Protocol:

CRE 12-305

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

Funding Agency:

HSR&D

Clinical Trials:

NCT02360293

Principal Investigator/Study Chair:

Laura Damschroder, MS, MPH

Submission

Version 7: July 24, 2014
Version 9: May 14, 2015
Version 10: September 15, 2015
Version 11: October 26, 2015
Version12: April 17, 2017
Version 13: January 16, 2018
Version 14: May 2, 2018
Version 15: July 11, 2018
Version 16: October 18, 2018

Abstract

Veterans from Afghanistan and Iraq (OEF/OIF/OND) are at high risk for becoming overweight and obese; 86% were overweight or obese at their first visit to the VA as reported in one recent study. However, existing VA programs are not designed for younger Veterans who are more comfortable with technology-mediated interventions than older Veterans and who may not yet have developed obesity related chronic diseases. Additionally, OEF/OIF/OND Veterans include a relatively high percentage of women compared to previous Veteran cohorts. These differences should be addressed in lifestyle interventions customized to OEF/OIF/OND Veterans.

Technology-mediated lifestyle interventions that include continuous, objective home monitoring of physical activity, automated internet mediated feedback, and e-coaching increase physical activity and improve weight loss in non-Veteran populations. When delivered on a large scale, such interventions represent low cost but effective alternatives to face-to-face lifestyle change interventions. The VA health care system is in a strong position to implement such interventions on a national scale because of existing structures such as a national electronic medical records system. Such interventions can be centrally administered and marketed directly to Veterans, capitalizing on economies of scale, expanding intervention reach, and reducing the burdening of recruitment on the existing health care team. However, with the exception of one pilot study, prevention focused technology-mediated physical activity programs that include continuous, objective home monitoring of physical activity, automated internet or cell-phone mediated feedback, and e-coaching have not been customized and tested for OEF/OIF/OND Veterans.

This project will test the feasibility and effectiveness of the prevention focused, internet mediated healthy lifestyle Stay Strong program tailored to the needs, preferences and demographics of OEF/OIF/OND Veterans. If successful, the Stay Strong program could be implemented as a national program to augment the VA's current panel of options for OEF/OIF/OND Veterans who need support to maintain a healthy lifestyle and prevent future disease. The specific aims of this project are to 1) evaluate the impact of an automated, centrally administered, internet-mediated, physical activity intervention, Stay Strong with coaching, on the primary outcome of average minutes of moderate to vigorous physical activity among OEF/OIF/OND Veterans; 2) evaluate the impact of Stay Strong with coaching on the secondary outcomes of weight loss, depression and pain among OEF/OIF/OND Veterans; and 3) test for moderation of the intervention effect of the Stay Strong with coaching intervention by gender with respect to the primary outcome of minutes of moderate to vigorous physical activity per day, as well as secondary outcomes of weight loss, depression and pain.

In this randomized controlled study, OEF/OIF/OND Veterans will be randomized into either a Stay Strong control arm or the Stay Strong with coach intervention arm for one year The primary outcome is change in minutes of moderate to vigorous physical activity per day averaged over 7 days. Weight loss, pain and depression are secondary outcomes. Because gender moderates the impact of physical activity interventions, we will tailor Stay Strong on gender and over-sample women. The trial is innovative in that study staff will have no face-to-face contact with participants. All participant recruitment, eligibility screening, informed consent, baseline assessment, randomization, intervention delivery and outcome assessment will be internet or cell-phone mediated. A constrained longitudinal data model in which baseline physical activity is modeled as a dependent variable in conjunction with the constraint of a common baseline mean across the treatment group will test for a between-group comparison in physical activity from baseline to 12 months in the intervention and control groups.

List of Abbreviations

AE – Adverse Event

ANCOVA – Analysis of Covariance

BMF – Bodymedia Fit device

BMI – Body Mass Index

CDW – VA Corporate Data Warehouse

CIRB – Central Institutional Review Board

cLDA – constrained longitudinal data model

CPMP – Committee for Proprietary Medicinal Products

DOB – Date of Birth

DUA – Data Use Agreement

ER – Emergency room

FAQs – Frequently Asked Questions

IBM – Information-Motivation-Behavior Skill Theoretical Model

HIPAA – Health Insurance Portability and Accountability Act

HSR&D – Health Services Research and Development

HTTPS – Hypertext Transport Protocol Secure

IP – Internet Protocol address

LSI – Local Site Investigator

NCP VHA National Center for Health Promotion and Disease Prevention:

OEF – Operation Enduring Freedom

OIF – Operation Iraqi Freedom

OND – Operation New Dawn

PA – Physical Activity

PC – Project Coordinator

PHI – Private Health Information

PI – Principal Investigator

QUERI – VA Quality Enhancement Research Initiative

SAE – Serious Adverse Event

SSN – Social Security Number

SSL – Secure Socket Layer

TLS – Transport Layer Security

UC – Usual Care

USB – Universal Serial Bus

VA – Veterans Affairs

VAMC – VA Medical Center

VHA – Veterans Health Administration

VINCI – VA Informatics and Computing Infrastructure

VISN – Veterans Integrated Service Network

VSSC – VHA Support Service Center

Contents

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

1.0 Study Personnel

Principal Investigator/Study Chair:

Laura Damschroder, MS, MPH	VA Ann Arbor Healthcare System HSR&D (152) PO Box 130170 Ann Arbor, MI 48113-0170 (734) 845-3603 Laura.Damschroder@va.gov	Research Scientist Ann Arbor VA Center for Clinical Management Research Implementation Research Coordinator, Personalizing Options through Veteran Engagement (PROVE) QUERI Ann Arbor VA HSR&D Center of Excellence	8/8

Co-Investigators:

Mona AuYoung, PhD	VA Ann Arbor Healthcare System HSR&D (152) PO Box 130170 Ann Arbor, MI 48113-0170 734- mona.auyoung@va.gov	Post-doctoral Research Fellow	8/8
Lori Anne Bastian MD, MPH	VA Connecticut Healthcare System Newington Campus 555 Willard Avenue Newington, CT 06111 Lori.Bastian@va.gov	Senior Research Associate, VA Connecticut Professor of Medicine, Yale University School of Medicine	5/8
Lorraine Buis, PhD	VA Ann Arbor Healthcare System HSR&D (152) PO Box 130170 Ann Arbor, MI 48113-0170 734-998-7120 ex 312 Caroline.Richardson@va.gov	Assistant Professor, Dept of Family Medicine, University of Michigan	WOC
Jennifer Gierisch, PhD	Center for Health Services Research in Primary Care Durham VA Medical Center 508 Fulton Street (152) Durham NC 27705 919.668.5519 Jennifer.gierisch@va.gov	Research Health Science Specialist, HSR&D, Durham VA Medical Center Assistant Professor, Duke University Medical Center Adjunct Assistant Professor, Gillings School of Global Public Health, Univ of NC Chapel Hill	7/8
Maren Olsen, PhD	Center for Health Services Research in Primary Care	Biostatistician, HSR&D, Durham VA Medical Center	7/8

	Durham VA Medical Center 508 Fulton Street (152) Durham NC 27705 919.668.5519 Maren.Olsen@va.gov	Associate Professor, Duke University Medical Center	
Eugene Z. Oddone, M.D., M.H.Sc.	Center for Health Services Research in Primary Care Durham VA Medical Center 508 Fulton Street (152) Durham NC 27705 919.286-6936 Eugene.oddone@va.gov	Senior Researcher, HSR&D Coin, Durham VA Health Care System Professor of Medicine, General Internal Medicine, Duke University Phone: 919-286-6936	8/8

2.0 Introduction

OEF/OIF/OND Veterans have high physical and mental health burden that may impede physical activity participation. While active duty men and women have good levels of fitness, many of them find it difficult to maintain this routine in their civilian life. This is particularly common among younger Operation Enduring Freedom, Operation Iraqi Freedom and Operation New Dawn (OEF/OIF/OND) returning Veterans. In addition to the usual barriers to a physically active lifestyle faced by all Americans, these Veterans also often suffer from conditions including chronic pain, mental illness and substance abuse, which influence their physical activity behaviors. The type and intensity of physical activities performed, by the OEF/OIF/ONS population; change considerably from active duty to post-deployment. This is often due to relatively unstructured nature of civilian life as well as any service-connected illnesses or injuries.(7) The transition from being physically fit and active to being sedentary and disabled often results in rapid weight gain and increased risk of adverse health outcomes including diabetes, heart disease, joint disorders and some cancers. In a large cohort of OEF/OIF/OND Veterans who were seen frequently in the Veteran Health Administration (VHA), 86% were overweight or obese at their first visit.(1) Early intervention with individually tailored lifestyle program targeting physical activity and prevention of weight gain has the potential to improve mental and physical health and reduce long-term disability. Thus, there is a need to develop novel approaches that deliver evidence-based physical activity interventions at low cost for OEF/OIF/OND Veterans.

Technology-mediated lifestyle interventions that employ objective monitoring increase physical activity and increase weight loss. Internet-mediated interventions have been shown to increase physical activity in non-Veteran populations.(8) Lifestyle change interventions that employ physical activity monitoring devices such as pedometers have been shown to improve health outcomes including weight loss.(9, 10) The combination of objectively monitored physical activity with internet-mediated feedback results in a potent lifestyle change intervention that is relatively inexpensive when implemented on a large scale.(11) Our previous research has demonstrated that by using remote monitoring, tailored motivational messaging and online coaching, it is

possible to deliver a low cost, implementation friendly, yet intensive, tailored physical activity intervention.(4, 5, 12, 13).

In Veterans, technology-mediated pedometer-based walking programs with web-based feedback have been shown to increase physical activity and decrease weight. In a pilot study using an uploading pedometer with internet-mediated feedback for obese Veterans, average weight loss among the 12 participants was just over 4 lbs (paired t test, P = .004) and mean daily step counts increased by 1339 steps per day, or 0.6 miles per day (P = .04).(6). Additionally, in Veterans Walk For Health study, 255 obese Veterans with risk factors for cardiovascular disease were randomized to one of three different walking programs (time-based walking goals, simple pedometer and uploading pedometer with web-based feedback). Those in the technology-mediated arm lost significantly more weight than those in either time-based walking goals or simple pedometer arms.(14)

Two recent randomized controlled trials in non-Veteran populations used the objective physical activity-monitoring device, Bodymedia Fit (BMF), similar to the Fitbit device that will be used in this trial. In both previous trials, interventions yielded more weight loss than in standard group-based behavioral weight loss programs. In the first trial, by Pellegrini and colleagues (3), 51 subjects (age: 44.2 ± 8.7 years, BMI: 33.7 ± 3.6kg/m 2) participated in a 6- month behavioral weight loss program and were randomized to one of three groups: standard behavioral weight loss, standard behavioral weight loss plus BMF system or BMF system only. At 6 months, those in the BMF only arm lost 5.8 ± 6.6kg compared to 3.7 ± 5.7kg in the standard behavioral weight loss program ($P < 0.001$). However, more weight was lost by those randomized to BMF plus traditional counseling arm (8.8 ± 5.0kg). In a similar trial by Blair and colleagues (2), with 197 participants randomized to four arms (a no intervention control, a standard behavioral weight loss group, a BMF-only arm and a combination arm with both the weight loss group and the BMF intervention), those in the BMF-only group lost 3.55 kg compared to 1.86 kg in the behavioral weight loss group and .89 kg in the no-intervention control group ($p < .0001$).

Numbers of women OEF/OIF/OND Veterans are increasing, and women respond differently than men to physical-activity promoting interventions. The recent wars in Iraq and Afghanistan have engendered a growing population of women Veterans seeking health care through the Veterans Affairs (VA). In the last decade, the number of women Veterans utilizing the VA has nearly doubled from 159,000 in FY00 to over 315,000 in FY10, outpacing the growth rate in the male Veteran population.(15) As the population of women Veterans seeking care in the VA increases and as the average age of this population decreases, preventive services for women Veterans become more important. In non-VA populations, gender is known to moderate efficacy of weight loss interventions. (16-18) For example, among users of a commercial web-based weight loss program, men using the exercise diary were more likely to lose weight, but not women. On the other hand, online forums were significantly associated with weight loss in women, but not for men.(18) Our recent pilot study of home-based weight loss programs in OEF/OIF/OND Veterans, (described in more detail below) provided qualitative confirmation of this interaction with women Veterans emphasizing the importance of the support they received from the online forums while men focused on the positive effect of diet and

exercise tracking (unpublished data). Women also differ from men in their motivational responses to exercise-promoting messages. For example, women have a more positive motivational response to exercise-promoting messages that emphasize daily wellbeing than they do to messages emphasizing weight loss; however, the opposite is true for men.(17) **Because of the known gender differences in response to physical activity interventions, gender-tailored physical activity programs for Veterans are likely to serve both men and women in the OEF/OIF/OND population better than generic, untailored physical activity interventions.**

VA MOVE! and other available physical activity programs are not optimized to serve OEF/OIF/OND Veterans. The VA Health Systems' MOVE! Program, initiated and supported by the National Center for Health Promotion and Disease Prevention (NCP), is an innovative and broad-reaching program of lifestyle modification targeting Veterans with body mass index (BMI) > 30 or those who already have multiple cardiovascular disease risk factors. The MOVE! Program is generally delivered in facility-based group classes and it emphasizes moderate-intensity physical activity such as walking. MOVE! participants are given a pedometer to track walking. While MOVE! is a well-designed standard group-based behavioral weight loss program, it was designed for older and sicker Veterans. Younger OEF/OIF/OND Veterans have different needs, preferences and demographics and may be better served by a program like Stay Strong. Stay Strong is a remotely delivered, internet- and smart-phone-mediated intervention that is more convenient for Veterans who are often employed and who may find it difficult to attend a facility-based program regularly. Stay Strong is not limited to Veterans who are already obese or who already have cardiovascular risk factors. Instead it emphasizes both weight loss for obese Veterans as well as primary prevention of obesity for those who have not yet gained a significant amount of weight. Rather than providing participants with a pedometer that tracks walking, Stay Strong uses newer technology, the Fitbit device that can objectively assess wider range of physical activity preferred by OEF/OIF/OND Veterans including higher intensity physical activity and resistance exercise such as weight lifting.(7). **Stay Strong is designed to address the unique needs, preferences, and demographics of OEF/OIF/OND Veterans.**

3.0 Objectives

SPECIFIC AIMS

Anticipated Impacts on Veteran's Healthcare: Veterans from Afghanistan and Iraq (OEF/OIF), despite their relatively recent active duty status, are at high risk for becoming overweight and obese, with 86% overweight or obese at their first visit to the VA in one recent study.(1) However, existing VA programs such as MOVE! are not designed for these younger Veterans who are more comfortable with technology-mediated interventions than older Veterans and who may not yet have developed obesity-related chronic disease. Additionally, OEF/OIF/OND Veterans include a relatively high percentage of women compared to previous Veteran cohorts. These differences between

OEF/OIF/OND Veterans and older Veteran cohorts have important implications for lifestyle intervention design. This project will test the feasibility and effectiveness of the prevention-focused, internet-mediated healthy lifestyle Stay Strong program tailored to the needs, preferences and demographics of OEF/OIF/OND Veterans. If successful, the Stay Strong program could be implemented as a national program to augment the VA's current panel of options for OEF/OIF/OND Veterans who need support to maintain a healthy lifestyle and prevent future disease.

Project Background: Technology-mediated lifestyle interventions that include continuous, objective home monitoring of physical activity, automated internet-mediated feedback, and e-coaching increase physical activity and improve weight loss in non-Veteran populations.(2, 3) When delivered on a large scale, such interventions represent low cost but effective alternatives to face-to-face lifestyle change interventions. The VA health care system, with its national electronic medical records system and well established patient facing e-Health portal is in a strong position to implement such interventions on a national scale. Such interventions can be centrally administered and marketed directly to Veterans, capitalizing on economies of scale, expanding intervention reach and reducing the burdening of recruitment on the existing health care team. Technology-mediated physical activity programs that include **continuous, objective home monitoring of physical activity, automated internet or cell-phone mediated feedback and e-coaching** (4-6) have been tested in Veterans, but with the exception of one pilot study, such interventions have not been prevention focused and have not addressed differences in needs, demographics and preferences specific to OEF/OIF/OND Veterans.

Barriers and facilitators to implementation of centrally administered, automated, internet- or cell-phone mediated interventions employing objective physical activity monitoring devices and marketed directly to Veterans are likely to be different than those for face-to-face interventions. In such interventions, issues of scalability, data security, privacy and patient safety overshadow traditional implementation issues such as facility buy-in, provider work flow and intervention fidelity. Implementation barriers unique to this type of automated, centrally administered and remotely delivered, prevention-focused intervention have not been studied in the VA.

Stay Strong Specific Aims:

1. To evaluate in a randomized control trial the impact of an automated, centrally administered, internet-mediated, physical activity intervention, Stay Strong with coaching, on the primary outcome of average **minutes of moderate to vigorous physical activity** among OEF/OIF/OND Veterans who receive care in the VA health system.

2. To evaluate the impact of Stay Strong with coaching on the secondary outcomes of **weight loss, depression and pain** among OEF/OIF/OND Veterans who receive care in the VA health system.

3. To test for **moderation of the intervention effect of the Stay Strong with coaching intervention by gender** with respect to the primary outcome of minutes of moderate to vigorous physical activity per day, as well as secondary outcomes of weight loss, depression and pain.

Hypotheses:

H1: OEF/OIF/OND Veterans who participate in the Stay Strong with coaching intervention will increase their mean daily minutes of moderate to vigorous physical activity by 10 minutes or more at 1 year compared to a Stay Strong control group.

H2: OEF/OIF/OND Veterans who participate in the Stay Strong with coaching intervention will lose 4 lbs more on average at 1 year compared to a Stay Strong control group.

H3: The Stay Strong with coaching intervention will be equally effective for both men and women OEF/OIF/OND Veterans and there will be no statistically significant interaction between gender and treatment arm on the primary outcome of mean minutes of moderate to vigorous physical activity per day

The theoretical orientation of Stay Strong with coaching is informed by the information-motivation-behavioral skills (IMB) model and self-regulatory theory. Both models have been successfully applied to physical activity and describe processes of behavior change mediated through goal attainment and skills mastery and acknowledge the central role that self-efficacy plays in sustained behavior change.

The IMB hypothesizes that cognitive and behavioral skills are a prerequisite for any health behavior change like increasing physical activity. However, skills are the product of information that is relevant to health problem and personal and social (i.e. social support) motivation to change behavior. Thus, information interacts with motivation to enhance self-efficacy and build skills mastery to facilitate sustained behavior change. Informed by our pilot data and the IMB, we will boost social support and information transfer though a key strategy of Stay Strong, the e-coaching support component. E-coaches will act as a source of social support. Also e-coaches will provide information to enhance motivation and facilitate goal setting through 1) helping interpret Fitbit device feedback about past goal attainment and assistance in setting realistic future goals grounded in the objective physical activity monitoring provided through Fitbit device; 2) providing tailored motivational messages to help overcome barriers to lifestyle changes; and 3) facilitating connections with local VA and community resources.

The theory of self-regulation also informs the core components of Stay Strong with coaching. In self-regulation, individuals participate in self-directed behaviors. These self-directed behaviors are thought to be managed through a dynamic feedback loop in which individual process information about their past behavior and integrate that information into their goals and motivation to change future behaviors (i.e., self-monitoring). Thus, similar to IMB, self-regulation involves both cognitive and behavioral processes to facilitate goal attainment. A key strategy of Stay Strong with coaching is enhancing motivation and facilitating goal setting though enhanced self-monitoring. The Fitbit device will provide detailed self-monitoring information through the objective measurement of physical activity. The self-monitoring and feedback loop will act on self-efficacy via two pathways: 1) influencing participants' goal setting and motivation to adhere to goals and 2) providing data for the e-coaches to customize motivational messages about goal attainment and future goal setting. Increased self-efficacy will mediate positive changes in physical activity and healthy eating which will, in turn, lead to secondary outcomes of weight control and improved overall mental and physical health status.

4.0 Resources and Personnel

- Study Staff for this project will be located at 3 sites:
    - Ann Arbor
    - Durham
    - VA New England Healthcare System Newington Campus
    - VA Puget Sound Health Care System

Project Team Member	Project Role	Involvement	Access to Identifiable data? Yes/No	Obtaining Informed Consent? Yes/No
Ann Arbor HSRD COIN Staff				
Laura Damschroder, MS, MPH	PI	Responsible for the scientific integrity and oversight of all aspects of the study	Yes	No
Mona AuYoung, PhD	Co-Investigator	Advise PI on manuscript preparation.	Yes	No
Lorraine Buis, PhD	Co-Investigator	Advise PI, particularly on mHealth technologies and manuscript preparation.	Yes	No
Jennifer Burns,	Data Analyst	Obtaining recruitment list and VA data about consented participants, Assisting with cleaning and	Yes	No

		analyzing study data		
Richard Evans	Data Analyst	Assisting with cleaning and analyzing study data	Yes	No
Gwendolyn Hooks, MA	Research Assistant	Mailing recruitment and study material, weekly incentive mailings, and technical support for participants. Administer the medical clearance protocol. Assisting with cleaning and analyzing study data.	Yes	No
Reema Kadri	Consultant	Advise PIs on all aspects of study management.	No	No
Hyungjin (Myra) Kim	Co-Investigator/ Biostatistician	Assisting with analyzing study data	Yes	No
Caroline Richardson, MD	Consultant	Advise PI on all aspects of study design	No	No

Durham HSRD COIN Staff				
Project Team Member	Project Role	Involvement	Access to Identifiable data? Yes/No	Obtaining Informed Consent? Yes/No
Aviel Alkon, BS	Software Developer	Lead on database design and management	Yes	No
Bradley Dokter, BS	Computer Scientist	Ensuring database set-up and ongoing data security and storage requirements are maintained	No	No
Jennifer Gierisch, PhD	Site PI/ Co-Investigator	Training and supervision of the e-coaches, messaging content creation, advise PI, manuscript preparation.	Yes	No
Karen Juntilla, M.Ed.	e-coach	Responsible for conducting telephone sessions with the veterans in the intervention arm	Yes	No
Felicia McCant, MSSW	Project Coordinator /Durham Site PC	Assist the PIs with all aspects of study management. Assist RA with medical clearance protocol. Assist with cleaning and analyzing of study data. Facilitate Study and Durham regulatory documentation/ maintenance	Yes	No
Eugene Oddone, MD	Co-Investigator/	Advise PI, focus on prevention, Adverse Event	Yes	No

	Study MD	and medical clearance oversite and manuscript preparation		
Maren Olsen, PhD	Co-Investigator and Senior statistician	Advise PI, Senior statistician performing data analysis, collaborating with database design and management	Yes	No
Lesa Powell, BS	Programmer	Database setup and management	Yes	No
Courtney White-Clark, MS	e-coach	Responsible for conducting telephone sessions with the veterans in the intervention arm	Yes	No

VA New England HCS - Newington Campus Staff				
Project Team Member	Project Role	Involvement	Access to Identifiable data? Yes/No	Obtaining Informed Consent? Yes/No
Lori Anne Bastian MD, MPH	Co-Investigator/ Study MD	Advise PI, particularly on gender issues and Adverse Event and medical clearance oversite, and manuscript preparation	Yes	No
Rebecca Czlapinski	Research coordinator in Newington	Facilitate Newington regulatory documentation/maintenance	No	No
Eric DeRycke	Research coordinator in Newington	Facilitate Newington regulatory documentation/maintenance	No	No

VA Puget Sound Health Care System				
Project Team Member	Project Role	Involvement	Access to Identifiable data? Yes/No	Obtaining Informed Consent? Yes/No
Kristen Gray, PhD	Consultant	Advise PI in analysis of PA and technology data, and manuscript preparation.	No	No

- We will also be utilizing the services of two vendors:
    - Qualtrics will be the vendor for our online surveys for data collection and to obtain informed consent. We will be using a contract to ensure Qualtrics protects our research data as required.

- Vibrent Health will be the Stay Strong platform vendor for the intervention and control group. We will be using a contract to ensure Vibrent Health protects our research data as required.

5.0 Study Procedures

5.1 Study Design

Study Design: In this randomized controlled study, OEF/OIF/OND Veterans will be randomized into either a Stay Strong control arm or the Stay Strong with coaching intervention arm with equal probability for one year. The use of a control group is necessary because the effect of the intervention is unknown and the control group will be receiving current standard of care. The primary outcome is change in average daily physical activity. Weight loss, pain and depression are secondary outcomes. Because gender moderates the impact of physical activity interventions, we will tailor Stay Strong on gender and oversample women. The trial will be unusual in that we will have no face-to-face contact with participants. All participant recruitment, eligibility screening, informed consent, baseline assessment, randomization, intervention delivery and outcome assessment will be internet or phone mediated. We will mail study materials to participants from the Ann Arbor location. The Stay Strong app for both groups will remain active for an extra 30 days to ensure that sufficient endpoint physical activity and weight data are uploaded.

Risk: We identify the following risks to participation.

- Musculoskeletal injuries including minor injuries like strains or sprains, and more serious injuries like fractures from slipping or falling if running or walking
    - Can occur from exercise for the research intervention or at the advice of their primary care provider.
- Adverse cardiovascular events
    - Can occur from exercise for the research intervention or at the advice of their primary care provider.
- Weight loss which could lead to changes in blood glucose or blood pressure requiring modifications to existing medication regimens and possibly causing dizziness and/or light headedness.
    - Can occur from exercise for the research intervention or at the advice of their primary care provider.
- Risks associated with transmitting data online including loss of confidentiality
    - A risk of the research intervention alone

- Risks associated with use of the Fitbit device including development of an allergic reaction or contact dermatitis associated with the materials in the band
    - A risk of the research intervention alone
- Participant frustration with any technical problems or barriers in using the Fitbit device or the Fitbit Connect syncing software necessary to transmit the data to the Fitbit servers, or the Vibrent Health app, necessary to view the intervention or control platform
    - A risk of the research intervention alone

To minimize the risk associated with starting a diet and exercise program, automated goals and health coaches will guide participants to gradually increment their physical activity and to maintain a healthy balanced diet. This proposal targets younger Veterans all of whom have recently returned from active duty. As such their risk for adverse cardiovascular events even with vigorous exercise is very low. To mitigate even this small risk, health coaches and research staff will be trained to screen for and respond to any reports of chest pain or other concerning cardiovascular symptoms reported by participants during the study. If a patient is temporarily suspended from the study due to a serious adverse event that may be a contraindication to diet, exercise or weight loss, we will require medical clearance from a provider before returning to active status in the study. Additionally, health coaches will assist veterans with setting gradually incrementing physical activity and diet goals.

To minimize the risk of loss of confidentiality, identifying data will be stored on a secure VA server behind the VA firewall, on vendor servers covered under a contract (Qualtrics or Vibrent Health), or on the Fitbit servers. The Fitbit Connect software, which collects and stores IP address at each data transmission, is not covered under a contract, but we will require the participants to complete an online HIPAA form to authorize this collection and temporary storage. Additionally, to protect participants PII, we will direct that they participants use a nickname that is not their real name when registering in the Stay Strong app. Email is not required anywhere. The study team will use aliases info to register the participants with a study Fitbit account prior to sending devices to participants.

Participants will be warned in FAQs to monitor for a rash related to the band. Participants who report a rash from the band will be removed from the study.

If successful this intervention will add to VHA's prevention "toolkit" and will improve physical functioning for OEF/OIF/OND Veterans, which, in turn, will reduce the burden of chronic illnesses.

Study Population: The proposed population for Stay Strong are OEF/OIF/OND Veterans who may also be students, could be employed by the VA, are women who are in their childbearing years, or may be economically or educationally

disadvantaged due to the poor job market for returning Veterans. While highly unlikely, some of our OEF/OIF/OND Veterans could have terminal diagnoses but if they self-report they have not been told by a healthcare provider that it is unsafe for them to participate in an exercise program, they can participate in this minimal risk program.

Our recruitment pool will include up to 30,000 individuals, but we will consent up to 750, and randomize 350.

Vulnerable population protection – pregnant women: Pregnant women will always be reminded to consult with their healthcare provider on appropriate diet and exercise first. Women who self-report as pregnant at any of the three assessment points (baseline, 6 month and 12 month) will not be included in physical activity and weight loss analyses.

Potential Study contacts:

The study will use the following methods to contact participants during the course of the study:

- Recruitment/Invitation letter:
- Welcome letter
- Technical call: Call to provide technical assistance with using the Fitbit device, Fitbit connect software, Vibrent App or weight scale connection to the Vibrent App.
- Vibrent App Reminder messages
- Outcome Assessment Due ltr/call/text message: Used to proactively inform participant that it is time to complete their 6 & 12 month outcome assessments and to watch for a notification within the Stay Strong app.
- Unable to contact letter/call/text message: If necessary used in case we are unable to reach participants prior to baseline randomization or at 6 & 12 month outcome assessments and they were not responsive to program messages from phone or app. If participants respond to call we will offer to complete survey on the phone with them for their convenience. Also used by coach to reach intervention participants for coach calls if necessary.
- Thank you letter 6 &12 month: Used to thank participant for completion of outcome assessment and provide a method to deliver study payment.
- Baseline Feedback letter: A template for providing participants with overview of the baseline characteristics of study participants.
- Study results Feedback letter: A template for providing participants with final study results.

5.2 Recruitment Methods

Number of Subjects:

We plan to consent up to 750 Veterans. Due to the lengthy process of randomization and the steps involved, we are anticipating a drop-out rate of up to 50% of those consented. We plan to block randomize 350 Veterans by gender, physical activity level and smart phone operating system into the two groups on a 1:1 ratio, with 175 per arm.

Subject Identification:

To identify up to 30,000 OEF/OIF/OND Veterans under the age of 65, we will use the OEF/OIF/OND Roster from the VHA Support Service Center (VSSC) or the current VA resources in CDW to identify the necessary participants. Using the scrambled SSNs from the OEF/OIF/OND Roster we will retrieve current mailing addresses via the VHA Corporate Data Warehouse (CDW) dataset, located at the Austin Information Technology Center via the VINCI or another secure platform. In the event we are unable to use the OEF/OIF/OND Roster, we will use CDW data fields related to OEF/OIF/OND status.

Recruitment Steps:

Participants will be mailed an invitation letter with steps to enrollment and a brief study overview sheet. Those who complete the online eligibility screening and screen eligible will be invited to complete the Informed Consent document by clicking “yes” on a radio button. Those who consent to participate will then be directed to an online HIPAA form to complete by clicking a “yes” radio button. After completion of both the consent and online HIPAA the participants are directed to complete the baseline survey online and to provide their contact information. Those who complete the baseline survey and contact information form will be directed to install and use the Stay Strong app administered by Vibrent Health to verify that they are able to use the system. A welcome package will then be sent to the participants. It will contain a welcome letter, devices (Fitbit device & Scale), instructions for syncing devices, FAQs document. Participants will be instructed to set up the devices and use them for next two weeks. Participants will use the Fitbit device and scale throughout the year of program participation. If the participant has not met the required amount of daily wear in order to be randomized, Ann Arbor study staff members will call the participant to follow-up, and a new date for data transmission will be set to attempt to obtain the required data. Staff will work with the participant to set transmission dates which are sensitive to the needs of the participant, with the final call to set a new date of transmission to occur approximately 6 weeks since the device was issued to the participant. After 3 total attempts to collect data have failed, the participant will be withdrawn from the study.

If the participant is unable to install or use the Fitbit Connect software to transmit the device data, or to install or use the Stay Strong app to view the data, the participant will be withdrawn from the study.

Groups:

Stay Strong Description:

Participants randomly placed in the Stay Strong group will be encouraged to wear the Fitbit device during waking hours and to upload the device data via the Fitbit Connect software on their computer weekly. Participants will also be reminded to follow-up with their healthcare provider as needed for the next 12 months. Participants will be asked to complete a survey on the Qualtrics website at 6 months and 12 months after the date of randomization. Participants will have access to the Stay Strong mobile app showing a dashboard based on their uploaded data. Throughout the program period, the app will send reminder messages asking the participant to inform the study staff of any changes to in their medical condition.

After completing the 12-month survey and a final Fitbit device upload, the participants' study-issued Fitbit accounts are deactivated, and the participant will be able to setup their own personal account at their discretion. The Fitbit device and scale are kept by the participant at the end of the study. At this time, the use of the Fitbit device and access to the data uploaded to the Fitbit servers is free for the lifetime of the device. We cannot guarantee indefinite access to the Fitbit system after participation in the study is complete.

Stay Strong with coaching Description:

Participants randomly placed in the Stay Strong with coaching group, will receive everything described for the Stay Strong Program. In addition, each week the participant will receive a new physical activity goal that has been automatically calculated and personalized for the participant. They will also receive tips to help them stay engaged in healthy lifestyle habits and personalized motivational messages through the Stay Strong app approximately 3 days per week. Participants will have up to 3 phone calls with the Stay Strong e-coach within the first 9 weeks of the study. The coach will have access to participants' survey responses and synced Fitbit data and will work with them to help them meet their physical activity goals. The e-coaches calls will be recorded for quality control and education purposes for our VA coaching staff.

Recruitment materials:

- All participants will be sent a recruitment letter that includes a brief overview of the project and instructions to log onto the survey site for more details on the study and how to enroll for participation.
- The other recruitment documents will be embedded in the Qualtrics survey site that the participants log into and will contain the approved HIPAA authorization and study information sheet, as well as the screening eligibility survey, baseline survey, contact information survey and instructions for downloading the Stay Strong app administered by Vibrent Health.

- The welcome package will include the welcome letter with instructions for syncing devices (Fitbit device & Scale), the devices, a copy of the Study information sheet, HIPAA form and a FAQs document.
- Communication materials and FAQs within the app may be periodically updated to reflect changes in technology that are outside study control

Medical Clearance:

The designated study staff administers the medical clearance process. The Medical Clearance form is provided to participants who are suspended from the study due to concerns about participant safety. The form is mailed to the Veteran at the time of suspension (or after the Veteran indicates ability to return to exercise) and the Veteran is directed to complete the form and take it to their provider for signature. The provider may fax the form back to designated study staff that can reactivate the participant as indicated, or the participant can return the completed form in a provided postage paid and pre-addressed envelope. We expect few medical suspensions for this project due to this younger and healthier cohort. Participants will require a new medical clearance form for each suspension. If a participant calls or responds in survey that they are in crisis (suicidal) we will us the Ann Arbor VA standard operating procedures to assist the participant. These events will be considered a serious adverse event and will need to be reported by the study team.

Payments:

Participants are provided with a $25 gift card at 6 and 12 months as compensation for the time and inconvenience of completing the study surveys. The full survey must be submitted, but blank surveys will be accepted as “completed” surveys.

The $25 gift cards will be from a national or online retailer (e.g. WalMart, Amazon.com) and will be mailed from the Ann Arbor VA to the mailing address on file on a weekly basis using the 6 or 12 month thank you letter.

5.3 Informed Consent Procedures

Due to the nature of the recruitment strategy for this project, obtaining written informed consent and the documentation of it is impracticable and we are requesting a waiver for the entire study. Participants will not be meeting with study staff in person. Instead, they will receive a brief overview of the project with the study recruitment/invitation letter. Full study information will be provided on the Qualtrics website. Additionally, a full copy of the study information document as well as the HIPAA form will be mailed with the welcome package. The recruitment letter invites interested participants to go to the Qualtrics study

web address and enter a participant-specific code listed in their recruitment letter to gain more information about the study and to take a brief eligibility survey.

Participants who are eligible and who wish to enroll in the study must first review a digital version of the Study Information Sheet and then click a radio button on the website with their decision to participate. The options:

1) "Yes, I consent and agree to participate in this research study."

2) "No, I do not consent and do not wish to participate in the research study."

3) "Not yet. I am interested but I have questions and would like to talk to a member of the study staff."

Those who choose 1 will proceed on to review the online HIPAA Authorization page. Those who choose option 2 are thanked for their time and consideration via a message on the website with no staff follow-up/contact. Those who choose option 3 are directed to call the study hotline to speak with a staff member and may not continue beyond that point until a staff member talks with them and re-sets the question for them on the website. The participant could then choose 1, 2, or 3 again as desired.

Participants who have consented must next review a digital version of the HIPAA Authorization sheet and then click a radio button on the Qualtrics website with their decision to participate.

The options:

1) Yes, I give my authorization (permission) for the use and disclosure of my individually identifiable health information per VA Form 10-0493.

2) No, I do not give my authorization (permission) and do not wish to participate in the research study per VA Form 10-0493.

3) Not yet. I am interested but I have questions and would like to talk to a member of the study staff.

Those who choose 1 proceed on to the baseline survey. Those who choose option 2 are thanked for their time and consideration via a message on the website with no staff follow-up/contact. Those who choose option 3 are directed to call the study hotline to speak with a staff member and may not continue beyond that point until a staff member re-sets the question for them on the website. The participant could then choose 1, 2, or 3 again as desired.

Study team members do not obtain informed consent or HIPAA authorization over the phone, but instead review the study protocol and answer any participant questions before

directing the participant back to the Qualtrics website. At no time will the participant be directed to contact Qualtrics staff to discuss the study or surveys.

Those who consent and who complete the baseline surveys are sent a written copy of the Study Information Sheet and HIPAA form with their study materials.

Participants who do not respond to the recruitment mailing will not be contacted by study staff.

5.4 Inclusion/Exclusion Criteria

Inclusion criteria

1. OEF/OIF/OND Veteran
2. Can identify a VA Medical Center and VA Health Care Provider responsible for his/her care in the system
3. Interested in starting a physical activity program in the next 30 days
4. Access to a computer with an internet connection and a working USB port
5. A smartphone running a compatible iOS or Android operating system
6. Younger than age 65

Exclusion criteria

1. Veteran self-reports that a health care provider has told the patient that it is currently unsafe to exercise in an unsupervised or unmonitored setting.
2. History of eating disorders or a BMI < 20
3. Not competent to consent to a research study by self-reporting a legal guardian who makes medical decisions for the Veteran.
4. Have worn a Fitbit device or other physical activity sensor within the last 30 days (we will allow users of lifestyle (including PA) apps who do not use a wearable device)

Justification: The inclusion criteria ensure our participants are OEF/OIF/OND Veterans who are current users of VA Healthcare (our target population) who would be willing to participate in an exercise program and have the computer and Internet access and skills necessary to interact with the Stay Strong app and therefore the entire intervention. The exclusion criteria ensure that our participants can safely participant in an exercise program.

5.5 Study Evaluations – see attached.

- Eligibility screener (Qualtrics)

- Baseline survey (Qualtrics)
- Contact information update sheet (Qualtrics)
- 6 month survey (Qualtrics)
- 12 month survey (Qualtrics)

5.6 Data Analysis

All data will be analyzed by the statistical team in Ann Arbor unless specified otherwise.

Recruitment Pool: A research study conducted by Dr. Richardson which used a similar recruitment strategy had a 2.5% response rate, so we feel that **30,000 potential subjects** will be required to reach our target Consented number.

Sample Size – Consented: Due to the lengthy process of randomization and the steps involved, we are anticipating a drop-out rate of up to 50% of those consented. In order to meet our target number of randomized Veterans, we will be **consenting up to 750** Veterans.

Sample Size – Randomized: The sample size estimate is based on the primary hypothesis: OEF/OIF/OND Veterans randomized to the Stay Strong with coaching intervention arm will have greater mean minutes of moderate to vigorous physical activity at 12 months than OEF/OIF/OND Veterans randomized to the Stay Strong control arm. A 10 minute differential improvement at 12 months will be the definition of a minimally clinically significant difference. This represents the differential between the intervention and control arms at 12 months; therefore, the power and sample size considerations apply even if the control arm mean also improves over the 12-month study period (i.e., “volunteer” or “placebo” effect). For example, if the Stay Strong control arm improves from 53 to 60 minutes, we will have adequate power to detect a 10 minute differential improvement – the Stay Strong with coaching intervention arm improves from 53 to 70 minutes. Sample size calculations are based on ANCOVA methods as presented in Borm et al.(76) We used data from the LEAN study(2) and our feasibility study (unpublished data) to estimate quantities needed for the sample size calculation. We anticipate a common mean 53 minutes, a standard deviation of 28 minutes in both treatment groups at baseline, and a correlation between baseline and 12 months equal to 0.49. Finally, based on previous studies, we estimate a 25% attrition rate by 12 months. To be conservative against deviations from our assumptions, we set our power to be 90%. From the calculation, we determined that we will need to enroll and **randomize 350 patients (175 in each group)** to detect a 10 minute improvement at 12 months with 90% power and a type-I error of 5%.

Descriptive statistics, including graphical displays, will be used to summarize all study variables overall and by intervention arm. Evidence of imbalance in baseline characteristics will be noted and discussed as to whether they are clinically significant. As recommended by CPMP guidelines we will consider sensitivity analyses adjusting for these baseline characteristics to ensure that an observed intervention effect is not due to this baseline imbalance.

Intent-to-Treat Analysis. All of the proposed primary and secondary analyses focus on the effect of Stay Strong as compared to control. We, therefore, plan to use the intent-to-treat assumption for all analyses; participants will be analyzed as part of the group to which they are randomized, regardless of intervention adherence. Women who self-report pregnancy at any of the three assessments (baseline, 6 month, 12 month) will not be included in the analyses for the primary outcome of physical activity or for weight loss.

Primary Analyses. The first primary outcome is mean number of minutes per day of moderate to vigorous physical activity as measured by the Fitbit device at baseline and 12 months. The between-group comparison in physical activity from baseline to 12 months will be examined with the following model:

$$Yit = \beta0 + \beta1StayStrong*month12 + \beta2*obese*month12 + \beta3*gender*month12 + \beta3*physical\_activity*month12$$

Where Yit is minutes of physical activity for subject i at t=month0, month12. This model is often referred to as a constrained longitudinal data model (cLDA)(75) in which baseline physical activity is modeled as a dependent variable in conjunction with the constraint of a common baseline mean across the treatment groups. In this way, the cLDA model is comparable to an ANCOVA model. However, unlike an ANCOVA, subjects who are missing the month 12 physical activity measurement are included in the model because baseline is part of the response vector. The between-group comparison will also be adjusted for the dichotomous stratification variables: obese, gender, and physical activity level. We will estimate the parameters in the model using the SAS procedure MIXED (Cary, NC), and we will test to see if there is a difference in mean physical activity at the end of the intervention period between the Stay Strong and control groups.

Secondary Analyses. The secondary outcomes of weight loss, depression and pain will be analyzed using the same methods and models as presented above for the primary outcome of physical activity. To test for moderation of the intervention effect of the Stay Strong intervention by gender, the model specified above will be expanded to include the gender by Stay Strong interaction.

VA utilization and expenditures. To determine which programs are most effective, historical and future VA utilization and expenditures will be examined by the Durham team. Medical records data (using approved VA data bases) will be reviewed for up to

two years prior and two years following each subject's study participation to assess VA utilization and VA total expenditures. Medical record data will include: name, scrambled SSN, DOB, race, sex; lab results and dates; vitals and dates; date and nature of all clinical visits or encounters, and tests; cost information. Data from this part of the study will be analyzed by study staff at the Durham VA as part of the CREATE- Project 4 - Risk Stratification; CRE-306, Durham IRB 01771.

5.7 Withdrawal of Subjects

- Participants may be withdrawn from the study without their consent if the PI feels that it is unsafe for the participant to continue to participate.
- Participants may be withdrawn from the study without their consent for failure to comply with study protocol.
- Participants may be withdrawn from the study without their consent if they are unable to provide Fitbit device data that meets the minimum number of hours of required wear for randomization purposes, or if they are unable to access the Vibrent app. Participants can withdraw from the study at any time by contacting the study staff via the study hotline or by written request.

6.0 Reporting

Because this is a minimal risk study involving a telephone and app-based intervention similar to those commonly available to any U.S. adult, we do not anticipate serious adverse events triggered by participation in the study. However, safety information will be monitored at each interaction with the patient by the Prevention Coach via telephone sessions and participants will be requested to call the study toll-free voicemail hotline to report any adverse events or unanticipated problems. Due to the age range and relative health of the participants identified for participation in the study, hospitalizations and other health events, including diagnosis of new medical conditions, surgeries, ER visits, unrelated to the study are expected. Any events that fall into one of these categories will be reported at continuing review. It is also expected that participants will miss phone calls during the required time window and the 6 or 12 month outcome assessment survey and we will not consider either of these events protocol deviations. Study physicians (Drs. Bastian and Oddone) will be on call at all times.

Every 90 days for all randomized participants, to begin after the first participant is randomized, a notification within the app will be sent to remind participants to report any

adverse events. Those participants who have been in the program fewer than 30 days will not receive a notification, so their first AE notification will be within 120 days of their randomization to reduce burden on those participants who have not been in the study very long. Monitoring of the hotline and mailing of all study materials will occur at the Ann Arbor site by the project team.

A study physician (co-investigator) will review all adverse events identified by the research team. All adverse events reported will be briefly summarized in a tracking database form with an alert flag added to prompt a return call to the participant by the designated project team member for full classification of the AE and to initiate SAE or other CIRB required reporting, and medical suspension and re-clearance process initiated as required. The staff will use the CIRB Adverse Event protocol and Ann Arbor suicide protocol to ensure standardization of reporting.

- Neither the Ann Arbor staff monitoring the study hotline nor the e-coaches in Durham are clinicians.

- The first response to any participant complaining of new or worsening symptoms is to advise the participant to speak with their provider – this is to occur whether the participant is speaking with an e-coach at the Durham site or to Ann Arbor staff. The study team members do NOT provide medical care or provide medical advice to participants except to direct participants to seek medical attention.

- Participant study materials will have the following notice at the bottom of all messages, technical instruction documents, or incentive letters, etc.: “Any changes in your medical condition should first be reported to your primary healthcare provider. We also want you to report changes in your medical condition to us by telephone”.

- The staff that will be following up on AEs have a combined 7 years of experience in working with participants participating in Internet-mediated physical activity interventions under the study physician.

- All AEs are classified by research team, under the study physician’s supervision and continued monitoring, by the following criteria: seriousness, severity, expectedness, relatedness, whether the incident occurred during or after exercising for the program, and whether the participant has contacted their medical provider. All of the classifications and general information about the incident (including date/time of the incident and location) are entered into a database restricted to study staff which allows tracking and prompts follow-up of unresolved issues.

- All AEs meeting or possibly meeting Central IRB definitions of serious are reviewed with the study physician within 24 hours of first receipt.

- All AEs which indicate that it might not be safe for the patient to continue an exercise program (repeated falls, low blood sugar episodes, dizziness, etc.) are also reviewed by the study physician with 24 hour of first receipt.

- The staff are trained to “suspend first, ask questions later”: Upon learning of a new AE, the participant is advised to seek medical attention and that they are currently suspended from the program, to NOT exercise to meet any study-provided goals, and that the study physician may require that the medical clearance process be completed before the patient may resume active participation.

All SAEs will be continuously monitored, and total number of AEs will be tabulated every six months by the study groups and by their relatedness. We will also utilize graphs to display the data such as relative risks of presence of any related AEs in one group over the other, and similar summary measures over time. In general, the safety data will be assessed using descriptive summaries as the study is not powered to detect safety difference.

We will have monthly conference calls with all staff to monitor research activities, with weekly calls as needed. All staff will be directed to report any SAEs, protocol deviations, and unanticipated problems to the Project Coordinator as soon as possible. The Project Coordinator or the PI will submit the appropriate forms via the VA Central IRB SharePoint or contact a VA Central IRB representative for guidance if the concerning issue does not appear to correspond to existing reporting forms. Privacy complaints will be reported to the Privacy Officer within one-hour of discovery.

7.0 Privacy and Confidentiality

PHI will be obtained from existing sources including medical records and clinical databases for recruitment purposes and looking at VA expenditures and utilization. PHI will be obtained directly from participants as they are screened over the Qualtrics web survey. We will be obtaining scrambled SSNs for recruitment purposes. We will also use those scrambled SSNs from randomized participants to obtain missing weight values. We will be obtaining Service Connected status and information about co-morbidities from the participants VA medical record. To determine which programs are most effective, historical and future VA utilization and expenditures will be examined. Medical records data (using approved VA data bases) will be reviewed for up to two years prior and two years following each participant’s study participation to assess VA utilization and VA total expenditures. Medical record data will include: name, scrambled SSN, DOB, race, sex; lab results and dates; vitals and dates; date and nature of all clinical visits or encounters,

and tests. Data from this part of the study will be analyzed by study staff at both the Durham VA and Ann Arbor VA.

Non-VA entities will have data access as detailed below:

Qualtrics – vendor to obtain and temporarily store survey data for the eligibility, baseline, 6 month, and 12 month surveys, as well as to provide the Informed Consent questionnaire. Respondents submit data using HTTPS (SSLv3 also known as TLSv1). Data are processed by application servers and sent to database servers for storage. Web data are delivered to the respondent in the form of survey questions, graphics, and other content created in the survey design. Qualtrics uses Transport Layer Security (TLS) encryption (also known as HTTPS) for all transmitted data and protect surveys with passwords and HTTP referrer checking. Data is stored at their C7 Data Center in Lindon, Utah. Data stored temporarily at Qualtrics will be covered by a contract.

Vibrent Health – vendor for the Stay Strong app Participants will be able to review their submitted physical activity data using the Stay Strong app. The security features of this vendor meet the required VA contract requirements. We will be obtaining a full copy of the Stay Strong/Vibrent data for each participant/account for the study, and the data will be removed from the Vibrent servers at the end of the study.

Fitbit Inc – manufacturer of the physical activity monitoring device and transmission software. The participant will be required to authorize release of their IP address via an online HIPAA form prior to enrolling in the study, as Fitbit does not have systems which meet VA data security requirements and we will not be securing a VA contract with Fitbit Inc. Participants will use the Fitbit device to collect their data and the Fitbit Connect software to transmit the device data. The study team will use aliases to register the participants with Fitbit accounts prior to sending the devices out. The participant's de-identified/anonymous Fitbit account will be deactivated at the conclusion of the study. The data stored at the Fitbit servers will be deleted at the end of the participant's study participation.

All VA-generated electronic study data including participant identifiers such as patient names, phone numbers, physical mailing address, and health data will be securely maintained on a VA restricted server in an access-limited folder, with access given only to specified project staff.

All participant-provided electronic data except Fitbit data will be stored temporarily on the Qualtrics or Vibrent Health servers and copies of that data will be securely transferred and stored on VA restricted servers. Until transfer to the VA, all data at rest are

encrypted, and data on deprecated hard drives are destroyed by U.S. DOD methods and delivered to a third-party data destruction service.

All paper records with patient identifiers will be kept in a locked office, in locked file cabinets in the Ann Arbor HSR&D offices. Access to the file cabinets will be restricted to approved study personnel.

VA Servers – Data for this project will be stored at both Durham and Ann Arbor VA medical centers. Both the Durham and Ann Arbor Centers for Health Services Research computing infrastructure is comprised of a network, end-user and server hardware, software and applications, PCs, laptops, printers, and scanners. The computer network connects the end-user hardware to shared resources such as Center specific servers, and to local facility, VISN, and national data warehouses and computing resources. Full-time computer and network support staff support ensure efficient operation of computer equipment, network, and servers. The server rooms are equipped with dedicated climate control and power protection systems. Both VPN access and Citrix Access Gateway connections are available to networked equipment. The various servers provide file storage, databases and supporting tools such as report generators, web applications, and a .NET infrastructure to support various locally developed applications. The Centers maintain a full complement of sophisticated software applications for statistical analysis, project management, and data management including Microsoft SQL 2000, DatStat Illume (Durham only), ACCESS, SAS, Stata, AMOS, SPSS, and R, as well as locally developed intervention software. All computerized data entry systems are backed by a series of related SQL data tables that reside on certified and accredited VA servers which are accessible only by designated systems administrators. Center computers have access to all hospital resources such as internet/intranet connectivity, CPRS, Outlook email, and hospital data storage resources.

Once data has been analyzed and final data sets created for the study, we plan to share data with the wider research community. Patients who participated in the project will be sent a summary letter to thank them for their participation as well as provide them with de-identified summary information regarding study participants. We will take the following steps to ensure that the information shared maintains the protection of patient privacy.

First publications from this research will be made available to the public through the National Library of Medicine PubMed Central website within one year after the date of publication and study results will be available on Clinical Trials.gov within 1 year of the final follow-up with last study participant. Next, final data sets underlying all publications resulting from the proposed research will be available by request to researchers outside the VA through the provision of a de-identified, anonymized dataset under a Data Use Agreement (DUA), which include a written agreement prohibiting the recipient from

identifying or re-identifying any individual whose data are included in the data set. A study statistician will certify that the dataset contains no PHI prior to distribution. Data will be provided to requester in electronic form. Final data sets will be maintained locally until enterprise-level resources become available for long-term storage and access. Guidance on request and distribution processes will be provided by ORD.

8.0 Communication Plan

- All engaged participating sites must follow the most current version of the protocol, and use the most current version of the study information sheet and HIPAA authorization. When documents are revised, the PI ensures the local site study teams are notified by doing the following:
    - Reviewing the change in a meeting prior to the submission of any amendment/modification requests to the CIRB of that change to ensure the needs of the local site area considered.
    - Disseminating the revised materials via email with a formal staff meeting to follow prior to implementation of the changed materials.
    - Audit of practices as appropriate to ensure new materials are being used as required.
    - All amendments and amended documents will be posted to the study folder upon CIRB approval.
    - Outdated study materials will be removed immediately to an archive folder.

- The PI must notify the Director of any facility deemed not to be engaged in the research, but on whose premises research activities will take place, before initiating the study (when applicable).
    - Not applicable – no research activities will take place on the premises of studies not engaged in research.

- All amendments and modifications to the protocol and the study information sheet must be communicated to the engaged participating sites. All required local facility approvals will be obtained, if required, before the amendment or modification is implemented. This will be achieved by doing the following:
    - Reviewing the change in a meeting prior to the submission of any amendment/modification requests to the CIRB of that change to ensure the needs of the local site area considered.
    - Disseminating the revised materials via email with a formal staff meeting to follow prior to implementation of the changed materials.
    - All amendments and amended documents will be posted to the study folder upon CIRB approval.

- All engaged participating sites will safeguard VA data as required by VA information security policies. The PI will ensure this is achieved by doing the following:

- Thorough testing of the systems in place to protect data prior to study start.
- The PI will ask that each site maintain current records of all research staff members' required training certificates.
- Bi-annual review to ensure data safety practices are being followed
- The Health Services Research & Development IT Group at the Durham VAMC will monitor all equipment and databases at Durham, while the IT Group at Ann Arbor will do the same there.
- All study data stored on the VA server will be backed up on a nightly, monthly, and annual schedule. Monthly and annual backups will be kept on static media throughout the duration of the study.
- Any paper-based documents (i.e., medical clearance form) will be stored in a locked filing cabinet in a locked office.

- SAEs that have the potential to affect implementation of the study will be communicated to all engaged participating sites. This will be achieved by doing the following:
    - All engaged sites will be directed to review the SAE report submitted to the CIRB with a conference call to follow-up to ensure all parties are aware.

- Study events and interim results (if appropriate) are communicated regularly to engaged participating sites. This will be achieved by doing the following:
    - Regularly scheduled team meetings
    - Ad-hoc meetings or email conversations as needed

- LSIs must conduct the study appropriately. This will be achieved by the PI/SC doing the following to ensure adequate monitoring:
    - Thorough training prior to study start and ongoing.
    - Regularly scheduled team meetings will include discussion of any updates to the protocol, recruitment processes, and/or any other study procedures.
    - Minutes for these meetings, and any updated documentation, will be posted to the study folder, to which all study staff will have access.

- All non-compliance with the study protocol or applicable requirements must be reported in accordance with VHA Handbook 1058.01 and the VA Central IRB Table of Reporting Requirements. This will be achieved by doing the following:
    - LSIs and team members will communicate non-compliance to the Project Coordinator PC) and/or the PI immediately. The PC or PI will upload the appropriate reporting form to the CIRB SharePoint promptly per posted CIRB regulations.

- All local facility directors and LSIs are notified when a multi-site study reaches the point that it no longer requires engagement of the local facility (e.g., all subsequent follow-up of subjects will be performed by the PI from another facility). This will be achieved by doing the following:
    - Not applicable – the local sites will remain engaged until the study is terminated.

9.0 References

Bibliography of cited literature

1. Rosenberger PH, Ning Y, Brandt C, Allore H, Haskell S. BMI trajectory groups in veterans of the Iraq and Afghanistan wars. Prev Med. 2011;53(3):149-54.
2. Shuger SL, Barry VW, Sui X, McClain A, Hand GA, Wilcox S, et al. Electronic feedback in a diet- and physical activity-based lifestyle intervention for weight loss: a randomized controlled trial. The International Journal of Behavioral Nutrition and Physical Activity. 2011;8:41. PMCID: 3112373.
3. Pellegrini CA, Verba SD, Otto AD, Helsel DL, Davis KK, Jakicic JM. The comparison of a technology based system and an in-person behavioral weight loss intervention. Obesity (Silver Spring). 2012;20(2):356-63.
4. Krein SL, Metreger T, Kadri R, Hughes M, Kerr EA, Piette JD, et al. Veterans walk to beat back pain: study rationale, design and protocol of a randomized trial of a pedometer-based Internet mediated intervention for patients with chronic low back pain. BMC Musculoskelet Disord. 2010;11:205. PMCID: 2945952.
5. Moy ML, Janney AW, Nguyen HQ, Matthess KR, Cohen M, Garshick E, et al. Use of pedometer and Internet-mediated walking program in patients with chronic obstructive pulmonary disease. J Rehabil Res Dev. 2010;47(5):485-96. PMCID: 3018275.
6. Richardson CR, Brown BB, Foley S, Dial KS, Lowery JC. Feasibility of adding enhanced pedometer feedback to nutritional counseling for weight loss. J Med Internet Res. 2005;7(5):e56. PMCID: 1550681.
7. Buis LR, Kotagal LV, Porcari CE, Rauch SA, Krein SL, Richardson CR. Physical activity in Post deployment Operation Iraqi Freedom/Operation Enduring Freedom veterans using Department of Veterans Affairs services. J Rehabil Res Dev. 2011;48(8):901-11.
8. Davies CA, Spence JC, Vandelanotte C, Caperchione CM, Mummery WK. Meta-analysis of internet delivered interventions to increase physical activity levels. The International Journal of Behavioral Nutrition and Physical Activity. 2012;9(1):52.
9. Richardson CR, Newton TL, Abraham JJ, Sen A, Jimbo M, Swartz AM. A meta-analysis of pedometer-based walking interventions and weight loss. Ann Fam Med. 2008;6(1):69-77. PMCID: 2203404.
10. Bravata DM, Smith-Spangler C, Sundaram V, Gienger AL, Lin N, Lewis R, et al. Using pedometers to increase physical activity and improve health: a systematic review. Jama. 2007;298(19):2296-304.
11. Richardson CROmaacapcipai. Objective monitoring and automated coaching: a powerful combination in physical activity interventions. Phys Ther Rev. 2010;15(3):154-62.
12. Kim C, Draska M, Hess ML, Wilson EJ, Richardson CR. A web-based pedometer programme in women with a recent history of gestational diabetes. Diabet Med. 2012;29(2):278-83.
13. Richardson CR, Buis LR, Janney AW, Goodrich DE, Sen A, Hess ML, et al. An online community improves adherence in an internet-mediated walking program. Part 1: results of a randomized controlled trial. J Med Internet Res. 2010;12(4):e71. PMCID: 3056526.
14. Goodrich DE, Larkin AR, Lowery JC, Holleman RG, Richardson CR. Adverse events among high-risk participants in a home-based walking study: a descriptive study. The International Journal of Behavioral Nutrition and Physical Activity. 2007;4:20. PMCID: 1891313.

15. National Center for Veterans Analysis and Statistics. America's Women Veterans: Military Service History and VA Benefit Utilization Statistics. Washington DC: Department of Veterans Affairs, Statistics NCfVAa; 2011 November 2011 Contract No.: Document Number|.
16. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996;34(3):220-33.
17. Segar ML, Updegraff JA, Zikmund-Fisher BJ, Richardson CR. Physical activity advertisements that feature daily well-being improve autonomy and body image in overweight women but not men. Journal of Obesity. in press.
18. Johnson F, Wardle J. The association between weight loss and engagement with a web-based food and exercise diary in a commercial weight loss programme: a retrospective analysis. The International Journal of Behavioral Nutrition and Physical Activity. 2011;8:83. PMCID: 3162876.
19. Buis LR, Poulton TA, Holleman RG, Sen A, Resnick PJ, Goodrich DE, et al. Evaluating Active U: an Internet-mediated physical activity program. BMC Public Health. 2009;9:331. PMCID: 2754457.
20. Richardson CR, Mehari KS, McIntyre LG, Janney AW, Fortlage LA, Sen A, et al. A randomized trial comparing structured and lifestyle goals in an internet-mediated walking program for people with type 2 diabetes. The International Journal of Behavioral Nutrition and Physical Activity. 2007;4:59. PMCID: 2212636.
21. Hawkins MS, Storti KL, Richardson CR, King WC, Strath SJ, Holleman RG, et al. Objectively measured physical activity of USA adults by sex, age, and racial/ethnic groups: a cross-sectional study. The International Journal of Behavioral Nutrition and Physical Activity. 2009;6:31. PMCID: 2701914.
22. Strath SJ, Holleman RG, Ronis DL, Swartz AM, Richardson CR. Objective physical activity accumulation in bouts and nonbouts and relation to markers of obesity in US adults. Prev Chronic Dis. 2008;5(4):A131. PMCID: 2578774.
23. Janney CA, Richardson CR, Holleman RG, Glasheen C, Strath SJ, Conroy MB, et al. Gender, mental health service use and objectively measured physical activity: Data from the National Health and Nutrition Examination Survey (NHANES 2003-2004). Ment Health Phys Act. 2008;1(1):9-16. PMCID: 2782873.
24. Richardson CR. A lifestyle physical activity program for persons with serious mental illness. Psychiatr Serv. 2005;56(3):354.
25. Richardson CR, Faulkner G, McDevitt J, Skrinar GS, Hutchinson DS, Piette JD. Integrating physical activity into mental health services for persons with serious mental illness. Psychiatr Serv. 2005;56(3):324-31.
26. Piette JD, Richardson CR, Himle J, Duffy S, Torres T, Vogel M, et al. A randomized trial of telephone counseling plus walking for depressed diabetes patients. Med Care. 2011;49(7):641-8.
27. Ostbye T, Krause KM, Lovelady CA, Morey MC, Bastian LA, Peterson BL, et al. Active Mothers Postpartum: a randomized controlled weight-loss intervention trial. American Journal of Preventive Medicine. 2009;37(3):173-80. PMCID: 2774935.
28. Gierisch JM, Bastian LA, Calhoun PS, McDuffie JR, Williams JW. Comparative effectiveness of smoking cessation treatments for patients With depression: A systematic review and meta-analysis of the evidence: Department of Veteran Affairs Evidence-based Synthesis Program 2010 Contract No.: Document Number|.
29. Carter-Edwards L, Bastian LA, Schultz M, Amamoo MA, Ostbye T. An internet-based weight loss intervention initiated by a newspaper. Prev Chronic Dis. 2009;6(3):A101. PMCID: 2722395.
30. Gierisch JM, DeFrank JT, Bowling JM, Rimer BK, Matuszewski JM, Farrell D, et al. Finding the minimal intervention needed for sustained mammography adherence. American Journal of Preventive Medicine. 2010;39(4):334-44. PMCID: 2939860.
31. Bastian LA, Pathiraja VC, Krause K, Namenek Brouwer RJ, Swamy GK, Lovelady CA, et al.

Multiparity is associated with high motivation to change diet among overweight and obese postpartum women. Womens Health Issues. 2010;20(2):133-8. PMCID: 2849268.
32. Carter-Edwards L, Ostbye T, Bastian LA, Yarnall KS, Krause KM, Simmons TJ. Barriers to adopting a healthy lifestyle: insight from postpartum women. BMC Res Notes. 2009;2:161. PMCID: 2746232.
33. Gierisch JM, Earp JA, Brewer NT, Rimer BK. Longitudinal predictors of nonadherence to maintenance of mammography. Cancer Epidemiology, Biomarkers and Prevention. 2010;19(4):1103-11. PMCID: 2852896.
34. Bastian LA. Pain and smoking among cancer patients: the relationship is complex but the clinical implication is clear. Pain. 2011;152(1):10-1. PMCID: 3053043.
35. Pettee KK, Brach JS, Kriska AM, Boudreau R, Richardson CR, Colbert LH, et al. Influence of marital status on physical activity levels among older adults. Med Sci Sports Exerc. 2006;38(3):541-6.
36. Segar M, Jayaratne T, Hanlon J, Richardson CR. Fitting fitness into women's lives: effects of a gender-tailored physical activity intervention. Womens Health Issues. 2002;12(6):338-47. PMCID: 2578875.
37. Segar ML, Eccles JS, Richardson CR. Type of physical activity goal influences participation in healthy midlife women. Womens Health Issues. 2008;18(4):281-91.
38. Segar ML, Eccles JS, CR. R. Superordinate exercise goals and participation: uncovering discrepancies between values and behavior. International Journal of Behavioral Nutrition and Physical Activity. 2011 in press.
39. Buis LR, Janney AW, Hess ML, Culver SA, Richardson CR. Barriers encountered during enrollment in an internet-mediated randomized controlled trial. Trials. 2009;10:76. PMCID: 2744913.
40. Gierisch JM, Straits-Troster K, Calhoun PS, Acheson S, Hamlett-Berry K, Beckham JC. Tobacco use among Iraq- and Afghanistan-era veterans: A qualitative study of barriers, facilitators, and treatment preferences. Prev Chronic Dis. 2012;9:110-31.
41. Campbell-Sills L, Stein MB. Psychometric analysis and refinement of the Connor-davidson Resilience Scale (CD-RISC): Validation of a 10-item measure of resilience. J Trauma Stress. 2007;20(6):1019-28.
42. Amico KR, Barta W, Konkle-Parker DJ, Fisher JD, Cornman DH, Shuper PA, et al. The information-motivation- behavioral skills model of ART adherence in a Deep South HIV+ clinic sample. AIDS Behav. 2009;13(1):66-75. PMCID: 3018830.
43. Fisher JD, Amico KR, Fisher WA, Harman JJ. The information-motivation-behavioral skills model of antiretroviral adherence and its applications. Curr HIV/AIDS Rep. 2008;5(4):193-203.
44. Fisher JD, Fisher WA. Changing AIDS-risk behavior. Psychological Bulletin. 1992;111(3):455-74.
45. Steinhardt MA, Dishman RK. Reliability and validity of expected outcomes and barriers for habitual physical activity. J Occup Med. 1989;31(6):536-46.
46. Pearson ES. Goal setting as a health behavior change strategy in overweight and obese adults: a systematic literature review examining intervention components. Patient Education and Counseling. 2012;87(1):32-42.
47. Kelly S, Melnyk BM, Belyea M. Predicting physical activity and fruit and vegetable intake in adolescents: a test of the information, motivation, behavioral skills model. Research in Nursing and Health. 2012;35(2):146-63.
48. DuVall C, Dinger MK, Taylor EL, Bemben D. Minimal-contact physical activity interventions in women: a pilot study. Am J Health Behav. 2004;28(3):280-6.
49. Ashford S, Edmunds J, French DP. What is the best way to change self-efficacy to promote lifestyle and recreational physical activity? A systematic review with meta-analysis. Br J Health Psychol. 2010;15(Pt 2):265-88.

50. Rhodes RE, Dickau L. Moderators of the intention-behaviour relationship in the physical activity domain: a systematic review. Br J Sports Med. 2012.
51. Williams SL, French DP. What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour--and are they the same? Health Education Research. 2011;26(2):308-22.
52. Carver CS. Self-regulation of action and effect. In: Baumeister R, Vohs K, editors. Handbook of self-regulation: Research, theory, and application New York, NY: Guilford Press; 2004. p. 130-48.
53. St-Onge M, Mignault D, Allison DB, Rabasa-Lhoret R. Evaluation of a portable device to measure daily energy expenditure in free-living adults. Am J Clin Nutr. 2007;85(3):742-9.
54. Williams GC, Grow VM, Freedman ZR, Ryan RM, Deci EL. Motivational predictors of weight loss and weight-loss maintenance. J Pers Soc Psychol. 1996;70(1):115-26.
55. Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary care evaluation of mental disorders. Patient health questionnaire. Jama. 1999;282(18):1737-44.
56. Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-59. PMCID: 3100405.
57. D'Agostino RB, Sr., Grundy S, Sullivan LM, Wilson P. Validation of the Framingham coronary heart disease prediction scores: results of a multiple ethnic groups investigation. Jama. 2001;286(2):180-7.
58. Wilson PW, D'Agostino RB, Levy D, Belanger AM, Silbershatz H, Kannel WB. Prediction of coronary heart disease using risk factor categories. Circulation. 1998;97(18):1837-47.
59. What is EQ-5D. EuroQol Group 2009 [updated 2009; cited 2012 June 3]; Available from: http://www.euroqol.org/eq-5d/what-is-eq-5d.html.
60. Hughes E, McCracken M, Roberts H, Mokdad AH, Valluru B, Goodson R, et al. Surveillance for certain health behaviors among states and selected local areas--behavioral risk factor surveillance system, United States, 2004. MMWR Surveill Summ. 2006;55(7):1-124.
61. Macera CA, Ham SA, Yore MM, Jones DA, Ainsworth BE, Kimsey CD, et al. Prevalence of physical activity in the United States: Behavioral Risk Factor Surveillance System, 2001. Prev Chronic Dis. 2005;2(2):A17. PMCID: 1327711.
62. Villejo RE, Humphrey LL, Kirschenbaum DS. Affect and self-regulation in binge eaters: effects of activating family images. Int J Eat Disord. 1997;21(3):237-49.
63. Ajzen I. Perceived behavioral control, self-efficacy, locus of control, and the theory of planned behavior. Journal of Applied Social Psychology. 2002;32:665-83.
64. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Serv Res. 2005;40(6 Pt 1):1918-30. PMCID: 1361231.
65. Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR. The development of scales to measure social support for diet and exercise behaviors. Prev Med. 1987;16(6):825-36.
66. Prins A, Ouimette PC, Kimerling R, Cameron RP, Hugelshofer DS, Shaw-Hegwer J, et al. The Primary Care PTSD Screen (PC-PTSD): Development and operating characteristics. International Journal of Psychiatry in Clinical Practice. 2004;9:9-14.
67. Calhoun PS, McDonald SD, Guerra VS, Eggleston AM, Beckham JC, Straits-Troster K. Clinical utility of the Primary Care-PTSD Screen among U.S. veterans who served since September 11, 2001. Psychiatry Research. 2010;178(2):330-5
68. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Archives of Internal Medicine. 1998;158(16):1789-95.
69. Committee for Proprietary Medicinal Products (CPMP): points to consider on adjustment for baseline covariates. Stat Med. 2004;23(5):701-9.
70. Hedeker D, Hedeker GR. Longitudinal data analysis. Hoboken, NJ: John Wiley & Sons; 2006.

71. Collins LM, Schafer JL, Kam CM. A comparison of inclusive and restrictive strategies in modern missing data procedures. Psychol Methods. 2001;6(4):330-51.
72. Panel on Handling Missing Data in Clinical Trials National Research Council. The Prevention and Treatment of Missing Data in Clinical Trials. Washington, D.C.: The National Academies Press; 2010.
73. Schafer JL. Analysis of Incomplete Multivariate Data. London: Chapman & Hall; 1997.
74. Molenberghs G, Kenward M. Missing Data in Clinical Studies. Sussex, England: John Wiley and Sons; 2007.
75. Liang K, Zeger S. Longitudinal data analysis of continuous and discrete responses for pre-post designs. The Indian Journal of Statistics (Series B). 2000;62:134-48.
76. Borm GF, Fransen J, Lemmens WA. A simple sample size formula for analysis of covariance in randomized clinical trials. J Clin Epidemiol. 2007;60(12):1234-8.
77. Bennett GG, Glasgow RE. The delivery of public health interventions via the Internet: actualizing their potential. Annu Rev Public Health. 2009;30:273-92.
78. Glasgow RE. Enhancing the scientific foundation of internet intervention research. Ann Behav Med. 2009;38(1):46-7.
79. Glasgow RE, Nelson CC, Kearney KA, Reid R, Ritzwoller DP, Strecher VJ, et al. Reach, engagement, and retention in an Internet-based weight loss program in a multi-site randomized controlled trial. J Med Internet Res. 2007;9(2):e11. PMCID: 1874718.