A Randomized Trial of Behaviorally Designed Gamification and Social Incentives to Increase Physical Activity Among Overweight and Obese Veterans

NCT05554601

June 18, 2024

Participant's Name: _____ Date: _____

Title of Study: A Randomized Trial Of Behaviorally Designed Gamification and Social Incentives To Increase Physical Activity Among Overweight and Obese Veterans

Principal Investigator's Name: Scott R. Greysen, MD, MHS

Principal Investigator's Complete VA Address:
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Philadelphia, PA 19104

Name of Study Sponsor: VA HSR&D

RESEARCH DETAILS

WHY AM I BEING ASKED TO VOLUNTEER?

You are being asked to voluntarily participate in a research study because you are an adult Veteran who receives care at one of the medical centers (PA: Altoona, Butler, Coatesville, Erie, Lebanon, Pittsburgh, Philadelphia, Wilkes-Barre; DE: Wilmington) within the Veterans Integrated Services Network (VISN) 4. Your participation is voluntary, which means you can choose whether or not you want to take part. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The study doctor and/or a member of the research team will talk to you about the research study. You are encouraged to discuss this study and consent form with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of the study is to test ways to increase veterans' physical activity. All veterans will: receive a Fitbit activity tracking smartwatch scale and blood pressure cuff, set goals, and then will be randomly assigned to one of three physical activity programs. There are no medications or drugs involved in this study. We will enroll up to 459 veterans in this study.

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?

You will be involved with this study for 9 months. You will NOT need to have any additional visits at any medical centers listed above. We plan to enroll a total of 459 Veterans from the medical centers in VISN 4.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

You will be asked to do the following:

- Complete a series of surveys at the start and end of the study.

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Use a Fitbit activity tracking smartwatch for about 9 months to track your activity including step counts and sleep patterns. Use a weight scale and blood pressure cuff to track your weight and blood pressure. These devices will be mailed to you at no cost. This includes downloading the smartphone application or using the online website. At the end of the study, you will be able to keep the Fitbit, scale, and blood pressure cuff.

- Create an account on a research technology platform based at the University of Pennsylvania called "Way to Health." This platform allows you to connect your Fitbit, scale and blood pressure cuff to remotely send us your daily activity levels, weight, and blood pressure data.
- You will be randomly assigned to one of three physical activity programs. These programs offer different ways to provide feedback on your performance and motivate you to achieve your goals. Feedback will be delivered by encrypted email or text messaging, based on your preference. Depending on your cellphone plan, text messaging fees may apply. You may select to have all your messaging delivered by email.
- Complete short milestone questionnaires on Way to Health every 3 months over a 9-month period.

You will receive up to $150 for participating in the study: $30 for enrolling in the study, $45 for completing 6-months, and $75 for completing all 9 months. You may have the opportunity to earn more throughout the study. The payments will be credited to your bank account via direct deposit or the direct express debit mastercard card.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

A possible risk of the study is injury from physical activity. You should not participate if a doctor has told you not to exercise. Most physical activity is safe but excessive amounts can lead to muscle soreness. You will be encouraged to increase your activity levels gradually and not excessively. Another possible risk is breach of your data. The study team has taken multiple steps to ensure the security of your data including using a secure, encrypted, password protected server and remove any identifying information when possible.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

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Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

Benefits of participating in the study are that you may increase your physical activity level and gain insights into your activity from the wearable device. However, it is also possible that you may not receive any benefits from the study.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You have the choice not to participate in this research study. Participation is voluntary and you do not have to participate if you do not want to.:

WILL I HAVE TO PAY FOR ANYTHING IF I PARTICIPATE IN THIS STUDY?

You will not have to pay for any research procedures or tests that result from participating in this study.

If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

There are several ways your information may be used as part of this study. First, we will collect information to verify your identity such as your name, age, and contact information to communicate with you such as your home address, email address, and a phone number you are comfortable receiving voicemail messages. Second, we will ask you to complete surveys by phone on your demographic characteristics, activity patterns, and experiences with technology on Way to Health. Third, we may access your medical record to document your participation in the study and obtain information on your medical conditions and clinical measures. Fourth, data from the Fitbit will be transmitted to the Way to Health research technology platform and contain data on your step counts and sleep patterns to evaluate changes in your activity from participating in the study. Fifth, we will ask you to provide your bank account number and relevant information to authorize study payments via direct deposit or direct express debit mastercard card. Lastly, data from your scale and blood pressure cuff will also be transmitted to the Way to Health platform and contain data on your weight and blood pressure readings to evaluate changes.

All of this information will be stored on secure VA servers located within the VA firewall and accessed only using password-protected computers that are not connected to the Internet and

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are entirely compliant with Federal Information Security Management Act (FISMA) standards. Data pulled to Way to Health will be encrypted and securely stored in the database layer of the platform. The system will also have audit logging capabilities to ensure the protection of personal health information and has the highest level of security. Only people who must access this information for the purposes of this research study will be able to access this data. A research oversight committee, the Institutional Review Board at the Crescenz VA Medical Center may inspect study records for quality assurance.

The results of this study may be published. However, data will be presented in aggregate and no veterans will be individually identified. Further, your medical records will not be revealed unless required or authorized by law. All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

Your name and social security/medical record number will be used only as necessary within the **CMCVAMC** for the study**.**

If you have an accident or reaction during the course of the study, your entire medical record may be used and disclosed as clinically necessary.

Internal monitors from the CMCVAMC Institutional Review Board (IRB), a research oversight committee, may inspect study records for quality assurance.

All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
You should contact your primary care physician. You should also notify the study team by email or phone.

WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?
You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. To withdraw from the study, please contact the study staff at 215-823-5800 ext:206641 or at VHAPHIvhaphistep4v@va.gov. If you withdraw, you may be asked to return for a final study visit

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in order to assure your safety. Even if you withdraw, we can continue to use information about you that has been collected up to that point. No information will be collected after you formally withdraw.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

You have read or have had all of the above read to you. Dr. Greysen and or a member of the research team has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you.

In case there are medical problems, research related injuries or questions, you have been told that you should call your primary care doctor or a member of the research team.
If you would like to discuss problems, complaints, concerns, or questions with someone who is not directly associated with your participation in this study or you have any questions regarding your rights as a research subject or you want to check the validity of the study and its personnel within the VA, you should contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM Monday through Friday.
If you have concerns or complaints about the research study, you should contact the research staff involved with this study at 215-823-5800 ext:206641.

As a Veteran, we value your input into how research is conducted at the CMCVAMC. If you would like to offer suggestions and opinions, or if you would like to participate in future discussions of research in Philadelphia, please call the Research and Development (R&D) Administrative Officer at (215) 823-6020 or R&D Associate Chief of Staff at (215) 823-5893.
Every reasonable safety measure will be used to protect your well-being. The CMCVAMC will provide necessary medical care and treatment for any injury that is a result of participation in this study for Veterans. Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

There will be no cost to you for participation in this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co- payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed, for research-related interventions or procedures that are required by the protocol.

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You voluntarily consent to participate in this study. You have read this consent document or it has been read to you; it explains what this research project is about and how and why it is being done. A copy of this consent will be given to you or sent to you via postal mail.

This page is being used to ascertain consent. This is not the subject's signature.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms…… h**as explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.**

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document.		
Print Participant's Name	**Participant's Signature**	**Date Signed**

Individual Obtaining Consent (required)		
Print Individual's Name Obtaining Consent	**Signature of Individual Obtaining Consent**	**Date Signed**