Maintaining Activity and Nutrition through Technology-Assisted Innovation in Primary Care (MAINTAIN-pc)

Protocol Number: PRO13020257
Principal Investigator: Margaret Conroy
Funded by:
Agency for Health Research and Quality (R18HS021162-02) and
National Institutes of Health through Grant Number UL1TR000005 (University of Pittsburgh CTSI, providing research registry support)

Trial Registration: ClinicalTrials.gov (NCT01946191)
https://clinicaltrials.gov/ct2/show/NCT01946191?term=01946191&rank=1

Version Number: MAINTAIN-pc05232017,

Update: 5/23/2017

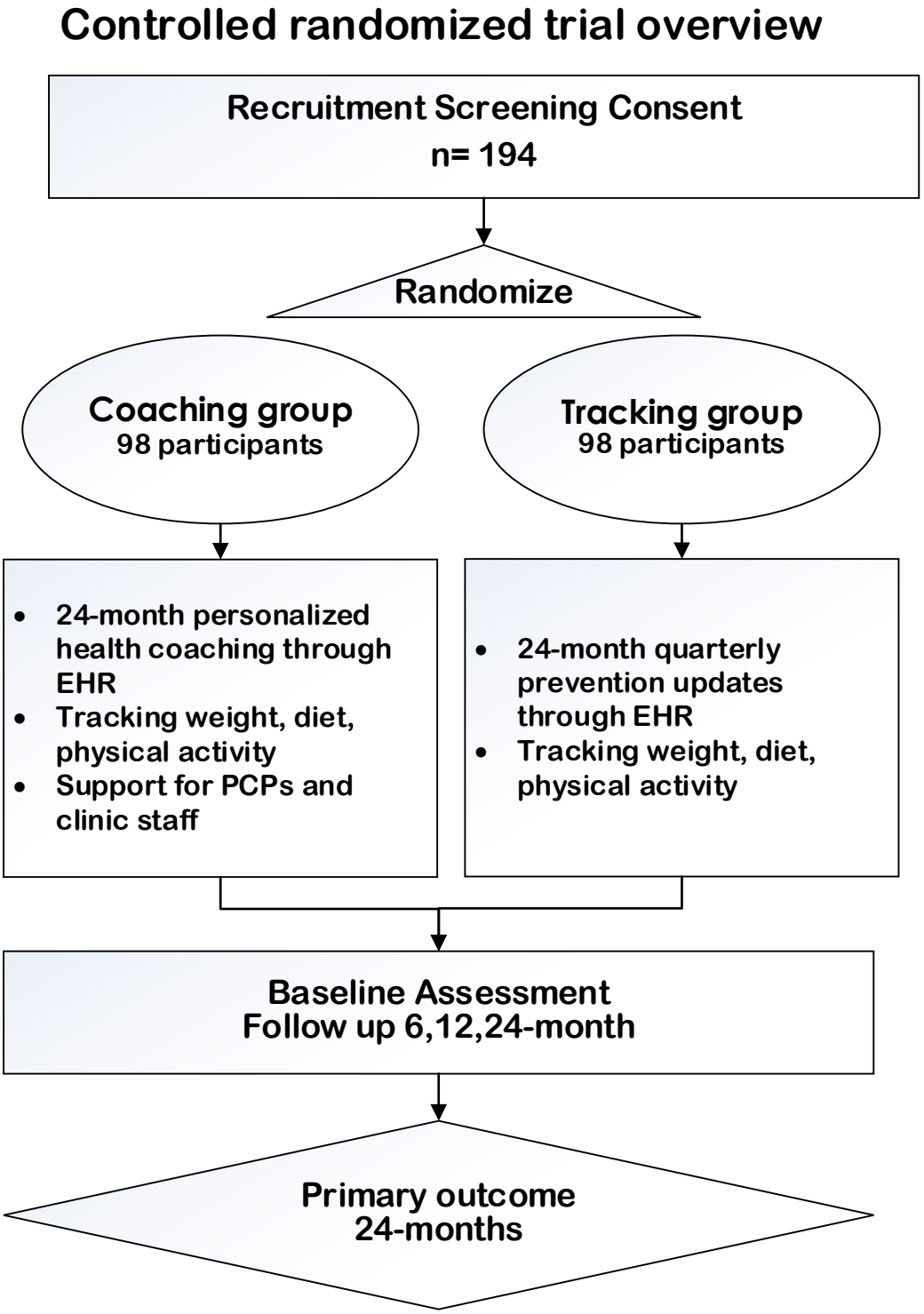
Table of Contents

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Maintaining Activity and Nutrition through Technology-Assisted Innovation in Primary Care (MAINTAIN-PC)
Study Description:	(MAINTAIN-PC is a randomized controlled trial to test whether online tracking tools and weight maintenance "coaching" visits for patients and "real time" electronic progress reports for primary care providers (PCPs) [Coaching] will support more successful weight maintenance than online tracking tools alone [Tracking] in a group of primary care patients who have lost ≥ 5% of their body weight. The online coaching visits for participants will be delivered through the primary care site's electronic patient portal (HealthTrak) and the electronic progress reports for PCPs delivered through the electronic health record (EHR). Participants will be randomized into one of two study groups, comparing the effects of continued online coaching and PCP support with online tracking only. In order to ensure optimal integration of the MAINTAIN-PC PCP decision support tools into routine clinical practice, we will also get feedback from the PCPs prior to the start of the intervention. In order to ensure optimal integration of the MAINTAIN-PC PCP decision support tools into routine clinical practice, we will also get feedback from the PCPs prior to the start of the intervention.
Objectives:	This study aims to translate an evidence-based lifestyle intervention into the primary care setting, using health information technology to promote weight maintenance and relapse prevention in patients who have successfully lost weight.
Specific Aim:	To determine the efficacy of online coaching and electronic progress reports delivered through the primary care site's electronic health portal to support weight maintenance after initial weight loss of ≥ 5%.
Study Design:	This is a randomized controlled trial comparing two online weight maintenance strategies in the primary care setting.
Endpoints:	Primary Endpoint: 24-months for participants
Study Population:	Outpatient adults (BMI ≥ 25 kg/m^2) with intentional 5% weight loss in past 2 years and with no bariatric procedures in past 2 years.
Description of Sites/Facilities Enrolling Participants:	10 UPMC Health primary-care practices in Pittsburgh, PA.
Description of Study Intervention:	EHR tools for both groups include weight, diet, and physical activity (PA) tracking flowsheets; standardized surveys; and reminders. Coaching participants will receive 24-months personalized coaching through EHR patient portal.
Study Duration:	60-Months
Participant Duration:	30-months

1.2 SCHEMA


Controlled randomized trial overview
Recruitment Screening Consent
n= 194
Randomize
Coaching group
98 participants
Tracking group
98 participants
24-month personalized health coaching through EHR
Tracking weight, diet, physical activity
Support for PCPs and clinic staff
24-month quarterly prevention updates through EHR
Tracking weight, diet, physical activity
Baseline Assessment
Follow up 6,12,24-month
Primary outcome
24-months

1.3 SCHEDULE OF ACTIVITIES (SOA): MONTH +/- 6 WEEKS

PROCEDURES	PRE-INTERVENTIO	SCREENING	ENROLLMENT BASELINE	ORIENTATIO N	MONTH 6	MONTH 12	MONTH 24	MONTH 30 EXPLORATOR
Participant verbal consent for phone screening		X						
Phone screening		X						
In person screen visit		X						
Addendum of Informed consent		X						
Completion of Baseline assessment			X					
Randomization			X					
Study Orientation (Group or Individual)				X				
Research data collection								
Demographics		X						
Work & travel		X						
Medical history & medications that influence weight		X						
Computer use and skills assessments			X					
Health literacy[1] (NVS)			X					
Weight, diet & physical activity history			X					
Prior physician weight loss advice			X					
Substance use & marital status			X					
Physical activity estimate			X		X	X	X	X
Dietary measures[2] (Diet Habit Survey)			X		X	X	X	X
Health survey[3] (SF-36)			X		X	X	X	X
Function[c] (WOMAC)			X		X	X	X	X
Quality of life[4] (EuroQOL)			X		X	X	X	X
Social support[5] (ISEL)			X		X	X	X	X
Stress level[6](Cohen)			X		X	X	X	X
Depression scale[7] (PHQ)			X		X	X	X	X
Sedentary behavior			X		X	X	X	X
Weight maintenance strategies			X		X	X	X	X
Self-efficacy & sleep			X		X	X	X	X
Health & medication update			X		X	X	X	X
Important medical events					X	X	X	X
Measurement of Tracking and Online Visit Usage				X	X	X	X	X
Participant tools use feedback (survey)					X	X	X	X
Patient satisfaction (TSUQ)					X	X	X	X
Research measures								
Height		X			X	X	X	X
Weight		X		X	X	X	X	X
Waist Circumference		X			X	X	X	X
Blood Pressure		X			X	X	X	X
Physical activity measured by research pedometers				X	X	X	X	X
PCP Feedback								

PCP recruitment	X	X						
Patient progress report template	X							
Post-recruitment & intervention surveys (Qualtrics)						X	X	
Progress reports: 10 lb. loss or gain reports (coaching group only)					X	X	X	
Between follow-up visit reports (coaching group only)					X	X	X	
Annual/Final progress reports (coaching and tracking groups)					X	X	X	X

1: The Newest Vital Sign (NVS) Health Literacy Western
2: Dietary Habit Survey
3: 36-Item Short-Form Health Survey (SF-36)
4. Health Related Quality of Life (EuroQOL)d: Test of Functional Health Literacy in Adults (The Newest Vital Sign)
5: Interpersonal Self Evaluation List (ISEL)
6: Perceived Level of Stress (Cohen)
7: Patient Health Questionnaire (PHQ) Depression Scale

1.4 INVESTIGATORS

Molly B. Conroy, MD, MPH
Kathleen M. McTigue, MD, MS, MPH
Cindy L. Bryce, PhD
Dana Tudorascu, PhD
Bethany Barone Gibbs, PhD
Jonathan Arnold, MD, MSE
Diane Comer, BA
Kimberly Huber, MPH
Laurey R. Simkin-Silverman, PhD
Gary S. Fischer, MD

1.4.1 KEY ROLES

Principal Investigator: Conroy, McTigue
Study concept and design: Conroy, McTigue, Bryce, Hess, Simkin-Silverman, Fischer
Statistical analysis: Tudorascu, Arnold, Comer
Administrative, technical, or material support: Conroy, Arnold, Huber.
Study supervision: Conroy, McTigue

2 INTRODUCTION

2.1 STUDY OBEJECTIVES

2.1.1 PRIMARY OBJECTIVE AND HYPOTHESIS

To determine the efficacy of online coaching and electronic progress reports delivered through the primary care site's electronic health portal to support weight maintenance after initial weight loss of ≥ 5%.

Hypothesis. Patients randomized to have online coaching and PCP receipt of electronic progress reports (Coaching group) will be more likely than those randomized to use only online tracking tools (Tracking group) to maintain weight loss, higher levels of physical activity and healthy eating behaviors.

2.1.2 SECONDARY OBJECTIVE AND HYPOTHESIS

To evaluate whether online weight maintenance tools will be acceptable to patients and primary care providers (PCPs) when integrated into routine clinical workflow, and assess barriers to patient and PCP up-take.

Hypothesis 1. Patients will find the online tools dedicated to weight maintenance acceptable and an enhancement to their ongoing care, with higher satisfaction levels observed in coaching group compared to tracking group.
Hypothesis 2. PCPs will find the online tools dedicated to weight maintenance acceptable, useful, and easily integrated into their routine clinical workflow.

2.1.3 ADDITIONAL OBJECTIVE AND HYPOTHESIS

To determine the cost effectiveness of online coaching and electronic progress reports delivered through the primary care site's electronic health portal.

Hypothesis. Online coaching and electronic progress reports delivered through the primary care site's electronic health portal will be a more cost-effective strategy than use of tracking tools alone to promote weight loss maintenance.

2.2 STUDY RATIONALE

Weight gain after a lifestyle intervention is common and it is important to investigate mechanisms for promoting longer-term maintenance of a healthy body weight. Physicians are a trusted source of health advice for many adults, so may play an important role in helping to establish and sustain healthy body size, in the interest of long-term health. Yet, implementing effective chronic care for obesity in a clinical setting has been challenging. Health IT may be an important tool for overcoming these barriers. Here we test online approaches for delivering a weight maintenance intervention to individuals with high weight-related health risk.

2.3 BACKGROUND

Obesity is a major and increasing health problem in the United States.(1) While many interventions have resulted in short-term weight loss, few programs support successful maintenance of a healthy body weight,(12-14) and fewer still are applicable to a primary care population.(15, 16) Obesity tends to be a chronic, lifelong condition and relapse after weight loss is common.(17, 18) Despite the fact that obesity is associated with a host of medical diseases,(2-5) weight loss interventions are usually conducted in a vacuum, divorced from the participants' usual medical care and without the input from the primary care team.(15, 16) Therefore, there is a great need for interventions that can assist with long-term maintenance of healthy body weight in the general population and in persons with existing medical conditions. Furthermore, such efforts should be linked to ongoing medical care. Our research team has developed an intervention (19) that successfully uses health information technology (HIT) and standardized online coaching protocols to promote weight loss among primary care patients. We now propose extending our work to evaluation of HIT tools designed to promote weight maintenance and prevent relapse (i.e., weight regain) in primary care patients who have successfully lost weight. Our proposal leverages recent developments in HIT, such as online visits(20) and electronic health records,(21) to track progress and support primary care patients and their providers in patients' ongoing weight maintenance efforts.

2.4 RISK/BENEFIT ASSESSMENT

2.4.1 KNOWN POTENTIAL RISKS

We categorize the frequency of known potential risk using the following categories:

Category	Frequency
• Likely	Occurs in >25% of people
• Common	Occurs in 10-25% of people
• Infrequent	Occurs in 1-10% of people
• Rare	Occurs in <1% of people

Participants

INCREASING PHYSICAL ACTIVITY

The recommended physical activity may cause muscle soreness or fatigue (likely). There is also the possibility that the following could occur during exercise: injury of a joint or muscle (common), broken bones (rare), falls from an exercise bicycle or treadmill (infrequent). aggravation of pre-existing podiatry problems (common), shortness of breath (common), abnormal blood pressure (common), fainting (rare), disorders of heart rhythm (rare), and heart attack, stroke or even death (rare). If participants are on anti-hypertensive medication, the risk of hypotension (infrequent) exists.

WEIGHT LOSS

The risks of weight loss are constipation (common), and some dizziness upon standing (common). Rapid weight loss increases the chances of developing or enlarging gallstones (rare). Other risks of weight loss

include hypoglycemia (infrequent) and light-headedness or weakness (common), and hunger (likely). Since participants may require dose adjustment of medications with weight loss, hypotension (infrequent) or hypoglycemia (infrequent) may occur among those treated for hypertension or elevated blood sugars, respectively.

LOSS OF PRIVACY

Study participation and outcomes collection may entail risk for loss of privacy regarding the collected information. For participants in the coaching group, there is a possibility of loss of privacy from posting information on the Internet, although the HealthTrak portal is a password-protected site meeting stringent security requirements for transmission of medical information. UPMC HealthTrak provides a web-based patient portal that permits enrolled patients to view portions of their medical record and communicate with their physician offices through secure messaging. Access to information is controlled through secure access codes, usernames, and passwords. HealthTrak uses 128-bit SSL encryptions technology with no caching to automatically encrypt the session with UPMC HealthTrak. To reduce the risk of unintended access, HealthTrak utilizes a 10 minute idle time out. In addition, HealthTrak undergoes an annual review of our System Security Plan, an in-depth security assessment used to evaluate the security posture and risks. To validate the security plan and to test the system, host-based network vulnerability assessments and web application vulnerability assessments are performed by the Information Security Group (ISG). Any discovered policy gaps and vulnerabilities are addressed or remediated within 30-days.

Providers
The only potential risk to the PCP participants is loss of privacy, although the surveys will be anonymous, making this risk unlikely.

2.4.2 KNOWN POTENTIAL BENEFITS

- Free of charge services:

Participants will be to tracking sheets to self-monitor weight, diet and physical activity and participate in online visits related to prevention.
Each participant will be given a pedometer and a calorie book.
They may also receive personalized lifestyle coaching, and feedback on their self-monitoring.

- Improved health and quality of life:

Weight loss and physical activity have been linked with improved health and quality of life, so we anticipate that participants may feel better and possibly have improved long-term health. It is possible that some may be able to reduce their medication needs (e.g. blood pressure or anti-glycemic agents).

2.4.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Since the risks of participating are minimal, and the benefits may be considerable, participating in this intervention should be a reasonable option for primary care patients.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS
Primary	
Assess change in body weight from baseline/enrollment	24-months
Secondary	
Assess maintenance of a 5% weight loss	24-months
Assess change in BMI from baseline/enrollment	24-months
Assess change in physical activity (steps per day) from baseline/enrollment	24-months
Assess change in quality of life from enrollment/baseline (EuroQOL)	24-months
Function (WOMAC)	24-months
Assess changes in blood pressure from enrollment/baseline	24-months
Assess patient satisfaction and perceived usefulness of a technologic intervention to improve self-management	24-months
Assess PCP satisfaction	24-months
Exploratory	
Assess change in dietary habits from enrollment/baseline	24-months
Assess change in body weight from baseline/enrollment	30-months

4 STUDY DESIGN

4.1 OVERALL DESIGN

- **Trial design**: Randomized Control Trial
- **Randomization**: 1:1 to tracking tools with or without coaching
- **Randomization sequence generation**: Computer-generated permuted block randomization with block sizes of four and six individuals and stratified by sex and site of primary care
- **Allocation sequence**: by study statistician
- **Allocation concealment mechanism**:
  - Study staff to obtain assignment from data center website
  - Assignments to be given to participants after baseline assessment and before orientation by study staff
- **Blinding:** Not blinded

4.2 END OF STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed at least one follow up visit of the study including the last visit or the last scheduled procedure shown in the Schedule of Activities (SoA), Section 1.3.

5 STUDY POPULATION: SELECTION AND ENROLLMENT OF PARTICIPANTS

5.1 INCLUSION CRITERIA

Participants

1. Adults aged 18-75
2. BMI of ≥ 25 prior to this intended weight loss
3. Have experienced and maintained intentional weight loss of at least 5% of body weight in the past 24 months
4. Plan to maintain a PCP relationship in one of the participating primary care practices
5. Have or be willing to get an account with the electronic health portal (HealthTrak) embedded in the EHR

Providers

- For progress report feedback:
  1. Primary care physician practicing at one of the designated UPMC sites with Epicare access
  2. Willing to review and comment on electronic progress reports
- For intervention feedback: PCP who has sent at least one patient to the MAINTAIN-PC study

5.2 EXCLUSION CRITERIA

Participants

1. Medical conditions that might cause unintended weight loss such as cancer or thyroid disease
2. Provider's assessment that patient is unable to safely undertake moderately intense unsupervised physical activity (the equivalent of 30 minutes of brisk walking)
3. Edematous state that interferes with body weight assessment (e.g., severe congestive heart failure, end-stage renal disease, or ascites)
4. Bariatric surgery in the last 2 years, or planned during the next 3 years
5. Current or planned pregnancy in the next 3 years
6. Currently breastfeeding
7. Perceived lack of basic computer or Internet skills.
8. Unable to attend the orientation session or comply with the protocol procedures
9. Any other underlying reason or concomitant condition, which in the opinion of the principal investigator, could confound the results of the study or put the participant at undue risk.

Provider

1. Not a primary care physician practicing at one of the designated UPMC sites
2. Does not have Epicare access
3. Unwilling/unable to review and comment on electronic progress reports

5.3 ENROLLMENT PROCEDURES

Participants

- Phone screening
- In-person screening visit
- In-person written consent at screening visit
- In-person written consent addendum form

Providers

- For progress report template feedback: Anonymous

- For post-recruitment and post-intervention feedback: IRB-approved mechanism for obtaining consent over the Internet at the time of completing the survey

5.4 SCREEN FAILURES

Individuals who do not meet the criteria for participation in this trial (screen failure) will be told the reason why they cannot participate by the research staff. Should the participant be willing, there is the possibility of them coming back for a re-screening visit if they meet the entry criteria at a later date during the study's recruitment phase. Rescreened participants should be assigned the same participant number as for the initial screening.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

5.5.1 RECRUITMENT

Participants

- **Provider Referral -** Health care providers from the participating clinics will be educated about the study and may refer patients to it during routine medical care. If a patient verbally indicates interest in participating in the study, the health care provider may fill out the Referral Form or may enter an electronic referral order into the patient's chart. The referral will verify that moderate physical activity and a relatively low-fat diet is medically appropriate for the referred patient. When the referral is electronically signed, it will be forwarded automatically to a research staff member. A study staff member will call referred patients to conduct the study's standard brief phone screen to determine preliminary eligibility criteria. Dr. MollyConroy, the study's Principal Investigator, is a UPMC employee, and will be available to provide as-needed clinical and research expertise to the staff member receiving the referrals. We will create a best-practice alert (BPA) to alert PCPs to patients with a weight loss of ≥ 5% of body weight who may qualify for a weight maintenance study, and will also target patients directly through posters and flyers in clinic and mailings to our primary care research registry. The BPA has been a successful strategy to recruit for numerous studies in our practice setting, including the VLM pilot, OCELOT-PC and Healthy Bodies, Healthy Hearts. The BPA recruitment has been demonstrated to increase participation from minority patients when compared to traditional staff-based methods. We will also recruit directly to patients via the patient portal of the EHR (HealthTrak) by sending them a brief electronic message if they have lost weight in the past year. We will also visit the regularly scheduled practice meetings of the designated practices to orient PCPs to the study and answer any questions they may have

- **Self-Referral** - Recruitment flyers/brochures will be located in the exam rooms and waiting areas of the participating clinics. Interested individuals can call a phone number to complete the brief phone screen to assess preliminary eligibility criteria. In the UPMC Montefiore practice, the standard computerized intake survey will ask patients if they would be interested in learning more about an online weight management study. If they answer "yes", an email will be sent to a study staff member, who will then call these patients to conduct the study's standard brief phone screen to determine preliminary eligibility. If the individual meets the phone screen's eligibility standards, research staff will contact the appropriate health care provider to request a referral. Patients who are not eligible based on the phone screening will be informed of their

ineligibility at the conclusion of the phone screen and asked for permission to retain their contact information for possible future participation. Once a physician referral is received by the program staff and preliminary eligibility of the potential participant has been determined via the phone screening process, then the potential participant will be scheduled for an in-person SCREENING VISIT at one of the Center for Research on Healthcare's offices in Oakland or at another approved site.

- **OCELOT-PC (IRB#PRO09080118) sample**. Consented participants who previously participated in the OCELOT-PC study will also be targeted for recruitment and screening for this study. The participants will be contacted by a member of the OCELOT-PC study team (either by phone, email or mail) informing them of the study. If they are interested and would like to find out if they are eligible to participate, the MAINTAIN-pc study contact number and email will be provided. A MAINTAIN-pc study staff member will then conduct a brief phone screen to determine their eligibility.

- Potential participants may also learn of the study through mailings of potential studies due to their participation in the CTSI Research Participant Registry or UPMC/University mailings.

- A study summary for advertisement will be submitted in the UPMC Extra! newsletter and in system-wide communications targeted to UPMC MyHealth Weight Race participants.

- Printed materials will also be distributed and displayed at UPMC primary care outpatient offices, in buildings in and around the Oakland area, to UPMC MyHealth Weight Race staff, and to organizers of other weight-loss related programs.

Recruitment for Providers

- For progress report feedback: All PCPs present at site orientation meetings will be invited to provide anonymous feedback on what they would like to see included in the patient progress report template
- For post-recruitment and post-intervention feedback: Invitations and reminders for confidential PCP surveys (Qualtrics) sent through campus e-mail

5.5.2 RETENTION

Participants

Enrolled patients will be tracked in the EHR research module, allowing to both monitor their progress in the trial and run reports on their adherence.
The study multifaceted retention plan consist of the following:

1) Minimizing burdens during protocol design
2) Setting expectations up-front during recruitment and orientation session including weight loss the demands of joining a randomized controlled trial, and making eating and activity changes,
3) Promptly respond to inquiries and messages
4) Weekly reminders to track their weight, diet, and exercise through the personal health record
5) Reminders for upcoming visits and tasks
6) Show appreciation and recognition and accommodate to participant’s schedule as much as possible

7) In addition, we believe that PCP engagement will improve retention.
8) Finally, understanding why a participant chooses to discontinue the intervention will be valuable information to obtain. This feedback may provide insight into what changes can be implemented to improve retention in future.
9) Use retention enhancement techniques proven to work by us and other clinical trials:
    a. Create 'project identity' that participants can recognize by using similar colors and fonts on trial materials
    b. Track eligibility status of potential participants on a computer database
    c. Write protocols to systematically address common participant questions
    d. Adhere to trial protocols and procedures
    e. Provide support to all participants
    f. Offer flexible scheduling
    g. Attempt to be on time for clinic appointments
    h. Make multiple attempts to contact participants for complete data email, and phone
    i. Encourage participants who move from the area to continue completing questionnaires, and have clinic data (e.g. weight, blood pressure) collected and verified by another health professional
    j. Send birthday cards to all participants
    k. Determine two secondary contacts by asking participants to sign letters notifying contacts of trial participation and giving permission to provide forwarding information (letters also served as an implicit behavioral commitment to complete the trial)

Providers

Retention plan consist of minimizing burdens during protocol design for provider's participation including:

1. IRB-approved mechanism for obtaining consent and administering confidential PCP surveys over the Internet
2. Invitations and reminders for PCP surveys sent through their campus e-mail

6 PRE-INTERVENTION ACTIVITIES

PROGRESS REPORT FEEDBACK

Providers

All PCPs present at site orientation meetings will be invited to complete a brief anonymous survey to get their general opinion on the patient progress report template. A script will be read to them describing the reason for collecting the information. If they are interested, they are welcome to review the report template and complete the survey. No identifiable information from this sample will be collected or retained.

7 STUDY INTERVENTION

7.1 STUDY PROCEDURES

7.1.1 SCREENING

Participants

- PHONE SCREEN:
  - Ensure potential participants are preliminarily eligible to participate
  - Research staff will:
    - Use PHONE SCRIPT
    - Confirm 5% weight loss and a BMI greater than or equal to 25 within the past two years
    - Confirm Additional Inclusion criteria
    - Complete PHONE SCREEN ELIGIBILITY CHECKLIST
    - Notify eligible participants of weight and BMI verification retrieving medical records

- IN-PERSON SCREEING VISIT:
  - Determine preliminary eligibility
  - Duration: approximately 1 hour
  - Scheduled post-phone screen
  - Research staff will:
    - Explain study in lay language to each potential research participant
    - Address participants questions and concerns
    - Ask for **informed consent** signature before undergoing any additional screening or research procedures.
    - Obtain additional BASELINE PROCEDURES if participant is eligible
      - Please refer to Schedule of Activities (SoA), Section 1.3 for complete list of baseline questionnaires and activities.
  - **It is possible that after the screening measures are collected, the participant will not be eligible to participate in the study.**
  - Dr. Conroy available to speak to the potential participant to further explain the details of the study, if necessary.
  - Location:
    - At one of the designated sites in Oakland affiliated with the University of Pittsburgh's Center for Research on Health Care
    - Another approved location by trained research staff.

7.1.2 CONSENTING PROCEDURE

Participants

- For Phone screening
  - Verbal informed consent for the phone screening will be obtained using the phone screening script. If the patient does not provide verbal consent, the phone screening will not be conducted.

- For Screen Visit
  - After the phone screen, the participant will be sent a copy of the consent form to review prior to their screening visit appointment

  - At the screening visit, the Informed Consent document will be reviewed carefully with each participant.
  - Participants will have the opportunity to ask any additional questions.
  - If uncomfortable with the study requirements, the participant may choose **not** to enroll in the study at that time.
  - The participant will also have the option to reschedule for a future screening visit if more time is needed for a decision about participation
  - All documents specifically state that participation in the study is voluntary and the decision NOT to participate in the study will have no negative consequences for the participant
  - Any listed investigator or designated research team member, will be able to obtain informed consent from each participant before the start of any research procedures
  - Potential study participants will read the consent form and be asked for a verbal indication of their understanding of the material contained in the consent form
  - The consenter will be available to answer any questions that arise
  - Participants will then be asked to sign the informed consent document if they agree with the material contained in the form
  - The consenter will sign the consent document and provide a copy to the participant
  - Research team members obtaining consent will have completed the approved University of Pittsburgh training to consent individuals for research
- For enrollment
  - For enrolled participants who have completed either their screening/baseline or both screening/baseline and orientation visits, new information will initially be presented to them by phone or in-person using the currently IRB approved **addendum consent form.**
  - Written informed consent will either be obtained by mail or at their next scheduled visit
  - Participants who do not give their addendum consent will not be able to continue their participation in the study or will be considered lost to follow-up

Providers
For progress report feedback: survey is anonymous
For intervention feedback: confidential web-based PCP surveys has detailed script provided before the survey questions. A box is included at the end of the script and will be required to check to indicate their approval to participate.

7.1.3 BASELINE ASSESSMENT

- Participants who are eligible after the collection of screening measures will be asked by a trained research staff member to complete additional baseline questionnaires at the in-person screening visit.
- Baseline questionnaires will be approximately 1 hour
- Please refer to Schedule of Activities (SoA), Section 1.3 for complete list of baseline questionnaires and activities.

7.1.4 RANDOMIZATION

After the completion of the baseline assessment participants will be randomized to participate in either the coaching or tracking group intervention (approximately 98 individuals will be randomized to each group).

7.1.5 BLINDING

Not blinded

7.1.6 FOLLOW UP VISITS

IN-PERSON ORIENTATION SESSION

- Successfully screened and randomized participants attend an in-person GROUP OR INDIVIDUAL ORIENTATION session for the group to which he/she was assigned
- Sessions take place in one of the computer training labs or in the research office in Oakland
- GROUP ORIENTATION VISIT:
    - Approximately 5-10 participants per session
    - Duration: approximately 90 minutes (evenings only)
    - Conducted by appropriately trained study investigator(s) and study staff

- INDIVIDUAL ORIENTATION VISIT**:**
    - One participant per session with appropriately trained research staff
    - Duration: approximately 1 hour
    - Post-baseline visit, at another scheduled time in Oakland, or on the phone (during daytime hours).
- At the end of the in-person orientation visit participants will:
    - Complete practice orientation survey
    - Receive health goals based on their most recent weight obtained at this visit
    - Receive recommendation to maintain at least a moderate level of physical activity (e.g., brisk walking) for up to 150-200 minutes per week
        - The type of physical activity will be chosen by the participant and will be unsupervised by the research staff
    - Receive pedometer to keep and calorie tracking book to keep along with instructions on how to use them
    - Receive a brief (45 minute) review of the most important concepts from the Diabetes Prevention Program (DPP)
    - Receive a brief review and link to access the most important concepts from the Diabetes Prevention Program (DPP), on line and free of cost
    - Receive lessons on how to set realistic goals and tips for physical activity, healthy food choices, and portion control
    - Receive research pedometers for the purpose of collecting objective physical activity data for up to two weeks
        - Data will be collected for comparison with the pedometer data planned for collection at each follow-up visit
    - Receive additional instruction and education
        - Coaching Group
            - Receive additional information about the online visits for weight maintenance
            - Learn how to access weight maintenance behavior based surveys to complete at designated times

- Learn how to communicate with their assigned health coach and PCP through the HealthTrak portal
- Complete an online questionnaire for practice
- Receive encouragment to start tracking their weight, physical activity (e.g., average daily steps), calories, and fat grams via HealthTrak on a weekly basis
- Be assigned a Health Coach to provide them with consistent feedback, information, and education
- Learn that their PCP will receive regular summary reports on their progress
- Receive encouragement to follow-up with their PCP on a routine basis

- Tracking Group
  - Receive an overview of online visits on a lifestyle topics unrelated to weight maintenance
  - Learn how to access health promotion-based surveys to complete every 3 months
  - Learn how to communicate with their PCP through the HealthTrak portal
  - Receive encouragement to start tracking their weight, physical activity (e.g., average daily steps), calories, and fat grams via HealthTrak on a weekly basis.
  - Learn that their PCP may choose to discuss the data they receive through HealthTrak as a part of their routine medical care.
  - Receive encouragement to follow-up with their PCP on a routine basis

FOLLOW UP VISIT:

Participants

- Schedule, activities, and contact for both groups

FOLLOW UP ACTIVITIES	RESPONSIBLE	CG[1]	TG[2]	MONTH 1	MONTH 2-6	MONTH 7-12	MONTH 13-24	MONTH 25-30
Complete online visits: Virtual Lifestyle Management (VLM) surveys	Participant	X		Weekly	Biweekly	Monthly	Every 3 months	
Complete online weight maintenance questionnaires	Participant	X		Weekly	Biweekly	Monthly	Every 3 months	
Receive feedback from coach	Participant	X		X	X	X	X	
Complete additional questionnaires, if necessary	Participant	X		X	X	X	X	
Track physical activity and calories/fat in HealthTrak	Participant	X	X	X	X	X	X	X
Make regular PCP appointments	Participant	X	X	X	X	X	X	X
Wear pedometer for 2-weeks at end of:	Participant	X	X		Month-6	Month-12	Month-24	Month-30
Research measurements: • Waist • Blood pressure • Return pedometer	Participant	X	X		Month-6	Month-12	Month-24	Month-30
Complete online outcome questionnaires, feedback and satisfaction. At end of:	Participant	X	X		Month-6	Month-12	Month-24	Month-30
Complete health promotion topics. At end of:	Participant		X		Month-3 Month-6	Month-9 Month-12	Every 3 months	
Review VLM survey	Coach	X		X	X	X	X	
Provide additional educational lessons if need	Coach	X		X	X	X	X	
Review notification of 10 lb. weight gain or loss from EHR	PCP	X		X	X	X	Month-24	
Receive real-time progress report prior to patients' appointment.	PCP	X	X (annual only)	X	Month-6	Month-12	Month-24	
Feedback and satisfaction survey	PCP	X	X				Month-18 Month-24	

[1] Coaching Group
[2] Tracking Group

- Additional contacts throughout the study: From research staff via letters, phone calls, emails, newsletters, post card reminders, etc.

Providers:

- Sustained support through study

- PRE-INTERVENTION PHASE: Progress report feedback
- RECRUITMENT PHASE: Referring appropriate study candidates
- INTERVENTION PHASE:
    - Respond to alert reports for weight change >= 10 lbs to, which could prompt an office visit
    - Reviewing EHR intervention reports. Estimated time for review of reports is 2 minutes
        - Progress reports prior to scheduled office visits: summary of self-monitoring data on weight, fat, calorie intake, physical activity
        - Interim progress reports: counseling tips suggested for incorporating into office visit
        - End-of-study summary reports
- POST-RECRUITMENT AND POST-INTERVENTION PHASE: intervention feedback
    - All PCPs at targeted clinical practices (i.e., PCPs who have and have not referred patients) and PCPs at other UPMC sites who approved participation for patients to participate in this study will also be asked to complete a confidential feedback survey after the first year following the start of recruitment and the end of the study.
    - The surveys will be created and distributed via the Qualtrics web-based system using a confidential link.
    - Even though the Qualtrics anonymous link does not record name or email address, it does collect the user's IP address. We have no plans to use the IP address to identify survey respondents. For data analysis, a study-specific number will be assigned to each survey by the research staff. Whether or not the PCPs choose to enter the prize drawing, survey responses will remain de-identified. For those PCPs wanting to enter the prize drawing, they will be re-directed to a separate survey where they will be asked to provide their contact information. Any potentially identifiable information collected will be kept separate from the survey data.

7.1.7 FINAL EVALUATION

- Please refer to Schedule of Activities (SoA), Section 1.3 for complete list of endpoint questionnaires and activities.

7.2 STUDY INTERVENTION FIDELITY

A clear process evaluation protocols for monitoring the intervention groups to ensure that the integrity of the intervention is maintained will be used. An Intervention Team, made up of Drs. Conroy, McTigue, and Simkin-Silverman, the project coordinator and lifestyle coaches will meet weekly throughout the study. At these meetings, we will review progress (e.g., participant recruitment, online program use), check record-keeping to make sure it is up to date, and address problems as they arise. We have developed online tools that not only monitor patient progress, but also track whether the lifestyle coaches are delivering the virtual intervention per the designated schedule, and facilitate the auditing of online coaching notes (e.g., to check length and content). The co-investigators will provide the staff with feedback based on these intervention audits, and initiate additional training as needed.

8 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

8.1 DISCONTINUATION OF STUDY INTERVENTION

Participants may withdraw voluntarily from the study or the PI may discontinue a participant from the study. Participants who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Participants who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, will not be replaced.

8.1.1 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

- Participants are free to **withdraw** from participation in the study at any time upon request
    - Will be documented as: Withdraw by participant

- An investigator may **discontinue** a participant from the study for the following reasons:
    - Primary care provider feels that it is not in the participants best interest to stay in the study
    - Change in health condition which requires discontinuation of the study intervention
    - Pregnancy
    - Significant study intervention non-compliance
    - Underlying or concomitant condition, which in the opinion of the principal investigator, could confound the results of the study or put the participant at undue risk
    - If study is stopped
    - Participants who do not give their addendum consent
    - Will documented as: Protocol Violation or other appropriate documentation

- The reason for participant discontinuation or withdrawal from the study will be recorded on the NOTE TO FILE form.

8.2 LOST TO FOLLOW-UP

- Participants are considered lost to follow-up when they stop reporting to scheduled study visits and cannot be reached to complete all protocol-required study procedures.
- A participant will be considered lost to follow-up if he or she fails to return for scheduled visits and is unable to be contacted by the study site staff.
- The following actions must be taken if a participant fails to return to the clinic for a required study visit:
    - The site will attempt to contact the participant and reschedule the missed visit within 24-hours of a missed visit and counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study.
    - Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's study file.

- For participants unable to contact/schedule but had not formally withdrawn, EHR weights were used.

9 STUDY ASSESSMENTS AND PROCEDURES

9.1 EFFICACY ASSESSMENTS

Weight change: weight, height, BMI	Change in body weight from baseline/enrollment is the primary outcome. Secondarily, maintenance of a 5% weight loss and change in body mass index (BMI). Weight and height will be measured using a calibrated scale and stadiometer, respectively.
Fat distribution change: waist circumference	Waist circumference measured at end-expiration at the level of the iliac crest, as a measure of body fat distribution, since central adiposity has been linked with increased cardiovascular risk.
Lifestyle behavior change: physical activity, dietary habits	**Physical activity** measured as change in physical activity (steps per day) from enrollment. Assessed in all groups at baseline, 6 months, 1-year, 2-year and 3-years using pedometers. This objective approach has been widely used in research and community physical activity programs,(22-27) as well as in OCELOT-PC. Participants will be asked to wear a piezo-electric pedometer for 2 weeks and then return it in person or by mail. These pedometers are validated for use by obese individuals(22) and postage-paid protective packaging will be provided.
	Dietary habits: assessed using a self-reported tracking information provided by participants (fat and calories) as well as a validated diet habit survey.(28)
Quality of Life and Function change : RAND-12, IWQOL-Lite, and short-form WOMAC function scale	RAND-12,(29) a commonly used, and often preferred(30) generic quality of life measure will be used. It includes measures of physical, mental, and social functioning. Its 12 questions are summarized into mental and physical health composite scores. It has been used in obesity studies,(31) is responsive to increasing levels of weight (e.g., those with increasing BMI have more HRQOL impairment),(31, 32) and improves with weight loss.(33) In addition to the RAND-12, we will administer the EuroQOL (EQ-5), a brief (5-item) measure of HRQOL.(34, 35) Like the RAND-12, the EQ-5D is generic and therefore applicable to many health states; it is also a preference-based measure of HRQOL and can be used to compute quality-adjusted life years (QALYs), which will be important for the cost-effectiveness analysis phase of the study. Obesity-specific HRQOL assessed with the Impact of Weight on Quality of Life (IWQOL-Lite), a brief, psychometrically valid, self-administered, disease-specific HRQOL instrument.(36, 37) Its questions cover multiple domains (physical functioning, self-esteem, sexual life, public distress, and work), but, unlike generic instruments, questions are

	phrased with the stem "because of my weight". The short-form of the Western Ontario and McMaster Universities (WOMAC) function scale to measure functional status. The scale was shortened based on input from patients with knee or hip osteoarthritis and their rheumatologists(39) and is externally validated.(40) It includes 8 items, each describing an activity which may be limited. The degree of limitation is scored on a Likert-scale from 0 (none) to 4 (extreme).(39)
Cardiovascular risk factors change: blood pressure and medications for weight-related cardiovascular risk factors	blood pressure measured at baseline, 6, 12, 24-Months.. changes in prescribed doses for anti-glycemic, anti-hypertensive, and lipid-lowering medications at these time points to be recorded
Patient satisfaction and perceived usefulness	We will adapt the "Use and Impact" questions from the Telemedicine Satisfaction and Usefulness Questionnaire (TSUQ; Appendix F)(41) to assess patient satisfaction. The TSUQ has been found to be valid, reliable, and readable at an eighth-grade level.(41) The 10 questions making up its Use and Impact factor are scored on a Likert scale from 1 (strongly disagree) to 5 (strongly agree), and assesses different aspects of the participants' satisfaction and perceived usefulness of a technologic intervention to improve self-management. They can be summed for a total factor score.
Provider satisfaction	PCP satisfaction survey (Appendix E) to any PCP who had a patient enroll as a participant in MAINTAIN-PC. PCP satisfaction surveys will be administered twice – at the end of year 1 of the intervention (i.e. Year 2 of study), and at the end of the intervention (year 4). PCPs will receive an incentive of $25 for completing each survey. The survey will assess PCP's opinions on the various components of the study, including electronic summary reports received 24-48 hours before routine visits, paper reports generated every 12 months, and notifications for participants who have lost or gained 10 lbs. We will take into account in our skip pattern on the PCP satisfaction survey the fact that not all PCPs will receive all of these reports or messages if they have not had a patient randomized to the coaching. For PCPs who do endorse familiarity with any component of the MAINTAIN-PC intervention, we will ask them to complete a validated IT "Perceived Usefulness and Perceived Ease of Use" instrument, adapted from Davis.(42) The 12 questions making up the Perceived Usefulness and Perceived Ease of Use scales are scored on a Likert scale from 1 (extremely likely) to 7 (extremely unlikely). The scales have excellent Cronbach alpha reliability (0.98 and 0.94, respectively) and have been found to be predictive of current and future IT use, which is an important dimension to consider when thinking about longer term uptake and dissemination of the MAINTAIN-PC intervention in clinical practice. In addition to these scales, we will also ask the PCPs specific

	questions about how well the MAINTAIN-PC tools were integrated into their clinical workflow, including any barriers to integration. We will also collect basic information about PCP (sex, years practicing, sessions/week, self-efficacy with weight loss counseling). We will use the results of the PCP survey to make modifications to the MAINTAIN-PC tools prior to further dissemination efforts.

9.2 ADVERSE MEDICAL EVENTS

9.2.1 SEVERITY OF EVENT

Participants will be asked about any adverse medical events that might have affected their participation in usual daily activities at each follow-up assessment and self-rate the severity of the event

For adverse medical events the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities
- **Moderate** – Events result in a low level of inconvenience or concern with the intervention measures. Moderate events may cause some interference with functioning
- **Severe** – Events interrupt a participant's usual daily activity. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious"

- **Serious Adverse Event**: fatal or life-threatening, requires or prolongs hospitalization, produces a persistent or significant disability/incapacity, results in a congenital anomaly/birth defect, or based on appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention

9.2.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention assessed by the clinician who examines and evaluates the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

9.2.3 EXPECTEDNESS

Although the investigators do not anticipate any adverse events related to this study, all participants will be given contact information for the study's lifestyle coaches at the orientation sessions, and instructed to contact them right away regarding any problems that they experience. This recommendation will be reiterated at each outcome assessment visit.

9.2.4 ADVERSE EVENT REPORTING

Any unexpected adverse events associated with the research that are fatal or life threatening will be reported to the IRB within 24 hours. Any unexpected adverse event associated with the study that are moderate to severe in nature, but not life threatening, will be reported to the IRB in 10 days.

10 STATISTICAL CONSIDERATIONS

10.1 SAMPLE SIZE DETERMINATION

Participants

- Sample size calculation is based on the primary outcome: change in weight (kg) at 36 months/3 years or final visit. For aim 1 we hypothesize that the mean weight loss for the coaching group will be greater than that for the tracking group. Using group samples size of 136 (each group with 68), we can achieve 80% power to detect a difference of 2.3 kg assuming estimated three year change score standard deviation (SD) of 5.4 kg for each group (estimated from the weight change data from the DPP-OS where SD is estimated as IQR/1.35) and with a significance level (alpha) of 0.05.122 A minimum of 98 participants in each group will allow us to detect planned difference while accounting for a dropout rate of 30% (for outcome assessment). Since change in weight will also be measured at 6 mos, 1, 2 and 3 years/Final Visit we can also achieve 80% power to detect an overall difference (across all time points) of 1.7 kg under the same assumptions. If we are falling short of our recruitment goals, our strategy would be to expand the number of clinics from which we are recruiting, rather than lower the minimum weight loss requirement required for study entry. Because our pilot data indicate that most interested participants are about 50 years old and female, with fairly low immediate cardiovascular risk, we anticipate that any benefit in terms of cardiovascular events will be quite delayed. However, we will be able to detect a change in physical activity, physical functioning and HRQOL over the time-frame of this study. Significant change in blood pressure has been achieved by chronic care management models using a similar sample size.123

PCPs

For the pre-study sample, feedback from approximately 12 PCPs recruited from previously identified sites should be suitable to determine the optimal integration into the clinical workflow.

10.1.1 GENERAL APPROACH

Descriptive statistics will be reported for participants in both groups. Statistical significance of group differences in distributions will be tested using two sample t-test for continuous variables with a normal distribution, Wilcoxon test for continuous variables that did not follow a normal distribution, and $\chi 2$ test or Fisher's exact tests for categorical variables, as appropriate.

A linear mixed model will be estimated with treatment group and time represented as 4 dummy coded variables (baseline as the reference time point) as well as their interactions (where significant) as primary predictors. The models will adjust for sex, hypertension, maximum percent weight loss, and clinic type (main General Internal Medicine clinic [practice of authors MBC, GSF] vs. other). We will include clinic type as we thought most patients would be recruited from our large academic practice and they might differ from patients recruited elsewhere. We omitted an initial plan to use a last observation carried forward analysis, as this approach has fallen out of favor for studies.(20-23) The mixed model allows us to include participants with missing data (i.e., lost to follow-up at one or more time points) in analyses.(9) A repeated factor of time and a compound symmetry covariance structure will be used for mixed model analysis. We considered a multiple imputation approach for missing data, but statistical literature does not support its use in context of longitudinal data analysis technique with mixed models (23). We will use 2-sided testing and a significance threshold of 0.05. All our analyses will be performed in SAS 9.3 (SAS Institute, Cary NC) using proc mixed and proc glimmix procedures.

Missing Data

We will perform a multiple imputation analysis on the wide data set and then we will combine our estimates and compared those with the estimates from our model where multiple imputation will be performed with the MNAR option in proc MI. If our data has an arbitrary missing pattern, we will use proc MI for this approach (with the fcs option).

(ref.https://www.sas.com/content/dam/SAS/support/en/sas-global-forum-proceedings/2018/1738-2018.pdf)

11 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

11.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

11.1.1 INFORMED CONSENT PROCESS

IRB approved consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention.

11.1.1.1 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. The investigator or study staff will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be

informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

All research personnel obtaining consent will have completed the appropriate research compliance education (IRB modules) and will be trained by the project coordinator on the appropriate consenting procedures, as set forth by the University of Pittsburgh IRB. An investigator will be available by phone if the participants have additional questions or concerns that they would like to discuss before they provide their informed consent, as specified in the informed consent documents.

11.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency and IRB.

11.1.3 CONFIDENTIALITY AND PRIVACY

- After consent is obtained, participants will be assigned a study ID number. All subsequent information will be identified only by this ID number.
- Strict confidentiality of information collected will be maintained.
- All research staff will complete required research information and training modules.
- HealthTrak is accessed by participants via a password-protected website which is hosted on a secure UPMC server.
    - Each authorized participant logs in with an assigned user name and secure password and then can access online lessons and input and information about his or her weight, daily intake of calories or fat, and physical activity.
    - An individual is only able to access his or her own information about lifestyle modification.

  - Secure passwords will include at least seven characters, including at least three of the following: lowercase letters, uppercase letters, numbers, and symbols.
  - The participant will be able to send messages to his or her lifestyle coach via the HealthTrak messaging system.
  - The program generates reminder emails, which are sent to the email account that each participant designates. However, no web-page within the HealthTrak program displays a list of these email addresses.
  - All participant information from the HealthTrak website, including participant research codes and email addresses, is encrypted using triple-DES encryption.
  - The encryption key is stored within the application in a compiled format and not in a database or flat file. Only an authenticated supervisor-level user can create new users on the system, and no deletions or updates are supported through any user interface.
- All paper-based data will be kept in a secure, locked location, accessible only to research staff.
- Electronic data will be kept in a password-protected database that is only accessible to research staff. Data confidentiality will be closely supervised.

Future use of data

- Data collected for this study will be analyzed and stored at the Division of General Internal Medicine Data Center. Data analyses will be conducted on de-identified data.
- Research records including identifiable data will be securely stored according to the current IRB guidelines. Data will be anonymized, and the link destroyed (shredded) after this time.

11.1.4 DATA SAFETY AND MONITORING PLAN

An Internal Advisory Board will be convened to review the inclusion/exclusion criteria, the design of the intervention for safety, and plans for monitoring participants for adverse events. They will also review protocols for protection of privacy and confidentiality of data. The investigators anticipate that the Board will meet prior to implementation of recruitment and every year thereafter. Meetings will be closed to non-members of the group, to ensure participant confidentiality. The Internal Advisory Board will include a representative from a clinical practice, to ensure that the participants' health interests are being adequately represented, a member of the Division of General Internal Medicine Data Center, to ensure integrity of data handling practices, and a clinical obesity researcher not affiliated with this study. At least one member will be a physician; study investigators will be excluded from membership. The roles of the DSMC will include review of the research protocol and plans for data and safety monitoring; and evaluation of the intervention (e.g., periodic assessments of data quality and timeliness, participant recruitment and retention, issues of risk versus benefit.). The monitoring will also consider how changes in the fields of behavioral medicine or preventive health may have influenced the safety of the participants. The DSMC will be charged with making recommendations to the IRB and investigators concerning study continuation or modification.

11.1.4.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant enrolled in the study.

Routine Center for Research on Health Care Data Center procedures will be used to ensure that privacy is protected around the collection and storage of outcomes data. Physical measurement data will be manually entered into the study data base. All manual data entry will be key-entered, using a double entry system to ensure data integrity. The study forms will be paperless in that the data will be directly entered over the Internet at the time of data collection via a Secure Socket Layer (SSL) web server with 128 bit encryption. A relational database management system will be stored on a dedicated web server where only select research team members will have access to the database through a secure login. Data will be protected by a network firewall, preventing unauthorized access. The database will include routine data edit checks for consistency both within and between forms. Once edited, temporary files will be merged to generate files for data analysis. All files will be backed-up daily and archived weekly. Database development and maintenance will occur with SQL Server and .Net programming available through the CRHC network.

All study participants will be assigned unique study identifiers that will appear on all data collection instruments, tapes, documents, and files used in the statistical analysis and manuscript preparation. In order to be HIPAA compliant, no personal information concerning study participants will retained in the analysis database. A list linking ID numbers and patient names will be maintained in a locked file in the PI's office.

The intervention software we will use includes extensive measures to ensure the privacy of participants' information-related information. The UPMC online visit program and HealthTrak portal have been developed to be HIPAA compliant, according to standard University of Pittsburgh Medical Center protocols. It is accessed by participants via a password-protected website. Each authorized participant logs in with an assigned user name and password and then track weight, daily intake of calories or fat, and physical activity or complete an online visit. The participant can also send messages to his or lifestyle coach via the HealthTrak messaging system. An individual is only able to access his or her *own* information about lifestyle modification. The program generates reminder emails, which are sent to the email account that each participant designates. However, no web-page within HealthTrak displays a list of these email addresses. This pilot utilizes lifestyle coaches, who will have coach-level access to HealthTrak. An authorized coach-level user can access only the names, self-reported lifestyle modification information, online questionnaires and messaging for the participants.

11.1.4.2 STUDY RECORDS RETENTION

Study documents should be retained for a period of five years from the date of NIH Federal Financial Report (FFR) submission.

11.1.5 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Hgrouponisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The

noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site investigator to use continuous vigilance to identify and report deviations within <specify number> working days of identification of the protocol deviation, or within <specify number> working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents, reported to <specify NIH Institute or Center (IC)> Program Official and <specify Data Coordinating Center or sponsor>. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.]

11.1.6 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested by researchers after the completion of the primary endpoint publication by contacting Dr. Conroy.

11.2 ABBREVIATIONS

AE	Adverse Event
GMP	Good Manufacturing Practices
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Hgrouponisation
IRB	Institutional Review Board
ITT	Intention-To-Treat
MAINTAIN-pc	Maintaining Activity and Nutrition through Technology-Assisted Innovation in Primary Care
NIH	National Institutes of Health
PCP	Primary Care Physician
PI	Principal Investigator
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities

11.3 SUMMARY OF IRB APPROVED CHANGES

Affected Section(s)	IRB Modification Number	Date	Summary of Revisions Made to Protocol	Rationale
N/A	MOD13020257-01	5/16/2013	**Change in protocol:** Added invitation for all primary care physicians at participating sites to complete a very brief anonymous survey regarding their opinion on the template for the real-time progress reports	Get a broad range of opinions in order to ensure the best possible incorporation of the reports into routine clinical practice
N/A	MOD13020257-02	6/5/2013	**Submit documents for IRB review:** 1. New advertisement 2. Updated exempt script for anonymous PCP report template surveys 3. PCP template report example	Compliance to IRB guidelines and regulations
1.3	MOD13020257-03	2/12/2013	**Change in protocol:** clarification study procedures prior to the initial recruitment of subjects	Clarification
11.1.4 5.2	MOD13020257-04	9/17/2013	**Change in protocol**: Edits to the data and safety monitoring plan **Addition of exclusion criteria:** Bariatric surgery in the last two years or planned during the next three years	Clarification In an attempt to include bariatric patients, we needed to add limitations to who could safely benefit from the MAINTAIN-pc intervention
5.1	MOD13020257-05	10/16/2013	**Change in protocol:** **Deletion of inclusion criteria:** no bariatric procedures in past 5 years	Inclusion criteria would eliminate a larger portion of participants in need of weight maintenance strategies
7.1.6	MOD13020257-06	11/23/2013	**Change in protocol:** Clarification of electronic pedometer collection procedures	There was some initial confusion with the interpretation of the protocol regarding the distribution of these pedometers. (*two pedometers given to each participant – one*

				for them to keep for use throughout their study participation and one to wear for 14 days for collecting an objective research measure of average steps at baseline and each follow-up time point).
6.1.1	MOD13020257-07	12/21/2013	**Change in protocol:** Addition of in-person individual time frame options for orientation sections during daylight hours	Provide more opportunity for participants to attend the orientation session In-person group sessions required that all participants attend during evening hours from 6:00 PM – 8:00 PM. Allowing participants to choose the orientation time that was most convenient for them increased session attendance and continuation in the study.
5.5.1	MOD13020257-08	2/11/2014	**Change in protocol**: Addition of recruitment method	Increase reach for recruitment
	MOD13020257-09	3/6/2014	**Change in protocol** :Update on recruitment methods and materials	Increase reach for recruitment
1.3	MOD13020257-10	5/10/2014	**Change in protocol**: follow up activity to include participants' feedback at each follow up visit	Capture feedback changes about the program at 6M, 12M, 24M and 30M
6 7.1.6	MOD13020257-11	1/17/2015	**Change in protocol**: addition of anonymous PCP feedback on newly created patient progress report template form	Obtain unbiased input from PCPs on data points to included in the patient progress reports to be received during their patient's study participation
1.3, 6, 7.1.6	MOD13020257-11	1/17/2015	**Change in protocol**: Change in the procedures and time frame for PCP feedback data collection	Streamlined content of patient progress reports (based on PCP comments) and clarified time points when PCPs receive them.

7.1.6	MOD13020257-12	2/27/2015	**Change in protocol**: Replaced the term 'anonymous' with 'confidential' in the PCP General Agreement Script for the PCP feedback survey	Since the IP address is collected through Qualtrics, the survey is not considered anonymous.
N/A	MOD13020257-13	4/21/2015	**Submit advertisement:** Uploaded email text for approval prior to sending Qualtrics survey link to PCPs	Compliance to IRB guidelines and regulations
1.1, 1.2, 1.3, 3	MOD13020257-14	9/11/2015	**Change in protocol**: Modification of intervention endpoint to 24-months.	Shorten the intervention from 36 months to 24 months due to significant delays in EHR build and recruitment. If not modified, study would surpass grant-funding period.
7.1.6	MOD13020257-14	9/11/2015	**Change in protocol**: Change in weekly online communication procedures	In addition to sending participants' weekly reminder messages to their online health portal mail, we included an option to also send the messages to an alternative e-mail address where they will read them on a more routine basis.
1.3	MOD13020257-14	9/11/2015	**Change in protocol**: Addition of an exploratory 30 month weight outcome to assess duration of effect after the intervention concluded	Secondary to changes for end point of trial
	MOD13020257-16	2/10/2016	**Change in study team:** Addition of a Co-Investigator	
1.3.1	MOD13020257-18	10/7/2016	**Change in study team:** Co-I Rachel Hess, MD, MSc will be replaced by Co-I Dr. Gary Fischer, Associate Medical Director of the Ambulatory eRecord.	Dr. Hess accepted new position at University of Utah
1.31	MOD13020257-19	5/23/2017	**Change in study team:** PI, Dr. Margaret Conroy will be replaced by Co-I, Kathleen McTigue from after Dr. Conroy's departure until the end of the trial.	PI, Dr. Margaret Conroy, accepted a new position as the Chief of General Internal Medicine at the University of Utah. The grant to remain at the University of

				Pittsburgh and the study will continue to be conducted under the general direction of Dr. Conroy. Current Co-I's, Kathleen McTigue, agreed to serve as the PI after Dr. Conroy's departure until the end of the trial. Dr. Conroy will continue to be actively involved in the project and will remain in touch with the study staff and investigators during bi-weekly and monthly conference calls, and as needed via email and phone contacts.

12 REFERENCES

1. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999-2008. JAMA. 2010;303(3):235-41.
2. McTigue KM, Harris R, Hemphill B, Lux L, Sutton S, Bunton AJ, et al. Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. Annals of internal medicine. 2003;139(11):933-49.
3. Messier SP, Loeser RF, Miller GD, Morgan TM, Rejeski WJ, Sevick MA, et al. Exercise and dietary weight loss in overweight and obese older adults with knee osteoarthritis: the Arthritis, Diet, and Activity Promotion Trial. Arthritis Rheum. 2004;50(5):1501-10.
4. Must A, Spadano J, Coakley EH, Field AE, Colditz G, Dietz WH. The disease burden associated with overweight and obesity. JAMA. 1999;282(16):1523-9.
5. Peeters A, Bonneux L, Nusselder WJ, De Laet C, Barendregt JJ. Adult obesity and the burden of disability throughout life. Obes Res. 2004;12(7):1145-51.
6. Kayman S, Bruvold W, Stern JS. Maintenance and relapse after weight loss in women: behavioral aspects. The American journal of clinical nutrition. 1990;52(5):800-7.
7. Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer-and service-specific estimates. Health Aff (Millwood). 2009;28(5):w822-31.
8. Services CfMaM. [Available from: *http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Intensive%20Behavioral%20Therapy%20for%20Obesity&bc=ACAAAAAAIAAA&NCAId=253&*.
9. Kushner RF. Barriers to providing nutrition counseling by physicians: a survey of primary care practitioners. Prev Med. 1995;24(6):546-52.
10. Tsui JI, Dodson K, Jacobson TA. Cardiovascular disease prevention counseling in residency: resident and attending physician attitudes and practices. J Natl Med Assoc. 2004;96(8):1080-3, 8-91.
11. Wee CC, Hamel MB, Davis RB, Phillips RS. Assessing the value of weight loss among primary care patients. J Gen Intern Med. 2004;19(12):1206-11.
12. Dansinger ML, Tatsioni A, Wong JB, Chung M, Balk EM. Meta-analysis: the effect of dietary counseling for weight loss. Ann Intern Med. 2007;147(1):41-50.
13. Jeffery RW, Drewnowski A, Epstein LH, Stunkard AJ, Wilson GT, Wing RR, et al. Long-term maintenance of weight loss: current status. Health Psychol. 2000;19(1 Suppl):5-16.
14. Wadden TA, Crerand CE, Brock J. Behavioral treatment of obesity. Psychiatr Clin North Am. 2005;28(1):151-70, ix.
15. Tsai AG, Wadden TA. Treatment of obesity in primary care practice in the United States: a systematic review. J Gen Intern Med. 2009;24(9):1073-9.
16. Leblanc ES, O'Connor E, Whitlock EP, Patnode CD, Kapka T. Effectiveness of primary care-relevant treatments for obesity in adults: a systematic evidence review for the U.S. Preventive Services Task Force. Ann Intern Med. 2011;155(7):434-47.
17. Barte JC, ter Bogt NC, Bogers RP, Teixeira PJ, Blissmer B, Mori TA, et al. Maintenance of weight loss after lifestyle interventions for overweight and obesity, a systematic review. Obes Rev. 2010;11(12):899-906.
18. Wing RR, Hill JO. Successful weight loss maintenance. Annu Rev Nutr. 2001;21:323-41.
19. McTigue KM, Conroy MB, Hess R, Bryce CL, Fiorillo AB, Fischer GS, et al. Using the internet to translate an evidence-based lifestyle intervention into practice. Telemed J E Health. 2009;15(9):851-8.
20. Rohrer JE, Angstman KB, Adamson SC, Bernard ME, Bachman JW, Morgan ME. Impact of online primary care visits on standard costs: a pilot study. Popul Health Manag. 2010;13(2):59-63.

21. Bodenheimer T, Grumbach K. Electronic technology: a spark to revitalize primary care? JAMA. 2003;290(2):259-64.
22. Crouter SE, Schneider PL, Bassett DR, Jr. Spring-levered versus piezo-electric pedometer accuracy in overweight and obese adults. Med Sci Sports Exerc. 2005;37(10):1673-9.
23. Melanson EL, Knoll JR, Bell ML, Donahoo WT, Hill JO, Nysse LJ, et al. Commercially available pedometers: considerations for accurate step counting. Prev Med. 2004;39(2):361-8.
24. Moreau KL, Deggroupo R, Langley J, McMahon C, Howley ET, Bassett DR, Jr., et al. Increasing daily walking lowers blood pressure in postmenopausal women. Med Sci Sports Exerc. 2001;33(11):1825-31.
25. Schneider PL, Crouter SE, Bassett DR. Pedometer measures of free-living physical activity: comparison of 13 models. Med Sci Sports Exerc. 2004;36(2):331-5.
26. Swartz AM, Strath SJ, Bassett DR, Moore JB, Redwine BA, Groer M, et al. Increasing daily walking improves glucose tolerance in overweight women. Prev Med. 2003;37(4):356-62.
27. Thompson DL, Rakow J, Perdue SM. Relationship between accumulated walking and body composition in middle-aged women. Med Sci Sports Exerc. 2004;36(5):911-4.
28. Connor SL, Gustafson JR, Sexton G, Becker N, Artaud-Wild S, Connor WE. The Diet Habit Survey: a new method of dietary assessment that relates to plasma cholesterol changes. J Am Diet Assoc. 1992;92(1):41-7.
29. Hays R. RAND-36 Health Status Inventory. San Antonio, TX: Psychological Corporation, A Harcourt Assessment Company; 1998.
30. Johnson JA, Maddigan SL. Performance of the RAND-12 and SF-12 summary scores in type 2 diabetes. Qual Life Res. 2004;13(2):449-56.
31. Wee CC, Davis RB, Hamel MB. Comparing the SF-12 and SF-36 health status questionnaires in patients with and without obesity. Health Qual Life Outcomes. 2008;6:11.
32. Sturm R, Wells KB. Does obesity contribute as much to morbidity as poverty or smoking? Public Health. 2001;115(3):229-35.
33. Gorman RS, Stern DL, Inclan DV, Presutti RJ, Swain JM, Hentz JG. Outcomes, health status, and medical resource utilization after bariatric surgery. Compr Ther. 2006;32(1):34-8.
34. EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group. Health Policy. 1990;16(3):199-208.
35. Kind P, editor. Quality of life and PhgroupacoEconomics in clinical trials. Second edition. Philadelphia: Lippincott-Raven; 1996.
36. Kolotkin RL, Crosby RD. Psychometric evaluation of the impact of weight on quality of life-lite questionnaire (IWQOL-lite) in a community sample. Qual Life Res. 2002;11(2):157-71.
37. Kolotkin RL, Head S, Hamilton M, Tse CK. Assessing Impact of Weight on Quality of Life. Obes Res. 1995;3(1):49-56.
38. Wadden TA, Phelan S. Assessment of quality of life in obese individuals. Obes Res. 2002;10 Suppl 1:50S-7S.
39. Tubach F, Baron G, Falissard B, Logeart I, Dougados M, Bellamy N, et al. Using patients' and rheumatologists' opinions to specify a short form of the WOMAC function subscale. Ann Rheum Dis. 2005;64(1):75-9.
40. Baron G, Tubach F, Ravaud P, Logeart I, Dougados M. Validation of a short form of the Western Ontario and McMaster Universities Osteoarthritis Index function subscale in hip and knee osteoarthritis. Arthritis Rheum. 2007;57(4):633-8.
41. Bakken S, Grullon-Figueroa L, Izquierdo R, Lee NJ, Morin P, Palmas W, et al. Development, validation, and use of English and Spanish versions of the telemedicine satisfaction and usefulness questionnaire. J Am Med Inform Assoc. 2006;13(6):660-7.

42. Davis FD. Perceived Usefulness, Perceived Ease of Use, and User Acceptance of Information Technology. MIS Quarterly. 1989;13(3):319-40.