

NCT02957539

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

## Consent to participate as a Research Subject in: Financial vs. Non-Financial Rewards for Weight Loss

We are inviting you to be in a research study. The purpose of this Consent Form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully.

You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

### 1. Who can I contact with questions while I am in this research study?

During business hours (8:00 a.m. – 4:30 p.m.), please call the Research Coordinator at (206) 277-4797 or Principal Investigator at (206) 277-4165. After business hours (nights and weekends), please call (206) 277-4797 and leave a message with your name and telephone number. A research staff member will return the call promptly once the messages are checked.

The study researcher(s) listed above must be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your medical care issues.

You may also contact the Institutional Review Board (IRB) at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

### 2. What is the purpose of this research study?

The purpose of the study is to examine how receiving **financial rewards** (such as a check), **non-financial rewards** (such as tickets to a local event), or **no rewards** (such as usual care) affect how Veterans are able to achieve weight-loss goals. By randomizing study subjects into these three reward types, we hope to better understand what types of reward, if any, are effective as motivation for people who are trying to reach their weight-loss goals.

You may be eligible to participate if you are between the ages of 18 and 69, have a body mass index of at least 30, weigh less than 400 pounds, are active in VA primary care (at least one visit in the past two years), have access to a phone, have a phone that can receive text messages, and have regular access to the internet.

#### Principal Investigator:

Paul L. Hebert, PhD

#### Research Staff:

Alyson Littman, PhD  
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#### Study Title:

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

This study aims to enroll approximately 280 Veterans at VA Puget Sound Health Care System (“VA Puget Sound”). The study will last 3 years; however, if you decide to enroll, your participation in the study will last about a year. We will ask you to weigh yourself on a weekly basis, complete four surveys, and come to VA Puget Sound for four in-person study visits (for a total of approximately 15 hours).

Dr. Hebert and the research team have no financial conflicts of interest.

### **3. What will I be asked to do in this research study?**

At your first (baseline) study visit we will discuss the following:

- Study overview
- Participant portal
- Participant surveys
- Reminder text messages and/or emails

### **Portal**

We will enroll you in our secure online patient portal. We will assign you a unique study ID and password. This is the information you will use to access the portal.

Your name or identifiable information will not be used. If you forget your password, you may use the password reset option on the portal login page. If you forget your study ID, you may contact the study coordinators to retrieve it by calling (206) 277-4797 during business hours (8:00 a.m. – 4:30 p.m.).

The portal is a federal government website and all information entered will be kept behind the VA firewall. No identifiable information is associated with the website. You will use the website to complete the four surveys and enter your weekly weights.

### **Scales**

At the end of your Baseline Visit, you will take home a wireless-capable Blipcare digital scale. You may or may not be randomized to receive a Connect device that transmits the data wirelessly. If you receive a Connect device, upon plugging the Connect device into an electrical outlet, it will send your weight to the Carematix company, who will then send the data directly to us. Carematix is the parent company for the Blipcare scales. No personal or protected health information will be shared with Blipcare or Carematix. The only information Carematix will have is your weight. If you do not receive the Connect device, your weight data may be downloaded from the scale at or after the Week 16 visit. You may be asked to return your wireless scale at the Week 16 visit. If you are asked to return your scale, you will be given a regular digital scale to track your weight during the remainder of the study.

### **Survey**

You will complete the four surveys in the portal using your unique study ID and password. We ask that you complete the baseline survey at least 2 days before your first weight is due.

The survey will include questions such as, “When you feel lonely, do you console yourself by eating?” and “In the last 30 days, were you ever hungry but didn’t eat because there wasn’t enough money for food?” You will also need to identify experiences or conditions which apply to you, such as family or relationship problems, PTSD, eating disorders, and feeling badly about yourself. You may refuse to answer any questions that you do not wish to answer.

After you have completed the first survey, the portal will tell you which study group you will be in. You will be randomly assigned to one of three study groups. You will have a 36% chance of being in the Financial Rewards Group, a 36% chance of being in the Non-Financial Rewards Group, and a 28% chance of being in the No Rewards Group (usual care). All groups are important to this research.

Regardless of which group you are assigned, you will be asked to attend four in-person study visits at VA Puget Sound as outlined in the table below:

<b>STUDY VISIT SCHEDULE</b>	<b>Baseline Visit</b>	<b>Week 16 Visit</b>	<b>Week 32 Visit</b>	<b>Week 52 Visit</b>
<b>Length of Visit (minutes)</b>	<b>45-60</b>	<b>15</b>	<b>15</b>	<b>15</b>
Study overview	✓			
Consent process	✓			
Weigh-in	✓	✓	✓	✓

### **Weigh-in**

You will decide which day you wish to enter your weight. For example, if you pick Saturday, you will need to log in to the portal every Saturday and enter your weight. If possible, it's best to weigh yourself in the same way, every day. We recommend that you weigh yourself every morning after going to the bathroom and before eating.

No identifiable information is entered or stored in the website. You will receive a unique username and password provided at the first study visit that you will use to enter your weight every week.

After you record your weight, the website will provide you with your goal for the following week.

We will send you text message and/or email reminders before and on your weigh-in days as well as reminders for missed weight entries.

### **Phone Calls & Text Messages/Emails**

Throughout the study, you will be contacted with phone calls and text messages and/or emails many times. During Weeks 1-32, you will receive weekly text messages and/or emails asking you to log in to the portal and enter your weight. If you choose to receive text messages, text message rates may be charged by your cell phone provider. Even if you are in the group that receives a Connect device that wirelessly transmits your weight data, you will still be asked to log in to the portal and enter your weight every week.

### **Interview**

Some participants will be asked to participate in a phone interview during the last portion of the study (after Week 32) or if you decide to withdraw.

## **Resources**

There are many free and high-quality resources available. We will also provide you with a:

- **MOVE! Workbook Resource Guide** that contains healthy tips for losing weight in a healthy manner, tips to increase your physical activity, how to create meal plans with new low-cost healthy recipes, and tips in lowering stress.
- **Progress Tracking Guide** that can help you create goals and track your progress.
- **Reference Documents packet** that includes an overview of the study and what occurred during the Baseline Visit for future reference, portal instructions, scale instructions, Connect instructions, and copies of the Consent Forms and HIPAA Authorizations for this study as well as for the associated repository, if applicable.

Please review the resources we give you and think about how you want to lose weight. This is a self-directed program and no specific diets or weight loss programs are provided or recommended. You may use whatever weight loss methods you think will be helpful. We want you to lose weight in a healthy way that makes you feel good.

## **Week 1 – Week 16: REWARDS PHASE**

The Rewards Phase of the study will last from Week 1 through Week 16. During these weeks, if you are in the Financial Rewards Group or the Non-Financial Rewards Group, you will have opportunities to receive rewards for hitting your weight-loss targets. The goal is for you to lose about 1 pound per week for a total of 16 pounds over the 16-week Rewards Phase.

Your weekly goal weight may be adjusted every 4 weeks if you do not reach your target (on Weeks 4, 8, and 12). This gives you the opportunity to keep earning rewards by losing weight at a slightly faster pace. We will never ask you to lose more than 4 pounds a week. If you reach a point where you would need to lose more than 4 pounds a week to obtain your 16-pound weight-loss goal, you will no longer be eligible to receive a reward. We will still encourage you to remain in the study and do the best you can. If you lose more than 10 pounds in a week, a member of the study team will call and ask you questions about your weight loss. They may ask you questions about your general health, use of medications, or illness.

If you receive a Blipcare wireless scale with a Connect device, we will be collecting your weight data wirelessly every time you weigh yourself. If you do not receive a Connect device, we may download your weight data from your scale at or after your Week 16 visit. Your rewards will always be based on your self-reported weight. Please note that you must enter your weight into the portal to be eligible to receive a reward, even if you have a Blipcare wireless scale with a Connect device.

We want you to be successful in reaching your weight-loss goals, and we strongly encourage you to use the resources we have provided. It is important to try to lose weight in a healthy and sensible manner, such as making nutritious food choices and getting enough exercise.

We may ask you to return your Blipcare scale and wireless Connect device at your Week 16 visit. If you are asked to return your Blipcare scale, we will give you a new non-wireless scale to keep. We will see you again at Week 16 to either exchange scales or upload your scale data and have you weigh in on a study scale.

## **Week 17 – Week 32 WEIGHT MAINTENANCE**

After Week 16, you will no longer have study-determined weight-loss goals, but you're encouraged to continue to lose weight in a healthy manner or to maintain the weight that you lost. You will need to continue entering your weight into the portal during Week 17 through Week 32, even though you will no longer be earning rewards for hitting weight-loss targets. You may earn random token items for simply entering your weight every week. We will weigh you at your Week 32 appointment.

## **Week 32 – Week 52: PHONE INTERVIEW**

After Week 32, we may ask you to participate in a one-time phone interview, which will take about 30-45 minutes. If you are contacted, you may refuse to participate and can still remain enrolled in the study.

The purpose of these interviews is to understand participants' experiences with receiving or not receiving rewards for losing weight, strategies they used to try to lose weight, and motivations. Some examples of questions that will be asked during the phone interview are, "Have you ever changed your diet to lose weight?" and "Did anything make participating in the study difficult?" You may refuse to answer any questions that you do not wish to answer.

We will audio record the phone interviews. This recording will be transcribed (written down word for word) so that approved study staff members will be able to review the responses as part of the data collected for the study. The recording may be reviewed by approved study staff during data analysis to make sure that the transcript accurately captured what was said and how it was said.

### **4. What are some risks of joining this research study?**

The procedures in this study may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. You may be asked to sign an updated Consent Form to document that this new information has been explained to you. Below are study-related risks that are known at this time:

- **Health risk.** Losing weight may pose a health risk if it is achieved in an unhealthy manner. We will provide you with a **MOVE!** workbook that has been an effective tool in the VA's Weight Management Program. If you are losing weight at a rate that is deemed unsafe, we will contact you to discuss your weight-loss methods and may have to withdraw you from the study. You may contact study staff at any time with any concerns you have about your weight loss.
- **Weight changes.** There is the potential for weight regain or weight fluctuation during and after the study.
- **Survey or interview questions.** During the surveys or possible phone interview, you may feel uncomfortable answering some questions. You may choose not to answer any question you do not wish to answer.
- **Participant website (portal).** There will be no identifiable information entered or stored in the website. The website will have your unique username, weight entries, and survey responses. All data entered into the portal will be kept behind a secured VA firewall. The information you entered will then be matched to you in a secured password-protected database on a VA server. We will take every precaution to keep your information confidential.

- **Confidentiality.** We will keep your participation in the study confidential. There is the risk that a breach of confidentiality could occur; however, every effort will be made to prevent this from happening. Your personal information will be kept secure and only accessed by authorized study staff as needed to conduct this study.

If you participate in the phone interview, we will not include your name or any identifying information on the recording. However, the sound of your voice is considered a personal identifier. This means that if someone acquires the recording, they may be able to identify you.

If any of the risks included in this Consent Form become significantly updated during this study, we will let you know.

#### **5. What are some benefits of joining this research study?**

You may not receive a direct personal benefit by participating in the study. You may benefit from losing weight, increasing your physical activity, and overall living a healthier lifestyle. The study will help us learn how weight loss is affected by different types of rewards. This information can help us better design weight-loss programs in the future.

#### **6. Are there other ways I could receive these benefits?**

You may choose to lose weight in other ways without participating in this research study.

#### **7. Who will see my information and where will it be stored?**

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study. If you agree to participate in this study, we will be accessing your medical record at various points to update your contact information, collect your weight records from the previous 5 years, monitor any new medications that may affect your weight, and for follow-up and payment purposes.

If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research
- The VA Puget Sound Fiscal Department and U.S. Department of the Treasury will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study

The access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

The data that we collect for this study will be kept confidential. Your name and other identifying information will be kept in a secure password protected database. Your social security number will be stored in a separate, secure folder so study payments can be processed. Study data will be stored in a password-protected folder on the secure VA network and will only be accessed by approved study team members. Any paper records will be stored in locked file cabinets accessible only to study staff.

If you participate in this study and also choose to participate in the research study “Rewards Project Data Repository,” the data we gather and the data you provide will be included in the Data Repository.

If you are contacted to participate in the study phone interview, and if you decide to participate, we will use an audio recorder to record your responses. This recording will be used for study staff to create a transcription, or a word-for-word text file, to make sure that your responses are recorded accurately. The audio recording and transcription files will be stored to a secure folder on the VA network and accessible only to study staff.

Once this study is completed, we will not link you to your data for any additional research. We will store the code linking you to your data in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will keep your coded data indefinitely.

In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing.

We will use the information that we collect for this study only for research purposes, not for profit. However, in the future, researchers may use this research information for the development of new ways to encourage weight loss in people who are overweight or obese. Neither you nor your family will gain financially from discoveries made using the information you provide.

## **8. What are some other things to think about before I decide to join this research study?**

The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

### **Compensation for all study subjects**

To compensate all study subjects for travel costs to and from VA Puget Sound for in-person study visits, everyone will receive \$20 for each of the four study visits (\$80 possible total, if all visits were attended).

To comply with Internal Revenue Service (IRS) guidelines, we will collect your social security number. You may receive an IRS Form 1099.

### **Compensation for Financial Rewards Group**

- **Weeks 1-8:** If you hit your target weight, you will have a 1-in-8 chance of winning \$100.
- **Weeks 1-16:** If your weight is at or below your target weight, you will earn \$25 every 4 weeks (Weeks 4, 8, 12, and 16).
- **Weeks 9-16:** If you hit your target weight, you will have a 1-in-4 chance of winning \$100.



- **Weeks 17-32:** For simply entering your weekly weights, you will have a 1-in-4 chance every week of receiving token rewards (e.g., movie tickets), regardless of your weight.

You will immediately be mailed a check every time you earn a reward. However, there is often a delay of 8-16 weeks before you will receive it.

#### **Compensation for Non-Financial Rewards Group**

- **Weeks 1-8:** If you hit your target weight, you will have a 1-in-8 chance of winning a reward equaling 20 points.
- **Weeks 1-16:** If your weight is at or below your target weight, you will earn a 5-point reward every 4 weeks (Weeks 4, 8, 12, and 16).
- **Weeks 9-16:** If you hit your target weight, you will have a 1-in-4 chance of winning a reward equaling 20 points.
- **Weeks 17-32:** For simply entering your weekly weights into the portal you will have a 1-in-4 chance every week of receiving token rewards (e.g., water bottle, movie tickets, etc.), regardless of your weight.

You will be mailed a non-financial reward every time you earn one. If you have an appointment before the items can be mailed, and it is convenient for you, you may be allowed to pick up the items at VA Puget Sound. If you prefer to pick your items up in person, please notify a coordinator at your baseline appointment. The items will be either “5-point items” or “20-point items.” Some examples of 5-point items include movie tickets and local zoo admission. Some examples of 20-point items include memberships to local organizations and headphones. You will not be able to choose which item is mailed to you.

#### **Compensation for No Rewards Group**

If you are in the No Rewards Group (usual care), you will not receive rewards for losing weight, but you will still be compensated \$20 for attending each of your in-person study visits.

#### **Early (passive) withdrawal**

If you have not completed the online baseline survey after 4 weeks and we are unable to contact you after 3 attempts, you will be considered withdrawn from the study. The baseline survey must be completed prior to entering weekly weights, so no rewards can be earned if you are withdrawn this way.

#### **9. What will happen if I decide I don't want to be in this research study later?**

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits.

If you decide to withdraw from the study, no new information will be collected from you. Information already collected up to that point will continue to be used for the study. At the time you notify us you no longer wish to be in the study we may ask you to participate in the interview. The interview will help us better understand what your experience in the study was like.

If you decide to withdraw, or if you are terminated from the study, a person from the study team may need to meet with you to discuss the steps that are necessary to end your participation in the study. This may include being asked to come into the VA for one final study visit if possible.

The Principal Investigator and the study clinician may decide to terminate your participation in this study due to medical concerns or an unhealthy rate of weight loss.

If you are in one of the rewards groups and are withdrawn from the study, you will be paid the reward money that you earned up until the point of withdrawal or will be mailed non-financial gifts equivalent to the point value that you earned up until the point of withdrawal.

#### **10. What will happen if I am hurt in this research study?**

If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this Consent Form.

#### **11. What am I agreeing to by signing this form?**

I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts I may encounter in the study, of the possible benefits of the study, and of the other choices of treatment that are available to me.

My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a copy of this Consent Form.

I agree to participate in this research study as described in this document.

\_\_\_\_\_  
Subject Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Subject

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Person Obtaining Consent