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Financial vs. Non-Financial Rewards for Weight Loss and Weight Maintenance: A Randomized Controlled Trial

Human Subjects Protocol

VA Puget Sound IRB

Financial vs. Non-Financial Rewards for Weight Loss and Weight Maintenance: A Randomized Controlled Trial, IIR 15-459

MIRB# 00928

Funding Agency: VA HSR&D

Principal Investigator: Paul L. Hebert

4/27/2021

Abstract

Project Background: Behavioral economics suggests that our chronic inability to make the daily behavioral changes that can help us lose weight may be the result of "present bias," which is a tendency to value small, immediate rewards over large rewards in the distant future. For many of us, the immediate gratification of eating an unhealthy food is a more powerful motivator than is the elusive dissatisfaction of the long-run health consequences of an unhealthy diet. Patient rewards may overcome present bias by moving the rewards for healthy behaviors forward in time. In a patient reward program, patients are given tangible, timely rewards for achieving specific health goals, such as losing one pound per week over 16 weeks. Meta analyses of randomized trials have found that rewards for weight loss are effective during the reward period, but the weight loss was not sustained after the reward was removed. Thus, the key challenge to a reward program is not achieving weight loss, but maintaining it. The proposed study tests the hypothesis that the significant weight regain found in prior reward trials can be attributed to use of financial rewards—e.g., cash or the equivalent of cash—in those trials. Experiments in behavioral economics have found that providing participants with financial rewards for participating in a study invokes behavior defined by reciprocity—the effort the participants gave in the study was proportional to the amount of money that they were given. When participants were given non-financial rewards, they exhibited no reciprocity—the effort was consistently high and did not vary with the quantity of the non-financial reward. By using financial rewards, prior trials may have invoked money-market norms of reciprocity, such that patients' efforts toward weight loss were high when rewards were offered, and reduced when they were discontinued. We hypothesize that non-financial rewards, like tickets to a Seattle Mariners baseball game, will not invoke reciprocity or the consequent weight regain.

Project Objectives: The goal of this study is to test, through a randomized trial, the effectiveness of providing overweight Veterans with financial or non-financial rewards for a one pound weight loss per week over 16 weeks. The primary outcome is weight loss at 2 weeks—16 weeks after the discontinuation of the rewards. Secondary outcomes include weight loss at 16 weeks and 12 months.

Project Methods: We will conduct a three-armed randomized trial of patient rewards for losing one pound per week over 16 weeks. The three treatment groups will receive financial rewards, non-financial rewards, or no rewards. We hypothesize that: 1) patients who receive non-financial rewards for weight loss over 16 weeks will have greater weight loss at 32 weeks than patients who do not receive rewards; 2) patients who receive non-financial rewards for weight loss over 16 weeks will experience weight loss at 16 weeks that is not inferior to the weight loss of patients who receive financial rewards; and 3) weight regain will be greater among patients who received financial rewards compared to patients who received non-financial rewards or no rewards. We will also conduct post-intervention qualitative interviews and perform a cost analysis.

List of Abbreviations

VA = U.S. Department of Veterans Affairs

CM = Contingency management

VAPSHCS = VA Puget Sound Health Care System

SMI = Serious Mental Illness

MOVE (and variations of) = MOVE is not an acronym. MOVE is the VA Weight Management Program

ERIC= Epidemiologic Research and Information Center

DMAP= Data Management Access Plan

REBS= Regulation of Eating Behavior Survey

NHANES = National Health and Nutrition Examination Survey

NHIS = National Health Interview Survey

SHEP= Survey of Health Experiences of Patients

TFEQ = Three Factor Eating Questionnaire

CDW = Corporate Data Warehouse

VSSC = VHA Support Service Center

CPRS= Computerized Patient Record System

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2.0 Introduction

Obesity and overweight are major health problems for Veterans. An estimated 37% of Veterans are overweight, and 38% are obese.[1] Veterans who are overweight or obese have higher rates of hypertension and diabetes, and are more likely to report being in poor health.[2] Weight loss is associated with reduced rates of morbidity and mortality.[3] In response to the obesity epidemic, the VA created the MOVE! program. MOVE! offers a set of tools, resources, and guidance for weight management and is available to Veterans through a variety of formats, including individual and group meetings, telephone and web-based coaching. However, in a 2012 study, Littman et al found that less than 5% of Veterans who were eligible for MOVE! participated in at least one MOVE! related visit.[1] Consequently, MOVE! is not meeting the needs of the great majority of eligible Veterans. VA National Center for Health Promotion and Disease Prevention is responding by adding more technology-based tools, but other options, including patient rewards for weight loss, should also be explored.

Recent research in behavioral economics suggests that a patient reward program for weight loss may be an effective option for Veterans. Behavioral economists argue that our chronic inability to lose weight may be explained by present bias, which is a tendency to value small immediate rewards over large, future rewards.[4] The immediate satisfaction of consuming an unhealthy but desirable food is a relatively powerful reward compared to the distant satisfaction associated with improved health later in life that healthier diet and exercise choices bring. Individuals are also more motivated to engage in behaviors that yield concrete rewards rather than less tangible ones;[5] reducing the probability of a myocardial infarction in the future may be too intangible to motivate present health behavior.

Patient reward programs may help to overcome present bias by providing patients with a timely, tangible reward for achieving a health-related goal. There is a growing body of evidence suggesting that rewards work for some health behaviors, including smoking,[6,7] medication adherence,[8] vaccinations[9,10,11] and screening.[11,12] Rewards are especially effective among lower-income patients, who are common in the VA population.[6] There has been robust success using rewards for treatment of substance abuse,[13] where it is referred to as contingency management (CM). CM has been widely implemented in addiction treatment clinics across the VA.[14]

Financial rewards for weight loss are also effective. Several meta analyses and systematic reviews[6,11,15,16,17] have studied the variety of forms of financial rewards, designed to make use of common decision errors. Group-based payments allow individuals who achieve a weight loss goal to share the reward of individuals in their group who failed to meet the goal, which takes advantage of our tendency to assume that we are each better than average.[12] Lotteries take advantage of our tendency to over-estimate the probability of rare events. Deposit contracts, in which a participant forfeits their own money if they do not reach a target weight, takes advantage of loss aversion, whereby a loss decreases our perceived wellbeing by more than similar sized gain increases wellbeing. Across these various interventions, there is consistent evidence that rewards help people to lose weight while they are being given rewards, but there is little evidence that rewards lead to sustained weight loss after rewards were removed. Except for two recent trials, patients who were given rewards regained weight, such that the weight loss at follow-up was not statistically different from usual care. Thus, the key question for incentivizing weight loss is not only how to get patients to lose weight, but also how to structure the rewards so that patients maintain the weight loss after rewards are removed.

Summaries of three relevant randomized controlled trials of financial rewards for weight loss are shown in Table 1. These studies serve as a model for the proposed study; we will adhere very closely to the procedures used in these highly-respected trials, and collect and present data so that results are easily compared. We focus on these trials because the results largely support the findings of systematic analyses and meta-analyses of rewards for weight loss, and two of the studies were conducted at the VA. Two observations regarding these studies are noteworthy. First, each study found significant weight loss during the incentivized period, despite differences in the populations studied, and form and duration of the reward. The study published in JAMA[8] had especially impressive results with half of the reward group meeting the target weight loss. Second, each study found weight regain after the financial reward stopped; however, the regain in the study published in Annals (2013)[12] was only 3.2 lbs. in the group reward arm, resulting in a 7.5 lbs. mean weight loss that was statistically significantly different from usual care. Weight regain in the lottery arm of the JAMA (2008)[8] study was only 3.9 lbs., which resulted in a statistically significant 9.2 lb. decrease in weight compared to baseline, although not compared to usual care. Thus, while few trials have sustained weight loss

after the reward period, we do not have far to go. The key is to design the reward with a specific emphasis on minimizing regain after the rewards are removed.

Table 1. Three model studies of financial rewards for weight loss, and the proposed study

Study characteristics	JAMA (2008) [8]	JGIM (2011) [18]	Annals (2013)[12]	Proposed study
Setting	Philadelphia VAMC (95% male)	Philadelphia VAMC (83% male)	Employees of Children's Hospital (89% female)	Seattle VAMC
Weight loss goal	1 lb./week	1 lb./week	1 lb./week	1 lb./week
Trial arms (participants per arm)	Usual care (n=19) Lottery: expected value ~$90/month; (n=19) Deposit contract: max $75/month (n=19)	Usual care (n=22) Deposit contract: max $84/month (n=44)	Usual care (n=35) Individual: $100/month (n=35) Group: $500/month split among 5 patients (n=35)	Usual care (n=80) Financial lottery (n=100): expected value $100/month; Non-financial raffle (n=100): expected value ~$100/month.
Duration of rewards/total follow-up	16 weeks/28 weeks	32 weeks/68 weeks	24 weeks/36 weeks	16 weeks/32 weeks
Weight change at termination of rewards (lbs.)	Usual care: -2.9 Lottery: **-13.1*** Deposit contract: **-14.0***	Usual care: -1.2 Deposit contract: **-8.6***	Usual care: -1.1 Individual: -3.7 Group: **-10.6***	Min detectable difference Usual care: -1.6 Lottery: -8.1 Raffle : -8.1
Weight change at follow-up (lbs.)	Usual care:-4.4 **Lottery: -9.2** **Deposit contract: -6.2**	Usual care:-0.3 **Deposit contract:-1.2**	Usual care: -0.9 Individual: -1.8 **Group: -7.5***	Min detectable difference Lottery: -3.1 Raffle : -8.1

Our target population for this study is overweight or obese Veterans, ages 18-69. Please see section 5.4 for additional information on our inclusion/exclusion criteria.

3.0 Objectives

The proposed study is based on the hypothesis that the regain found in prior reward studies was due in part to their use of financial rewards, and financial rewards may make patients especially susceptible to regain. Experiments in behavioral economics have found that when participants were provided financial rewards for performing a task, their behavior toward the task was defined by reciprocity—the effort the participants gave was proportional to the amount of money that they were given. When participants were given non-financial rewards, they exhibited no reciprocity—the effort was consistently high and did not vary with the quantity of the non-financial reward. These findings have been confirmed in field studies, and experiments using functional MRIs: money as a reward makes us think and behave differently. By using financial rewards, prior trials may have invoked money-market norms of reciprocity, such that patients' efforts toward weight loss were high when rewards were offered, and reduced when they were discontinued. We hypothesize that non-financial rewards, such as tickets to a Seattle Mariners baseball game, will not invoke reciprocity or the consequent weight regain. We also hypothesize that the affective or emotional characteristics of non-financial rewards can make them more powerful than financial rewards. A patient's thoughts about receiving a non-financial reward, such as tickets to baseball game, can create a positive emotional reaction that can be more salient than the cash value of the reward.

The goal of this study is to test, through a randomized trial, the effectiveness of providing obese Veterans with financial or non-financial rewards for losing 1 lb. per week over 16 weeks. The primary outcome is weight loss at 32 weeks—16 weeks after the discontinuation of the rewards. Secondary outcomes include weight loss at 16 weeks and 12 months. The specific aims are outlined below.

Aim 1. Conduct a 3-armed randomized trial of patient rewards for losing 1 lb. per week over 16 weeks. The 3 treatment groups will receive financial rewards, non-financial rewards, and no reward (usual care).

- Hypothesis 1a: Patients who receive non-financial or financial rewards for weight loss over 16 weeks will have greater weight loss at 32 weeks than Veterans who do not receive rewards.

- Hypothesis 1b: Patients who receive non-financial rewards for weight loss over 16 weeks will experience weight loss at 16 weeks that is not inferior to the weight loss of Veterans who receive financial rewards.
- Hypothesis 1c: Weight regain between week 16 and the 32-week and 12-month follow-up, respectively, will be greater among Veterans who received financial rewards compared to Veterans who received non-financial rewards or no rewards.

Aim 2. Conduct post-intervention qualitative interviews of trial participants.

- We will conduct post-intervention qualitative interviews to gain a deeper understanding of how the rewards in the proposed trial affected patient motivation for weight loss.

Aim 3. Conduct an analysis of intervention costs.

- We will conduct an analysis of the cost of implementing a patient reward program for weight loss and compare this cost to the cost of the MOVE! program.

Overweight and obesity are associated with the development of chronic diseases. In addition, poor health behaviors, such as the failure to maintain a healthy weight, explain half of the socioeconomic disparities in cardiovascular mortality. Thus, this grant addresses VA priority areas of chronic conditions and disparities.

4.0 Resources and Personnel

Research will be conducted by the research team listed on the study staff sheet in consultation with Drs. Maciejewski and Desai. Research will take place at VA Puget Sound Health Care System.

Various study staff roles include accessing data, recruiting participants, obtaining informed consent, administering surveys/interviews and performing data analysis. See the chart below for a full description.

Paul Hebert, PhD, Principal Investigator, VA Puget Sound HSR&D, is an Investigator in the Denver-Seattle Center of Innovation (COIN) for Veteran-Centered and Value-Driven Care, and a Research Associate Professor in the Department of Health Services, University of Washington. Dr. Hebert is a highly-experienced health services researcher who has collaborated with Drs. Liu, Sayre, and O'Hare on numerous VA-funded studies. Dr. Hebert will have overall responsibility for the project, and primary responsibility for implementing the randomized controlled trial, data extraction, the analysis plan, and reports and manuscripts developed from this research.

Alyson Littman, PhD, MPH, Co-Investigator, VA Puget Sound ERIC, is a Research Health Scientist at the Epidemiologic Research and Information Center (ERIC) and a Research Associate Professor in the Department of Health Services, University of Washington. Dr. Littman specializes in weight management, and has also studied the effectiveness of the VA MOVE! program. Dr. Littman's studying weight loss and physical activity in Veterans will guide the implementation of the study. Dr. Littman will assist with the study implementation; consult on any challenges faced during the intervention, and will assist with manuscript preparation and data analyses.

Ann O'Hare, MD, MA, Co-Investigator, VA Puget Sound HSR&D, is a nephrologist, VA HSR&D Investigator at the Seattle COIN, and Professor of Medicine at the University of Washington. Drs. O'Hare and Hebert have previously collaborated on several VA-funded grants, and are currently collaborating on a study analyzing the timing of dialysis initiation within and outside of the VA, as well as a study examining advance care planning for Veterans with kidney disease. Dr. O'Hare will provide clinical expertise, and will assist in developing the analysis plan, interpretation of analyses, and preparation of reports and manuscripts for publication.

George Sayre, PsyD, Co-Investigator, VA Puget Sound HSR&D, is the Qualitative Resources Coordinator at the Seattle COIN and a Clinical Assistant Professor in the Department of Health Services, University of Washington. He is a highly experienced qualitative researcher who will be responsible for leading Aim 2 activities. Dr. Sayre will oversee the interviews and interview coding using Atlas.ti software. Dr. Sayre will not act in a clinical role on this study.

Ashok Reddy, MD, Co-Investigator, VA Puget Sound HSR&D and Assistant Professor of Medicine at the University of Washington. Dr. Reddy will provide clinical expertise and will assist with study design and implementation. Dr. Reddy will also train staff on meeting with participants.

Larry Swanson, Data Analyst, will be responsible for construction of the Access database to track participants and participant interactions as they progress through the study. Mr. Swanson will complete merges between different data sets (Vinci, mail merges, text messaging and/or email reminders, the scale website and participant weight website). Mr. Swanson will be responsible for creating and maintaining an access database to facilitate data entry from research coordinators.

Jamie Douglas, MA, Data Analyst, will be responsible for analysis of study data. She will work on all sub analysis and manuscript preparation.

Emily Neely, MPH, Research Coordinator, will be responsible for the coordination of all regulatory submissions and data requests, and will assist with manuscript and report preparation. Ms. Neely will also be responsible for coordinating and scheduling patient recruitment for the trial, enrolling, consenting, and tracking trial patients, speaking on the phone with trial participants to provide timely feedback, meeting trial patients to perform in-patient scheduling and conducting patient interviews.

Christine Sulc, BA, Research Coordinator, will provide routine administrative support for the project, and will assist with regulatory submissions and data requests. Ms. Sulc will also assist Ms. Neely with activities such as regulatory paperwork, coordinating the trial, coordinating and conducting the interviews, fielding the surveys, and conducting in-person weigh-ins.

Taryn Oestreich, MPH, MCHES, Research Coordinator, will be responsible for potential participant recruitment, participant follow-up, participant visits, participant mailings and interviews.

Jeffrey Todd-Stenberg, BA, Data Manager, will be responsible for pulling data from VA resources such as CDW, Vinci and Vista, among others. Mr. Todd-Stenberg will also merge data files.

Matthew Maciejewski, PhD, Co-Investigator, Durham VA Medical Center, is a Research Career Scientist at the Durham Center for Health Services Research in Primary Care, and Professor in the Department of Medicine at Duke University. Dr. Maciejewski will provide expertise in weight loss and the effect of financial rewards, as well as methodological expertise.

Sohilkumar Naria, RN, Cohort Creator, will be responsible for running VistA fileman programs for recruitment purposes.

Ashley Mog, PhD will conduct patient interviews and the qualitative analysis with Dr. Sayre.

Ed Udris, MPH, Research Coordinator, will be responsible for potential participant recruitment, participant follow-up, participant visits, participant mailings and interviews.

We will be consulting with Dr. Desai, a Research Fellow at the HealthPartners Institute for Education and Research. Dr. Desai is an experienced investigator who has worked on several patient rewards trials previously. Dr. Desai will provide guidance on implementing and analyzing a rewards trial. Dr. Desai will not receive compensation for consultation; however, we are requesting travel money for two face-to-face meetings over the span of the project.

Table 2: Study personnel

Study Staff	Access to PHI	Patient Recruitment	Informed Consent	Conducting Interviews	Data Analysis (including surveys/interviews)
Paul Hebert	**X**	**X**	**X**	**X**	**X**
Alyson Littman	**X**	**X**	**X**		
Ann O'Hare	**X**				
George Sayre	**X**	**X**	**X**	**X**	**X**
Ashok Reddy	**X**	**X**			**X**
Jamie Douglas	**X**				**X**

Emily Neely	X	X	X	X	X
Christine Sulc	X	X	X	X	X
Larry Swanson	X				X
Jeffrey Todd-Stenberg	X				X
Taryn Oestreich	X	X	X	X	X
Matthew Maciejewski					
Jay Desai					
Sohilkumar Naria	X	X			
Ashley Mog	X			X	X
Ed Udris	X	X	X	X	X

5.0 Study Procedures

5.1 Study Design

This is a randomized controlled trial that will enroll participants on a rolling basis. Each participant will be enrolled for approximately 1 year. However, participants may also choose to be consented into the associated repository, "Rewards Project Data Repository (MIRB-00982)." Please refer to the attached study flow chart for a visual depiction of study events and timeframe of participant activities. An overview of what the website (portal) looks like and functionality is in the document titled "website mock up," and portal screen shots.

There are two points of randomization. After patients are enrolled in the study, they will be enrolled in the portal. At portal enrollment, they will be randomized to either receive a wireless (Blipcare) or the wireless Blipcare scale and the Connect device. At enrollment all participants will receive the Blipcare wireless scale. There are two different types of scales: wireless Blipcare scales and a non-wireless digital battery powered Taylor scales. The Blipcare scales are wireless scales that transmit weight data through a cellular hub, "Connect." Regardless of the scale the participant receives, all participants will be encouraged to record their weight manually to better keep track of their weight (Appendix N). All participants in all arms will also record their weight into the study portal as outlined below. The participants that receive a Blipcare scale with the Connect device will have their weight recordings sent automatically to research study staff via the Connect device. At the 16-week study visit, participants may be asked to exchange their scales for a Taylor scale, depending on our Blipcare scale inventory. Due to the mechanism of reusing the Blipcare scales and Connects, some participants may only receive Taylor scales, and some participants may be able to keep their Blipcare scales.

5.1.a Study group-specific procedures.

No-reward (usual care):

At the enrollment visit, the coordinator will fully explain the study to the participant. After the explanation, the patient will be consented by a trained member of the study team. The participant will have the option to also consent into the associated data repository (MIRB# 00982). If the participant declines, none of their information will ever enter or be associated with the repository. The participant will then be enrolled in the participant portal by the study staff member.

The participant will be given a unique study ID (login) and temporary password to login to the portal. No identifiable information will be entered, kept or associated with the portal. The coordinator will enroll the participant into the portal. The enrollment will generate a unique username and password which will be given to the participant. The coordinator will record the participants unique user name in the password protected database on the J:drive. No participant information will be entered, stored or disclosed to the portal.

If the participant forgets their login information, or the website address, they will be able to reset their password by entering in their study id, gender and preferred day of the week for weight entry (no identifiable information). If the participant forgets the portal url, they can contact the study team members or refer to their handout. If the participant still cannot access the portal or forgets their user ID they can contact the study team who will provide it again after verifying the participant's ID. If they are having trouble logging in, they can contact the study team. The participant will change their password the first time they log in to the website.

The website has two data entry options: weight entry and survey (website mock up). The participants will enter in their weight on a predetermined week day as determined by them. We will encourage them to continue to do this for one year. They will be instructed to enter in the weight exactly as it is shown on the scale XXX.X. For the follow-up participant survey, it be available starting on the day it is due (16 weeks, 32 weeks and 1 year) and for three weeks after. At baseline, the participant can complete the survey anytime between baseline and two days hours before their first weight is due. The study coordinator will demonstrate accessing the website by logging in to a test account. The participant is weighed and the weight reading is entered in to the portal by the coordinator in the administrator website. This weight measurement is the baseline measurement for the study. Section 7 below covers privacy matters related to text messaging and/or email reminders and the portal.

The patient portal is a secure federal government website. All data is housed at the VA Austin Data Center. The website is designed and created by the VA Cooperative Studies Program Clinical Research Pharmacy Coordinating Center in Albuquerque with all information stored behind the VA firewall on VA servers in Austin, TX. None of the information entered in to the portal is associated or connected to the study participant. The participant will only be able to access the portal by using their login name and temporary password provided at enrollment. The first time the participant logs in they will be forced to change their password. Their name and any other identifier is never associated with the website. The crosswalk linking the participant's name and portal login information will always be kept in the secure J:drive folder. Only the study team will have access to it. Data entered into the website (weights and survey responses) and user ID will be exported from the portal (website) in a comma delimited file (.csv) by the study team in Seattle and saved directly onto the secure J:drive study folder.

The participant will be registered in the portal by the coordinator under the administrative login. After the participant's login becomes active it will alert the coordinator and participant which scale the participant receives: either a Blipcare scale or a Blipcare scale and Connect (wifi) device. This is done through a randomization table built into the portal. Each participant will receive either a wireless Blipcare scale or wireless Blipcare scale and wifi Connect device (Carematix). Each participant will be given a scale and an extra set of batteries. Upon plugging the Connect device in to an electronic outlet, it will send all weight readings to the Carematix company which will be accessible by the VA study team. Participants may be asked to return their Blipcare Scales and Connect devices at the 16-week study visit. Participants will receive a phone call and text message/email from the coordinator the day before their visit. If they are being asked to return their Blipcare scales they will be reminded of this. If they received a Connect device, they will be asked to return those. They will also receive a reminder postcard the week before their visit (Appendix L.c, and U). This is further described in section 7. Participants in both groups will be asked to enter their weight into the portal each week.

Participants will be counselled to weigh themselves daily, after urinating and before eating. Participants are given a sheet to document their self-reported weekly weight (Appendix N). Appendix N is solely for the participant to use and for their convenience.

The participant will then select the most convenient day of the week to record their weight. If it is less than 7 days from the baseline visit, it will be the following week. If it is exactly 7 days away, they will be given 14 days to start. Even if the participant chooses the next day, the participant's first actual weigh-in day will be the following week, so no matter what the scenario, the participant will always have at least eight days to start the

study. All participants will record their weekly weights in the participant portal (website). This is to give the participants the maximum amount of time to successfully start the study.

Example:

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		Baseline study visit				
	Monday is the best day for the participant					
Last day for participant to complete baseline survey	This would be the first day the participant enters their weight into the website					

Every week on the day chosen by the participant, they will login to the patient portal and record the weight reading on their scale. The participant will login using their unique study ID and password. The participant will not be able to change their study ID. The participant will be forced to change their password the first time they login. If the participant forgets their password they can reset it by entering their study id, gender, and preferred weigh-in day.

The day before the weight recording is due, the participant will receive a text message and/or email reminding them to login to the portal (Appendix V). Participants will not be able to reply to the text message and/or email. It will only function as a reminder for study procedures. On the day their weight is due, a reminder text message and/or email will be sent. If they miss a weigh-in, they will receive a text message/email reminding them to enter their weight. If it is not feasible for the participant to log in to the portal and enter their weight, the coordinator will record their self-reported weight in the portal (Appendix V and X). Up to three attempts will be made to contact the participant about their weight each week via text message and/or email (day before, day of, day after). If a participant misses 4 weight entries in a row, they may receive up to three phone calls and may receive a post card. The website option to enter their weight will be available the day before and the day after their scheduled day. The participant will have 72 hours to complete their weekly entry. In the example above this would-be Sunday through Tuesday. A summary of follow-up and reminder activities is in Appendix AE, follow-up schedule. Follow-up and withdrawal will be explained to the participant in detail by the study coordinator.

Rarely the website is down for routine maintenance. As a result participants will not be able to enter in their weekly weights or complete the survey. We will be sending this message to all impacted participants-

“The portal will be unavailable on (day of the week, date) from (beginning – end time). If you would like to record your weight during that time, please leave a voicemail by calling 206-277-4797. We apologize for any inconvenience this may have caused. Full portal functionality will be restored after (end time).”

Once the participant records their weight into the participant portal a message will come up depending on their weight. For example, “Congratulations on reaching your goal! You’ve worked hard. Your goal for next week is XXX.” The message will reflect the data the participant provided and how close they are to their goal (See Appendix T).

Participants will receive an automated text message and/or email the day before their weight entry is due (Appendix V). They will not be able to respond to the text message and/or email. All participants will be able to enter their weight the day before, the day of and the day following their weight due date (72-hour window).

After the participant's account becomes active the coordinator will provide the participant with the website portal instructions, user ID and password (Appendix S). All participants will use the portal to enter in their weekly weights and complete the four participant surveys (baseline, 16 and 32 weeks and one year).

Participants will be instructed to login to the portal at their convenience to complete the baseline survey anytime until 24 hours before their weight is due. Participants may receive an automated text message and/or email reminding them to complete the survey in the portal. The survey option will only become active when their weight is due at the baseline, 16-week, 32 week and one year interval. For survey entries at 16, 32 weeks and one year the survey will be available for 21 days following their weigh in date.

Participants will then tentatively schedule the next study visit with the study coordinator, and will be given the visit date and time.

As of 3/6/2020 we have temporarily stopped doing study visits in person. We have attached a phone script that is comprehensive of scheduling phone visits and completing each of the three follow-up visits. Once we have additional information on the current situation, we will update the protocol again. Each participant that records their weight with us during one of the phone visits will still receive the $20 they would have received for the in-person visit. We will send the request for the $20 check in as we have done.

For participants that are currently in week 1-32 of the non-financial rewards arm we are requesting to send them a letter to indicate there could be a delay in shipping the items they have won. A draft letter is included in this modification.

We are requesting to send the enclosed letter to all study participants to informed them of over the phone visits and that they will still be compensated as they would have been if they had come to an in-person visit.

These three study visits will be the 16 and 32-week visits and the 1-year study visit. At the 16-week study visit, participants may be asked to return their devices (Appendix U). To increase adherence and increase the number of returned scales, if applicable, participants will receive a reminder postcard for their visit and to return their scales. 24-48 hours before their visit participants will also receive a reminder phone call. If the participant fails to show up at their 16-week visit, we will make every attempt to meet them after their next scheduled visit or to encourage them to return their device(s) at their 32 week visit. As a last resort, we will send a postage paid packages from them to return their device(s). All participants who are asked to return their Blipcare scales will receive a Taylor scale at the 16-week visit.

Prior to the conclusion of the baseline study visit, participants will be reminded to login to the portal and complete the baseline survey at least one day before their first weigh in. Participants may receive an automated text message and/or email reminding them to complete the survey in the portal, and may also receive a phone call if their survey has not been filled out by the time it's due. Study staff may extend the timeframe for the baseline survey completion if necessary.

The study participant will find out which arm of the study they are in after they have completed the baseline survey.

All participants will be given the modified MOVE! workbook (Appendix D) that serves both as an information resource on diet, lifestyle, food choices, portion size and a few pages that have been used as an educational handout in the Vet Coach study (pages 155-160). Participants will also be given a tracking book which contains educational resource (government wellness resources and phone applications, Appendix F), a summary page with a timeline of actions, a place to record their weekly weight and their new weekly goal (Appendix N), and 43 pages to track a weekly goal/motivations and outcomes and steps taken to reach the goal. Participants will also receive a reference guide including all topics covered in the baseline study visit (Appendix R), portal instructions (Appendix S), copies of the consent & HIPAA forms for this study and the associated repository #00928, a scale instruction manual (Appendix AA) and instructions on how to use the Connect (Appendix AB).

To schedule the remaining study visits, we will call patients 2-4 weeks prior to their 16-week, 32 week and 1 year appointment. We may also send a reminder text message and/or email asking the participant to call the study team to schedule their appointment. Additionally, we will call participants and send reminder text messages/emails 24-48 hours before their scheduled follow-up visits.

Participants will all be told what the goals of the study are: We want them to lose 16 pounds in 16 weeks and keep the 16 pounds off for another 16 weeks. From week 16 to week 32 we want them to at least maintain their weight loss. When the participant enters their weight into the portal, a new goal weight will be generated. The weight goals will be re-calibrated every month based off the participant's entries. Weight loss goals will be capped at a maximum of 4 pounds. If the participant reaches a point where they must lose more than 4 pounds in a week the goal remains a maximum of 4 pounds for the next week. If the participant reaches a point where they must lose more than 4 pounds a week to reach the 16-pound goal the rewards will be removed because we do not want to incentivize unhealthy or safe behaviors. If a participant loses 10 pounds or more in a week they will be contacted by a study staff member (coordinator (Neely, Sulc, Oestreich or Udris), PI (Hebert) or physician (Reddy or O'Hare) to ensure they are using an appropriate weight loss method. The participant will also be asked of any illness or new medical treatments. Participants that are within .4 pounds of the goal will receive the reward if they are in the financial or non-financial groups. Participants within the financial or non-financial rewards group will earn $25 (or equivalent non-financial reward) for every successful monthly weigh-in. This occurs at weeks 4,8,12 and 16. Participants in these groups will have the opportunity to randomly win $100 (or point equivalent for non-financial rewards) at three random times for successful weigh-ins at their goal weight (±.4 pounds). During weeks 16-32, participants in the two rewards groups will be eligible for a token reward just for entering their weight.

Financial reward: Veterans in the financial reward arm receive all the services of the usual care arm, plus opportunities to earn rewards in two ways: assured rewards and seemingly (to the participant) random rewards. For the assured reward, participants will receive $25 at the end of each month (defined as a four-week period) that they are at or below their target weight on the last day of that period. For the random awards, each week that a participant is at or below their target weight, the patient has a perceived opportunity to receive $100 via a raffle. Over the first eight weeks the patient will be told they have a 1-in-8 chance of receiving a random reward for achieving their weight loss target. To operationalize this, for each patient, we will use a random number generator to randomly sort numbers from 1 to 8 and pick the top listed number as the week on which the patient will receive $100 for an on-target weight in this week. This looks the same as a random reward from the patient's perspective, but caps the study's reward expenses.

This is also a mild form of deception: The patient award week comes only once in the first 8 weeks of the study. After that week, has passed, the patient has no chance of receiving a random award until weeks 9-16 (as described below). We use this deception so that the patient remains motivated to lose weight. In addition, alternative ways of delivering the random reward had other drawbacks. For example, we could randomly assign reward weeks over the entire study population, such that some patients received more opportunities to earn a random reward than others, but this would not be equitable, and maybe frustrating to a Veteran who met each weight target but, by chance, never earned a random reward.

In order to ameliorate the effects of habituation to the reward as Jeffery (2012)[17] suggests, we will improve the perceived odds of winning to a 1-in-4 chance over weeks 8-16. For each patient, we will use a random number generator to randomly sort numbers from 1 to 8 and pick the top two listed numbers as the two weeks on which the patient will receive $100 for an on-target weight. Veterans who meet all weekly targets will receive $100 in guaranteed rewards, and $300 in random rewards, for a total expected earnings of $400 (average of $100/month), used in the JAMA, JGIM, and Annals studies described in Table 1. If a patient misses a monthly weight target, their weekly target weight for the remainder of the reward period will be recalibrated so that the patient can still earn rewards if the patient's weight loss trajectory puts them on track to lose 16 lbs. in 16 weeks, if the weight loss does not exceed 4 lbs. per week.

Once the participant completes his/her weight entry in the portal they will immediately be told if they won their reward or not. If the patient withdraws they will receive what they have earned up to that point in time and we will ask them to participate in an interview to better understand why this study didn't work for them. For participants in the financial reward group, they will receive a check in the mail for their reward. Receipt of the check can take between 3-12 weeks. Depending on enrollment, we will either request the check be issued within one week of when it was earned and the participant is notified or we will submit a request at 16 weeks for the participant to be paid then. To collect the reward, we will ask that the patient come to the clinic for an in-person weigh-in with study staff, but we cannot require it. They will receive the reward regardless of their in-person weight. We do this in part because weight can fluctuate throughout the day and because the true test of whether rewards work will be determined at the 16 and 32 week in-person weigh-ins. Knowing there will be a

weigh-in prior to collecting the reward may also reduce the under-reporting of weight. Participants may login to the portal at any time and see how much they have earned (financial or non-financial).

Finally, over the 17-32-week period, Veterans in this group will receive random token rewards for tracking and reporting their weekly weights regardless of whether it was on target. We will again randomly generate one reward week for each of the four 4-week periods, for a total of up to four winning weeks during the week 17-32 period. Each reward week that the patient enters his/her weight into the portal, he/she will receive a token reward, similar to 5-point items in Appendix H. The token rewards include a reflective light, water bottle, thermal grocery bag and vegetable peeler. These rewards will be mailed to participants (Appendix Y and Z).

Non-financial reward: Procedures for the non-financial rewards arm are identical to procedures for the reward arms, except that the Veteran will earn points rather than cash. The point value will either be 5 points or 20 points which correspond to the level of reward (20 point is a larger reward then a 5-point item). These points will not be cumulative. When a participant earns points at a monthly or random weigh-in they will be immediately notified of their success. They will be told they earned a non-financial reward that will be mailed to them. Each point is assigned a value of approximately $5 so each weekly random reward will be worth 20 points (or approximately $100). They will not be allowed to “cash-out” their points. The non-financial rewards will be mailed to the Veterans within one week of them earning their rewards. Veterans in this group will also receive the same types of random, token rewards in weeks 17-32 that Veterans in the financial arm receive.

5.1.b Potential risks. The health intervention itself poses no undue risks. There will be minimal risks to the participants responding to the study questionnaires. The survey, including health history questionnaires, could potentially induce stress secondary to invasion of privacy. Although unlikely, some respondents may find some questions intrusive or offensive. Participants are free to skip any questions they do not wish to answer. The patient portal is housed within the VA network in Austin on secure VA servers. Participants will be given a schedule of visits and will be free to withdraw from the study at any time without penalty or loss of any rewards they have already earned.

Patients may benefit from participating in the study by losing weight, increasing physical activity and overall living a healthier lifestyle. These potential benefits make the minimal risk reasonable in relation to the anticipated benefits.

We have been informed by the MOVE coordinator that if participants are in this research study they can not participate in the MOVE! program because the participant would be double dipping and influence the MOVE! group dynamics. Therefore, if someone enrolls in this program they will not be eligible for standard care for the duration of their participation.

The absolute maximum that could be earned would be $580 assuming the patient achieves all weight loss goals and all token rewards for reporting their weights. All medical centers are required to track the amounts paid to patients during a year. If the amount is $600 or more in a calendar year, the institution is required by the Internal Revenue Service (IRS) to issue a form 1099MISC to the participant and send a copy to the IRS. This is reported as "miscellaneous" income to the IRS. This amount could have the potential to change Veterans’ eligibility for social services in the coming tax year. Scheduling conflicts can and will arise. A medical letter excusing absence from work to attend study check-ins will be offered. We will follow a standard lost to follow-up protocol for locating lost participants.

A delay in (financial) subject payment may cause stress for some participants. Due to the VA payment process participants, can expect to receive financial payment in 8-16 weeks from notification of reward. All financial payments will come in the form of a check issued by from the Austin Payment Center. The check itself is issued by the U.S. Treasury. The payment process could also cause a burden for economically disadvantaged participants and/or those without access to a checking account or banking services. We will explain the payment process during the phone screening, so all participants are fully aware of the potential delays and process for receiving a check. If participants have further questions about how to access banking options, they will be referred to social work services.

Potential risks from study participation may include breach of PHI, stigma from being associated with a weight management research study, stress due to trying to reach the study goals, and in some patients, unhealthy behaviors to reach study goals. Precautions have been put in place to minimize these risks.

The Principal Investigator and co-Investigators will review any critical incidents (death or hospitalization). Dr. O'Hare, a practicing nephrologist and health services researcher, and Dr. Hebert will evaluate the potential for causal relations between the incident and study interventions. Adverse events will immediately be reported to the participants care provider, project manager/coordinators, IRB and research compliance staff. Dr. Hebert and O'Hare will be available to meet with any providers or patients to discuss concerns. The participants will bear no financial risk from any adverse effects of encounters from the study.

Several steps will be taken to minimize the risk of invasion of privacy. Initial contact with prospective participants will be made via an introductory letter with a stamped return post card allowing her/him to opt out of further contact by the study team, thus limiting risk for invasion of privacy. Several steps will be taken to ensure confidentiality and data protection throughout the rest of the study. All data gathered at the enrollment visit (the surveys, weigh-ins, health goals) and subsequent information will be confidential and will be housed on secure password protected VA servers. Data will be kept in offices at VA Puget Sound HSR&D with locked filing cabinets and password protected computers. The investigators, project coordinators and data analysts will be the only staff to have access to confidential records. Data collection, storage and management for this research project will adhere to all applicable VA policies, the VA Puget Sound Health Care System's Automated Information Systems Security Policy, and the established Data Security Policy of the Seattle HSR&D. Access will be restricted to study investigators, the study data analyst, research coordinators and the HSR&D Center data manager. Protected health information will not be disclosed, copied, transmitted by email, or transmitted in total or in part to anyone not connected with the approved protocol and not approved by the VA (via a Data Use Agreement, if necessary) to access the identifiers.

The participant information for the portal will be pulled from a crosswalk housed on the secure J:drive folder and within the project access database. The portal will only record the unique study ID. This is not associated with the participant at any point until matched with the study crosswalk on the J:drive by study staff. Information that will be within the portal includes: weekly weights and survey responses. The information housed within the portal will downloaded from the website on to the J:drive. The analyst will then identify the participants and their responses by matching the unique study ID with the participant's name. Due to the current extenuating circumstances we are trying to maintain as much data integrity as we can. When a phone visit is done, the participants verbalized weight will be entered into the database and will also be entered into the excel file included with this modification. We are adding the excel file as another way we will be able to indicate which data points were validated during an in person visit compared to a self-reported weight, verbally provided over the phone. This excel file will be store in the folder J:/rewards, titled PhoneVisits[date].

The Carematix system will work the same way. Each scale will be given a unique code. We will keep the crosswalk with the code to the participant's name on the secure J:drive folder. Carematix will only know the unique code and whatever weight readings are recorded by the scale. Carematix will have no information on any participant in the study. Each week research study staff will login to the Carematix dashboard website and download the Excel document of recorded weights. This excel file will then be saved on the secure J:drive folder and then matched with the participant's name and loaded into the project access database. All matching of study data and participants will only occur within the study team and will not be shared or transmitted with anyone else.

We will take stringent precautions to protect the confidentiality of participants' personal information, including PHI. Study data and PHI will comprise patient data, interview recordings and survey data. Data will be extracted, merged and matched on patient identifiers. We require patient identifiers to extract and merge previously collected data. There will be two separate crosswalks (see attached crosswalks). One crosswalk will be for the participant portal and the other crosswalk will be for the wireless Blipcare scales.

During the study period and when we are interacting with patients it is not feasible to use study ID numbers in lieu of identifiable information. As part of the study, individuals will be reassured that information is to be kept confidential. All data files will be maintained on password protected computers and password protected computer networks. Only aggregate data will be presented to external audiences. Individual identifiers will be deleted when they are no longer necessary and at the conclusion of all participant participation for the project, for no less than three years and no more than 6 years after the study has been closed. No data will be destroyed until all applicable approvals from facility staff have been received. Health care data on Veterans will be stored on secure VA servers within the VA HSR&D COIN in Seattle.

Participants will interact with the patient portal using only a registered and secure ID and password. Coordinators will keep a crosswalk in the secure password protected J:drive folder. Participants will be able to reset their password by entering their study ID, gender, and preferred weigh-in day. Participants may only recover their study ID by communicating directly with study staff. Prior to releasing their study ID research staff will validate the participant's identity by asking for their address or date of birth.

Data will be made available to the public as described in the Data Management and Access Plan (DMAP) form by publication on the National Library of Medicine PubMed Central website. Study data will be de-identified. Prior to release of any study data, the final dataset will be published in a machine-readable format that ensures individuals cannot be re-identified.

Numerous participants have requested to learn the results of the study. We are planning to send basic study results in three separate newsletter mailings, spring 2021, fall 2021 and spring 2022. All newsletters and letters will be approved by the IRB prior to mailing.

After all manuscripts are published (estimated December 2022), all human subject identifiable files and crosswalks (if applicable) will be destroyed in accordance with approved data destruction policies. Electronic media used to store identifiable data will be cleaned or destroyed in compliance with governing information security regulations. Should there be improper disclosure the facility ISO and Privacy Officer will be notified within one hour of becoming aware of the situation.

While we will make every effort to keep information confidential, no system for protecting confidentiality can be completely secure in this operational context. Individuals may choose to share with others the fact of their participation or opinions about the rewards, the survey, the interview or any other part of the study. We will not disclose participation in the study or responses to any questions to anyone outside our research team.

Interviews will be recorded using Microsoft Skype for Business, a VA-issued recorder, or the Audacity software program and will be saved directly or immediately transferred onto the secure VA network, in an access-restricted folder behind the VA firewall. ATLAS.ti software will be used to code the interview findings.

5.1.c. Study population.

We will approach approximately 5,000 patients with introductory letters. We will enroll and consent up to 350 patients. Our target enrollment is 280 Veterans total—80 in the no-reward arm, and 100 in each of the two reward arms. As of 3/6/2020 we have currently stopped enrolling. We have presently enrolled 274 participants. Once we have additional information about coronavirus to make an informed decision about recruitment we will either formal close enrollment at 274 or we will continue.

5.2 Recruitment Methods

Please refer to study flowchart for a complete visual depiction of the study procedures.

5.2.a Enrollment goals. Our target enrollment is 280 Veterans total—approximately 80 in the usual care arm, and 100 in each of the two reward arms.

All potential study participants will be patients enrolled in primary care at VA Puget Sound Health Care System. Potential participants will be identified by querying the scheduling database, CDW, VistA and/or VSSC as explained below.

5.2.b. Recruitment procedures. Participant recruitment will occur by a study team member in the role of Principal Investigator (Hebert), research coordinators (Neely/Sulc/Udris/Oestreich), co-Investigators (Littman/Sayre), or study clinician (Reddy/O'Hare).

We will have a table during research week for recruitment. We will be giving potential participants a handout basic information about the study (Appendix AG). We will also have postcards (Appendix AH) that potential participants can complete with their name, phone number, date of birth and best time to call. These participants will be screened and then given a phone call. Potential participants that do not wish to leave their information can call the participant line and will follow all of the procedures as outlined below.

Dr. Reddy has flyers that he can pass out to other VA primary care providers in order to give to primary care patients who may be eligible for the study.

In addition, we will have flyers that Veterans can give to interested family or friends who can call us to complete a phone screening. We will collect their full names and dates of birth in order to conduct a CPRS screen.

For all non-referred patients, using a waiver of informed consent and HIPAA authorization for recruitment purposes, we will query the VA Puget Sound scheduling database, CPRS, VistA, CDW and/or VSSC. We will include patients who fall within the following parameters: between 18 and 69 years of age, last recorded weight under 390 pounds, BMI greater than or equal to 30 and Veterans. We will exclude patients who have a behavioral flag, a diagnosis of an eating disorder, PTSD with sexual trauma, serious mental illness or on antipsychotic medication, participated in the MOVE! program in the past 4 months, or are pregnant, using insulin to treat diabetes, or a prisoner. Initial study eligibility will be determined with a combination of a CDW/VSSC/VistA data pull using the aforementioned inclusion/exclusion criteria and CPRS chart review if needed (see Section 5.4.a for detailed description and rationale for the exclusion criteria.) Access to these data sources requires access to real SSNs.

Weekly a list of potential participants will be generated in either CDW, VSSC, or VistA (using fileman). If using CDW the cohort will be generated by VINCI personnel and stored in the VINCI workspace. When the file is ready, either a copy of the data will be downloaded from the VINCI workspace to the secure J:drive study folder or our database will connect directly with the VINCI SQL tables. Patients who have "opted-out" will not be contacted again. For VistA, fileman will be used to query VistA to find patients who fall within the inclusion/exclusion parameters. For participants that do end up enrolling in the full study we will do a second pull to collect all of their weights recorded in CPRS for the previous five years.

Participants meeting the initial criteria will be sent a recruitment letter (Appendix J) and opt-out post card (Appendix K). If we do not receive the post-card back within a few weeks a study team member will call them, explain the study and invite them to participate. We will make up to five attempts to recruit potential participants. During this phone call, the study team member will ask the potential participant screening questions (see section 5.5). Under a waiver of documentation of informed consent and HIPAA authorization, if participants give verbal approval, we will retain their screening information regardless of their eligibility. If participants are deemed eligible, the study team member will set up a convenient time to meet them. We will make every effort to have this occur directly before or after their primary care or women's clinic appointment, if they have one. Participants are free to ask questions about the study or study procedures at any point, and are free to withdraw or refuse to participate in any aspect of the study without penalty.

At the in-person visit, potential participants will be consented (Appendix A) and asked to sign the HIPAA authorization form (Appendix B). After initial study evaluations are conducted, the participants account in the portal will become active, the coordinator will provide the participant with the website portal instructions, user name and password (Appendix S). All participants will use the portal to enter in their weekly weights and complete the four participant surveys (baseline, 16 and 32 weeks and one year). Participants will be

randomized to a study group (financial, non-financial or control) once they have completed the participant survey (see section 5.5 for details regarding study evaluations).

Because of the importance of women's health to the VA, we will oversample women to ensure that 25% of the sample (n=70; approximately the total number of participants in the JAMA 2008 or JGIM 2011 reward trials) will be women and then stratify by gender. To enroll 280 Veterans, we can recruit as few as 10 per month per site over 15 months. This is a similar recruitment rate to JAMA (2008)[8] (12/month per site) and a recently funded clinical trial at VA Puget Sound Health Care System (Nelson IIR# 14-063: 390 Veterans over 24 months). By randomizing in blocks of 14 and recruiting at least 20 Veterans per month we ensure that treatment arms will be balanced in terms of the season of the year the participants entered the trial.

5.2.c. Participant payments.

Participant payments are shown in Table 3.

Table 3. Participant maximum possible payments:

	Participation	Assured	Random	Token	Total
No rewards	$80	--	--	$100	$180
Financial rewards	$80	$100	$300	$100	$580
Non-financial	$80	$100	$300	$100	$580

No rewards (usual care) group: To encourage continued participation, usual care participants will be given $20 for each in-person study visit attended, for a total of up to $80.

Financial rewards group: To encourage continued participation, financial reward participants will be given $20 for each in-person study visit attended, for a total of up to $80. They will also have the chance to earn up to $400 in reward money. They can earn $100 from monthly assured rewards (4 months x $25); $300 in random rewards (three chances to earn $100 on random, pre-selected weeks; and 4 chances to earn token rewards (t-shirts, movie tickets, etc.) for reporting their weight in weeks 17-32, with an approximate value of $25 each.

Non-financial rewards group: To encourage continued participation, non-financial reward participants will be given $20 for each in-person study visit attended, for a total of up to $80. They will also have the chance to earn up to approximately $400, or 80 points, worth of non-financial rewards (each point is worth approximately $5. They can earn 20 points from monthly, assured rewards (4 months x 5 points), plus 60 points in random rewards (three chances to earn $100 on random, pre-selected weeks. These are not cumulative. If they meet all their goals they will receive a total of seven rewards. They will also have 4 chances to earn token rewards (t-shirts, movie tickets, etc.) for reporting their weight in weeks 17-32.

There is a delay in financial payment that is beyond our control. Due to VA Puget Sound facility policies and practices all financial payments will be processed through the Austin Payment Center. Unfortunately, this process often takes up to three months. All participants will be made aware of this delay.

Real SSNs will be collected for payment purposes, but will be stored separately from study data.

5.3 Informed Consent Procedures

For recruitment purposes, we will seek a waiver of informed consent and a waiver of HIPAA authorization. At enrollment, participants will need to complete an informed consent form and HIPAA authorization to participate in the study.

Informed consent and HIPAA authorization will be obtained by the Principal Investigator, qualitative researcher, study coordinators or qualitative analyst/coordinator. The study staff obtaining consent will be trained to provide adequate time and opportunity for the participant to consider all options, respond to the participant's questions, ensure that the participant has comprehended this information, obtain the participant's voluntary agreement to participate, and continue to provide information as the participant or situation requires. We will ensure there is opportunity for the researcher and the participant to exchange information and ask questions.

5.4 Inclusion/Exclusion Criteria

5.4.a. Inclusion criteria.

Determined through CPRS, VistA, CDW or VSSC:

- Age 18-69
- Weight <390
- BMI ≥ 30 (weight (kg)/height^2(m^2))
- Active patient in primary care or women's clinic (1+ visit in last two years)
- Primary care/women's clinic visit located at the following VAPSHCS locations: Seattle, American Lake, Bellevue CBOC, Federal Way CBOC, Seattle (Lake City) CBOC or Bremerton CBOC

The inclusion for weighing less than 390 pounds is because the scales that we can economically provide are rated for 400 pounds or less, and we want to expand the criteria to include as many participants as possible. The inclusion of BMI ≥ 30 (kg/m^2) ensures that the target weight loss of 1 lb. per week is safe and beneficial for all Veterans. Enrolling Veterans age < 70 is because the evidence for the benefit of weight loss age 70+ is relatively weak.[19] We are excluding patients with primary care/women's clinic visits at sites other than those listed above because participants are only being paid $20 for each visit and expecting participants to drive for > 2 hours one-way (or 4 hours round trip) seems unreasonable and inadequate.

5.4.b. Exclusion criteria.

Determined through CPRS, VistA, CDW or VSSC:

- Behavioral flag
- Diagnosis of eating disorder, PTSD with sexual trauma, Serious Mental Illness (SMI; see ICD-10 exclusions below) or antipsychotic medication[20]
- MOVE! participation in past 4 months
- Pregnant
- Prisoner
- Using insulin to treat diabetes
- Homeless

Patients with a behavioral flag will be excluded because of potential disruption to study procedures and randomization. The exclusion for serious mental illness (SMI) is because antipsychotics cause weight gain, and consequently Veterans with SMI benefit from specific training for weight loss.[20] We will exclude Veterans with the following ICD-10 diagnosis codes: F30.2: Manic episode, severe with psychotic symptoms; F31.2: Bipolar affective disorder - current episode without psychotic symptoms; F31.5: Bipolar affective disorder - current episode severe depression with psychotic symptoms; F32.2: Severe depressive disorder without psychotic symptoms; F32.3: Severe depressive disorder with psychotic symptoms; F33.3: Recurrent depressive disorder, current episode with psychotic symptoms. Veterans with serious mental illness including bipolar, schizophrenia and a recent history of suicidality or psychiatric hospitalization will be excluded as determined by chart review. Patients with a diagnosis of PTSD will be evaluated on a case-by-case basis by the study clinician and the patient's mental health and primary care provider to determine the appropriateness

of participation.[21] To avoid adverse effects of rewards, we will exclude Veterans with documentation in chart notes of eating disorders, or Veterans with PTSD and a history of sexual trauma, who may have issues regarding body image. The restriction that Veterans have no MOVE! participation in the prior 4 months is to ensure that we do not recruit active MOVE! group participants. The MOVE! meeting dynamics may be adversely affected if some of the Veterans are receiving rewards for weight loss. Women currently pregnant will also be excluded due to potential risks of losing weight.[22] Prisoners are excluded because they must be able to come in for in person weigh-ins. If a potential participant is an employee or student we will not exclude them based on this information. We do not have compelling evidence that participation in this trial would impact their status as an employee or student. Veterans currently taking insulin for diabetes are excluded due to insulin's effects on weight loss. Homeless patients are excluded due to the numerous mailings that are involved in participating in this study. There may be additional conditions identified during chart review indicating that a Veteran may not be an appropriate fit for the study. In these cases, the charts will be reviewed by the Principal Investigator or the study clinician in order to determine potential eligibility.

Determined or confirmed after chart review, patient self-report:

- Blindness
- Inability to read
- Cognitive impairment
- Inability to remove socks and shoes
- Inability to stand independently
- No access to a phone in the Veteran's household
- Pregnant or planning pregnancy in the next 12 months
- MOVE! participation in past 4 months
- Using insulin to treat diabetes
- No availability or willingness to come to VA (American Lake or Seattle) for research purposes
- Indicator that they do not live at the same place for the entire year*
- No phone that can receive a text message or no email address
- No routine internet access

The exclusion for blindness and inability to read is necessary because the participants will be given MOVE! workbooks as part of the intervention, and will be required to read a home digital scale. Patients with impaired decision making will be excluded because patients need to have fully cognition of the choices they are making in this study. The inability to remove socks and shoes is included because it is a requirement to successfully use the scale. Participants will also need to independently stand on the scale without assistance which could modify the recorded weight. Access to a text capable phone is necessary to receive study reminders. Routine access to the internet is necessary to update weekly weight and participate in the four patient surveys.

If text messages are the patient's preferred method of reminders, text messages will be sent to participants' phones using the VA Outlook system. This will be done by adding their cell phone carrier's unique email address to their phone number. The general format will be phonenumber@carrier.com. For example for AT&T it would be 1234567@txt.att.net, Verizon 1234567@vtext.com, T-Mobile 1234567@tmomail.net, etc. From our perspective, it will look as though we are sending an email, while they receive a text message. We will do this from our study email account: pugrewards@va.gov. Participants will not be able to respond to text messages. Text messages will only be used as reminders (Appendix V). If a patient prefers, we will send reminder emails in lieu of text messages, which includes the portal URL. If a participant has cricket wireless they will have to receive email reminders because text messaging does not work on cricket wireless. If the participant doesn't not have an email then they will not receive weekly reminders. We will use the study email address to email participants. Participants will not be able to respond. All text messages and emails will note that any responses will not be seen. The emails will contain the required email disclaimer (Appendix V).

The above exclusion and inclusion criteria are patterned on those used in the Journal of the American Medical Association (JAMA) and Journal of General Internal Medicine (JGIM) trials[8,18,12] that were conducted in the VA. We want to capture patients that are willing to participate in the in person study visits and we want patients that

live in the area year round. We are trying to screen out “snow birds,” or patients who live in the area only part of the year. However, eligibility will be determined on a case-by-case basis, depending on if patients will be in the area for the 4 in-person study visits at baseline, 16 weeks, 32 weeks, and 1 year.

5.5 Study Evaluations

5.5.a Phone screening.

The phone script (Appendix L) outlines the phone screening conversation with potential participants. During the phone call to ascertain interest in participating in the study, study staff will also ask potential participants specific questions regarding all of the inclusion and exclusion criteria including: access to a phone, ability to stand without assistance, ability to take shoes and socks on and off, ability to read, MOVE! participation in last 4 months, blindness, pregnant or planning pregnancy in next 12 months, current height and current weight, insulin use, Veteran status, cognitive impairment, questions about their phone, access to the internet, smart phone, cell service provider and any weight loss medication/supplements or nutritional product use. If they “screen out” they will be thanked for their time and enrollment will not proceed, though they will be offered participation in the associated repository 00982 if interested. If the potential study participant is eligible, a study team member will set up a convenient time to meet them for an in-person appointment. We will also be collecting patient self-reported demographic data including gender, ethnicity and race, and questions about owning a smartphone or a phone that can receive text messages, and cell phone service provider. Demographic data and cell phone/service provider questions will not be used to determine eligibility.

At the in person (baseline) appointment after the participant has completed the HIPAA authorization and consent form (described in section 5.3), participants will be given access to the baseline survey in the portal (Appendix C). The participant will be given all the study information, resources and will be weighed.

5.5.b. Surveys. The survey will be given at the four intervals: baseline, 16 and 32 weeks and one year. The survey will be completed through the patient portal. The survey will only be active for three weeks following their 16 week, 32 week, and one year appointments. The baseline survey will be active from the day of their baseline visit until two days before their first weigh-in is due (6-12 days, depending on their chosen weigh day). Coordinators can edit the active survey dates if the participant is unable to complete the survey before its due. However, if the participant is unable to complete the baseline survey within 4 weeks they will be withdrawn (see Passive Withdraw, section 5.7.b). The survey is a comprehensive assessment of standardized survey instruments used in clinical trials and clinical operations. The assessment has a combination of assessments to create a wide-ranging survey tool covering items from race, food insecurity, eating habits to lifestyle and previously use theories for weight loss.

Summary of survey components:

Screening for motivation to lose weight, and free text field on what motivations are.

Demographics):

VA MOVE11 partial survey: The survey is the standard enrollment intake survey of the MOVE! program. It covers, height, weight, BMI, ethnicity, race and various health behavior and lifestyle indicators, Regulation of eating behavior survey (REBS): Questions to determine the internal motivation or regulation of a behavior.

Health status from the SF12

Additional sleep and alcohol questions

Financial distress questions from the Prawitz Financial Distress Scale

Three factor eating questionnaire (TFEQ-18): Questions regarding eating patterns and behaviors.

Personal Health Questionnaire Depression Scale (PHQ-8): This is an established diagnostic and severity measure for depressive disorder in large scale clinical trials.

International physical activity questionnaire (IPAQ): Activity level over 7 days, from vigorous, moderate, walking and sitting.

Weight Efficacy Lifestyle Questionnaire Short Form (WEL-SF): Confidence level in controlling certain behaviors

Food insecurity questionnaire (from NHIS): Eating behaviors and food purchasing behaviors based on financial stability and socio-economic status.

NHANES Weight Loss Strategies: Covers a variety of common methods used for weight loss and participants use of them.

Additional Questions: These questions ask a participant why they want to lose weight and how motivated they are to lose weight.

Participants will complete the survey at all four points in the study through the online patient portal (baseline, 16 weeks, 32 weeks, one year). Participants will complete the surveys in the participant portal. The information from the survey will then be downloaded from the secure Austin server and saved directly into the J:drive access database.

5.5.c. Weight measurements. Participant weights will be taken at the in-person visits. The participant will be asked to step onto a scale. The weight shown on the scale will be recorded. After the participant, has completed the survey instrument and had their weight taken, they will be randomized to one of three groups, as described in section 5.4. Weight measurements will be taken at all four in-person visits. Participants will also we counseled to weigh themselves daily before eating and after using the bathroom and recording their weight weekly into the portal.

5.5.d. Study interview (Appendix G).

We will conduct post-intervention, semi-structured phone interviews with selected Veterans from each arm (10-30 participants from each arm, or until saturation). Participants selected for an interview will receive a letter in the mail followed by a recruitment phone call to schedule (letter submitted with modification). The goals of the qualitative interviews are: 1) to provide depth to the quantitative analyses of patient surveys and 2) learn what worked and did not work in the present trial in order to run a better trial in the future. Participants who are still enrolled in the study at week 32 will be interviewed after the primary outcome measurement at the 32 week weigh-in. On occasion it is not convenient for some participants to be interviewed between week 32-52 of the study. Participants will be sent a letter for the interview and the two follow-up efforts between week 32-52, but to better accommodate participants with busy schedules we will interview participants after their week 52 visit if they wish to participate and if that is most convenient for them. Groups will be purposively sampled to include both male and female Veterans. We will use a semi-structured interview guide (Appendix G) with open-ended and semi-structured follow-up questions. Structured open-ended prompts will be used in order to elicit rich descriptions of patients' experiences with specific aspects of the intervention, including how the discontinuation of the reward affected their behaviors, resources they used and motivations. Interview questions will elicit information about what aspects of the non-financial rewards (evaluability, justifiability, separability/instrumentality, and social reinforcement) were motivating; how the reward affected behaviors; whether experience-based rewards such as tickets to an event had a lingering and positive effect on motivation; and whether other features could be added to create a more acceptable reward program. We will also interview usual care patients to elicit descriptions of experiences associated with other Veterans receiving rewards when they did not. Interviews will be conducted via telephone and recorded on a secure VA digital recorder then immediately moved to a secure VA data server. Interviewers will take notes for each interview including descriptive data (time, date, etc.), theoretical memos, methodological issues, and reflexive memos (personal responses). We expect the interviews to take 30-45 minutes. All interviews will be recorded using either Microsoft Skype for Business, VA-issued recorder, or the Audacity software program and will be saved directly or immediately transferred onto the secure VA network, in an access-restricted folder behind the VA firewall. ATLAS.ti software will be used to code the interview findings. Consent to participate in this interview is covered under the study Consent Form that is signed at baseline; however, interviewers will

also obtain verbal approval to record the interviews immediately prior to conducting them. Regardless of the participant's enrollment in the repository their interview and any qualitative data will not be included in the repository.

As soon as we have any initial findings or when the last participant is done with the study we will mail all study participants preliminary study findings.

5.6.a. Data Analysis

All data will be analyzed at VA Puget Sound Health Care System by one of the data analysts and/or investigators.

We will use an intent to treat analysis. To test each hypothesis we will estimate an equation of the form $\Delta Y_{it} = \beta_0 + \beta_1 Weight_{i0} + \beta_2 M_i + \beta_3 F_i + u_i$ (1) where ΔY_i is change in weight from baseline to follow-up time t for patient i; $Weight_{i0}$ is baseline weight for patient i; F is the financial rewards (arm 2); M is an indicator for assignment to non-financial rewards (arm 3); and u is a random error. To gain a small amount of efficiency we can also estimate (1) using repeated measures of change in weight from baseline to the three follow-up measures (16 weeks, 32 weeks and 12 months) using GEE models of the same form as equation (1), except with dummy variables for follow-up periods and interactions between these variables and the treatment group dummies.

Hypothesis 1a implies a test of <u>superiority</u> and will be assessed using two-sided tests of $\beta_2 = 0$ for non-financial rewards, and $\beta_3 = 0$ for financial rewards. Large positive or negative values of β_2 and β_3 are evidence against the null hypothesis of no difference between reward and non-reward groups.

Hypothesis 1b implies a <u>non-inferiority</u> test. We will reject the hypothesis that non-financial rewards are inferior to financial rewards if β_2 is statistically significantly greater than zero (i.e., there was statistically significantly more weight loss in the non-financial reward arm than in usual care) and if $(\beta_3 - \beta_2) < 2.5kg$, where $(\beta_3 - \beta_2)$ is the adjusted difference in mean weight loss between the financial and non-financial reward arms, and 2.5 kg is half the 5 kg weight loss assumed to be clinically significant. Although there are no defined rules for choosing a range of indifference for a non-inferiority test, researchers often use half the minimum clinically significant amount. Values of $(\beta_3 - \beta_2)$ that are statistically significantly larger than 2.5 kg are evidence against the hypothesis that non-financial rewards are not inferior to financial rewards.

Hypothesis 1c implies a test of superiority and will be assessed using two-sided tests of $(\beta_3 = \beta_2)$ in comparisons of weight change from week 16 to week 32 and 12 months, respectively. We will use weight change at week 16 in place of weight at baseline in equation 1, such that differences in weight regain between treatment arms will be adjusted for weight lost over weeks 1-16.

Because all secondary outcomes are continuous variables, a similar equation will be used to assess changes in secondary outcomes. These analyses explore how rewards affect constructs that are believed to mediate the effect of rewards on weight loss.

Missing weight measures will be imputed using data from patients' medical records for routine medical visits and methods developed and tested via simulation by Hebert et al.[23] These methods involve estimating longitudinal mixed-effects linear models of weight collected both through the trial and at routine clinic visits as a function of polynomials of time since enrollment, with random components for patient intercept and time, and using the predicted values from this model for any post intervention day as an estimate of what the patient's weight would have been on that day if he/she kept their follow-up appointment.

We assumed a standard deviation of 11.0 lbs. for weight loss based on the results of the JAMA (2008) and JGIM (2011) trials[8,12,21] that were conducted in the VA and demonstrated statistically significant differences in

weight loss at the end of the reward period. We used a two-sided alpha of 0.025 to account for the multiple comparisons between treatment groups (including for hypotheses 1b and 1c, which compare only two groups). We chose a clinically meaningful minimal detectable difference of 11 lbs. (5 kg). This was the weight loss experienced by the lifestyle management arm of the Diabetes Prevention Program randomized trial,[24] which experienced lower rates of the incidence of diabetes. According to data from the 2012 NHANES, 11 lbs. is 5% of the average weight of 233 lbs. for obese men, and the FDA defines a weight loss drug as clinically effective if mean weight loss in the drug group is at least 5% of baseline weight.[25,26] With these assumptions we would require full data on 21 patients per treatment arm at follow-up, or 28 assuming 20% loss to follow-up, in order to have 80% power to reject hypothesis 1a. In order to conduct subgroup analyses with reasonable precision, and to increase the power to detect differences in weight regain between reward groups (hypothesis 1c), we will increase enrollment to 80 patients in the no-reward arm, and we will increase the ratio of patients randomized to control versus either reward group from 1:1 to 1:1.25 for a total of 280 patients (80 usual care+100 in each reward arm). This provides a minimum detectable difference of 5.1 lbs. between treatment arms, and 4.5 lbs. if the reward arms are combined. In the three studies in Table 1, the average weight loss in the control groups at the end of follow-up was 1.6 lbs. Thus, we expect 80% power to detect weight loss as small as 6.7 lbs. in each reward group. At the end of the reward period, the average weight losses in the reward groups was 10 lbs. (range, 14 to 3.7) among the trials in Table 1. In the JAMA (2008)[8] study, 50% of the reward group achieved their goal of 16 lbs. weight loss in 16 weeks. Thus, we have the power to detect achievable and clinically important weight losses across treatment arms.

With 100 patients per reward arm, the minimum detectable difference for hypotheses 1b and 1c is 4.8 lbs. We will have power of 0.94 for the one-sided test of hypothesis 1b (non-financial rewards are not inferior to financial rewards). The power for hypothesis 1c (regain is lower in the non-financial compared to financial reward arm) depends on expectations of regain. We extrapolated weight regain from the trials in Table 1 in two ways: a) by assuming the weekly weight regain between the end of rewards and the last measurement continued; and b) by using data from a systematic review[27] that found that in randomized trials of lifestyle changes for weight loss with a one year follow-up, the mean weight loss at one year was about half the weight loss achieved at 6 months. (See 2.0 Introduction for details.) We estimate that the weight regain by 12 months in the financial reward arms would be around 7.2 lbs. Thus, in order to have 80% power to reject hypothesis 1c, regain in the non-financial reward arm would need to be at most 2.4 lbs. (i.e., 7.2-4.8=2.4 lbs.). The power for subgroup analyses will be limited. Simulations[28] suggest our study sample would need to increase four fold to detect an interaction between female and treatment arm with the same power as the main analysis. We will interpret the subgroup results as exploratory, although we note that the proposed study will enroll 5 times as many female Veterans (n=70) as were enrolled in the JAMA (2008) (n=3) and JGIM (2011) (n=11) trials, combined, and more than the total enrollment of either of those trials.

5.7 Withdrawal of Subjects

Eligibility for rewards both financial and non-financial will be stated in the informed consent.

5.7.a. Active withdraw. Any participant may at any time notify the Principal Investigator or research coordinator(s) that they no longer wish to participate in the study and they will be considered withdrawn and will no longer participate in study procedures or activities. We will make every attempt to have a final study visit with the participant, ideally lining up with one of the three scheduled follow-up visits. For example, if a subject expresses that they'd like to withdraw from the study at week 11, we will halt all study procedures but will ask the participant if they could still come in for their week 16 visit and complete the interview. If they are not interested in coming in for a final study visit, and if they still have their Blipcare scale and/or Connect device, we will mail them a pre-paid box to return those items and they will be withdrawn immediately. If a final study visit is possible a final weight and survey will be recorded. At this point in time, depending on the arm of the study the participant was randomized to, they will be told the total amount they can expect to receive in the mail, or they will be notified of the non-financial reward(s) they have earned.

5.7.b. Passive withdraw. This study has multiple time-sensitive in person meetings, portal and phone communications. If we do not hear from a participant within 3 days of a missed in-person meeting we will call them and reschedule (Appendix O). If we do not reach them, we will make up to three total attempts to contact them. If the participant misses four weekly weight entries in a row we will make up to three attempts to contact them for every four week stretch they miss. We will make up to 30 total attempts to reach them via phone, voicemail, postcard and letter (Appendices E, O, Q and P), over the course of 19 weeks if we do not hear from them after the baseline appointment.

For each week the participant doesn't respond after the initial week a total of 3 attempts will be made to contact participants for each occurrence of not responding to study staff inquiries. Inquiries include reminder text messages, emails, phone calls from study staff and postcards.

If the participant doesn't complete the baseline survey within four weeks of their baseline study visit, they will be withdrawn from the study. Prior to being withdrawn, we will make up to three attempts to contact them. Depending on what study arm the participant is in, the participant will be compensated for their participation up to the point where they stopped participating.

5.8.c. Medical withdraw. If a participant loses more than 10 pounds in one week the research staff will discuss the participants' weight loss strategy with them. The physician researchers, Dr. Ann O'Hare or Dr. Ashok Reddy will also review their chart to determine if there is medical condition that would contra-indicate further participation. If the participant is engaging in unhealthy methods of weight loss they will be counseled against these methods, referred to their primary care provider, and the MOVE! workbook methodologies will be reiterated. The participants will also be told that if a clinician determines their weight loss exceeds healthy limits, they may be withdrawn from the study. If the participant discloses their pregnancy or the study team finds out they are pregnant they will not be able to continue in the study. If this occurs the same withdraw procedures will be followed for active withdraw. Participants will be compensated for all activities earned to the date of withdraw as outlined in the informed consent document.

6.0 Reporting

We do not anticipate any serious adverse events during this study. All unanticipated serious adverse event(s) or problem(s) will be reported to the IRB within 5 business days of becoming aware of the event. Serious adverse events, anticipated problems, non-serious protocol deviations, non-serious problems will all be reported to the IRB on the Continuing Review or project termination. As required by Handbook 1058.1the adverse event rate (injuries) will be reported to the Office of Research Oversight quarterly by the Principal Investigator.

6.1 Subject Accrual and Compliance

Measurement and reporting of participant accrual, adherence to inclusion/exclusion criteria: Review of the rate of participant accrual, adherence to inclusion/exclusion criteria will occur monthly during the recruitment phase.

Measurement and reporting of participant compliance to treatment protocol: Data on compliance to the treatment protocol will be collected monthly by research staff and reviewed by the Principal Investigator and the data analyst. Data collection will be recorded in the patient database (Appendix I).

6.2 Stopping Rules

PI will include an assessment of futility and will consult with a biostatistician if necessary to assess the impact of significant data loss due to problems in recruitment, retention or data collection.

6.3 Safety Review Plan

Study progress and safety will be reviewed monthly (and more frequently if needed). Patient weight loss will be closely monitored and if weight loss occurs at a rate of more than 5 pounds per week, a clinical review will be

completed. An annual report will be compiled and will include a list and summarization of adverse events. In addition, the annual report will address (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely.

7.0 Privacy and Confidentiality

Several steps will be taken to minimize the risk of invasion of privacy. Initial contact with prospective participants will be made via an introductory letter with a stamped post card allowing her/him to opt out of further contact by the study team, thus limiting risk for invasion of privacy. A number of steps will be taken to ensure confidentiality and data protection throughout the rest of the study. All data gathered at the enrollment visit (the survey, weigh-ins, health goals) and subsequent information will be confidential.

The participant information for the portal will be pulled from a crosswalk housed on the secure J:drive folder. The portal will only record the unique study ID. This is not associated with the participant at any point until matched with the study crosswalk on the J:drive by study staff. Information that will be within the portal includes: weekly weights and survey responses. The information housed within the portal will downloaded directly onto the secure J:drive.

The Carematix (Blipcare) system will work the same way. Each scale will be given a unique code. We will keep the crosswalk with the code to the participants name on the secure J:drive folder. Carematix will only know the unique code and whatever weight readings, dates and times are recorded by the scale. Carematix will have no information on any participant in the study. Carematix will not have any identifiable information on any participant. Each week research study staff will login to the Carematix dashboard website and download the excel document of recorded weights. This excel file will then be saved on the secure J:drive folder and then matched with the participants name. All matching of study data and participants will only occur within the study team and will not be shared or transmitted with anyone else.

PHI will not be disclosed outside the study team.

Data will be kept in offices at VA Puget Sound HSR&D with locked filing cabinets and password protected computers. The investigators, project coordinators and data analysts will be the only staff to have access to confidential records. Data collection, storage and management for this research project will adhere to all applicable VA policies, the VA Puget Sound Health Care System's Automated Information Systems Security Policy, and the established Data Security Policy of the Seattle HSR&D. Access will be restricted to study investigators, the study data analyst, research coordinators and the HSR&D Center data manager. Protected health information will not be disclosed, copied, transmitted by email, or transmitted in total or in part to anyone not connected with the approved protocol and not approved by the VA (via a Data Use Agreement, if necessary) to access the identifiers.

We will take stringent precautions to protect the confidentiality of participants' personal information, including PHI. Study data and PHI will comprise patient data, interview recordings and survey data. Data will be extracted, merged and matched on patient identifiers. We require patient identifiers to extract and merge previously collected data.

The participant's identity is blinded to both the portal and the wireless scales. There is no way that either system could become identifiable by anyone outside of the study team. Each crosswalk must be used to match the data with the participants. This will only be done within the access database on the J:drive by study staff.

While interacting with participants it is not possible to use ID numbers. As part of the study, individuals will be reassured that information is to be kept confidential, no single individual will be identified by name and all data will be aggregated. All data files will be maintained on password protected PCs and password protected computer networks. Only aggregate data will be presented to external audiences. Individual identifiers will be deleted when they are no longer necessary and deletion has been approved for the project. Health care data on Veterans will be stored on secure VA servers within the VA HSR&D COIN in Seattle.

After all manuscripts are published and the study is closed (estimated December 2021), the data will be retained for up to six years following the closure of the study. Assuming that the VA has approved the destruction of the data, all human subject identifiable files and crosswalks will be destroyed in accordance with VA policy. Electronic media used to store identifiable data will be cleaned or destroyed in compliance with governing information security regulations.

While we will make every effort to keep information confidential, no system for protecting confidentiality can be completely secure in this operational context. Individuals may choose to share with others the fact of their participation or opinions about the rewards, the survey, the interview or any other part of the study. We will not disclose participation in the study or responses to any questions to anyone outside our research team.
All interviews will be recorded using either Microsoft Lync, VA-issued recorder or Audacity software and will be saved directly or immediately transferred onto the secure VA network, in an access-restricted folder behind the VA firewall. ATLAS.ti software will be used to code the interview findings.

8.0 Communication Plan

VA Puget Sound Health Care System, Seattle and American Lake campuses, represent the only site involved in human subjects' research. Dr. Maciejewski, Co-Investigator, Durham VA, will consult with study staff at VAPSHCS on an as-needed basis, but will only have access to aggregate, de-identified data.

9.0 Information Security and Data Storage/Movement

All data that will be collected from an existing database is already housed within the VA (e.g., CPRS, Vista, CDW, VSSC). Access to these data sources requires access to real SSNs.

9.1 Types of Data

9.1.a. Participant data for recruitment.
Potential participants' names, contact information and healthcare data will be obtained from VistA, CPRS, CDW, and/or VSSC. This data will be stored electronically on secure VA servers within the VA HSR&D COIN in Seattle and/or within a VINCI workspace.

9.1.b Participant data during study visits. Data recorded during study visits will be identified only by subject ID and will include weight, reward given/level earned and anything the participants notes (Appendix I). This information will be housed on the secure VA server. This information will then be entered directly into a secure access database located on the secure research drive on VA servers within the HSR&D COIN in Seattle. Participants will complete the surveys in the portal. Survey responses will be downloaded to the secure J:drive folder where they will then be matched with participant information. All survey data will be recorded in a secured password protected database located on the secured VA HSR&D COIN researcher server in Seattle.

9.1.c. Participant weights recorded in the portal. Participants will be asked to report their weight every week on a pre-determined day they selected. They will login and enter their weight. All weights will be recorded by the portal and then sent directly to the secure J:drive folder located the VA HSR&D COIN network in Seattle.

9.1.d Weights obtained via wireless scales. Coordinators and project staff will discuss the wireless scales and data collection with participants prior to use. Participants in this arm will be given the wireless scale and a wireless router Connect device. Participants will need to plug Connect in within 50 feet of the scale. Every time the scale is activated the weight is automatically sent via the wireless router to the company server. The company will then send weights to the Principal Investigator through a standard secure socket shell (SSH) connection. Weights will be recorded in the study database located on a secure VA HSR&D server.

A subset of the study participants will receive Blipcare scales and Connect devices. Blipcare provides wireless digital scales with Bluetooth connection to a cellular device. The cellular device transmits the information from the scale to servers at Blipcare via the cellular network hotspot, thereby avoiding the use of the Veteran's own Wifi and/or smartphone and consequent charges to transmit data.

After the participant agrees to provide Carematix with their information (see Appendix A, informed consent), during the enrollment process, Blipcare scales will be assigned a study ID. The study team will have the crosswalk and will match participants to the weight data once the SSH transmission is complete. This is an added protection to protect against breach of confidentiality. No identifiable information will be transmitted to Blipcare or Carematix. Not all patients will receive the Connect devices because the cellular device and monthly contracts are costly. We will compare the self-reported weights with weights recorded on the Blipcare devices to see if there is any evidence that patients were misrepresenting their weights in order to earn an incentive. If patients do not receive a Connect device, we will download the stored data on the scale when they return them at their 16-week visit. Wirelessly transmitted weights from these scales will not be used as a substitute for self-reported weights. We will report the percentage of self-reported weights that were less than any wirelessly transmitted weights. We will also explore the extent to which weights collected at routine medical encounters could have been substituted for study-collected weights without loss of study integrity. We will estimate mixed effect linear models using weights collected at clinical encounters as a function of time, treatment arm, and treatment-by-time interactions. We will compare the difference in weight loss across treatment arms estimated from these models with the trial results. If the inferences are the same, then future weight loss studies could be conducted using primarily weight data from routine clinical encounters.

9.1.e. Participant interviews. All interviews will be recorded using Skype for Business, a VA-issued recorder, or the Audacity software program, and will be saved directly or immediately transferred onto the secure VA network, in an access-restricted folder behind the VA firewall. ATLAS.ti software will be used to code the interview findings. The ATLAS.ti software is located on the terminal server within the HSR&D COIN in Seattle.

All data and records with be retained in accordance with the National Archives and Records Administration (NARA), VA Records Control Schedule (RCS-10-1), record schedule number DAA-0015-2015-0004 and local policy IM-39. Data will be kept on local VA servers and either with the designated study file area within HSR&D, or the federal records facility (upon study closure and completion) for no less than three years and no more than 6 years after the study has been closed. No data will be destroyed until all applicable approvals from facility staff have been received.

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