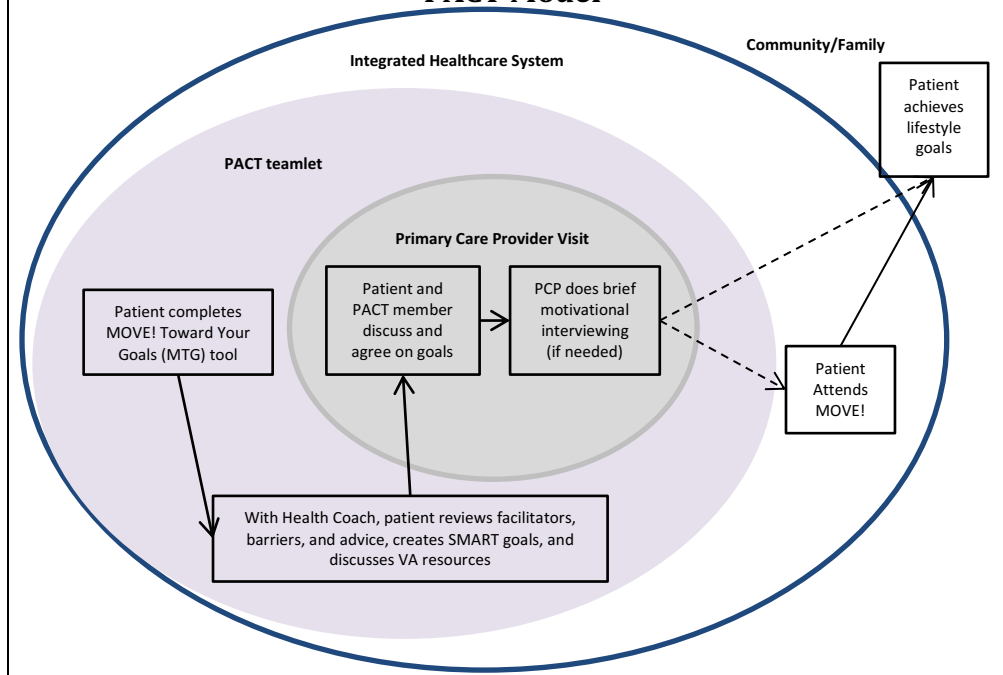
functionality in order to help patients use the tailored advice to set behavior change goals.

- **THE MOVE TOWARD YOUR GOALS INTERVENTION:**

To address this need, we developed the MOVE! Toward Your Goals (MTG) tool, a weight management and goal setting tool based on the MOVE!11 software, to support obesity management during the primary care visit. This tool has the potential to reach a greater percentage of individuals and may promote increased attendance to more intensive treatments (i.e. group therapy, individual counseling, TeleMOVE!) available through the MOVE! program. The MTG tool is designed to be part of a 5As, PC-based intervention withinPACT. Based on our preliminary studies (described below), our intervention will include training appropriate members of the PACT teamlets (PCPs, nursing staff) as well as health coaches to facilitate goal setting and deliver brief, targeted motivational interviewing to address ambivalence and resistance when necessary.

**Figure 2** below illustrates how we will use the MTG intervention within the PACT model to improve delivery of obesity care (based on preliminary studies described below). The patient completes the MTG tool (described in more detail below) prior to a PC visit with the assistance of a health coach. The tool facilitates goal setting conversations by guiding the patient to answer questions about weight, barriers to weight management, and current behaviors. It then provides tailored advice, guiding patients to create initial weight, nutrition, and physical activity goals. The tool then generates a personalized report, goal setting worksheets, and tailored educational materials. The health coach and patient use these tools to collaboratively refine and discuss specific behavior change goals. A provider report and the patient's preliminary goals are automatically sent to the practice team through a CPRS research note. After checking in for a scheduled primary care visit, the patient meets with their RN Care manager and PCP who review the tailored advice with the patient and review the goals. Either the RN care manager or PCP collaboratively refines and/or endorses the goals and does brief motivational interviewing to address barriers to achieving the goals. They also document these goals in CPRS so that they can be addressed during future visits. The patient then has the option of attending the MOVE! program and/or goes back to the community/family to work toward his or her behavioral weight management goals. The health coach or other member of the PACT team then calls the patient regularly to follow up on the patient's goal attainment (or lack of) will be addressed at subsequent visits.



**Figure 2: How the MTG Intervention Can Be Incorporated into the PACT Model**

**B. PRELIMINARY STUDIES**
- **PFIZER STUDY**

Usability Study with Latinas: We conducted usability studies of the MOVE!23 software with Latina women with various levels of computer literacy to work with the MOVE!23 software application (earlier version of MOVE!11) and materials, provide feedback about its design, and explore its potential application in creating weight management goals. Although generally well received, we found the MOVE!23 software was only marginally effective at facilitating goal setting. Patients had difficulty understanding some of the questions and interacted with the tool more readily when its language was familiar and content was personally relevant. When faced with ambiguity and uncertainty, they relied on the tool's visual cues and examples, actively sought relevant personal experiences, and/or requested facilitator support. Additionally, they appreciated the tailored health advice that the software provided, but failed to recall information needed to create goals and build a weight management plan. This study highlighted the need to develop a new software

component to facilitate goal setting. Although we did not conduct usability studies of the MOVE!23 with a Veteran population, many of our findings still applied and informed the development of our intervention.

- **CAREER DEVELOPMENT AWARD STUDY – FORMATIVE PHASE 1**

Key Informant Interviews: We conducted semi-structured key informant interviews with VA employees working within PACT and MOVE! and key administrative staff. The purpose of these interviews was to assess: 1) current attitudes and perceptions regarding obesity care; 2) obesity-related counseling practices 3) perceptions and experiences with the MOVE! program; and 4) targets for interventions to improve implementation of obesity care in the PC setting. We found that perceived role among PCPs was influenced by training, whereas personal experience with their own weight management impacted role perception among LPNs/RNs. Attitudes about whether or not they could impact patients' weight outcomes via counseling or referral to MOVE! varied. System-level communication about VA priorities through electronic health records and time allocation influenced teams to prioritize referral to MOVE! over weight management and lifestyle behavior change counseling. Overall, we found a diversity of attitudes, and practices within PACT, and identified factors that can enhance MOVE! implementation and inform interventions to improve weight management within PC. Most importantly, this study highlighted PACT teamlet barriers to obesity care and thus, we decided to train and incorporate health coaches in our intervention rather than rely exclusively on the PACT teamlet to help set initial weight management and lifestyle goals.

Patient Focus Groups: We conducted focus groups with Veteran patients to assess: 1) attitudes, barriers, and facilitators to healthy behavior change; 2) uses and understanding of goal setting; and 3) weight management-related experiences with health care providers in the PC setting, technology, and the MOVE! program. We found that military service continued to impact Veterans' lifestyles even years after service. We also identified individual/interpersonal-, community/environment-, and healthcare system-related factors affecting healthy behaviors. We found that Veterans want counseling and weight management advice from the health care team to be tailored to their individual preferences and needs. Findings from this study support offering more opportunities for weight management counseling within PACT teamlets where Veterans are seen frequently. Additionally, many of Veterans have used technology to assist in making health decisions and/or managing their weight, supporting the use of incorporating technology, particularly tablet computers as opposed desktop computers, into weight management interventions as long as there is adequate support or alternatives.

- **CAREER DEVELOPMENT AWARD STUDY – DEVELOPMENT PHASE II**

MTG Tool Development and Usability Testing: Based on findings from our Formative Phase I studies, we developed an interactive online tool, MOVE! Toward Your Goals (MTG), to facilitate goal setting for lifestyle behavior change within the PC setting at the VA, as well as conducted usability testing to further refine this tool and understand best strategies for its use among Veterans. It was designed at a 5th grade literacy level with low text density per page and simple navigation. The MTG tool uses the following algorithm: The patient completes a questionnaire about weight, barriers to weight loss, and lifestyle behaviors; each answer generates tailored weight loss or behavior change advice. The patient then indicates how much weight he or she wants to lose and assigns a number (1-10) indicating the perceived importance of each piece of advice. Based on this information, the tool guides the patient to choose a weight loss goal, up to 2 nutrition goals, and a physical activity goal. The tool then provides links for the health coach (or healthcare team member) to print out an individualized patient summary (health advice and initial goals), SMART goal setting worksheet, VA weight management resources, tailored educational handouts, and a report for the coach. The role of the coach is to help the patient make the goals "SMART" (specific, measurable, attainable, relevant, and time-based), address potential barriers, and link the patient to more intensive VA and community resources.

Usability testing of the MTG tool with Veterans suggested that the MTG tool can facilitate collaborative goal setting. Veterans appreciated the clean visual layout, the in-person support while using the tool, and had a strong positive reaction to the health coaching session and personalized binder of printouts. They left the session feeling motivated to work on their goals. Barriers to tool use were identified including problems with tool navigation, tablet use, and unclear wording of some questions. These informed iterative changes and refinement of the tool.

5As Intervention Development: As part of our Formative Phase I studies, we conducted Veteran focus groups and interviews with key VA PACT and MOVE! staff to assess a proposed brief intervention based on the 5As where patients use an online tool to create health goals and then bring these goals and advice discussed with their health coach to members of the PACT teamlets during their primary care visit.). Participants were also asked about their experiences with goal setting, weight management, and technology. Both Veterans and VA staff held positive views toward the use of goal setting for healthy behavior change and stressed the importance of social support in achieving goals. Veterans and staff appreciated that the intervention would provide individualized counseling from the healthcare team to achieve goals. Veterans did not want technology to replace human support. Physicians and nurses felt that time constraints would be a barrier to implementation, indicating that they could not spend more than 3-5 minutes on weight management. As a result, the revised intervention will use health coaches to provide support for the online tool and initial counseling about weight loss and lifestyle goals to allow the healthcare team to focus their time on brief counseling to address barriers and endorse goals.
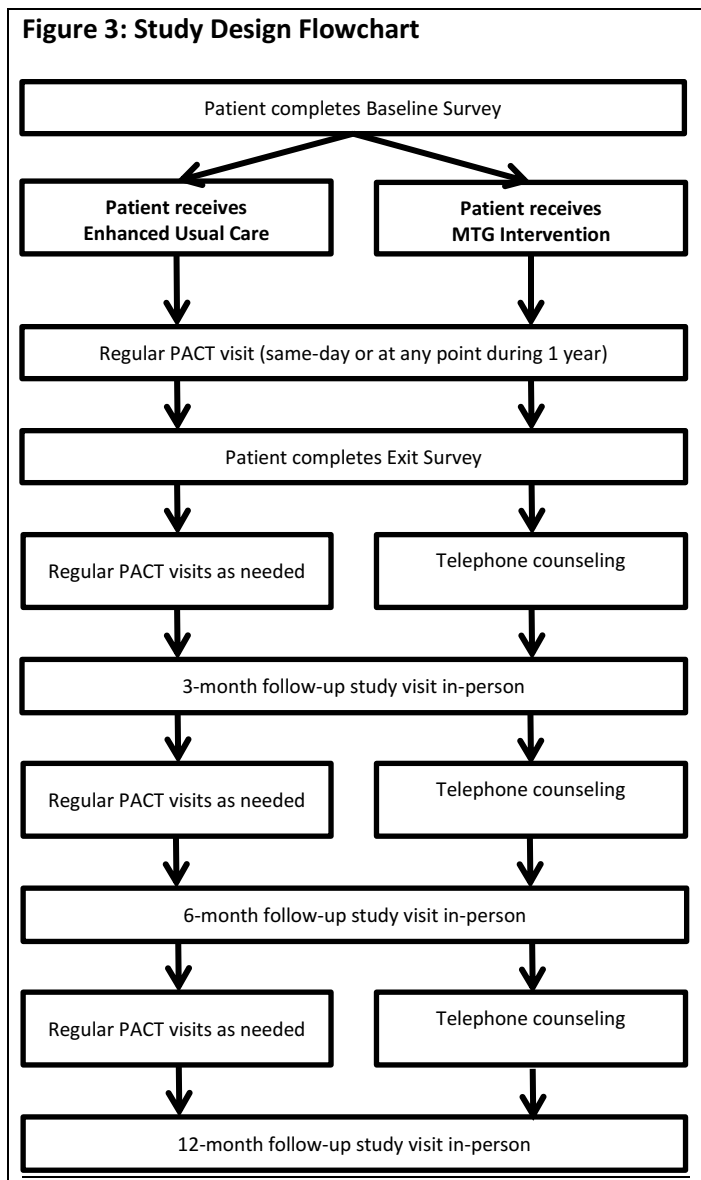
Based on this formative work, we have developed the following components of the intervention and measures: (subject to change based on the results from our ongoing pilot testing):

- Pre-/Post-surveys: We developed survey measures to be taken before and after the MTG tool to gather demographic information, as well as assess computer use, knowledge/participation in MOVE! programs, experiences with PACT, health literacy, their social/physical environment, quality of life, social support, level of patient activation, motivation to lose weight, self-efficacy, diet, and physical activity behaviors. Most of the question items are taken from validated measures.

- Health coaching Training: The literature supports the use of patient navigators or health coaches[46] who will help patients refine their goals and teach them how to discuss their lifestyle goals with their provider. At the Manhattan VA, RN Care Managers within the PACT teamlets currently receive training related to motivational interviewing and behavior change. Although our initial plan was to train RN Care Managers, based on our formative work, we found that RN Care Managers at the VA have very limited time to discuss lifestyle goals and behavior change with patients. Thus, we will be training research team members to be Health Coaches to guide patients through our intervention, specifically to use our MTG tool, review tailored advice, and assist patients with setting initial weight loss and behavior change goals. Specifically, health coaches will receive training in motivational interviewing, the 5As framework for obesity counseling, as well as MOVE! training to learn and thus advise patients about to the different weight management programs and resources available to them at the VA.

- Brief provider counseling training: After patients complete the MTG tool and create goals with their Health Coach, patients will briefly discuss their goals with their RN care manager or primary care provider who will endorse and/or improve upon the initial goals and address barriers at each visit. We will shorten and adapt a 5-hour obesity curriculum [47,48] that currently teaches obesity management, goal setting, and motivational interviewing to incorporate the current attitudes of the providers and the preferences, facilitators, and barriers of the patients into the curriculum. This will include role-playing and supervised practice of delivering brief counseling within a reasonable time frame for standard primary care visits. An academic detailing approach will be used to train PACT members in order to tailor the curriculum to each individual.

- CPRS Research Note/Reminders: The MTG tool creates a provider reported that will be cut and pasted into CPRS as a research note to summarize and communicate to the patient's PACT team the weight management discussions and initial goals agreed on between the patient and health coach. It includes the patient's self-reported BMI, risk-level, importance/confidence in controlling weight, level of social support, weight loss goal and SMART nutrition and physical activity goals, barriers, current behaviors, and interested VA resources. Completion of this note generates a reminder within CPRS for the PCP or RN care manager to read the research note, document whether they discussed the goals, resources, and barriers, and also document any additions or changes to the weight management plan. This research note and reminder system will also be used to document Health Coach telephone counseling as well as subsequent primary care visits by the patient.

- Developing telephone counseling model: The U.S. Preventive Services Task Force recommends providing more than

monthly counseling sessions within the first three months.[6] To increase the likelihood of achieving meaningful patient weight loss, we will incorporate 10-15 telephone counseling sessions over 12 months. Most successful PC-based counseling interventions have between 5-16 interactions within a 9-12 month period. Health Coaches will be trained to call to review the patients' goal and personalized advice, monitor goal adherence, set new goals when appropriate, and use motivational interviewing techniques to address barriers to behavior change. This is an optimal way to increase the impact of the intervention since higher frequency interventions are associated with better weight loss outcomes[49,50] and frequent goal setting is more effective.[30] Further, telephone contact may be just as effective as face-to-face contact and is more cost-effective.[49] Increasing the proportion of telephone visits is one of the T21 transformational initiatives and will become standard of care. A subset of participants will receive video conferencing calls instead of traditional telephone counseling to assess feasibility of this method of interaction as well.

## C. RESEARCH DESIGN AND METHODS

**Figure 3: Study Design Flowchart**



- **OVERVIEW**

The first 10-12 participants in the MTG intervention will not be randomized to ensure that the intervention can be implemented within PACT. We will then conduct a randomized, controlled pilot study in the VA NYHHS primary care clinic to test the feasibility of implementation and acceptability of the MOVE! Toward your Goals (MTG) intervention for patients and providers. There are two distinct phases of the randomized intervention: Pilot Phase 1 and Pilot Phase 2. We will assess intermediate (e.g. self-efficacy, goal attainment, motivation to lose weight), behavioral (diet and physical activity) outcomes, and weight loss at 3, 6, and 12 months. Pilot Phase 2 is a continuation of Pilot Phase 1, however the methods of recruitment and sequence of events will be modified to maximize ease and enrollment.

In both phases, we will train participating PACT teamlets and health coaches to facilitate goal setting and conduct motivational interviewing to facilitate goal setting and conduct brief telephone counseling so that they can deliver the intervention. We will recruit primary care patients and randomize to either receive the MTG intervention or Enhanced Usual Care. On the first Baseline study visit, all participants will complete a Baseline Survey and obtain weight and height measurements.

Those in the MTG intervention group will then complete the MTG tool on a tablet computer, receive a binder of personalized materials generated by the tool, and receive a 15-20 minute counseling session about weight loss and lifestyle goals with a Health Coach (research team member). Participants randomized to the Enhanced Usual Care control will receive a handout about local MOVE! programs and selected VA MOVE! and Healthy Living Message handouts related to weight management.

After this Baseline study visit, participants in the MTG intervention group will receive 10-15 follow up counseling phone calls with the health coach to review goals over a 12 month period. In Pilot Phase 1, participants will meet with their PCP during their regularly scheduled visit before taking an exit survey. In Pilot Phase 2, participants will meet with their PCPs at any point during the course of the one year intervention. During the visit, RN care managers and the PCPs will be prompted in CPRS to read a CPRS Research Note entered by a Health Coach. It will summarize the

interaction/discussion with the patient during the Baseline study visit, as well as any goals made or barriers discussed with the health coach (if the patient was randomized into the MTG Intervention arm). The PACT member may briefly counsel patients about lifestyle and weight. The PACT member will summarize this interaction in a specific CPRS note. Following the PCP visit, patients will be asked a series of questions about their experience during their baseline appointment (Pilot Phase 1) or at any of the follow-up research visits at the 3, 6, or 12 month mark (Pilot Phase 2). For all participants, we will measure intermediate and behavior change outcomes at 3-, 6- and 12-months via an in-person study visit. **Figure 3** shows a flow diagram of the study.

- ● **DESIGN**

Inclusion and Exclusion criteria of study participants: Criteria will include: aged 21-70 (this age range represents 96% of MOVE! participants [51]) and a Body Mass Index of ≥30kg/m$^2$ or a Body Mass Index of ≥25 with two or more co-morbidities based on NIH weight loss guidelines.[52] Individuals with a documented current history of substance abuse, diabetes, active psychosis, cognitive impairment, severe arthritis, valvular disease, cardiac arrhythmia, pregnancy, or other conditions limiting physical activity will be excluded. Patients who say they cannot read, do not have access to a telephone, and/or will not be available to be contacted at 3, 6, and 12 months for follow up will also be excluded.

Study Sites: The study will be conducted at the New York Harbor VA HCS. In 2009 and 2010, there were 16,000 total unique patients in primary care with 6,989 (44%) made by patients with a diagnosis of obesity. The Manhattan campus has 22 FTE primary care providers and 14 PACT teamlets with attending providers. Joseph Leung, MD, Director of Primary Care and other local PACT and MOVE! leaders have approved this study design and are supportive of PACT teamlet and patient participation in this study.

Time Frame: 12 months intervention, 2 year follow up.

Patient recruitment overview: We will recruit a consecutive sample of up to 160 overweight/obese patients (120 subjects who complete intervention assuming 25% patient dropout) from the VA primary care clinics. Since this is a pilot study, we may opt to stop recruitment earlier if study proves to be feasible and/or funding is obtained for a larger, cluster randomized efficacy study of the intervention. For Pilot Phase 1, we will obtain an electronic list of obese patients with appointments in the next month for participating providers and the RA will review charts for further eligibility. Lists of eligible patients will be sent to their respective primary care providers who will be asked to determine if any of the patients are medically ineligible to participate (e.g. have a condition where the PCP does not want the patient to engage in lifestyle behavior change). Potential participants will then be sent a letter from both the PI and their PCP describing the study and giving them the opportunity to opt out (i.e. request not to be contacted). Eligible participants will then be offered participation in the study via telephone. This recruitment strategy has been used by my mentor, Scott Sherman, MD, MPH, and was approved by the VA IRB.

For Pilot Phase 2, we will allow for participating PCPs to refer patients to the study. PCPs will be allowed to contact members of our team via phone or email with the contact information of patients they feel are a good fit for the study. As in the previously mentioned strategies, we will send letters to patients before contacting them by phone to explain the intervention, run through eligibility criteria, and review their medical charts. We will ask these PCP referred patients for permission to review their medical chart to determine medical eligibility. These patients will also be informed that they can opt out of receiving information by calling us.

For Pilot Phase 2, we will contact patients from an electronic list of overweight/obese patients who have been seen by their PCP in the past six months. From this list, we will mail out batches of recruitment letters (i.e. approximately 100 letters per week) to let patients know that they might be eligible to participate and that they can call us for more information at our study line. As in the aforementioned recruitment strategy, we will inform patients that they can opt out of receiving information by calling us.  We will also highlight that we have to ask eligibility questions by phone to make sure they can participate. Importantly, before we call, we will e-mail their respective PCPs to ensure that patients are medically eligible. After PCP approval, we will contact patients by phone to explain the intervention, run through

eligibility criteria, and review their medical charts. We will ask all patients on the phone if it is permissible to review their medical chart to determine medical eligibility.

PCP and Health Coach Recruitment and Training Overview:
We will invite 3-10 PCPs to participate in the pilot study by presenting at staff meetings and via word of mouth. We will then ask the RN care managers and LPNs on their PACT teamlets if they would like to participate as well. Only those willing to participate will be included in the study and receive training. The training will be less than one hour and scheduled either one-on-one or in small groups so as not to interfere with their VA clinical or administrative duties. They will review the 5As and practice brief motivational interviewing to augment their previous VA training so they can support participants' weight management and lifestyle goals and address barriers. Based on our formative data, we will allow PACT teamlets to decide who will discuss goals/barriers with patients and outline possibilities.

We will train research assistants with either a bachelor's or master's degree to serve as health coaches. The health coaches will receive additional training based on a previous 5As curriculum I used in as part of an evidence-based intervention.[53] The health coaches will receive 3-5 hours of training in small groups. They will practice counseling via role playing and videotape review.

Study Arms/Randomization: The first 10-12 participants will not be randomized—they will be recruited into the MTG intervention group only (see below) and outcomes for this group will be evaluated separately. The purpose of these first non-randomized participants is to ensure the feasibility of implementation prior to conducting the randomized portion of the pilot study. After screening patients for eligibility and obtaining consent, participants will be randomized (using a random number generator) to either the MTG intervention or Enhanced Usual Care.

*MTG Intervention group*: Participants will arrive to meet us in the 9th floor primary care area. After completing consenting materials and a Baseline Survey, participants will complete the MTG tool. They will then have a brief break and snack. After the break, they will work collaboratively with the Health Coach using tool-generated materials to modify their goals into SMART goals (specific, measurable, attainable relevant, and timely). The patient will then receive a binder containing an individualized report with a summary of their personalized advice, initial goals, and barriers and facilitators to weight loss. They will also receive a packet of MOVE! handouts tailored to their questionnaire responses. The Health Coach will also inform the patient of the resources available to them at the VA (e.g. MOVE, TeleMOVE!) that can assist them in achieving their goals. At the end of the visit, the Health Coach will enter a research note into the CPRS system detailing the patient's goals and other important information in the form of a provider report for the provider to review (generated by the MTG tool). This note will be attached to our administrative non-billable clinic, NYN PACT WEIGHT MGMT STUDY. For Pilot Phase 1, after health coaching, patients will meet with their PCP for their regularly schedule visit and afterwards complete an exit survey. For Pilot Phase 2, after health coaching, the patient will meet with the research team to complete an Exit Survey and then meet with their PCP during a regularly scheduled visit at any point during the course of the 1-year study. Based on information from the CPRS report generated by the health coach, the PCP will review lifestyle goals and conduct brief motivational interviewing to address potential barriers (3-5 minutes). The PACT member will summarize this interaction in a specific CPRS reminder. Over the 12 months of the intervention, the PACT teamlet will receive CPRS reminders to discuss the goals with the patients when they return for any PC visits. Research team members will contact the PCP directly should any serious issue arise while working a patient. Patients will follow up with VA resources if indicated/desired. Participants will return for separate 3, 6, and 12 month follow-up study visits to measure intermediate, behavior change, and weight outcomes.

- *Enhanced Usual Care*: Participants will arrive prior to scheduled PC visit and complete the same consenting materials and Baseline Survey as the intervention group. Instead of the completing the MTG tool and receiving health coaching, they will receive weight management handouts (Healthy Living Messages handouts and MOVE! handouts) as well as information about intensive weight management programs at the VA including MOVE!. For Pilot Phase 1, the patient will then meet with a PACT member (either the PCP or another participating PACT member) during their regularly scheduled PC visit and afterwards complete an Exit Survey. For Pilot Phase 2, the

patient will meet with their PCP at any point during the course of the study and afterwards complete an Exit Survey. Participants will follow-up with their PACT teamlets as needed when they return for their regularly scheduled PC visits. Patients will follow up with VA resources if indicated/desired. Enhanced Usual Care participants will return for separate 3, 6, and 12 month follow-up study visits to measure intermediate, behavior change, and weight outcomes.

- **COMPENSATION**

To compensate for travel and time spent completing survey measures and basic measurements, study participants will be given a cash voucher in the amount of 40 dollars for the Baseline study visit, 30 dollars for the 3 and 6 month study visits, and 60 dollars for the 12 month study visit. 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.

- **POTENTIAL BENEFIT/RISK**

Benefits:
- *Patients*: The patients who participate in the study will have the opportunity to receive weight management information, and potentially 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 lifestyle 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, RN Care Managers, and other VA employees*: VA 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, VA 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.

Risk:
- *Patients:* This research involves minimal risk for physical, psychological, social, and economic harm. The researchers understand that exploration of these topics and a persons' individual struggle with their weight can be emotionally charged for many people, particularly considering the stigma placed on obesity in our society. The researchers have been trained in order to effectively facilitate conversations on this sensitive topic and will seek to minimize any emotional discomfort you may feel during the study. Additionally, any potential behavior changes related to diet or exercise will be assessed and approved by properly trained individuals including select research staff, the Primary Investigator, and health professionals. Patients will be encouraged to slowly increase their physical activity under the supervision of their PCP. While there is always the risk of injury from starting or increasing physical activity, the benefits usually outweigh potential harms. We will monitor patients for adverse events.

- *VA employees*: This research involves minimal risk for physical, psychological, social, and economic harm.

- **MEASUREMENTS**

Assessment will occur at the following time points:
A. Baseline study visit: Baseline survey and basic physical measurements (weight, height, waist circumference)
B. In-person follow-up study visits at 3, 6 and 12 months: Follow-up in-person questionnaire and basic physical measurements (weight, height, waist circumference)

C. Follow-up telephone calls (only patients in MTG intervention): Follow-up telephone questionnaire
D. Chart review: This will occur periodically to assess MOVE! attendance, PACT teamlet visits (documentation of weight management-related conversations), and medical co-morbidities. Outcomes will be assessed through chart review up to 2 years after the baseline visit.

Baseline Data: Prior to the intervention, patients will receive a Baseline survey. To evaluate recruitment for the intervention, baseline data including socio-demographic information, perceived health status, health literacy, perceived environmental factors, and depression will be collected.[54–57] Co-morbidities will be determined through chart review of the electronic medical record. We will also collect health-related attitudes, beliefs, and baseline behaviors.

Weight & Height: Study personnel will obtain patient weight measurements using a standardized protocol which includes; 1) weighing before eating without shoes or heavy garments using a digital scale that will be calibrated monthly; 2) measuring height using the primary care clinic stadiometer and rounded to the nearest half inch, at each study time point (Baseline, 3, 6, and 12 months).

Waist Circumference: Waist circumference will be measured using procedures adapted from National Health and Nutrition Examination Survey (NHANES)[58]. Study personnel will use measuring tape to the nearest 0.1cm at the high point of the iliac crest at minimal respiration. This will be measured at baseline, 3, 6, and 12 months.

Feasibility: We will use process measures (from direct observation, to determine the feasibility of implementing the MTG intervention at the initial visit. Data on time to complete the MTG tool, number and types of goals made, number of patients reporting that their PACT teamlets engaged in goal setting conversations, number of reminders completed by the PACT teamlets, time spent doing the intervention, the impact of the intervention on workflow (physician and RN Care Manager report, qualitative interviews) will be collected. At 3 and 6 months into the study period, participating PACT teamlet staff will complete an attitudes survey based on one we have used previously pertaining to intervention implementation. We will also perform qualitative interviews with RN Care Managers and providers. We will use chart review to note the number of times patients in the telephone support arm actually receive telephone counseling.

Acceptability: We will collect data on patient satisfaction with the intervention and the overall visit [59,60] using patient and provider surveys. We will conduct interviews with participating providers and RN Care Managers to obtain qualitative data on acceptability.

Intermediate Outcomes: Our intermediate outcomes are based on the theory of planned behavior [31] where motivation and intention to perform a behavior, mediated by self- efficacy, predict behavior change. These constructs will be measured using previously used items that have been adapted for our survey measures by adding other elements of the Theory of Planned Behavior including behavioral beliefs, attitudes, subjective norms, and perceived behavioral control. We will also assess goal attainment at 3, 6, 12 months.

Behavioral Outcomes: We will assess diet and physical activity behaviors at baseline and again at 3, 6, and 12 months. Our main dietary outcomes will be servings of fruits and vegetables, fat intake, refined carbohydrates, and sweetened beverage intake via surveys. A subset of up to 20 participants will complete 24-hour dietary recalls, and this will allow us to assess total energy intake and energy density in this subgroup. Physical activity outcomes will be changes in duration and intensity. We will use chart review to evaluate attendance to TeleMOVE! or MOVE! (# of sessions) pre- and post-baseline visit and 3, 6, and 12 months post- intervention.

Treatment Fidelity: During patient surveys conducted after the patient sees the primary care provider, we determine whether patients recall reviewing goals and receiving obesity-related counseling from the provider. We will also audiotape up to 5 Baseline visits with each provider to evaluate the quality of counseling around patient goals and potential barriers to achieving them. Finally, we will do detailed chart reviews using a chart abstraction tool to monitor how often providers see patients and document goal-setting discussions during subsequent visits after the index visit.

Data Storage/Security

- *Research Activities:* The following will all take place in private room at the Manhattan VA with the PI and/or research staff – filling in consent forms, using MTG tool, receiving weight management information, receiving weight management counseling, completing survey measures.

- *Storage of data:* All written data will be kept in locked filing cabinets in a locked room only accessible by the PI and approved study personnel and all electronic data (including survey responses, audio files, and responses to online tool) on secure local VA servers and only accessible on VA password protected computers by the PI and study personnel. Original audio files will be removed from recorders. The data key link will be maintained as a password-protected Excel datasheet on a secure VA Harbor computer within a locked VA Harbor office by the PI, and destroyed upon completion of the final study dataset.  The data key link will be kept separate from all survey responses. Only study investigators will perform data entry, access either the surveys or datasets, or perform any analysis of the dataset.

- *Transcription:* For transcription of audio files, files will be sent as encrypted files through the secure server to the VA-contracted transcription company, Transcription Outsourcing, LLC. Transcripts will be de-identified by leaving all identifiable information out of the transcript and using only a unique coded identifier generated by the Principal Investigator. This unique identifier will not use any identifying information (i.e. it will not be generated using the subject's social security number, name, etc.) Recorded information will be transferred to Transcription Outsourcing via a HIPAA-compliant web portal using a VA computer. The transcripts will then be stored and analyzed on a VA secure server. This transcription procedure was approved by the IRB previously (MIRB 01333) under the consultation of the ISO and PO.

- *The MTG tool*: The MTG tool uses a web-interface to ask health questions and collect the data in order to deliver tailored advice. This website will be hosted on either a hired private programmer's server (approved research personnel) or an NYU server. In both cases, Data Use Agreements have been setup with both parties and the VA to protect ownership and use of collected coded data. Data will be regularly migrated from either server (private programmer or NYU) to the VA server via encrypted USB drive.  This data storage procedure was approved by the IRB previously (MIRB 01333) under the consultation of the ISO and PO.

Other Quality Control Procedures: The study staff will meet biweekly for the duration of the study to review patient recruitment and data collection procedures to ensure standardization. Research assistants will send reminders to Health Coaches when it is time to call patients in the telephone support arm.  To monitor for and address unanticipated adverse events, there will be discussions during meetings with research staff, PI, mentors of PI, and providers/VA staff.

- **DATA ANALYSIS**

Sample Size and Power Analysis: For weight loss outcomes, we will evaluate pre- and post-intervention in each arm separately and compare two arms. We base our sample size on within-person weight change at baseline and 12 months in each arm. Assuming  a mean weight change of at least -2.3kg (SD=5.3) in the MTG intervention arm and no weight change in the Enhanced Usual Care arm, based on a PC-based study of clinical support tools for lifestyle change and a systematic review of technology-assisted weight loss interventions in primary care.[39] Having 60 patients in each arm, the power is 82% to detect this pre- and post-intervention difference in each arm (at the two sided 0.05 significant level). We will also explore weight loss differences between two arms. We do not know how much additional weight loss that telephone support will lead to compared with the enhanced usual care arm. However, if we have 60 patients in each arm and assume the same SD in the weight change, we will have 80% power to detect a 2.8 kg difference between two arms. Assuming 25% dropout rate, we will randomize 160 subjects to obtain 120 evaluable subjects. We conducted sample size calculation using PASS 2008 software.

Statistics Analysis Plan: First, all the variables will be summarized using mean with standard deviation and median with interquartile range for continuous variables and frequency table for categorical variables, overall and by randomized arms, respectively. Mann-Whitney tests for continuous variables and Fisher exact tests for categorical variables will be used to check if baseline characteristics are balanced between two arms. Second, Mann-Whitney tests for continuous outcomes and Fisher exact tests for categorical outcomes will be used to compare outcome variables (including

intermediate outcomes, behavioral outcomes, and weight outcomes) between two arms at 3 months, 6 months, and 12 months, respectively. Wilcoxon rank tests for continuous outcomes and McNemar tests for binary outcomes will be used to compare them between follow-ups and baseline within each arm. Third, repeated measures modeling based on mixed models will be conducted to compare outcome variables between two arms, utilizing all the data at baseline and three follow-ups. Such modeling can adjust for baseline characteristics, take into account the correlation among repeated measures within subjects, and deal with missing data automatically assuming missing at random. Finally, we will conduct sensitivity analysis based on multiple imputation procedure to examine the impacts of missing data under some missing not at random assumptions.

We will conduct  several statistical analyses to describe Veterans participating in the study. Descriptive statistics, including numerical summaries, frequency tables and graphical displays, will be used to present baseline participant characteristics. Exploratory tests, such as chi-square tests and t-tests, will be used to investigate if baseline characteristics are balanced between two randomized arms. Analysis of missing data due to dropout or incomplete surveys will be investigated by inferring a relationship between baseline characteristics/risk  factors and 0-1 indicator that defines whether or not a measurement is observed. This analysis will help to identify factors that are likely to be associated with dropout. Additionally, we will investigate whether the dropout rates are different between two arms. For instance, participants with higher levels of motivation may be more likely  to be retained in the study. To deal with these missing, we will incorporate the multiple imputation procedure with the regression analyses to be discussed in the following, along with some sensitivity analysis.

Qualitative Data: The audio recordings of provider interviews and patients visits will be transcribed by a VA-contracted transcription company (methods used in our previous IRB-approved study MIRB 01333)**.** We will use detailed grounded theory-based procedures including open, axial, and selective coding.[61] After multiple readings of the transcripts and making marginal notes with a second researcher, we will develop, test, and refine a systematic coding scheme of themes and sub-themes, and relationships thereof using NVIVO qualitative data analysis software accessed through VINCI to assist in data analysis and interpretation. Analysis will be facilitated through constant comparison techniques.

- **EXPLORATORY AIM**

Exploratory Aim**:** To compare the intervention arm to a third study arm of non-enrolled PC patients matched for age, gender, and BMI ("Usual Care").

Analyzing the Third Arm: We will compare the two randomized study arms (Enhanced Usual Care and MTG intervention) arms with the third study arm of non-enrolled PC patients who are from the same cohort (seen by the same providers and eligible according to the same inclusion and exclusion criteria). Because the third study arm is not randomized, we do not expect the three arms are balanced at baseline characteristics and comparable. We will first identify important confounders (such as age, gender, BMI) and then use propensity score to adjust for these confounders when comparing the outcomes between three arms.

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**Study Personnel:**

**Melanie Jay, MD, MS**
*Grant Recipient/Principal Investigator*

Dr. Jay is an Assistant Professor at NYU School of Medicine and is a full-time staff physician if she gets this award. She currently devotes 80% of her time to research and leads the obesity counseling and prevention arm of the Research on Medical Education Outcomes Unit. She is also a primary care internist with clinical expertise in medical weight management. As a clinician, she started weight management programs at Bellevue Hospital and Gouverneur Healthcare Services. These multi-disciplinary clinics continue to provide care to underserved obese patients and feature English and Spanish support groups, medical intakes, individualized nutrition counseling, and nutrition education classes. Dr. Jay then left her full-time clinical practice after 4 years to pursue fellowship training (she received a Master's of Science in Clinical Investigation through the NYU Fellowship in Medicine and Public Health Research in 2009) and to work towards becoming a independent investigator dedicated to treating and preventing obesity in primary care.

Her previous clinical, administrative, and research experiences have prepared her well to complete the proposed research and training plan. She developed a multi-media intervention to improve food label comprehension and conducted a randomized controlled trial to study its impact on patients. She also surveyed 399 physicians from 3 different specialties about their competencies and attitudes about obesity treatment. As a research fellow, she studied the impact of an obesity counseling training intervention for physicians on patient care using a wait-list/control design. These experiences made her realize the importance of developing and studying interventions to aid clinicians in treating and preventing obesity during the primary care visit. They have also laid the groundwork for her proposed research through the development of surveys to evaluate clinician attitudes and competencies, and patient exit interview evaluations of physicians' obesity counseling. Further, they gave her experience in project administration and management and have led to publications peer-reviewed journals.

**Craig Tenner, MD**
*Co-Investigator*

Dr. Tenner is the Director of Health Promotion / Disease Prevention at the VA – New York Harbor Healthcare System and an Assistant Professor of Medicine at the NYU School of Medicine. He graduated NYU Medical School in 1992 before completing a residency in Internal Medicine at NYU/Bellevue Hospital Center. Since leaving residency, he has been an Attending Physician with a busy clinical practice at the VA – New York Harbor Healthcare System in Manhattan and an active member of the NYU Medical Center faculty. His personal areas of research interest include Preventive Medicine and Medical Informatics. More specifically, his research focuses on identifying the barriers in obtaining preventive healthcare and ways to improve healthcare delivery. Currently, he is working on a number of projects related to population health, panel management and the Medical Home model of care. He has provided significant input to the protocol design, as well as created the CPRS note system needed for this intervention study.

**Yixin Fang, PhD**
*Co-Investigator*

Dr. Fang has expertise and motivation necessary to successfully carry out the statistics analysis in the proposed work. Dr. Fang has a strong and broad background in clinical trials, multi-level analysis, survey analysis, observational studies, and many other biostatistical fields. As a PhD student at Columbia University, he received specific training and expertise in the fields of genetic epidemiology under the supervision of Professor Daniel Rabinowitz. As a postdoctoral research fellow in the Department of Psychiatry at Columbia University, he conducted data analysis for many real data problems across different disciplines. Overall, Dr. Fang has a demonstrated record of successful and productive research in biostatistics, and his expertise and experience have prepared him to accomplish the proposed project.