Human Subjects Protocol

VA Puget Sound IRB

IIR 19-450 Multiphase Optimization Trial of Incentives for Veterans to Encourage Walking

MIRB #01930, IRBNet 1588237

Funding Agency: HSR&D

Version 12.0

Abstract

Regular physical activity (PA) is essential to healthy aging. Unfortunately, only 5% of US adults meet guideline of 150 minutes of moderate exercise; Veterans and non-Veterans have similar levels of PA. A patient incentive program for PA may help. Behavioral economics suggests that our chronic inability to start and maintain a PA routine may be the result of "present bias," which is a tendency to value immediate rewards over rewards in the future. With present bias, it is always better to exercise tomorrow because the immediate gratification of watching television or surfing the internet is a more powerful motivator than the intangible and delayed benefit of future health. Patient incentives may overcome present bias by moving the rewards for exercise forward in time.

Recent randomized trials suggest that incentives for PA can be effective, but substantial gaps in our knowledge prevent the implementation of a PA incentive program in Veterans Affairs (VA). First, incentive designs vary considerably. They vary by the size of the incentive, the type of incentive (cash or non-financial), the probability of earning an incentive (an assured payment for effort or a lottery-based incentive), or whether the incentive is earned after the effort is given (a gain-framed incentive) or awarded up-front and lost if the effort is not given (a loss-framed incentive). The optimal combination of these components for a Veteran population is unknown. Second, the evidence about the effective components of incentives comes from studies conducted in populations that were overwhelmingly female; often employees at large companies, with high levels of education and income. VA users, in contrast, are mostly male and lower income, and most are not employed. This is important because we have theoretical reasons to believe that the effects of components of incentives are likely to vary by income and gender. Finally, few studies have managed to design an incentive such that the physical activity was maintained after the incentive was removed. Indeed, a common theme in incentivizing health behavior change is the difficulty in sustaining behavior change once the incentives are removed.

We propose to fill the research gaps through a Multiphase Optimization Strategy (MOST) trial of incentives for walking. A MOST trial is ideally suited for situations in which a proposed intervention has many potential intervention components. A MOST trial consists of three phases. A screening phase trial is used to efficiently identify—through a factorial designed randomized trial—the effective components of a complex intervention like incentives. A refining phase trial tests the optimal dose (size or duration) of the incentives. A confirmatory phase trial tests the optimal components and dose against a usual care control. The goal of the proposed study is to conduct the screening phase trial in 128 Veterans to identify the optimal components of incentives for increasing walking among physically inactive Veterans. All Veterans in this phase will be given various components of incentives for increasing average steps per day by 15% per week over a 12-week habit-building period, and then maintaining the increase through a 12-week habit maintenance period.

List of Abbreviations

Provide a list of all abbreviations used in the protocol and their associated meanings.

PA	Physical Activity
IPA	Intergovernmental Personnel Act
DUA	Data Use Agreement
MOST	Multiphase Optimization Strategy
NHANES	National Health Examination Survey
BMI	Body Mass Index
VA	Veterans Affairs
ERIC	Epidemiologic Research and Information Center
CDW	Corporate Data Warehouse
IRS	Internal Revenue Service
MPAM	Motivation for Physical Activity Measurement
ENRICHD	Social Support Instrument
HSR&D	Health Services Research & Development
PA	Physical Activity
PII	Personally identifiable information
PHI	Personal Health Information
WOC	Without Compensation Contents

Protocol Title:

1.0 Study Personnel

[REDACTED]

Collaborators (at other institutions, not covered under the VA IRB approval):

Qualtrics XM: We have obtained VA licenses through central office to use the Qualtrics XM software to administer the participant surveys and to collect responses (interested/opt-out) from potential participants after receiving the recruitment letter. The opportunity to let participants complete the surveys online is much more patient centered and will be much easier for participants to fully participate in the study. Participants will choose if they want to receive study updates by either text/email or both. Coordinators will enter that information into Qualtrics along with the participant's first name and first letter in their last name to field the survey. All responses will be recorded in Qualtrics and research coordinators and analysts will pull down the results and save them on the secure study folder in the J:drive.

2.0 Introduction

Physical activity (PA) is an inexpensive health behavior with numerous health benefits. Meta analyses of randomized trials have found higher levels of PA are associated with lower incidence of diabetes;[1] fewer depressive symptoms;[2] reduced blood pressure,[3] cholesterol,[4] and HbA1c levels;[5] and recovery from atherosclerotic disease.[6] Exercise is as effective as medication for the prevention of diabetes, and has benefits of life expectancy similar to those of medical therapy for the secondary prevention of coronary disease and rehabilitation after stroke.[7] Guidelines suggest adults should engage in moderate exercise, such as walking, for 150 minutes per week, more vigorous activities, such as running, for 75 minutes, or an equivalent combination of the two.[8] The walking pace to maintain a moderate level of activity is approximately 100 steps per minute (30 minutes of activity translates to 3,000 steps per day). This activity should be in addition to normal steps taken in the course of daily activities, which leads to the familiar recommendation of 10,000 steps per day on 5 days of each week[9], or roughly 7,000 steps per day. There is nothing clinically significant about the 10,000-step recommendation; it is only promoted because it is an easy number to remember. For the present study, which includes daily incentives for walking, we will use 7,000 steps per day as the target. Participants will be given a 15% increase in daily step count each week.
Despite the clear benefits of moderate exercise, most adults do not achieve the recommended dose of PA. Accelerometer data from the National Health Examination Survey (NHANES) suggest that 1 in 20 adults accumulate the amount of exercise necessary to maintain health,[10] and there are no significant differences between Veterans and non-Veterans in accelerometer-measured physical activity.[11]

Patient incentives might help. Behavioral economics suggests that our chronic inability to start and maintain a PA routine may be the result of “present bias,” which is a tendency to value immediate gratification over gratification in the future. We fail to exercise today because the gratification associated with watching TV or surfing the web is immediate and tangible, while the gratification of long-run health is distant and intangible. Patient incentives may overcome present bias by moving the rewards for healthy behaviors forward in time. In a patient incentive program, patients are given tangible, timely rewards for achieving specific health goals, such as increasing their steps by 15% per week.

There is a growing body of evidence suggesting that incentives work for some health behaviors, especially those that involve a single discrete act, such as receiving a vaccination[12-14] or a screening test.[14-15] Incentives are also effective at reducing long-term smoking rates.[16] However, a common theme in incentive research is the difficulty in sustaining behavior change once the incentives are removed. For example, incentives are proven effective at promoting short-term abstinence and treatment adherence in substance abuse treatment, where it is referred to as contingency management,[17] but contingency management has not demonstrated significant effects on long-run abstinence.[18-20] Similarly, although two recent trials of incentives for weight loss found sustained effects,[21,15] in most trials, the effects of incentives were not sustained after incentives were removed.[16,14,22,23,24] Thus, a key challenge in incentive research is habit maintenance.

Systematic reviews of incentives for PA[25] have found positive short-term effects. However, there are several reasons why the literature to date does not inform the optimal design of a PA incentive for Veterans. First, the incentive designs used in trials have varied considerably, and this heterogeneity complicates drawing concrete recommendations on what incentive designs work best. Incentive designs can vary by the size, the duration of time over which the incentive is given, the type (cash or non-cash), how it is earned (through individual effort or group effort), the probability of earning (an assured payment for effort or a lottery-based incentive), whether it is earned after the effort is given (a gain incentive) or awarded up-front and lost if the effort is not

given (a loss incentive), and whether the subject risks part of their own income for not meeting their PA target (a deposit contract). Which of these designs work best in which populations is unknown.

Second, most trials were conducted on study populations dissimilar to the VA. In studies to date, study subjects were overwhelmingly female and white, with high levels of education and income. Many studies enrolled students at a university or employees at large companies. VA users are mostly male and lower income, most are not employed, and likely have a higher burden of physical and mental health conditions. Veterans may not have access to a gym or other social and physical resources that could facilitate their increasing PA in response to incentives. Moreover, the effects of features of incentives are likely to vary by income and gender. The economic principle of a declining marginal utility of income suggests that cash and loss incentives may be more salient to lower income Veterans. On the other hand, lotteries are more popular among low than high income people[26] and men tend to have a higher risk preference than women.[27] Thus, the results of the previous study may be poor indicators of the optimal design of incentives for Veterans. Finally, few studies have managed to design an incentives trial where the physical activity was maintained after the incentive was removed. In sum, there is relatively little evidence on which design features of incentives for PA will work best for Veterans, especially after the incentive is removed.

The many ways that an incentive can be configured suggest that incentives are best tested with a Multiphase Optimization STrategy (MOST) trial design. The MOST trial design involves optimizing an intervention before it is tested against a usual care control. It is optimized in the sense that the various components of the intervention are tested against one another in a screening phase to assess which components add value to the intervention, and then only the valuable components are included in the final intervention. It is especially useful when an intervention has many potential combinations of components, as is the case with incentives. In a traditional trial, researchers would use theory or evidence from prior studies to choose an incentive design and test this package against usual care. Even if this package outperforms usual care in a randomized trial, we cannot tell whether this was the optimal package. Some components could have provided no benefit to subjects or delivered in too small a dose to be effective but were an administrative burden to study or clinic personnel. Other components could have been detrimental to subjects. There is no way to know if the components are all tested as a single package.

A MOST trial addresses this by breaking the experimental process into phases: a screening phase, a refining phase, and a confirming phase (Table 1). In the screening phase, various components of the intervention are tested against each other in a factorial designed randomized trial. In this phase, there is no usual care group; everyone in the trial receives the intervention, although the components of the intervention that a subject receives varies. This allows researchers to tease out which components of the intervention are contributing to better outcomes. The components that prove effective, acceptable to participants, and economical in the screening phase are retained for the refining phase. In the refining phase, the appropriate dosage—e.g., the duration or intensity of the intervention—is tested in a randomized trial. In the confirming phase, the components and dosages that were found to optimize the intervention are tested as a package against a usual care control group in a traditional randomized controlled trial. In the present pilot study, we focus only on the screening phase; the refining and confirming phases will be proposed together in a future grant submission.

Table 1. Phases of the full MOST study

Screening phase- the present study:
Components of the incentive intervention are tested against each other in a 2^4 factorial trial.
Components to be tested:

- Lottery vs. loss-framed incentive
- Financial vs. non-financial incentives
- Pre-commitment postcard reminder of patient's stated intrinsic reason for commitment to PA, mailed during habit maintenance period vs. no pre-commitment postcard
- Request for physical activity advice from Veteran vs. no request

Refining phase:
The intervention comprises the components of the intervention that worked best in the screening phase. The characteristics of the dose and frequency of the intervention are tested against each other in a 2^3 factorial trial. Characteristics to be tested:

- Standard ($14/week) vs. large ($21/week) incentives
- Weekly vs. daily frequency of incentive
- 12- vs. 16-week habit formation (i.e., incentive) period

Confirming phase: Components and dosage of the incentive from the refining phase are tested against a usual care control

In the screening phase, a factorial designed trial[28] is typically used because it is the most efficient way to test a variety of components of an intervention head-to-head. Factorial trials are underused in health research but are common in engineering and other fields that employ screening phase trials, as we propose in the present study. A factorial trial that tests k components with 2 levels for each component has 2^k treatment groups. The 2^4 factorial design proposed for the screening phase of the present trial is shown in Table 1. There are 16 combinations of factors, with 8 patients in each, for a modestly sized trial of 128 patients. However, each factor has 64 patients per factor level: there are 64 people receiving financial and non-financial incentives for meeting PA goals, respectively, and 64 patients receiving them in the form of a lottery and a loss-framed incentive. Every component is balanced with respect to the other components, which allows us to estimate the effects of all components with nearly the same power as if we had conducted independent trials of each component.

The primary limitation of a factorial design is that the treatment factors need to be safe to use in combination, which is clearly the case in the proposed study. In addition, a factorial design study with many factors can become burdensome to administers or subjects if each factor adds another feature to the intervention. For example, a 24 factorial study for smoking cessation[29] included factors for nicotine gum (yes/no), nicotine patch (yes/no) behavioral counselling (yes/no) and motivational interviewing (yes/no) such that some patients were receiving an intervention with all four components. The present study only has 2 factors that are additions, and neither is burdensome; the other factors are variations of an element (e.g., cash/non-financial incentive type) as described in Table 2.

Another limitation of factorial designs is that interactions between factors complicate the interpretation of the main effects of the factors. For example, cash incentives might work better as a lottery than a loss incentive (although we have no theoretical reason to expect this). Cash would look like a favorable component among subjects randomized to the lottery incentive and unfavorable among subjects receiving the loss incentive, so it is not clear if cash incentives should survive to the refining phase or not. Moreover, because these subsamples of lottery and loss-incentive subjects are half the size of the full study, we have less power to detect this interaction effect between cash and lottery. However, interactions among factors is not a significant limitation of factorial designs when they are used as screening trials, as we propose

here. Specifically, researchers recommend choosing factors from the screening phase based on their main effects after controlling for all two-way interactions of the factors.[28] A significant main effect on cash incentives, for example, means that these types of incentives perform better than non-financial incentives even when one takes into account the interactions between other factors. Interactions do not invalidate main effects. In sum, despite these limitations factorial designed trials are powerful tools for optimizing the design of multi-component interventions like incentives for PA.

Table 2. Factorial design of the proposed screening phase trial

	Cash incentive		Non-financial incentive		Total subjects
	Mixed Lottery	Loss Incentive	Mixed Lottery	Loss Incentive	
Request for advice- Yes					
Pre-commitment- Yes	8	8	8	8	32
Pre-commitment- No	8	8	8	8	32
No request for advice- No					
Pre-commitment- Yes	8	8	8	8	32
Pre-commitment- No	8	8	8	8	32
Total subjects	32	32	32	32	128

Eight recent and important studies are shown in Table 3. These studies were all conducted by the same teams of researchers and shared many characteristics. Several factors are notable. First, like most studies to date, 7 of the 8 studies were conducted in populations very dissimilar to the VA in terms of education and gender. Second, the studies clearly show that incentive design matters. The 8 studies included 16 incentive arms, and only 7 of the incentive designs were significantly different from no incentive. And some findings are not conclusive. For example, the combined lottery in Patel (2018) was significantly different from no incentive but the same incentive design in the Patel (2016a) study was not. Among the incentive designs tested, the design that involved incentives framed as a loss seem to have the strongest effect on PA. In this design, a participant is allocated points or money at the beginning of the week, and then loses points/money each time they fail to hit their steps goal. Third, only 4 incentive designs found step counts in an incentive group that were higher than the no-incentive group after incentives were removed. Notably, the Chokshi (2018) study had a study population that was most similar to the VA population in terms of education. A potential limitation of the Chokshi finding is that participants in the no-incentive arm did not receive daily feedback and goal setting that the participants in the incentive arm received, so it is not clear if the differences should be attributed to the incentive or other features of the incentive arm.

Fourth, non-cash incentives can be highly motivating. The Patel (2017) study involved no cash incentive—only a cleverly designed social incentive. The trial enrolled teams of (generally) 2 family members. Each week, teams in the intervention group were allocated 70 points—10 points for each day. Each day, one team member was chosen at random. If that person did not meet their goal that day the team lost 10 points. Teams that maintained a point threshold by the end of the study got a coffee cup. Two smaller trials, Andrade et al[30] (n=30 per arm) and Petry et al[31] (n=22 per arm), found significant effects on mean step count of a lottery for gifts ranging in value

of $1 to $100, but these trials included twice-weekly face-to-face contacts with study personnel and so are difficult to compare to other studies in Table 3.

Table 3. Recent trials of incentives for physical activity

Study	Population	Type/ frequency	Key finding during the incentive period	Sustained?
Patel (2016a)	(N=70) Employees 55% female 98% college degree 3 incentive arms	Cash/ Daily	• Cash Incentives framed as a loss superior to no incentive. • Cash Incentives framed as a gain and lottery-based incentive (*18% change of winning $5 and 1% change of winning $100*) were no different than no incentive.	No
Patel (2016b)	(N=70) Employees 60% female 95% college degree 3 incentive arms	Cash/ Daily	• Combined group + individual cash incentives superior to no incentive. • Individual only incentive and group-only cash incentive were no different than no incentive.	No
Patel (2018)	(N=70) Employees 75% female 95% college 3 incentive arms	Cash/ Daily	• Combined lottery (*18% change of winning $5 and 1% change of winning $100*) was superior to usual care. • A small reward lottery (25% chance to win $5) or a jackpot lottery (1 in 400 chance to win $500) were no different from usual care.	No
Kullgren (2014)	(N=46) Employees 72% female 83% college degree 3 incentive arms	Cash/ Weekly	• Group-based incentives with or without social reinforcement no different from usual care	No
Chokshi (2018)	(N=50) IHD patients 63% female 24% college degree 1 incentive arm	Cash/ Daily	• Cash Incentive framed as a loss superior to no incentive.	Yes
Patel (2017)	(N=~50) Family-based teams 56% female 73% college degree 1 incentive arm	Non-Cash/ Daily	• Gamified intervention with social incentives framed as a loss superior to no incentive.	Yes
Petry (2013)	(N=22) Community 80% female Mean 15 yrs education 1 incentive arm	Non-cash/ 2x-week	• Combined lottery (42% chance of winning gifts worth $1, 8% chance of $20 gifts, 0.2% chance of $500 gift) maintained a step count advantage over no incentive	Yes
Andrade (2014)	(N=30) Community 90% female Mean income $60k 1 incentive arm	Non-cash/ 2x-week	• Combined lottery of Petry (2013) with decreasing odds of winning over time maintained a step count advantage over no incentive	Yes

N= approximate number of subjects per treatment arm. IHD=ischemic heart disease. Sustained=step count in an incentive group higher than no-incentive group after incentives are removed.

3.0 Objectives

Study Population:

We will recruit physically inactive Veterans age 50-70 (69.25 at recruitment) with any of the following conditions: hypertension, overweight (BMI>25 and <40), diabetes or depression. These conditions are highly prevalent in physically inactive populations and are amenable to change through greater physical activity. PA confers additional benefits to people age 50+[34-35,4] in part because of the high prevalence of these conditions[2]. In addition, meta-analyses of PA trials have

found ample evidence that people in this age range can safely increase their level of PA through walking.[36] We will recruit physically inactive patients because proponents of Self Determination Theory believe that incentives may "crowd-out" intrinsic motivation to exercise among those who are already intrinsically motivated to exercise at baseline. Physical inactivity is defined as a step count <5,000 per day.[9] We are aiming to enroll physically inactive participants that walk between 2,000-5,000 steps per day during the 2-week trial period.

Regular physical activity (PA) is essential to healthy aging. Unfortunately, only 5% of US adults meet guideline of 150 minutes of moderate exercise; Veterans and non-Veterans have similar levels of PA. A patient incentive program for PA may help. Behavioral economics suggests that our chronic inability to start and maintain a PA routine may be the result of "present bias," which is a tendency to value immediate rewards over rewards in the future. With present bias, it is always better to exercise tomorrow because the immediate gratification of watching television or surfing the internet is a more powerful motivator than the intangible and delayed benefit of future health. Patient incentives may overcome present bias by moving the rewards for exercise forward in time.

Recent randomized trials suggest that incentives for PA can be effective, but substantial gaps in our knowledge prevent the implementation of a PA incentive program in Veterans Affairs (VA). First, incentive designs vary considerably. They vary by the size of the incentive, the type of incentive (cash or non-financial), the probability of earning an incentive (an assured payment for effort or a lottery-based incentive), or whether the incentive is earned after the effort is given (a gain-framed incentive) or awarded up-front and lost if the effort is not given (a loss-framed incentive). The optimal combination of these components for a Veteran population is unknown. Second, the evidence about the effective components of incentives comes from studies conducted in populations that were overwhelmingly female; often employees at large companies, with high levels of education and income. VA users, in contrast, are mostly male and lower income, and most are not employed. This is important because we have theoretical reasons to believe that the effects of components of incentives are likely to vary by income and gender. Finally, few studies have managed to design an incentive such that the physical activity was maintained after the incentive was removed. Indeed, a common theme in incentivizing health behavior change is the difficulty in sustaining behavior change once the incentives are removed.

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Aim 1: Conduct a 2^4 factorial designed screening-phase trial of incentives for increasing average steps per day to by 15% per week over 12 weeks among physically inactive Veterans. Every patient in the trial will be given a Fitbit Inspire activity monitor and assigned to a group that receives different components of incentives. We will test four different incentive factors: 1) lottery vs. loss framed incentives, 2) financial vs. non-financial incentives, 3) a pre-commitment postcard reminder of a Veteran's stated intrinsic reason for commitment to PA vs. no pre-commitment postcard, and 4) a request for PA advice from a Veteran on staying active

vs. no request. The first factor has never been tested in a population like the VA. Factors 2-4 are designed specifically to sustain the effects of incentives after the incentive is removed. Factor 4 is a novel hypothesis that has never been tested outside of educational research: specifically, that asking for advice from a Veteran is more motivating than giving advice to them, even if that Veteran is struggling with low physical activity themselves. The primary outcome is change in steps per week from baseline to week 24.

Aim 2. Conduct cost analyses and qualitative interviews. The cost of administering each component and qualitative assessments of the acceptability of each component to trial participants will inform the decision of which components to retain for the subsequent refining and confirmatory phase trials.

Aim 3. Convene an expert panel to choose components for the next phases of the MOST trial. The panel will weigh each component in terms of its effect on step counts (Aim 1), administrative costs and participant-reported qualitative assessments (Aim 2), and the strength of the theoretical basis for the component's effect on physical activity.

The proposed study has strong institutional support—the Director of MOVE! is a component of the intervention itself—and addresses the VA HSR&D focus area of chronic conditions with a novel, and theory-driven intervention and study design. The results of this study will be used in a future submission to conduct the refining and confirmatory phases of the MOST trial.

4.0 Resources and Personnel

All in person research activities will be conducted at VA Puget Sound Health Care System, Seattle Campus. If the participant activities cannot be done in person, all study activities will occur remotely, over the phone and sending documents through the mail.

Event to trigger a message Weeks 1-12	**Messages (text or email)**
Reminder	A friendly reminder we are scheduled to complete your Fitbit visit today/tomorrow at _____. If you need to reach us please call 206-277-4797.
Baseline period- enrolled	Welcome to the study [If needed] please remember to complete the [baseline/12-week/32-week] survey
Participant day of the week	Acknowledging steps New step goal Financial lottery group: financial winnings & cumulative winnings Non-financial lottery: point winnings & cumulative winnings Loss-framed: Start of week total, updated daily (ideal), weekly minimum
Throughout the study	1 text a week encouraging participants. Day will be random. Reminders (surveys, syncing, return Fitbit (if early withdraw), return postcards, return advice)

Messages week 12-24	Message
Participant day of the week	Message acknowledging steps, encouragement to continue, maintaining gains
Week 12 & 24	Reminder to complete survey, with $25 compensation
End of week 24	Thank you for participating, time & effort was/is important

Dummy email accounts:

Every participant will be assigned a dummy email account to use to login to the Fitbit account. The dummy emails will be made by research study staff and will be Gmail, Hotmail and/or other commercial email services. The research staff will create the Fitbit account using the dummy email which will have a different password then the dummy email. Research staff will track the accounts in a separate excel file. The applicable Fitbit login information will be housed in the Access database. The Fitbit account will be disconnected from the Fitbit device and deleted at week 24 or when the participant withdraws, whichever comes first. The dummy account contains no PII.

Fitbits:

For this study we will be using the Fitbit Inspire 2 ($80). We have received 150 Fitbit Inspire 2. Fitbits were deemed consumable for this study by the Assistant Chief Supply Chain Officer, Steven Peterson. Therefore, if a participant screens into the study they will be eligible to keep the Fitbit. There will be no Fitbit (an Alphabet) company contact with the research team and no data will be shared. This means that Fitbits will not be returned from participants unless participants withdraw from the study. If a participant withdraws or far exceeds the allowable step count during the baseline week, we will gladly accept any Fitbits the participants would like to return.

The Fitbit Inspire 2 can track numerous measures. We will instruct the participants to:

- **not sync the Fitbit with any other feature on their phone**
- **not use any of the options within the application**

Prior to distribution of the Fitbit, research coordinators will login to the dummy Fitbit account and disable all options aside from the daily step count. It is possible that participants would be able to login to the dummy account and enable these settings, but we will encourage them not to. If they do, there is minimal risk of accidental exposure of these data by the study team because the study team will not pull these data from the participants Fitbit account.

Data	Fitbit Statement/Description	What we are doing about it.
Premium Trial	Inspire 2 unlocks a free 1-year trial for new Premium users, complete with personalized insights, guided programs, advanced sleep tools, health metrics and more.	We are asking the participant to not do anything in the app except sync their Fitbit daily. Once they have completed their time in the study and logged out of the dummy account, they can make whatever decisions they choose.
24/7 Heart Rate	24/7 heart rate helps you maximize your exercise sessions, see heart rate zones, track sleep stages and better estimate calorie burn.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**

Resting Heart Rate	Wear Inspire 2 all day and night to record your resting heart rate and track your heart rate trends over time.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Breathing Rate	With Fitbit Premium, automatically measure your breathing rate while you sleep to help you understand your wellness and learn if there are signs of significant changes. View your nightly average and trends over time in the Health Metrics dashboard.***	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Heart Rate Variability	With Fitbit Premium, track heart rate variability (HRV)—the variation of time between each heartbeat— to see if your body is showing potential signs of stress, illness or fatigue. View your nightly average and trends over time in the Health Metrics dashboard.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Guided Breathing Sessions	Inspire 2 helps you find moments of calm throughout your day with personalized guided breathing sessions based on your heart rate.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Menstrual Health Tracking	Understand your body on a deeper level by using your tracker with the Fitbit app to follow your cycle, record symptoms and more.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Food Logging	Make the most of the Fitbit app by logging your meals and comparing calories eaten to calories burned as you go for your goals.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Active Zone Minutes	Active Zone Minutes help you make every minute count during workouts by buzzing your wrist when you enter your personalized target heart rate zone.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
All Day Activity	Every part of your day impacts your goals, so Inspire 2 tracks all-day steps, distance and calories burned.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will only pull daily step count.**
Heart Rate Zones	Inspire 2 personalizes your real-time stats based on your age and resting heart rate to show whether you're in fat burn, cardio or peak zone.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Cardio Fitness Level	Check your Cardio Fitness Score in the Fitbit app to see how fit you are, and get tips on how to improve it.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Swimproof & Swim Tracking	Inspire 2 is swimproof, so you can wear it in the shower, pool and beyond. Plus, it	We are asking the participant to not do anything in the app except sync their Fitbit daily.

	automatically tracks how long you've been swimming.**	**We will not pull this data.**
Real-Time Pace & Distance	Connect Inspire 2 to your phone's GPS to see real-time pace and distance on your wrist during walks, jogs, hikes and bike rides.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Workout Intensity Map- In App Only	After outdoor exercise, check your workout intensity map in the Fitbit app to see your heart rate zones throughout your route and learn where you put in the most effort.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
20+ Exercise Modes+SmartTrack	Choose from 20+ exercise modes to get real-time stats during your workouts—or let SmartTrack™ automatically recognize and record your exercises.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
All-Day Calorie Burn	Check Inspire 2 or the Fitbit app to see how many calories you've burned throughout the day so you can keep your nutrition on track.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Reminders to Move	Get friendly reminders that encourage you to stretch your legs and take 250 steps every hour—and get recognition when you hit that 250!	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Sleep Stages	See how much light, deep and REM sleep you get, and get tips in the app that can help improve sleep quality.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Sleep Score	Sleep Score is a quick, easy way to see how well you slept, watch your trends over time & celebrate your progress when you wake more energized.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Silent Alarms	Make mornings more peaceful. Set a silent alarm in the Fitbit app and Inspire 2 will wake you up with a quiet vibration on your wrist.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Sleep Mode	Before you turn in for the night, turn on sleep mode to disable screen wake and notifications so light and vibrations from your tracker don't interrupt your sleep.	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Personal setting	Name, address, time zone, sleep sensitivity,	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Privacy	(this is under the settings feature): study staff will lock all personal info, statistics and graphs	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**

Manage your Fitbit Data	If a participant logs into this feature they can delete data	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**
Notifications	We will enable all mobile notifications except auto-recognizing exercises, low battery	We are asking the participant to not do anything in the app except sync their Fitbit daily. **We will not pull this data.**

5.0 Study Procedures

5.1 Study Design

This is a factorial design study. Aim 1 is the largest and most involved portion of the study. Aim 1 is to conduct a 2^4 factorial designed screening-phase trial of incentives for increasing average steps per day by 15% a week over 12 weeks among physically inactive Veterans. Recruitment is expected to occur at a rate of 10-20 participants per month. There will be overlap between the aims of the study. Aim 2 is to conduct a cost analyses and qualitative interviews. The qualitative interviews occur after the participant has reached the week 24 mark of the study. Aim 3 is to convene an expert panel to choose components for the next phases of the MOST trial. This aim will occur at the very end of the study period, expected in study year 4, FY23. All participants will be invited to participate in the rewards research repository, #00982. An updated Visio diagram of the study flowchart is included with this submission.

To make the study as Veteran centric and successful as possible, we are soliciting feedback from a group of Veterans recruited from the repository, #00982. Participants will participate on a Cisco WebEx meeting prior to the start of enrollment. They will be compensated $50 for their participation. Research staff will ask for their input on increasing physical activity, incentives, motivation and messaging. At the conclusion of the study we will schedule a follow-up WebEx meeting to share the results and experiences based off of their input and feedback.

All participants are randomized into the following categories, or factors: financial or non-financial, mixed lottery or loss incentive, pre-commitment postcard or not, request for advice or not. There should be 32 participants in each group.

Table 2. Factorial design of the proposed screening phase trial

	Cash incentive		Non-financial incentive		Total subjects
	Mixed Lottery	Loss Incentive	Mixed Lottery	Loss Incentive	
Request for advice- Yes					
Pre-commitment- Yes	8	8	8	8	32
Pre-commitment- No	8	8	8	8	32
No request for advice- No					
Pre-commitment- Yes	8	8	8	8	32
Pre-commitment- No	8	8	8	8	32
Total subjects	32	32	32	32	128

Participants will either earn cash or points for achieving walking goals. How they will receive the cash or points is dependent on which factor mixed lottery or loss incentive they are randomized to. Each subject will choose a number between 0 and 99 when they are enrolled in the study. For each day of the trial, a random digit will be drawn from 0 to 99. The patient will win a small reward worth $7 (or points) if the first- or second-digits match (an 18% probability), and a $75 (or points) reward if both digits match (1% probability). This has a weekly expected value of $14.20. For the loss framed incentive, at the beginning of each week a subject is awarded $14 or 14 points. Each day the subject fails to meet her goal step count the subject loses $2 or points. The prizes are attached in appendix 31. The prizes were reviewed by participants in Exercise Collaborative meeting and prizes were adjusted accordingly.

Subjects randomized to the pre-commitment postcard arm will be asked at to fill out 3 postcards (appendix 2) that complete the sentence “I will meet my walking goals because…”. Participants will return the postcards in a prepaid envelope if randomized to this group. We will collect the postcards and mail them in sealed envelopes to the subjects at weeks 13, 17, and 21. Subjects in the no-pre-commitment arm will not complete this task and will not receive the postcards. Factor four is the request for advice or not. At the start of habit maintenance period in week 13, a letter from Dr. Susan Raffa, the VHA National Program Director for Weight Management, will be mailed to half of the subjects (appendix 3); other subjects will receive no letter. The letter will thank the Veteran for participating in the study and ask for their advice. An enclosed form (Appendix 4) will contain 2 boxes large enough for a few hand-written sentences in response to the following questions: “What is your best advice for Veterans who are trying to increase their physical activity?” and “What is your best advice for Veterans who are trying to stay active?” A return envelope will be enclosed.

There are the sixteen different possibilities for randomization:

1. Financial Reward, mixed lottery, pre-commitment postcard reminders, request physical activity advice
2. Financial Reward, mixed lottery, pre-commitment postcard reminders, no request physical activity advice
3. Financial Reward, mixed lottery, no pre-commitment postcard reminders, no request physical activity advice
4. Financial Reward, mixed lottery, no pre-commitment postcard reminders, request physical activity advice

5. Financial Reward, loss incentive, pre-commitment postcard reminders, request physical activity advice
6. Financial Reward, loss incentive, pre-commitment postcard reminders, no request physical activity advice
7. Financial Reward, loss incentive, no pre-commitment postcard reminders, no request physical activity advice
8. Financial Reward, loss incentive, no pre-commitment postcard reminders, request physical activity advice

9. Non-financial reward, mixed lottery, pre-commitment postcard reminders, request physical activity advice
10. Non-financial reward, mixed lottery, pre-commitment postcard reminders, no request physical activity advice
11. Non-financial reward, mixed lottery, no pre-commitment postcard reminders, no request physical activity advice

12. Non-financial reward, mixed lottery, no pre-commitment postcard reminders, request physical activity advice

13. Non-financial reward, loss incentive, pre-commitment postcard reminders, request physical activity advice
14. Non-financial reward, loss incentive, pre-commitment postcard reminders, no request physical activity advice
15. Non-financial reward, loss incentive, no pre-commitment postcard reminders, no request physical activity advice
16. Non-financial reward, loss incentive, no pre-commitment postcard reminders, request physical activity advice

The complete description of each group is detailed in Appendix 49.

Study Population: Current VA Puget Sound Health Care System Veterans that meet the following criteria. Populations targeted for recruitment include male, female, outpatients.

The inclusion and exclusion criteria are outlined in section 5.4 below.

Special populations of employees, students, economically and/or educationally disadvantaged persons, illiterate/limited or no English proficiency individuals will also be included as long as they meet the above criteria. Employees/students, economically and/or educationally disadvantaged persons, illiterate/limited or no English proficiency will be included in this research. All participants in this study are Veterans who will meet the inclusion criteria. We are leaving these vulnerable groups in because any benefit from participating is greater than any possible risk.

We are not excluding employees/students, economically/educationally disadvantaged and illiterate, limited or no English language proficiency. We will only be recruiting Veterans. We do not believe that being an employee, student or being economically or educationally disadvantaged would have any impact on an individual's ability to participate. Everything will be done remote, so an employee or student would not need to share their enrollment status with anyone. If the study visits cannot be completed remotely, we will make accommodations to complete the study in person following current guidance for in person visits. We expect this to be extremely rare. We are screening for homelessness or housing instability and will only exclude if the participant cannot receive mail or charge their electronics. We do not have a method of screening for someone being economical or educationally disadvantaged.

We are not doing any screening for a participant being illiterate or having limited or no English proficiency. We are only recruiting Veterans. If English is a Veteran's second or third language, we think they will be fully able to participate. We are also not screening for literacy because that is highly subjective, and we do not believe will impact someone's ability to understand the study. If a potential participant does not respond to our letter, a research coordinator will call them. Every aspect of the study will be explained in a variety of modalities including written (in the enrollment packet) and verbally. Participants and potential participants are free to not enroll or withdraw from the study at any time. We are including these groups because after study team conversations we do not believe this research study exposes these groups to any additional risk. The goal of this study is to increase participants' daily step counts in inactive persons. Increasing step count is a free and relatively easy health behavior that has a positive impact on all individuals regardless of socioeconomic status, educational attainment, or language.

All potential study participants will go through the study screening (CDW, medical record screen and phone screening). All participants will have ample time to ask any questions and go over all study procedures. Potential participants and enrolled participants are free to discuss the study with whomever they chose to make an informed choice about deciding to participate.

The health intervention itself poses no undue risks. Walking is the safest form of physical activity. The risk of minor injury is 0.2 per 1,000 hours of walking. These risks include falls, dehydration, blisters, glycemic control, angina, and worsening of breathing and blood pressure changes. The risks of remaining sedentary out-weigh the risks of adverse events associated with walking. The Physical Activity Guideline Committee 2018 report states that “adding a small and comfortable amount of walking, such as 5 to 15 minutes 2 to 3 times per week, to one’s usual daily activities has a low risk of musculoskeletal injury and no known risk of sudden severe cardiac events.” We put in place three safeguards in this study.

1) First, we screen Veterans for an ability to walk 20 minutes without problems (self-report).

2) Second, we ask if the potential participant thinks they will benefit from walking more.

3) Third, we make Veteran-specific step goals based on baseline step counts. Each week Veterans will be incentivized for increasing step counts per day by 15% over the previous week’s daily average. For a person with 2,000 steps/day at baseline, this represents an additional 300 steps, or roughly 3 minutes of walking per day. The maximum number of steps any participant will be asked to walk is 7,000 steps per day. If the participant reaches the maximum number of steps per day prior to the end goal at week 12, they will still be eligible for all prizes depending on what group they are in until they reach the maintenance phase at week 12. Once they hit 7,000 steps they will have a goal of 7,000 steps per day until the end of the study. No participants will ever have a goal of >7,000 steps per day.

There will be minimal risks to the participants responding to the study questionnaires (screening and surveys). The screening (appendix 5), surveys (appendix 6), including health history questionnaires, could potentially induce stress secondary to invasion of privacy. Although unlikely, some respondents may find some questions intrusive or offensive. Participants are free to skip any questions they do not wish to answer. Participants will be given a schedule of surveys and will be free to withdraw from the study at any time without penalty or loss of any incentives they have already earned.

All medical centers are required to track the amounts paid to patients during a year. If the amount is $600 or more, the institution is required by the Internal Revenue Service (IRS) to issue a form 1099MISC to the participant and send a copy to the IRS. This is reported as "miscellaneous" income to the IRS. This amount could have the potential to change Veterans’ eligibility for social services in the coming tax year.

The maximum that could be earned by a participant in the loss-framed incentives group is $318, assuming the patient achieves all step goals, completes both follow-up surveys, and completes the study interview. There is no way to calculate a maximum for the lottery incentives group, but we anticipate that the average maximum will not differ significantly from the loss framed rewards group. The IRS operates on a calendar year cycle. Veteran remittance will be tracked closely by study staff. Veterans will be notified of the $600 threshold through the informed consent process (appendix 7) and study overview document (appendix 8) provided and discussed at enrollment.

Participants in the incentive lottery will earn points towards items. Participants in the incentive loss-framed group will aim to not lose points. All points will be available to redeem at week 12 or if the participant chooses to withdraw early. Most incentives were selected by the pre-trial focus group participants. Most items follow a theme of walking or spending time outdoors. To date items include: trekking poles, national park walking guide, binoculars, picnic blanket, etc.

5.2 Recruitment Methods

Veteran Exercise Collaborative:
Prior to recruitment to the MOST trial, we will convene a focus group of Veterans enrolled in the rewards data repository, MIRB #00982, to get their feedback on the specifics of the trial. We are requesting a waiver of documentation of informed consent, waiver of HIPAA authorization and information statement for the exercise collaborative participants (appendix 9). The enrollment goal for the exercise collaborative is 10 participants. To reach this goal we will mail 30 letters (appendix 10) and postcards with prepaid return postage (appendix 11). Coordinators and study staff are on the approved study staff list for the repository and for this study. An approved repository modification outlining the physical activity exercise collaborative will be approved prior to any exercise collaborative activities. Once the study is fully approved coordinators will mail participants enrolled in the repository letters with pre-addressed postcards to indicate if they are interested in participating on an exercise collaborative. If we have not received a return postcard within two weeks of mailing research coordinators will call repository participants up to two times.

Participants will enroll with an information statement under a waiver of documentation of informed consent and a Waiver of HIPAA Authorization. Participants will be given an information statement (appendix 9). Participants will be sent the information for the meeting in the mail (appendix 13) and also sent a text or email message from the email account with the meeting information. The meeting will occur through an online meeting platform. Exercise collaborative participants will be compensated $50 for each of the two meetings they attend. Research coordinators will fill out the VA subject payment form and submit the payment through the approved VA Puget Sound research & development payment process. Due to the study payment, we will collect or access all exercise collaborative members social security number. Exercise collaborative participants will receive a thank you card in the mail (appendix 14).

Main Study:
The target enrollment is 128 participants, but we anticipate that some patients who enroll will not be able to install the Fitbit app and will need to disenroll before being assigned to a treatment group. Once the Fitbit is set-up, participants will complete a 2-week trial period to establish a baseline average daily step count. We will follow procedures used in previous trials (Patel 2016 a and b) to establish this baseline:

- The first week of data will be disregarded because the novelty of the device makes a participant walk more than usual.
- Average steps over the second week will be used as a baseline provided than at least four days of step counts are recorded by the device in that week—i.e, the participants remembers to wear the device on at least four days in week two.
- If fewer than four days of steps are recorded, we will call the participant to encourage them to wear the device, and we will follow them for another week or until four days of step counts are recorded over a 7-day period.
- If a participant screens into the study, we will call them to inform them. We will clarify what their chosen day of the week is to reset their goals. If their 2-week assessment period ends on a Tuesday, and their chosen day of the week is Monday, then their week 1 goal (and potential rewards) wouldn’t start until the following Monday.

If a participant walks <2,000 steps/day on average or >5,000 steps/day on average over their 7-day baseline period, then they will not be eligible to participate in the full study. We expect a fair number of people to not walk within these step parameters. Consequently, we are planning to enroll up to 200 Veterans in the main study with the expectation that 72 will be disenrolled prior to treatment assignment.

The consent and Fitbit set-up process will require patience and a lot of back and forth with the study team. The consent visit and Fitbit setup visits are two distinct visits that are necessary prior to starting the study. For this reason, we expect to do the CDW data pull for up to 5,000 records. We are requesting to pull up to 5,000 records which we believe is an appropriate figure based on our experience recruiting for MIRB #00928. Study coordinators will quickly screen the medical record to screen out participants that have one or more of the exclusion criteria. The screening is discussed in detail in section 5.4. From our experience in previous studies, we generally have been able to phone screen and potentially enroll 20% of all mail letters. We do not yet know how many potential participants will be interested in participating, how many will fail the phone screen and how many will stop participating during the baseline screening phase or the first week. To ensure that we are adequately recruiting minority Veterans we will see what percentage of racial minorities screens positive in the CDW and CPRS screen. We will aim to routinely mail out at least that percentage (higher of the two) of letters to minority Veterans in each mailing.

The CDW data pull will include VA Puget Sound Veterans between the ages of 50-69.25, and those who have a diagnosis of hypertension, depression, diabetes or a BMI between 25-40, have been seen in primary care or the womens clinic in the previous 2 years and email address. To assist in applying the exclusion criteria and creating the study database we will also pull birthday, SSN, PatientICN, medical record number, SID, ICD 9 or 10 codes for the exclusion criteria, blood pressure readings from the previous 24 months and diagnosis of diabetes. Veterans with a diagnosis of psychosis/mania, behavioral flag active suicidal or homicidal ideation will be excluded. We will also pull mailing address, phone number, height, weight, BMI, race/ethnicity, sex, gender and pronoun (if available). Prior to mailing the letters the CDW list will be further screened in the medical record.

The medical record screen will be checked to confirm the individual is a Veteran, confirm their age, 50-69.25, and screen negative for: behavioral flag, active psychosis/mania, diagnosis of dementia/Alzheimer's, suicidal or homicidal ideation, presently in the MOVE! Program or pregnant. If the potential participant has diabetes, we will screen their chart to see if they have a diabetic foot ulcer or peripheral neuropathy. Participants with either condition will be excluded. Participants in hospice or end of life care or who are/have been hospitalized in the past 3 months will be excluded. Veterans living in a nursing home, assisted living facility, or group home will be excluded. If data from the CDW data pull is missing or incomplete, we will validate the questionable measure from the medical record. Potentially eligible participants will be mailed a letter describing the study (Appendix 15) and either a self-addressed postcard (Appendix 11) or a QR code that directs them to a Qualtrics survey for them to indicate if they are interested or not (or both a postcard and a QR code). If patients do not opt-out, research staff may telephone patients and screen interested patients for eligibility. Potential participants will be asked a variety of questions to determine eligibility. The full screening questionnaire is included in this submission (Appendix 5). Alternately, the medical record screen may also be conducted after the mailings are sent, with screens only conducted for Veterans who reply with an "interested" response and/or for Veterans who do not respond. The option of conducting the screens after the mailings streamlines the process and allows study staff to prioritize those who are interested in

participating. Should a Veteran indicate interest and then "fail" the medical record screen, they will receive either a letter in the mail or a phone call to inform them. With this method it is likely that not all Veterans who receive recruitment letters will ultimately be contacted about their participation, though we will ensure all Veterans who explicitly indicate interest will be contacted.

If someone is interested and passes the telephone screening, we will schedule a virtual enrollment visit (either phone, VA Video Connect or other approved video visit software such as WebEx, Teams, Zoom, etc.) Prior to the virtual visit, we will ask the participant if they are able and comfortable receiving the documents virtually. If they are, we will utilize Docusign to send the consent and HIPAA authorization electronically. Using Docusign, the participant will also get electronic copies of the documents once they have signed the documents. If they prefer hard copies, we will mail them an enrollment packet with two copies of all documents (Appendix 16). One copy they will keep for their records and the second they will return to us in the prepaid envelope. If the participant prefers, they will be able to use DocuSign to remotely sign the documents. We will also give them the option to sign the paper copies and email back a photo of their signature on the consent, and the last page of the HIPAA completely filled out.

If a participant is apprehensive about completing the consent visit and/or Fitbit set up visit virtually, and current local conditions allow for an in person visit, we will offer the Veteran an in person visit for the consent and Fitbit set-up (as one visit) or the Fitbit set-up. Each visit will have the same compensation as the virtual visit ($25 each). For participants that complete both visits in person they will receive a link for the survey immediately following the visit. Participants must complete the survey by the end of the baseline period. Participants will not receive any additional compensation for completing the visit(s) in person and scheduling will be subject to local conditions and staff availability.

The enrollment packet will include the informed consent, HIPAA authorization, study overview, vendorization form and a postage paid envelope. The participant will go over the packet with a research coordinator. The coordinator will walk the participant through the informed consent and answer any questions they have. Once all of the participant's questions have been answered the participant will be instructed to return the signed copies through the pre-paid envelope or sign the electronic versions using DocuSign. Once the documents have been received by the research coordinator, the coordinator will immediately mail out the Fitbit packet.

There are two variations to the process above. We have created a flyer (appendix 17) with basic information about this study. Flyers will be distributed to the primary care clinic clinicians, physical therapy, occupational therapy and rehab to provide to patients that may be interested in participating. Occasionally in previous studies we have had participants who want to tell their Veteran group, friends or family about the study. The same flyers will be used to give to them.

If a Veteran receives a flyer, they will call the study line and go through the same process as the other Veterans. The only difference being that instead of a mailed letter as their first exposure to the study, their first exposure would be the study flyer. If an interested Veteran calls who was not in a CDW data pull, we will do a CPRS screen prior to doing the screen over the phone with them. This will be done under a waiver of informed consent for recruitment. For this specific population we will screen the medical record for the information that is normally gained through the CDW data pull and Medical record screen, as described above. Once we have the results of the medical record screening, we will call the Veteran back. If they are ineligible, we will tell them, if they seem to be eligible, we will continue with the phone screen. All steps with this group will be the same as participants in the CDW data pull.

To be compensated participants must be vendorized with VA Puget Sound Health Care System or agree to accept remittance in the form of electronic gift cards. Study staff will assist participants with this process. Participants can complete the vendorization process online, in person via the agent cashier or send/email their completed vendor form to the study staff. If a participant chooses to not be vendorized or cannot complete the form, the only other option to be compensated is electronic gift cards. All study compensation will be via direct deposit.
The payments for the enrollment visit, surveys and interview payments will be processed the same week the participant earns them. Participants will earn $25 for completing the enrollment visit (Consent visit), Fitbit set-up visit, baseline survey, week 12 survey, week 24 survey and interview (if selected). For completing the basic study procedures, visits and surveys, participants will earn up to a total of $150 if they complete all activities. These payments will be sent out as they are earned. All participants will be paid via direct deposit or electronic gift card. We have tentatively added in the process to vendorize Veterans at the beginning of the study. With the extensive payment issues experienced in prior studies we do not want to further delay any participants receiving payment. We are also adding in statements throughout the participant documents that we cannot guarantee they will be paid. While this is less then ideal, the research study staff has no method to ensure the Veteran is paid at all, appropriately or timely.

The financial rewards from the lottery and the loss-framed groups will be received as one payment. Research coordinators will process all their earnings after week 12. We are doing this to minimize confusion about receiving the correct amount of money. At week 12, participants will know exactly how much money they have earned.

5.3 Informed Consent Procedures

Veteran Exercise Collaborative (pre-trial focus group):

Exercise Collaborative:
Veterans enrolled in the rewards data repository, MIRB #00982, will be approached and asked of their interest in participating in a focus group about exercise. We are requesting a waiver of documentation of informed consent and waiver of HIPAA authorization (appendix 9) for the exercise collaborative participants. Coordinators and study staff are on the approved study staff list for the repository and for this study. Once the study is fully approved to begin, coordinators will mail participants enrolled in the repository letters with pre-addressed postcards to indicate if they are interested in participating on an exercise collaborative (Appendix 10). If we have not received a return postcard within two weeks of mailing, research coordinators will call repository participants. Participants will be told how the exercise collaborative will be virtual, what we will discuss, time commitment and compensation ($50). If the participant is interested, they will be mailed a hard copy of the information statement and meeting invitation information (url and passcode, Appendix 13). Coordinators will explain that the board will meet virtually, so participants will need to be able to participate in an online meeting. This will be done by emailing a meeting link to a webex or zoom meeting link to the participant's email. The link will come from a group email account to be set up. (This meeting occurred on August 11, 2021.)

Prior to the start of the exercise collaborative, coordinators will moderate the individuals joining the call to ensure the appropriate individuals are participating. At the beginning the exercise collaborative we will give an overview of the study and what we are trying to accomplish (Appendix 18).

Main Study:

We are requesting a waiver of informed consent and HIPAA Authorization for recruitment purposes and a written informed consent once a participant agrees and enrolls in the study (Appendix 19). We will offer paper informed consent, electronic DocuSign, and a photo of the last page of the consent and HIPAA authorization.

Participants from the CDW data pulls and the medical record screen will be sent a recruitment letter and response postcard and/or QR code that links to a Qualtrics survey to indicate interest or to opt out.

The QR code, which can be scanned by their mobile phone's camera, will open a hyperlink to a fully anonymous Qualtrics survey where participants can enter their Study ID and indicate if they are interested or not.

If someone is interested and passes the telephone screening (appendix 5 & 12), we will schedule a virtual enrollment visit. Prior to the virtual visit, we will mail them an enrollment packet with two copies of all documents or send electronic copies through Docusign. For the paper copies, one copy they will keep for their records and the second they will return to us in the prepaid envelope. The enrollment packet will include the informed consent form, HIPAA authorization, study overview and a postage paid envelope. The participant will have the option to complete the forms via DocuSign (electronic signature), or by signing the consent and completing the last page of the HIPAA authorization, taking a photo of their signatures and emailing it to the study email account.

If the participant completes the documents electronically, we will immediately send out the survey through Qualtrics.

If the participant completes paper copies, the survey will be sent through Qualtrics immediately upon the staff receiving the copies.

The coordinators will set up an enrollment visit approximately 1-2 weeks after the mailing of the enrollment packet/electronically signing the consent & HIPAA depending on the current speed of the mail handled by the United States Postal Service. The visit will follow the format in appendix 8. The format for the visit will either be telephone, VA Video Connect, Teams, WebEx, or Zoom, depending on whatever the Veteran prefers.

When the documents have been returned, the coordinator will immediately mail out the Fitbit packet and submit to VA Finance the request to mail the participant the $25 payment for completing the enrollment or provide an electronic giftcard. Each time the participant is paid they receive direct deposit. The participant will then speak with a research coordinator once they receive the Fitbit and will be instructed on how to set up the Fitbit up with their device (appendix 21). All participants will need to download the Fitbit app. Instructions provided to the participants and are included with this submission. Participants will be encouraged to open the application daily to sync their Fitbit with the app.

Consent staff:

The study staff obtaining consent will be trained to provide adequate time and opportunity for the participant to consider all options, respond to the participant's questions, ensure that the participant has comprehended this information, obtain the participant's voluntary agreement to participate, and continue to provide information as the participant or situation evolves. We will ensure there is opportunity for the researcher and the participant to exchange information and

ask questions. If a potential participant is unsure about participating, we will encourage them to think about it, discuss with people they trust, and we will set a time to follow-up with them.

Potential Issues:

We are not excluding employees/students, economically/educationally disadvantaged and illiterate, limited or no English language proficiency. We will only be recruiting Veterans. We do not believe that being an employee, student or being economically or educationally disadvantaged would have any impact on an individual's ability to participate. Everything will be done remote, so an employee or student would not need to share their enrollment status with anyone. If the study visits cannot be completed remotely, we will make accommodations to complete the study in person following current guidance for in person visits. We expect this to be extremely rare. We do not have a method of screening for someone being economical or educational disadvantaged.

We are not doing any screening for a participant being illiterate having limited or no English proficiency. We are only recruiting Veterans. If English is a Veteran's second or third language, we think they will be fully able to participate. We are also not screening for literacy because that is highly subjective, and we do not believe will impact someone's ability to understand the study. If a potential participant does not respond to our letter, a research coordinator will call them. Every aspect of the study will be explained in a variety of modalities including written (in the enrollment packet), verbally and interactive with an open question and answer dialog between the coordinator and participant.

Individuals that exhibit threatening, violent or otherwise troubling or inappropriate behavior during the screening phone call or consent visit will be excluded from this study. In previous research studies we had individuals that met all inclusion criteria but exhibited troubling behavior or made highly inappropriate comments towards study staff even after being asked to cease the behaviors. Study staff are not trained in all skills necessary to successfully interact with all individuals. We fully understand this is subjective, and we will do everything we can to avoid doing this. After reviewing uncomfortable interactions in previous studies, we are unaware of a screening method to avoid and screen these participants out. We are including this language, so the participant can have the best experience and to protect study staff.

5.4 Inclusion/Exclusion Criteria

Potential participants will be screened through a CDW data pull, medical records screen and phone screen.

Inclusion:

- Age 50-70. This age range is being focused on because the benefits of physical activity have the greatest benefit and individuals in this age range are more likely to have one of the conditions we are focusing on. The CDW data pull will include Veterans up to age 69.25, so as not to include Veterans who are about to turn 70.
- Diagnosis of hypertension, depression, diabetes or a BMI between 25-40. These conditions are highly prevalent in physically inactive populations and are amenable to change through greater physical activity. We will collect self-reported physical activity information, followed by asking participants if they think they would benefit from increased walking. Participants will also be asked if they are able to walk for 20 minutes without pain.

- Use of and/or own a smart phone. This is necessary to both sync the Fitbit and to receive the daily texts or emails
- Ability to receive mail.
- Ability to walk for 20 minutes without pain
- Has had a primary care or women's clinic visit in the past 2 years

Exclusion:

- Not a Veteran of the U.S. Armed Services: We only want to recruit Veterans. We are aware there are non-Veterans that have VA medical records, therefore only Veterans will be recruited.
- Currently in the MOVE! Program. We do not want to enroll participants that are in the MOVE group because group dynamics may be adversely impacted particularly if a participant is receiving incentives.
- Blind: participants will need to be able to read the value on their fitbit and the text messages/emails.
- Highly physical active according to self-report.
- Inability to walk 20 minutes without pain (self-report).
- Diabetic foot condition (ulcer or peripheral neuropathy): We do not want to encourage any activities or increases in activity that could cause harm.
- Dementia/Alzheimer's/cognitive impairment: Potential participants need to fully able to understand the study and what they are voluntarily choosing to participate in.
- Metastatic cancer, end-stage renal disease, hospice, palliative care, heart failure, undergoing chemotherapy, radiation or hemodialysis, have had or are on the list for an organ transplant: We do not want to recruit anyone that is battling a potentially life-threatening condition.
- Implanted cardiovascular device such as defibrillator or ventricular device
- Active psychosis/mania/behavioral flag: We are not able to accommodate potential participants with these conditions or behaviors.
- Pregnant women: We are excluding pregnant women because it is highly unlikely, we will have a 50-year-old plus, inactive female Veteran interested in participating in this study.
- Homeless or housing insecure: We will only exclude individuals experiencing homelessness or housing insecurity if they do not have a way to get mail or charge electronic devices.
- Has a paid caregiver that provides >50% of daily living activities, lives in a nursing home, assisted living facility or group home: Someone that has a caregiver for >50% of daily living activities is likely either medically complex or ill. We understand that many medical conditions and interpersonal relationships can be strained with additional tasks and activities. We do not want this study to interfere with caretaking or this relationship. Individuals that exhibit threatening, violent or otherwise troubling or inappropriate behavior during the screening phone call or consent visit will be excluded from this study.
- Presently own a Fitbit, have the Fitbit application and not interested or willing to login to the dummy account, and use the study provided Fitbit.

5.5 Study Evaluations

Phone Screening:

Interested participants will complete a telephone screen with a research coordinator. Potential participants will be asked a variety of screening questions to determine eligibility. The phone

screening questions are included as an appendix 5. The screening includes the above inclusion/exclusion criteria and also includes questions about current physical activity and movement, the walking ability assessment and the six-item screener to determine if the participant has any cognitive impairment. The participant screening responses will be recorded directly into the study database located within the study folder on the J:drive (J:\MOTIVATE Walking (MIRB#01930)).

2 Week Trial Period:

After the subject has enrolled and has set up the Fitbit they will start a 2-week trial period. The participant will be instructed to wear the Fitbit Inspire the study team provided for them daily for two weeks and walk/move as they normally would. To sync the data the participant will need to open the application on their smart phone in close proximity to their Fitbit. The participant's step data is stored within their Fitbit accounts that will be accessed by the study team. The study team will record their available step-count data from the two-week trial period and use the procedures described above to establish a baseline average daily step count. . Research staff will only review the participant step data from days 7-13 for eligibility. Participants will not be aware of the dates we are reviewing for study inclusion.

If a participant walked less than 2,000/steps/day or more than 5,000 steps/day they will not be eligible for the study. Research study staff will call the participant and inform them if they are in the study or not. If there are fewer then 4 days of data reported days 7-13, we will extend the baseline window up to 2 weeks until 4 days of data can be established.

If a participant is not eligible, they will still be compensated for all study activities up to that point (consent visit, Fitbit visit and baseline survey). At this time participants will be able to keep their Fitbit.

The participants week 1 start date will start on their selected day of the week. If their baseline assessment period ends on a Monday and the participants chosen day of the week starts on a Saturday, then their week 1 wouldn't start until the following Saturday. This will be the same process regardless of the randomized group.

Data Syncing:

To sync the data on most phones, the participant will need to open the application on their smart phone in close proximity to their Fitbit. The participant's step data is stored within their Fitbit accounts that will be accessed by the study team. The study team will record the participant's baseline step-count data in a study created Access database. Research staff will review the participant step data from days 0-7 to ensure it is being captured.

Surveys:

The participants will need to complete a baseline survey (appendix 6) and follow-up surveys at weeks 12 and 24. The participants will be emailed/texted a link to complete the survey through Qualtrics. The participant will need to complete the baseline survey before finding out what group they are in. Under very rare circumstances if the participant is unable to complete the survey through Qualtrics we will offer the participant the opportunity to complete the survey over the phone with a research coordinator or completing a paper survey. Due to mailing issues, we will strongly encourage the phone survey option. The participant will receive the Qualtrics link after they have been consented and before the Fitbit visit. If the participant still has not completed the survey

by the Fitbit call, we will encourage the participant to complete the survey over the phone. If the participant completes the baseline survey through Qualtrics or over the phone, we will tell them what randomization group they are in and what that means for them. If the participant declines the survey over the phone, we will need their paper copy returned prior to starting the study. Once we receive the paper survey, we will call them to tell them what group they are in and their baseline week start date. They will be instructed to complete the mailed follow-up surveys as soon as possible during week 12 and 24 (appendix 6). The surveys will be completed either through the Qualtrics link or over the phone. Surveys collected over the phone will be recorded either in Excel or the study Access database in the study folder on the J:drive. Once mailed surveys are returned study staff will manually enter survey responses into either the Excel file or the Access database. Another study coordinator will cross check recorded responses to the paper surveys to ensure accuracy.

The survey is comprised of a variety of different measures that account for the secondary outcomes. The secondary outcomes are self-efficacy, intrinsic/extrinsic motivation and mental health.

Self-efficacy: Measured using the Exercise Self-Efficacy Scale at baseline, week 12 and week 24 (McAuley E 1993). This measure has respondents indicate how confident they are they could exercise five times per week at moderate intensity for thirty minutes or more given various conditions. This scale ranges from 0 (not confident) to 10 (very confident).

Intrinsic/extrinsic motivation: Measured using the Motivation for Physical Activity Measurement (MPAM) at baseline, week 12 and week 24 (Frederick CM 1993). This assessment measures the reasons and motivations for participating in physical activity. The assessment has the subject indicate why they exercise given various reasons and has the subject rate them on a scale 1 to 5. 1 indicates *it is very true for me* and 5 *indicates very untrue for me*.

Mental Health: Measured using the PHQ-8 depression scale at baseline, week 12 and week 24. The rating for this measure asks questions for how often during the past 2 weeks participants bothered by various events. The rating goes from not at all (0 on the scale), several days (1), more than half the days (2), nearly every day (3).

Additional measures that will be used include sociodemographics (from the VA survey of Health Experiences SHEP and Federal Reserve Board Survey of Household Economics and Decision Making), ENRICHD Social Support Instrument (ESSI), Perceived Stress Scale, PROMIS sleep disturbance short form ((PHO) and PROMIS Cooperative Group), Importance of Money Scale (IMS, Franzen and Mad), Loss Aversion (Gachter, Johnson and Herrmann), PROMIS Global Health Scale. These instruments are used to gather demographic data and how much social support and daily interaction the participant has with others. All of these assessments will be presented in the form of a cohesive survey, where responses are recorded based on a scale. Participants will select the response on the scale that most closely matches their life on the day they take the assessment.

Participants will be able to skip any survey responses that they prefer not to answer. All of the surveys are included in in Appendix 6.

Main Study, weeks 1-24:

To participate, participants will be instructed to wear their Fitbits daily. Participants will need to open the Fitbit app on their phone and sync the Fitbit with the app on most phones. Participants will receive text message and/or emails with appropriate study updates. These updates will

include the new step goal for the next week, encouragement, reminders to sync the device with their phone, notification of non/financial incentives, lottery numbers, loss-framed results, reminders for surveys, transitioning into the maintenance phase, week 12-24 (appendix 22). All participants will select the day of the week when their new week starts. On the participants selected day, they will be given a new daily step goal for the next week.. The goal will be 15% more than the previous average weekly step count. If the participant is in a lottery group, they will participate in the lottery every day that they reach their new step goal. The text/email messages will be sent out the following day, i.e. "you won _____ in the lottery for your step count yesterday." For participants in the loss-framed group, the participants will get their update on points or dollar amount based on the previous day's steps.

Syncing:

Texts will encourage participants to sync their devices daily. If a participant fails to sync their Fitbit, they will continue to receive reminders to sync their Fitbit as soon as possible. Participants will receive text message reminders to sync their Fitbit or call us if they are having trouble. They will also get a reminder to charge their Fitbit if the charge drops below 15%. If a participant syncs sporadically, their step count will be adjusted to the most recent available data. In the absence of a full week of data, the average of the previous 7 days of data that was synced will be used.

Once the participant syncs their device (anytime week 1-12), they will get a text messages updating them on:

1) New daily step goal (the step goal will have been previously paused based on the most recent data we have. The next step goal will be based off whatever information is synced.)
2) All rewards won to date. Once a participant syncs their Fitbit, they will be sent a message with their lottery winnings or loss-framed point/dollar amount value based of off what data was collected when the sync occurred.

5.6 Data Analysis

There are 16 combinations of factors, with 8 patients in each, for a modestly sized trial of 128 patients. However, each factor has 64 patients per factor level: there are 64 people receiving financial and non-financial incentives for meeting PA goals, respectively, and 64 patients receiving them in the form of a lottery and a loss-framed incentive. Every component is balanced with respect to the other components, which allows us to estimate the effects of all components with nearly the same power as if we had conducted independent trials of each component.

We powered the analysis for a difference in steps between treatment groups at follow-up using a repeated measures design with 24 follow-up measures per person (weeks 1-24). We used data on the standard deviation in step count from the 2006 NHANES and applied the formula for a truncated normal distribution to estimate the standard deviation among subjects with <5,000 steps at baseline. This yielded an estimated standard deviation of approximately 2,300. We assumed an intra-class correlation of 0.8 for the follow-up measures. We will enroll 128 patients, or 64 patients per treatment arm. This is similar in size to the treatment arms in studies described in Table 3 that compared active treatment groups (n=70). The slightly smaller sample size in the present study is justified by the higher type 1 error probability assumption. Loss to follow-up in the trials in Table 3 ranged from 4-7%. With 128 patients we will have 80% power to detect a difference as small as 375 steps per day with 10% loss to follow-up. We anticipate recruiting at least 10 participants per month.

All data will be collected by the VA research study team. The data collected during the first week, week 0, also referred to as the baseline week, will be used for all future step goals. The VA research team will monitor this period to ensure the participant is actually participating and syncing the data. If there is no data, the VA study team will call and encourage the participant to participate or help troubleshoot any issues.

5.7 Withdrawal of Subjects

2-week trial withdraw. If a participant fails to walk an average of 2,000 steps/day or exceeds 5,000 steps per day, or cannot sync their Fitbit at the end of the trial period they will be withdrawn. The research staff will call them and thank them participating up to that point and inform them they are not eligible for the full study. The study Fitbit account will be closed, and the research study staff will delete their Fitbit account.

Active withdraw. Any participant may at any time notify the Principal Investigator or research coordinator(s) that they no longer wish to participate in the study, and they will be considered withdrawn and will no longer participate in study procedures or activities. We will make every attempt to have a final (remote) study visit with the participant. During the final visit we will encourage the participant to complete the final survey, and we will deactivate their Fitbit account and stop the text/email messages. At this point in time, depending on the arm of the study the participant was randomized to, they will be told the total amount they can expect to receive in the mail, or they will be notified of the non-financial reward(s) they have earned.

Passive withdraw. If a participant stops syncing their device, we will encourage them to start syncing it again and we will be available for troubleshooting. If the participant does not sync their device but syncs it before the end of week 24, they will be given all rewards up to that date (reward period week 1-12). If they do not explicitly tell us that they want to withdraw we will keep them in the study. If a participant syncs their device after week 24, they will no longer be eligible for rewards because they have phased out of the study data collection timeframe. After 6 weeks from the Fitbit set-up visit, if the participant has not completed and returned the baseline survey, they will be considered withdrawn.

Medical withdraw. At any point in time if a participant experiences a change in their health, is diagnosed with a new condition, gets medical advice to discontinue participation or feels that increasing their exercise is not in their best interest they can choose to withdraw. If a participant has medical questions about their involvement in the study, they can speak with the physician researcher and co-investigator. The physician researcher will review their chart and determine if there is anything that would contra-indicate further participation. Often participants mention their involvement in research to their medical care providers. If any of their medical care providers determine that participating is not beneficial, they may be withdrawn from the study. If this occurs the same withdrawal procedures will be followed for active withdraw. Participants will be compensated for all activities earned to the date of withdraw as outlined in the informed consent document.

6.0 Reporting

Participant reports: If a participant reports an unanticipated problem, we will immediately report it to the Principal Investigator. If it is a serious event, we will immediately report it to the IRB. If it is regarding subject payment we will track the issues in our study payment folder on the J:drive and

correspond with the R&D payment staff accordingly. All protocol deviations will be immediately reported to the IRB using the report of problems form.

7.0 Privacy and Confidentiality

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

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

ID numbers rather than names will be used whenever possible. As part of the study, individuals will be reassured that information is to be kept confidential, no single individual will be identified by name and all data will be aggregated in published manuscripts and presentations. All data files will be maintained on password protected PCs and secured computer networks. Only aggregate data will be presented to external audiences. Individual identifiers will be deleted when they are no longer necessary for the project. Health care data will be stored on secure VA servers within the VA HSR&D COIN in Seattle.

After all manuscripts are published (estimated December 2025), all human subject identifiable files and crosswalks will be destroyed in the manner approved by the VHA Records Control Schedule. Electronic media used to store identifiable data will be cleaned or destroyed in compliance with governing information security regulations.

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

Participants' personal identifiable information (PII) and Protected Health Information (PHI) will not be share outside the study team.

8.0 Communication Plan

VA Puget Sound is the only VA site engaged in research. There are no other researchers at any other VA site. In the future we hope to work with a University of Washington PhD student. Should this happen, the protocol and study staff list will be updated.

9.0 Information Security and Data Storage/Movement

Data flow: Data pulled from CDW will be stored in the study folder on the J:drive in an Excel file, VINCI folder and SQL server, and HSR&D SQL server. The medical record screening will be done from this file. Participants that meet the inclusion criteria will then be placed in an Access database. Recruitment letters will be mailed, and the participants response or lack of response will be tracked within the Access database electronically. Participant consent will be collected in hard copies through the mail and filed in locked cabinets in the locked office.

Once a participant has enrolled, their step data will be pulled from the Fitbit app by the research coordinators and saved in the J:drive folder. Participant survey responses and step counts will be collected by the research team. Research staff will collect all data and save it daily in the study folder on the J:drive. Approved research staff will then run a program (likely Stata) to match the step data with a crosswalk of participant group, current week and email/text address and preference. Coordinators will then do a mail merge to match the correct message to the correct address (text/email) and send the messages from the study email account. A daily file with the internal study ID, step count and messages will be saved by date in the J:drive to be able to cross check for errors if needed.

All qualitative interviews will be saved onto a VA issued recorder and saved immediately onto the J:drive study folder or recorded directly from Webex onto the J:drive study folder. Study interviewers will have an approved ATSI if using a portable recorder, authorization to transport data, so interviews can occur remotely or in one of the interview rooms. If using a recorder, once interviews are saved to the appropriate folder on the J:drive they will immediately be deleted from the recorders.

The data will be retained throughout the research study period on the VA Puget Sound Health Care System (VAPSHCS) network server or OI&T managed archived back-up media. All files containing individually identifiable information (III) for this study will be deleted from the VA Puget Sound Health Care System (VAPSHCS) network server folder and/or database no later than six months prior to the closure of the study. Only de-identified data will be retained thereafter on the VAPSHCS network server.

After all manuscripts are published (estimated December 2025), and assuming that the VA has approved the destruction of data, all human subject identifiable files and crosswalks will be destroyed. Electronic media used to store identifiable data will be cleaned or destroyed in compliance with governing information security regulations.

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