

Study Information Sheet

Stay Strong: A physical activity program for Afghanistan and Iraq Veterans

INTRODUCTION

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details by calling the study hotline at 1-800-753-3357 (option #3), which is staffed by the Ann Arbor VA team. Calls to study staff will be returned the next business day. Take your time to decide.

BACKGROUND AND PURPOSE

This project will test the effectiveness of an internet-based lifestyle program called Stay Strong. This program was designed for Operation Enduring Freedom/Operation Iraqi Freedom/ Operation New Dawn (OEF/OIF/OND) Veterans. With this research, we hope to learn whether the Stay Strong program could be used as a regular program in the VA system to help OEF/OIF/OND Veterans with maintaining a healthy lifestyle and prevent future disease.

This research study is funded by VA Health Services Research and Development (HSR&D). The study team is led by Laura Damschroder, MS, MPH. The study team consists of researchers and staff at the VA facilities in Ann Arbor, MI; Durham, NC; and West Haven, CT.

You will be eligible for the Stay Strong randomized controlled trial if you:

- Are an OEF/OIF/OND Veteran
- Have been seen in the VA Health Care system within two years prior to study recruitment start date
- Can identify a VA health care provider who is responsible for your care
- Have access to a computer with an internet connection and a working USB
- Own a smartphone running a compatible iOS or Android operating system
- Are interested in starting a physical activity program
- Younger than age 65

This research study uses a Fitbit device, worn on the wrist. The device can be worn during your waking hours and stores physical activity data.

Our goal is to invite up to 750 OEF/OIF/OND Veterans. We expect 350 to complete all necessary study activities to be randomly assigned to the Stay Strong with coaching group or the Stay Strong group.

DURATION OF THE RESEARCH

Your actual study participation can last as long as 14 months depending on situations including, but not limited to, study staff and/or participant availability.

STUDY PROCEDURES

Enrollment Procedures:

A code was provided in your invitation letter to use on this website, which is hosted by Qualtrics, a VA-vendor who will temporarily store and protect your data. This website contains a brief online description of the Stay Strong program and an eligibility checklist.

Once you are eligible then you will review this detailed information sheet about the study and a HIPAA authorization form. If you decide to be a part of the study, you will continue to receive all your usual care services. You will be asked to complete a survey online about yourself, your general health, specific diseases, social support, and satisfaction with care. You will also be asked to provide your current mailing address and additional contact information for use during the study period. You are free to skip questions that you would prefer not to answer. After these steps are completed you will be directed to install and use the Stay Strong app hosted by Vibrent Health to verify that you are able to use the system. We will then mail you a welcome packet with a Fitbit device to track your physical activity levels as well as a Bluetooth-enabled scale you can use at home to check your weight.

You will be asked to install the Fitbit Connect software on your computer. You will be asked to wear your Fitbit device for 7 days and sync your physical activity data to the Fitbit servers via the Fitbit Connect software. If you do not wear your Fitbit or sync your data within approximately 10 days, study staff will call you to help troubleshoot and facilitate completion of this initial phase. After 3 attempts to complete this initial phase, study staff will withdraw you from the study.

If you are unable to install or use the Fitbit Connect software or the Stay Strong app, study staff will withdraw you from the study.

Once your Fitbit data meets the minimum requirements of physical activity data in the initial phase, you will be randomly placed into either the Stay Strong program or the Stay Strong with Coaching program. You will have a 50-50 chance of receiving the Stay Strong program or the Stay Strong with Coaching program. We will decide randomly (like flipping a coin). The next sections describe the two programs.

Stay Strong Program Description:

If you are randomly placed in the Stay Strong program, you will have access to the Stay Strong app on your smartphone, which will provide step-by-step instructions for how to install and use your Fitbit device and Bluetooth-enabled scale. The app will also provide answers to Frequently Asked Questions. We will encourage you to wear your Fitbit device and to sync the device weekly via the Fitbit Connect software installed on your computer. You will be able to see your synced physical activity and uploaded weight data within the Stay Strong app. Throughout the program period, the Stay Strong app will send you periodic reminders to inform the study staff of any changes to your medical condition and to follow-up with your healthcare provider as needed. The Stay Strong app will send you a message asking you

to complete a survey on the Qualtrics website at 6 months and 12 months after you start the Stay Strong program. If the survey is not completed, study staff may call or mail you a reminder. You can also call the study hotline at 1-800-753-3357 (option #3) at any time and leave us a message. The Fitbit device and Bluetooth-enabled scale are yours to keep at the end of the study. Study Staff will deactivate your study created Fitbit account from Fitbit servers. At the end of the project, you will have the option to set up your own personal account on Fitbit if you choose. At this time, the use of the Fitbit device and access to the data you sync to the Fitbit servers is free for the lifetime of the device. We cannot guarantee indefinite access to the Fitbit system after your participation in the study is complete. At the conclusion of the program you will be sent a letter thanking you for your participation and you will receive a report of baseline and final results of the project.

Stay Strong with Coaching Program Description:

If you are randomly placed in the Stay Strong with Coaching group, you will receive everything described for the Stay Strong Program. In addition, each week you will receive a new physical activity goal that has been automatically calculated and personalized to you. You will also receive tips to help you engage in healthy lifestyle habits and personalized motivational messages through the Stay Strong app approximately 3 days per week. You will also have up to 3 phone calls with a Stay Strong health coach within the first 9 weeks of the study. Your coach will have access to your survey responses and synced Fitbit data and will work with you to help you meet your physical activity goals. These coaches are VA employees who work at our Durham NC site. The coach will ask at the start of each call if you are agreeable to having the session recorded.

POSSIBLE RISKS OR DISCOMFORTS

Starting an exercise program may improve your health and daily function. However, any research study has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur. You should continue your care with your current healthcare provider as needed. Your healthcare provider maintains oversight of your healthcare and it is important to keep them involved in any changes in your health.

Please inform your doctor and the study staff if you experience any of the following:

- Musculoskeletal injuries including minor injuries like strains or sprains, and more serious injuries like fractures from slipping or falling if running or walking.
- Serious problems with your heart like chest pain or heart attack if you already have an existing heart condition or develop one while in the study. For most people, exercise will reduce the chance of a problem with your heart.
- Weight loss which could lead to changes in blood glucose or blood pressure. This could mean you would require a change to your existing medicines to prevent dizziness and/or light headedness.
- Irritation or rash from the Fitbit device including development of an allergic reaction due to the materials in the band.

To minimize the above risks, we ask that you not exceed the weekly exercise goals we give you. We will also provide general safety information throughout the study period. There are also risks related to

the use of the Fitbit Connect software, the Stay Strong app, and the Qualtrics website. Please contact the study staff if you have any questions about or problems with the following during the study:

- Risks associated with transmitting data online, including loss of confidentiality.
- Frustration with any technical problems or barriers in using the Fitbit device, Bluetooth scale or the syncing software necessary to transmit your data to the Fitbit servers or Stay Strong app.
- Frustration with any technical problems or barriers in using the Stay Strong app.

We have protections in place to minimize these technical risks, including the use of secure logins limited to authorized VA staff and vendors, and data storage standards. To safeguard your personal information, we ask for you to do the following:

- Do not enter personal information in the Stay Strong app.
- Connect the study issued Fitbit device **only** to the Stay Strong app using the study created Fitbit account information.

Risks of the usual medical care you receive are not risks of this research study. Risks related to regular medical care 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 medical care.

POTENTIAL BENEFITS

It is possible that you will not receive any personal benefits from being in this study. It is possible you could become more physically active and feel better. Even if you do not benefit directly, findings from this study may help identify ways to help Veterans become more active and improve their health.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

You may choose not to participate in this study. If this is your decision, and if you are interested in an exercise program, you may contact your VA provider for more information about the MOVE! program. MOVE! is a national weight management program designed to help Veterans lose weight, keep it off, and improve health.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Any paper records will be stored in locked filing cabinets accessible to authorized study staff only.
- Electronic data will be stored and protected in the following ways:
 - Qualtrics is our VA-vendor for eligibility screening and surveys during the research study. Their servers are outside of the VA system and, therefore, the information you provide may not be protected with the same standards of data security established inside the VA. However, Qualtrics uses very high standards to protect your data. The data will be temporarily stored by Qualtrics and then moved to the VA servers for

storage. Access to this data is limited to authorized study personnel via login to a secure site. The original data on the Qualtrics server will be deleted after the data transfer.

- Fitbit Inc is the manufacturer of the Fitbit device and the Fitbit Connect software used to transmit your data to the Fitbit servers. Your IP address is captured during the syncing of your data and is stored on the Fitbit servers. Their servers are outside of the VA system and, therefore, the information you provide may not be protected with the same standards of data security established inside the VA. Your data and your IP address will be deleted at the end of your study participation.
- Vibrent Health is our VA-vendor for the Stay Strong research platform. Vibrent will not have personally identifying data about you at any time. All data provided to Vibrent will be transferred to the VA at the end of the study, and the data stored at Vibrent will be deleted.
- Servers administered by the vendors listed above are outside of the VA system of control and, therefore, the information you provide to them may not be protected with the same standards of data security established inside the VA. As with any internet-based service, there are no guarantees that your data residing on these servers will be 100% safe but our study vendors will take all possible measures to protect your data in accordance with their Privacy Policies. The study's vendors use very high standards to protect your data. By providing consent to participate in this study, you agree to allow your personal information to be stored on their servers for the duration of the study. When you access your data you will use your personal smart phone, and when study staff access your data we will use a secure login page.
- Study data about you will be stored on secure servers at the VA in Durham, NC and the VA in Ann Arbor, MI. These data are protected using the same standards that are used to protect all VA research data. This includes limiting access to your data to designated study staff or to others in special circumstances as described below.
- No personal identifiable information, health information, or promotional materials will be emailed during this study to you by any VHA research staff or from staff at Qualtrics, Vibrent, or Fitbit. If this occurs, please contact the Principal Investigator immediately using the study hotline at 1-800-753-3357 (option #3).

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you personally.

We will be obtaining additional information about you from your VA medical record including your general health and your Service Connected Status.

To determine which prevention programs are most helpful for Veterans, we are also going to review your medical record for 2 years before and 2 years after your participation in the study ends. This information will include your name, social security number, date of birth, race, sex; lab results and dates; vital signs and dates; the dates and nature of all your clinical visits or encounters, and tests and costs. Researchers from our study team located at the Durham VA in Durham, NC will be analyzing these research data and will also have access to personal health information only for the purposes of the research study.

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Food and Drug Administration, Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you to verify the study is safe and being done properly.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants:

There is no cost to participate in this study. If you usually have 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.

Payment Offered for Participation:

Participants in the study who complete the 6-month survey will be mailed a \$25 gift card to a national or online retailer such as Walmart or Amazon.com. Participants who complete the 12-month survey will be mailed a \$25 gift card to a national or online retailer such as Walmart or Amazon.com. The Fitbit device and scale to measure your weight are yours to keep at the end of the study.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured by taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to you not following the study procedures.

If you have a medical concern or get hurt or sick as a result of taking part in this study, please talk to your healthcare provider first or seek emergency care as needed. Emergency and ongoing medical treatment will be provided as needed.

Please then inform the study staff by calling our study hotline at 1-800-753-3357 (option #3). All calls to the study hotline will be returned the following work day.

You do not give up any of your legal rights and you do not release the VA from any liability by agreeing to participate in this research study.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether to take part in this study. If you decide to participate you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

Any data collected before you left the study will be kept, but we will not collect further data about you or your health except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

In certain cases, the researchers might decide it is best for you not to finish the study. For example, if your health changes it may not be safe for you to continue the study. If you are participating in another study, please tell the researchers for both studies.

PERSONS TO CONTACT ABOUT THIS STUDY

In case there are medical problems, an injury, or if you have questions, concerns or complaints about the research study, you can call the study hotline at 1-800-753-3357 (option #3) and ask to speak with Laura Damschroder, Principal Investigator for this study.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.