

Loss-Framed Financial Incentives and Personalized Goal-Setting to Increase Physical Activity Among Ischemic Heart Disease Patients Using Wearable Devices: The ACTIVE REWARD Randomized Trial

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Background—Regular physical activity reduces the risk of cardiovascular events, but most ischemic heart disease (IHD) patients do not obtain enough.

Methods and Results—ACTIVE REWARD (A Clinical Trial Investigating Effects of a Randomized Evaluation of Wearable Activity Trackers with Financial Rewards) was a 24-week home-based, remotely monitored, randomized trial with a 16-week intervention (8-week ramp-up incentive phase and 8-week maintenance incentive phase) and an 8-week follow-up. Patients used wearable devices to track step counts and establish a baseline. Patients in control received no other interventions. Patients in the incentive arm received personalized step goals and daily feedback for all 24 weeks. In the ramp-up incentive phase, daily step goals increased weekly by 15% from baseline with a maximum of 10 000 steps and then remained fixed. Each week, \$14 was allocated to a virtual account; \$2 could be lost per day for not achieving step goals. The primary outcome was change in mean daily steps from baseline to the maintenance incentive phase. Ischemic heart disease patients had a mean (SD) age of 60 (11) years and 70% were male. Compared with control, patients in the incentive arm had a significantly greater increase in mean daily steps from baseline during ramp-up (1388 versus 385; adjusted difference, 1061 [95% confidence interval, 386–1736]; $P<0.01$), maintenance (1501 versus 264; adjusted difference, 1368 [95% confidence interval, 571–2164]; $P<0.001$), and follow-up (1066 versus 92; adjusted difference, 1154 [95% confidence interval, 282–2027]; $P<0.01$).

Conclusions—Loss-framed financial incentives with personalized goal setting significantly increased physical activity among ischemic heart disease patients using wearable devices during the 16-week intervention, and effects were sustained during the 8-week follow-up.

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Key Words: behavioral economics • financial incentives • goal-setting • ischemic heart disease • physical activity • wearable devices

Ischemic heart disease (IHD) is the leading cause of morbidity and mortality in the United States.^{1,2} Regular physical activity reduces the risk of cardiovascular events among patients with IHD.^{1,3} For example, participation in

exercise-based cardiac rehabilitation has been demonstrated to reduce mortality by up to 30%.^{4–9} However, the majority of eligible patients do not participate in a cardiac rehabilitation program.^{8,10,11} Recent evidence also suggests that IHD

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Accompanying Data S1 and Tables S1 through S7 are available at <http://jaha.ahajournals.org/content/7/12/e009173/DC1/embed/inline-supplementary-material-1.pdf>

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Clinical Perspective

What Is New?

- Despite the many benefits of regular physical activity, most ischemic heart disease patients do not participate in exercise-based cardiac rehabilitation or obtain enough physical activity on their own.
- We evaluated a scalable approach to increase physical activity among ischemic heart disease patients by using insights from behavioral economics to design financial incentives and goal setting to address predictable barriers to behavior change and by using wearable devices to remotely monitor behaviors.
- The combination of loss-framed financial incentives and personalized goal setting significantly increased physical activity levels during the 24-week trial.

What Are the Clinical Implications?

- Providing only wearable devices to ischemic heart disease patients is unlikely to lead to significant changes in physical activity.
- Combining approaches based on behavioral economic insights with wearable devices can be used to deploy home-based interventions that significantly change behavior among ischemic heart disease patients.

patients do not often achieve physical activity goals on their own.¹²

Wearable devices have received significant attention for their ability to remotely monitor health behaviors such as physical activity.^{13,14} However, thus far there is limited evidence of interventions that use these devices to effectively sustain behavior change among high-risk patients.^{13,15,16} Our previous work found that financial incentive-based approaches that use mobile technologies can be effective in increasing physical activity,^{17–19} but only if they are designed to appropriately leverage insights from behavioral economics—a field that incorporates insights from psychology to design interventions that address predictable barriers to behavior change.^{20,21} For example, we found that the framing of financial incentives significantly impacted their effectiveness.¹⁸ A “gain-framed” incentive that used the standard economic approach of rewarding individuals only after physical activity goals were achieved was not effective. However, a “loss-framed” financial incentive that allocated money upfront to a virtual account, which could be lost if goals were not achieved, led to a 50% relative increase in physical activity.

In this study, our objective was to use a randomized controlled trial to test the effectiveness of loss-framed financial incentives with personalized goal setting to increase physical activity among IHD patients. We tested a potentially scalable design that recruited patients from 4 hospitals and

delivered home-based interventions remotely by using wearable devices and an automated technology platform.²²

Methods

The data, analytical methods, and study materials will not be made available to other researchers for purposes of reproducing the results or replicating the procedure.

Study Design

ACTIVE REWARD (A Clinical Trial Investigating Effects of a Randomized Evaluation of Wearable Activity trackers with Financial Rewards) was a randomized controlled trial conducted between March 7, 2016 and April 3, 2017 consisting of a 16-week intervention period (composed of an 8-week ramp-up phase followed by an 8-week maintenance phase) and an 8-week follow-up period. The study protocol (Data S1) was approved by the University of Pennsylvania (Philadelphia, PA) Institutional Review Board, and participants provided informed consent.

The study was conducted using Way to Health, a research technology platform at the University of Pennsylvania used previously for physical activity interventions.^{17–19,22} Patients used the study website to create an account, provide informed consent online, and completed baseline eligibility surveys and the MacNew heart disease quality of life questionnaire.^{23,24} Patients selected whether to receive study communications by text message, e-mail, interactive voice recording, or a combination of these. Eligible patients were mailed a wrist-worn wearable device (Misfit Shine) and authorized access for the study to capture step data. Our previous work demonstrated that these types of devices accurately track step counts.¹⁴

All patients received \$20 for completing enrollment, \$30 for completing the 24-week trial, and were allowed to keep the wearable device after the trial concluded. Patients were mailed a bank check at the end of each month with accumulated earnings.

Study Sample

Recruitment occurred from February 2, 2016 to September 21, 2016 at the following 4 hospitals in southeastern Pennsylvania: Hospital of the University of Pennsylvania, Penn Presbyterian Medical Center, Chester County Hospital, and Lancaster General Hospital. Outreach targeted patients eligible for, but not yet enrolled in, a cardiac rehabilitation program and focused on patients with a recent cardiac catheterization for evaluation of coronary artery disease. Patients were contacted by telephone or during cardiology outpatient visits. Patients were eligible to participate if they were aged ≥ 18 years, had a history

of acute coronary syndrome (unstable angina, non-ST-segment-elevation myocardial infarction, or ST-segment-elevation myocardial infarction), or had coronary catheterization for suspected ischemic heart disease that resulted in a definitive diagnosis. After enrollment, we used data from the electronic health record to check for the presence of IHD. Patients were excluded if they were already enrolled in a formal cardiac rehabilitation program within the past 1 year, did not have access to a smartphone or tablet compatible with the wearable device, were admitted to the hospital and were not being discharged to home, or had any other reason that participation was unsafe (eg, hemodynamic instability or New York Heart Association Class III–IV heart failure) or infeasible (eg, inability to provide informed consent).

Baseline Step Count

Before randomization, patients were told to spend 2 weeks getting accustomed to their device. During this run-in period, we estimated a baseline step count using the second week of data—a method used in previous work.²⁵ The first week of data was ignored to diminish the potential upward bias of the estimate from higher activity during initial device use. To prevent potential mismeasurement, we ignored any daily values less than 1000 steps because evidence indicates that these values are unlikely to represent capture of actual activity.^{26,27} If less than 4 days of data were available during the second week (n=5), the patient was contacted to inquire about any device issues and the run-in period was expanded until at least 4 days of data were captured.

Randomization

Patients with a baseline step count were then electronically randomized to a study arm using block sizes of 4, stratified by age (<65 years versus ≥65 years). All investigators, statisticians, and data analysts were blinded to arm assignments until the study and analysis were completed.

Interventions

Patients in the control arm had their step counts passively monitored by the wearable device, but were not informed of their baseline step count. The wearable device was preset with the goal of 10 000 steps per day and could be adjusted by the patient. The wearable device displayed progress toward that goal using a circular dial, and actual step counts were available within the smartphone application. Patients in this arm received no other interventions.

Patients in the incentive arm received daily feedback on their performance for all 24 weeks. In the ramp-up incentive phase (weeks 1–8), daily step goals increased gradually from

baseline by 15% each week with a maximum goal of 10 000 steps. After 8 weeks, step goals then remained fixed during the maintenance incentive phase (weeks 9–16) and the follow-up phase without incentives (weeks 17–24). During the 16-week intervention, patients were offered a loss-framed financial incentive. Each week, patients were informed upfront that \$14 was allocated to a virtual account. Each day the patient achieved his or her step goal, the balance remained unchanged, but each day the step goal was not achieved, the patient was informed that \$2 had been deducted. The balance was refreshed with \$14 every week on Monday. This design leveraged 4 important psychological principles: Individuals tend to be more motivated by losses than gains,^{18,28} favor immediate over delayed gratification,²⁹ try to avoid the feeling of regret,^{30–33} and tend to be more driven for aspirational behavior around temporal landmarks such as the beginning of the week (the fresh start effect).³⁴

After the 16-week intervention period and 24-week trial, patients in both arms were asked to complete self-reported surveys on healthcare utilization (participation in cardiac rehabilitation, cardiac catheterization, cardiology clinic visit, emergency room visit, and hospital admission) and perceptions of the overall study and wearable device.

Outcome Measures

The primary outcome was change in mean daily steps from baseline to the maintenance incentive phase. Secondary outcomes were change in mean daily steps from baseline to the ramp-up incentive phase and follow-up phase.

Statistical Analysis

Power calculations (a priori) were based on previous work^{17–19} and assumed a baseline mean step count of 6000 steps in the control group with an SD of 2000 steps, a 15% dropout rate, and a 2-sided α of 0.05. It was estimated that a sample of 148 patients (74 per arm) would ensure at least 80% power to detect a 1000-step difference between the incentive and control arms in the change in mean daily steps from baseline to the maintenance incentive phase. However, enrollment was closed with 105 patients because of funding constraints on the timeline. Based on these same assumptions, we had at least 80% power to detect a 1200-step difference.

All randomly assigned patients were included in the intention-to-treat analysis. For each patient on each day of the study (patient-day level), the number of steps achieved was obtained as a continuous variable. Data could be missing for any day if a patient did not use the activity tracking device or did not upload data. One patient had very high step counts compared to others in the study. After investigation, we learned

that the patient frequently played the drums and there have been reports of inaccurate step tracking from this activity.^{35,36} Therefore, all of this patient's data were deemed invalid and classified as missing. For the prespecified main analysis, we used multiple imputation for data that were missing and step values less than 1000. We have used this method in previous work^{17–19,25} and in this study because evidence indicates that step values less than 1000 may not represent accurate data capture.^{26,27} Five imputations were conducted using the mice package in R (R Foundation for Statistical Computing, Vienna, Austria), which allows for patient random effects with this data structure.³⁷ The following predictors of missing data were included: study arm, week of study, calendar month, baseline step count, age, sex, race/ethnicity, education, marital status, household income, body mass index, days since last cardiac catheterization, most recent ejection fraction, and history of diabetes mellitus, hypertension, hyperlipidemia, smoking, and valvular heart disease. Results were combined using Rubin's standard rules.³⁸ Secondary analyses were conducted using collected data without multiple imputation, both with and without step values less than 1000.

Unadjusted analyses estimated the change in mean daily steps from baseline to each week and each phase (ramp-up, maintenance, and follow-up) of the study. In adjusted analyses, we used PROC GLIMMIX in SAS (SAS Institute Inc, Cary, NC) to fit linear mixed-effects models with a random intercept, patient random effects, and to account for the repeated measures of daily step counts. In the main model, we included baseline step count and fixed effects for calendar month and study arm. To test the robustness of our findings, we also fit a fully adjusted model that included age, sex, race/ethnicity, education, marital status, household income, body mass index, days since last cardiac catheterization, most recent ejection fraction, and history of diabetes mellitus, hypertension, hyperlipidemia, smoking, and valvular heart disease. We assumed a normal distribution and obtained difference in steps between arms for each phase (ramp-up, maintenance, and follow-up) using the least squares means (LSMEANS) command. In a post-hoc exploratory subgroup analysis, we evaluated effects in patients with recent care for IHD by fitting the same models for only patients who had a cardiac catheterization within the 90 days preceding enrolling in the study.

Hypothesis tests were 2-sided using a significance level of 0.05. Analyses were conducted in SAS (version 9.4; SAS Institute Inc) and R software (version 3.4.0; R Foundation for Statistical Computing).

Results

In this trial, 105 patients with IHD were randomized (Figure 1). Patients had a mean (SD) age of 60 (11) years, 70% were male, and 74% enrolled in the trial within 90 days

after a cardiac catheterization. Baseline patient characteristics were well balanced across the study arms (Table 1). Baseline mean daily steps were 6577 (SD, 3084) in control and 7205 (SD, 3246) in the incentive arm, which was not significantly different ($P=0.32$).

One hundred three patients (98%) completed the entire 24-week study. During the maintenance period, 22.0% of observations were missing and 1.9% of step counts were less than 1000. In the control arm, these rates were higher with 38.6% observations missing and 1.4% of step counts less than 1000 (Table S1).

In the control arm, the unadjusted change in mean daily steps from baseline began near 500 during the first 6 weeks, but then slowly declined throughout the rest of the study (Figure 2). In the incentive arm, the unadjusted change in mean daily steps from baseline began above 1000 in week 1 and increased during the ramp-up incentive phase to nearly 2000. Mean change in daily steps from baseline remained above 1250 for the maintenance period and then slightly declined in the follow-up period ranging from 850 to 1250 (Figure 2).

In the main adjusted model compared with control, patients in the incentive arm had a significantly greater increase in mean daily steps from baseline during ramp-up (1388 versus 385; adjusted difference, 1061 [95% confidence interval [CI], 386–1736]; $P<0.01$), maintenance (1501 versus 264; adjusted difference, 1368 [95% CI, 571–2164]; $P<0.001$), and follow-up (1066 versus 92; adjusted difference, 1154 [95% CI, 282–2027]; $P<0.01$). Results were qualitatively similar in the fully adjusted model (Table 2) and in secondary analyses that used collected data (Tables S2 and S3).

Seventy-eight patients (74.3%) had recent care for IHD as indicated by a cardiac catheterization within the 90 days preceding enrolling in the study. Subset analyses among this group found that compared with control, patients in the incentive arm had a significantly greater increase in mean daily steps from baseline during ramp-up (1331 versus 276; adjusted difference, 1131 [95% CI, 466–1797]; $P<0.001$), maintenance (1445 versus 142; adjusted difference, 1509 [95% CI, 720–2297]; $P<0.001$), and follow-up (1225 versus 4; adjusted difference, 1455 [95% CI, 745–2376]; $P<0.001$; Table S4).

No adverse events were reported during the entire trial. Total cost of loss-framed incentives was \$5194, which averaged \$103.88 per patient. Self-reported healthcare utilization was similar between arms (Tables S5 and S6). By the end of the intervention, only 8 patients (3 in control and 5 in the incentive arm) reported joining a formal cardiac rehabilitation program. Most patients reported positive perceptions of their experience in the study, but more patients in the incentive arm agreed that they would continue to use the wearable device after the study completed (83.8% versus 5.8%; Table S7).

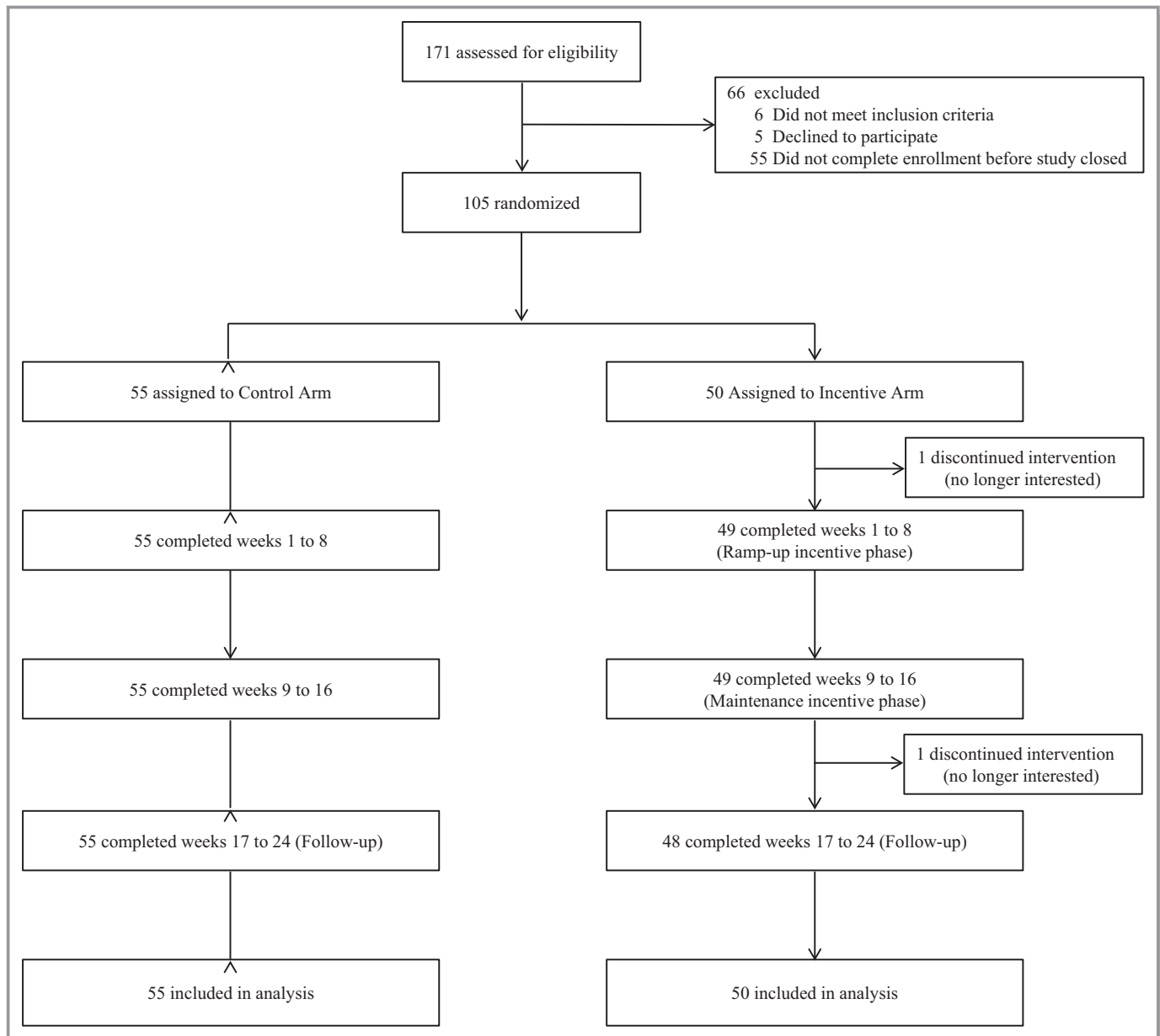


Figure 1. CONSORT diagram. Both arms used a wearable device to track daily steps. Patients in control received no other interventions. Patients in the incentive arm received a personalized step goal and daily feedback for 24 weeks. During the first 16 weeks, patients in the incentive arm also received a \$2 per day loss-framed financial incentive.

Discussion

In this trial, we found that loss-framed financial incentives with personalized goal setting and wearable devices significantly increased physical activity among IHD patients over a 6-month period including 8 weeks of follow-up without incentives. To our knowledge, this is 1 of the first studies to demonstrate the successful use of financial incentives and wearable devices to increase physical activity among this high-risk population. Subset analyses found similar results among the 74% of patients who had recent care for IHD as

indicated by a cardiac catheterization within the 90 days preceding enrolling in the study. This intervention remotely monitored patients using an automated technology platform and wearable devices and therefore has the potential to be scaled more broadly.

Our findings reveal several important implications for future intervention design. First, a key element of our study design was the use of loss aversion, a principle from behavioral economics.^{13,17–19,28–34} Most previous financial incentive-based physical activity interventions have used gain-framed incentives^{16,39–41}—individuals earn a reward after the

Table 1. Characteristics of the Study Sample

Characteristic	Control Arm (n=55)	Incentive Arm (n=50)	P Value
Sociodemographics			
Age, y, mean (SD)	59.1 (11.5)	60.0 (9.5)	0.65
Male sex, no. (%)	37 (67.3)	36 (72.0)	0.60
Race/ethnicity, no. (%)			0.46
White non-Hispanic	38 (69.1)	38 (76.0)	
Black non-Hispanic	14 (23.6)	8 (16.0)	
Other	3 (5.5)	4 (8.0)	
Education, no. (%)			0.29
Some high school	3 (5.5)	3 (6.0)	
High school graduate	10 (18.2)	12 (24.0)	
Some college or specialized training	18 (32.7)	8 (7.7)	
College graduate	24 (43.6)	26 (52.0)	
Missing	0 (0.0)	1 (2.0)	
Marital status, no. (%)			0.83
Single	11 (20.0)	12 (24.0)	
Married	35 (63.6)	29 (58.0)	
Other	9 (16.4)	9 (18.0)	
Insurance, no. (%)			0.82
Private	28 (50.9)	24 (48.0)	
Medicare	24 (43.6)	21 (42.0)	
Medicaid	2 (3.6)	4 (8.0)	
Military	1 (1.8)	1 (2.0)	
Annual household income, no. (%)			0.10
Less than \$50 000	21 (38.2)	18 (36.0)	
\$50 000 to \$100 000	17 (30.9)	7 (14.0)	
Greater than \$100 000	12 (21.8)	17 (34.0)	
Missing	5 (9.1)	8 (16.0)	
Baseline measures			
Baseline step count, mean (SD)	6577 (3084)	7205 (3246)	0.32
Body mass index, mean (SD)	30.1 (5.6)	31.0 (6.8)	0.48
Diabetes mellitus, no. (%)	18 (32.7)	15 (30.0)	0.76
Ejection fraction, mean % (SD)	57.8 (9.2)	58.2 (9.6)	0.85
Health-related quality of life score, mean (SD)	2.7 (1.0)	2.5 (0.8)	0.14
Hypertension, no. (%)	44 (80.0)	43 (86.0)	0.42
Hyperlipidemia, no. (%)	45 (81.8)	40 (80.0)	0.81
Previous cardiac catheterization, median days (IQR)	37 (16.232)	35 (23.73)	0.49
Previous cardiac catheterization within 90 days preceding enrollment, no. (%)	40 (72.7)	38 (76.0)	0.78
Smoking, no. (%)			0.17
Past smoker	28 (50.9)	19 (38.0)	
Active smoker	6 (10.9)	3 (6.0)	
Valvular heart disease, No. (%)	4 (7.3)	8 (16.0)	0.16

Health-related quality of life score obtained from the MacNew Survey. IQR indicates interquartile range.

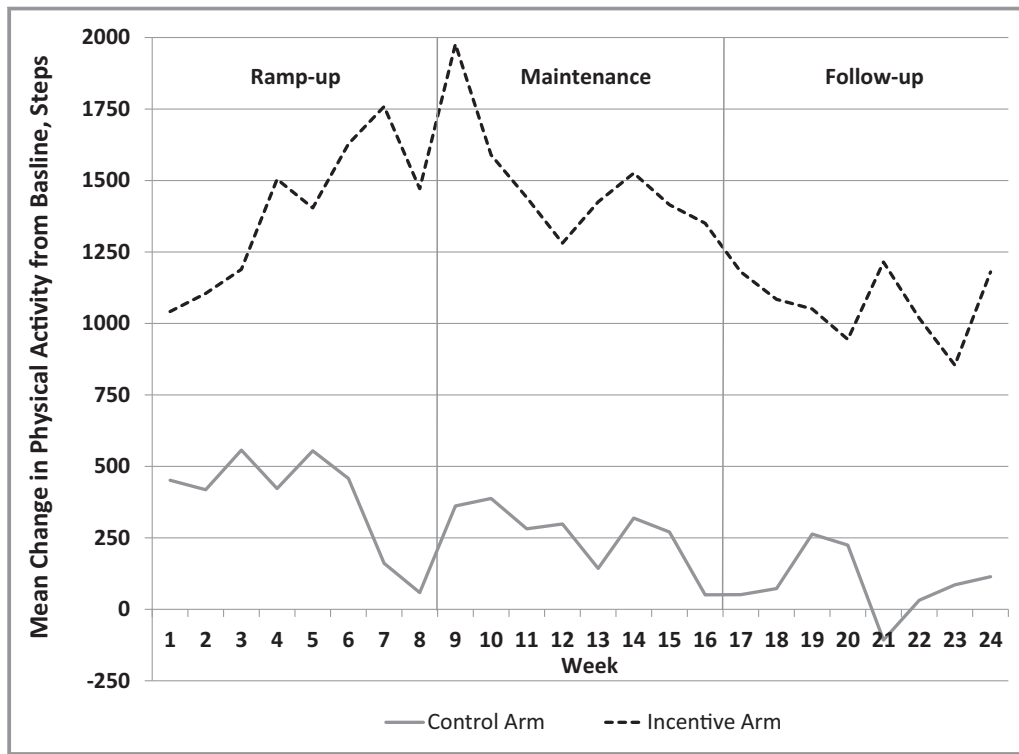


Figure 2. Central illustration, Unadjusted mean change in daily steps from baseline by study arm and week. Data presented are the difference between mean daily steps and mean baseline steps by week for each arm. Gray solid line represents patients in the control arm. Black dashed line represents patients in the financial incentive arm. Solid vertical gray lines represent the end of each study phase.

behavior is achieved. However, our previous work among overweight and obese individuals found that loss-framed incentives were more effective than gain-framed incentives.¹⁸ Results from this trial confirm that loss-framed incentives can significantly increase physical activity among high-risk cardiovascular disease patients. We also found that loss-framed incentives led to sustained effects during the 8-week follow-up without incentives (1154 more steps). Whereas physical activity in the incentive arm declined slightly from maintenance to follow-up, activity during both periods was higher than during the ramp-up phase (1061 more steps). It is also important to note that physical activity levels in the control arm declined over time, most rapidly during the follow-up phase. Nonetheless, future studies should evaluate the sustainability of incentive effects over longer-term periods and could compare incentive designs that vary in magnitude, duration, or frequency. Future studies could also evaluate financial incentives and personalized feedback independently to assess differential effects.

Second, our approach to goal setting was unique from most previous financial incentive-based intervention studies. Many physical activity interventions that use incentives are designed with static step goals that ask individuals to immediately achieve large step increases.^{16,40,42} In this trial,

we used a ramp-up phase to gradually increase physical activity goals (15% increase per week) and personalized these goals using the patient's baseline step count. This approach mirrors that of cardiac rehabilitation programs.^{5,7} Future studies could directly compare immediate versus gradually increasing step goals and evaluate different trajectories for step-goal increases.

Third, this trial used a home-based, remotely monitored intervention that could be scaled more broadly by leveraging technology. IHD patients in this study all met eligibility criteria for cardiac rehabilitation, but only 7.6% reported enrolling in a formal program by the end of the intervention. Nationally, cardiac rehabilitation enrollment rates are suboptimal.^{8,10,11} Although our intervention does not substitute for cardiac rehabilitation, it may be an effective method to increase physical activity in patients who are eligible but do not participate in these programs. Future studies could build upon this approach to further test a home-based, remotely monitored cardiac rehabilitation program.

Our study is subject to several limitations. First, patients were from 4 hospitals in southeastern Pennsylvania and needed access to a smartphone or tablet, which may limit generalizability. Second, we evaluated physical activity using step counts and did not have data on other measures of

Table 2. Physical Activity Outcomes

	Baseline	Ramp-up (Weeks 1–8)	Maintenance (Weeks 9–16)	Follow-up (Weeks 17–24)
Steps per day, Mean (SD)				
Control arm	6577 (3084)	6962 (3364)	6841 (3254)	6669 (3091)
Incentive arm	7205 (3246)	8593 (3204)	8705 (3107)	8271 (3003)
Main model				
Difference adjusted for baseline (95% CI)	...	1061 (386, 1736)	1368 (571, 2164)	1154 (282, 2027)
<i>P</i> value	...	<0.01	<0.001	<0.01
Fully adjusted model				
Difference adjusted for baseline (95% CI)	...	742 (–27, 1510)	1216 (350, 2082)	1063 (128, 1997)
<i>P</i> value	...	0.06	<0.01	0.03

Models compare the incentive arm with the control arm using imputed data and the least squares means command. Main model adjusts for baseline step count and fixed effects for calendar month and study arm. Fully adjusted model also added the following covariates: age, sex, race/ethnicity, education, marital status, household income, body mass index, days since last cardiac catheterization, most recent ejection fraction, and history of diabetes mellitus, hypertension, hyperlipidemia, smoking, and valvular heart disease. CI indicates confidence interval.

physical activity, device wear time, or other health outcomes. However, step counts are most commonly displayed by wearable devices and have been successfully used in interventions with small improvements in clinical outcomes across different populations.⁴³ Future studies could evaluate both changes in step counts and other clinical outcomes over longer periods. Third, the control arm had slightly higher missing data rates than the incentive arm. However, our imputation and regression models both used patient random effects to adjust for differential variation across patients and arms. We also found similar results when using imputed and nonimputed data. Fourth, whereas effects were sustained during follow-up, daily feedback was continued and physical activity did decline slightly. Further evaluations are needed to determine longer-term sustainability. Fifth, the control arm did not receive daily feedback or personalized goal setting, and so we were unable to isolate the effects of the financial incentive alone. Sixth, in this study, loss-framed incentives were compared with control and not with gain-framed incentives. Future studies could compare different ways to frame incentives in this study population to increase physical activity.

Conclusions

In this home-based, remotely monitored trial of IHD patients using wearable devices, loss-framed financial incentives with personalized goal setting significantly increased physical activity during the 16-week intervention, and effects were sustained during the 8-week follow-up. Our findings demonstrate that digital health interventions that leverage insights

from behavioral economics offer a promising approach to change health behaviors among patients with cardiovascular disease.

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Disclosures

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Supplemental Material

Data S1.

Study Protocol

Summary of Changes to the Protocol

The original study protocol was approved by the University of Pennsylvania Institutional Review Board (IRB) on January 7, 2016. Study recruitment began on February 2, 2016. This protocol had a target population of patients with ischemic heart disease that were discharged from the hospital within the past 30 days. Because of our funding timeline and slower than expected patient recruitment we submitted a modification to the IRB on May 19, 2016 to broaden the target population to allow enrollment of any patient with a history of ischemic heart disease. This was approved by the IRB on June 2, 2016. There were no changes to the statistical analysis plan.

Original Study Protocol

**A Randomized, Controlled Trial Evaluating Methods to
Increase Physical Activity After Hospitalization for Acute
Coronary Syndrome**

Study Protocol

January 7, 2016

Outline

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1. Abstract

Cardiovascular disease is the leading cause of mortality in the United States. Among patients that survive an acute myocardial infarction (AMI), cardiac rehabilitation (CR) has been demonstrated to effectively reduce risk of re-infarction, cardiac mortality, and all-cause mortality. However, despite CR being a Class I (standard of care) recommendation in multiple American Heart Association AMI guidelines, more than 80% of eligible patients do not receive appropriate CR and much of this is due to challenges in access to these programs. Recent innovations in technology allow us to passively monitor an individual's physical activity using wearable devices. Incentives designed using insights from behavioral economics have been demonstrated to motivate device engagement and behavior change. A remotely-monitored CR program could improve access for many individuals and potentially be more cost-effective because it is less resource- and personnel-intensive. The objective of this study is to use a randomized, controlled trial to test the effectiveness of a home-based, remotely monitored program using wearable devices and financial incentives to increase physical activity. Participants will go through four phases: baseline period (weeks 1-2), ramp-up period (weeks 3-10), maintenance period (weeks 11-18), and follow-up period (weeks 19-26).

2. Overall objectives

The objective of this study is to use a randomized, controlled trial to test the effectiveness of a home-based, remotely monitored program using wearable devices and financial incentives to increase physical activity

3. Aims

3.1 Primary outcome

The primary outcome variable is the change in mean daily step count from the baseline period (weeks 1-2) to the maintenance period (weeks 11-18).

3.2 Secondary outcome

Secondary outcomes include change in mean daily steps from baseline to follow-up period, change in time slept from baseline to maintenance period, change in six minute walk test from baseline to end of maintenance period (optional for participants), and healthcare utilization during the ramp-up and maintenance period as measured by number of hospitalizations and emergency department visits.

4. Background

Cardiovascular disease is the leading cause of mortality in the United States (1). Among patients that survive an acute myocardial infarction (AMI), cardiac rehabilitation (CR) has been demonstrated to effectively reduce risk of re-infarction, cardiac mortality, and all-cause mortality

(2). Patients completing CR have also been found to have improvements in blood pressure control, lipid levels, and a reduction in smoking (3).

Despite this, more than 80% of eligible patients do not receive cardiac rehabilitation (4). Access and affordability are some of the primary factors associated with the low compliance with CR (5). Since CR centers are often located in more urban areas, patients that live in more rural locations or without transportation may have difficulty reaching these centers.

Recent innovations in technology allow us to passively monitor an individual's physical activity using wearable devices (6). These devices have been demonstrated to be accurate for tracking step counts (7) and could be utilized to deploy a home-based intervention. Recently, the concept of a remotely-monitored, internet-based CR program has been shown to be safe and superior to usual care (in terms of reducing CVD risk) in a small Canadian pilot study (8). A remotely-monitored CR program would provide access for the many individuals that cannot reach a CR center and potentially, in the future, could be more cost-effective because it is less resource- and personnel-intensive. The optimal range of steps for secondary prevention of AMI is in the range of 6500-8500 steps/day (9).

[1] Murray et al, US Burden of Disease Collaborators. The State of US Health, 1990-2010. JAMA. 2013;310(6):591-608. [2] Lawler PR, Filion KB, Eisenberg MJ. Efficacy of exercise-based cardiac rehabilitation postmyocardial infarction: a systematic review and meta-analysis of randomized controlled trials. Am Heart J 2011;162:571-84.e2.[3] Taylor RS, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. Am J Med 2004;116:682-92. [4] Menezes AR, Lavie CJ, Milani RV, et al. Cardiac rehabilitation in the United States. Prog Cardiovasc Dis 2014;56:522-9. [5] Sandesara PB, Lambert CT, Gordon NF, Fletcher GF, Franklin BA, Wenger NK, et al. Cardiac rehabilitation and risk reduction. Time to "rebrand and reinvigorate." JACC. 2015;65(4):389-395. [6] Patel MS, Asch DA, Volpp KG. Wearable devices as facilitators, not drivers, of health behavior change. JAMA. 2015;313(5):459-460. [7] Case MA, Burwick HA, Volpp KG, Patel MS. The accuracy of smartphone applications and wearable devices for tracking physical activity data. JAMA. 2015;313(6):625-626. [8] Lear S, Singer J, Banner-Lukaris D, et al. Randomized Trial of a Virtual Cardiac Rehabilitation Program Delivered at a Distance via the Internet. Circ Cardiovasc Qual Outcomes. 2014;7(6):952-959 [9] Ayabe M, Brubaker PH, Dobrosielski D, Miller HS, Kiyonaga A, Shindo M, Tanaka H. Target step count for the secondary prevention of cardiovascular disease. Circ J. 2008;72(2):299-303.

5. Study design

5.1 Design

We will conduct a two-arm randomized, controlled trial comparing a control group that uses a wearable devices to track physical activity and sleep data to an intervention group that uses the same wearable devices and receives a financial incentive to adhere to a step goal program. Patients will be randomized to one of the two arms using a block size of four. To account for

possible differences in reimbursement for CR among patients with and without Medicare, we will stratify the randomization by age (less than 65 years vs. 65 years and older). Since referral to a standard health system CR program is recommended for all patients after an acute myocardial infarction, we will not attempt to modify current referral and adherence patterns to these programs. However, data suggest that more than 80% will not actually obtain this type of cardiac rehabilitation. During the study, we will ask all patients whether or not they participated in a standard cardiac rehabilitation program.

All participants will receive \$20 for enrolling and \$30 for completing the 26 week study. All participants will be given the option to have an in-person visit with the study coordinator at the beginning and after the maintenance period to conduct the six minute walk test. If a participant chooses to participate they will receive \$30 for each visit.

Participants in all arms will be informed of the CDC/federal recommendation guidelines for physical activity and receive additional interventions as follows:

Arm 1. Control: use a wearable device to track physical activity and sleep data. Receive reminders to use their device and sync their data.

Arm 2. Financial incentive-based program: Participants will be given a wearable device to monitor daily step counts and sleep patterns with automated feedback on physical activity goal attainment via text message, automated interactive voice call or email (based on participant communication choice). Based on recommendations for the optimal step count for secondary prevention of AMI, we will establish a baseline step count for each participant (weeks 1-2) and then recommend a 15 percentage point increase in daily step goal each week during the 8-week ramp-up phase (weeks 3-10) with a maximum goal of 10,000 steps. After the ramp-up phase, participants will be asked to maintain that daily step goal for the maintenance period (weeks 11-18). After 18 weeks, financial incentives will be stopped and the participants will be followed for an additional 8 weeks with the same step goal as the maintenance period (weeks 19-26). Participants will be given daily feedback on whether or not they achieved their daily step goal on the prior day, for the entire intervention and follow-up period. Participants will be told at the beginning of each week during the ramp-up and maintenance phases that \$14 has been placed in a virtual account for them. Each day during the week that the participant does not meet their daily step goal, \$2 will be removed from their account. Accrued winnings will be sent to the participant by check via US mail at the end of each month. There will be no financial incentive during the 2-week baseline period or the 8-week follow-up period.

5.2 Study duration

This is an 26-week study with rolling enrollment beginning in January 2016.

5.3 Target population

Adults age ≥ 18 years discharged from one of the University of Pennsylvania Health System hospitals to home after admission for acute coronary syndrome or after undergoing coronary catheterization for suspected coronary artery disease.

5.4 Accrual

The study population will be drawn from adults admitted and discharged from the inpatient cardiology services at one of the University of Pennsylvania Health System hospitals. We will aim to enroll 150 participants. We estimate that a sample size of at least 148 participants (74 per arm) will provide 80% power to detect a difference of 1000 steps in the change in mean daily step count from baseline to maintenance phase between intervention and control, using a 2-sided α of 0.05, assuming a baseline mean step count of 6000 steps in the control group with a standard deviation of 2000 steps, and accounting for a 15% dropout rate.

5.5 Key inclusion criteria

1) Age ≥ 18 years; 2) ability to read and provide informed consent to participate in the study; 3) admission to the cardiology service one of the University of Pennsylvania Health System hospitals and diagnosed with a) acute coronary syndrome (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); or b) patients having undergone coronary catheterization for suspected coronary artery disease.

5.6 Key exclusion criteria

1) Inability to provide informed consent; 2) does not have daily access to a smartphone compatible with the wearable device; 3) unable or unwilling to participate in a 26-week physical activity program 4) already enrolled in an exercise cardiac rehabilitation program prior to hospital admission; 5) hemodynamic instability or NYHA III-IV heart failure; 6) any other medical conditions that would prohibit participation in an 26-week physical activity program; 7) not being discharged to home.

6. Subject recruitment

Potentially eligible participants will be identified from the cardiology services at one of the University of Pennsylvania Health System hospitals by the study coordinator. Participants will be recruited either in person while in the hospital or by phone after discharge. Interested participants will be directed to the online Way to Health study website to review and provide informed consent, complete eligibility and baseline questionnaires, and if eligible enroll in the study.

7. Subject compensation

All participants will receive \$20 for enrolling and \$30 for completing the 26-week study. Participants that choose to attend the optional in-person visit for the six minute walk test will receive \$30 for each visit.

Participants randomized to Arm 2 (financial incentive program) will be told at the beginning of each week during the ramp-up and maintenance phases that \$14 has been placed in a virtual account. Each day that the participant does not meet their daily step goal, \$2 will be removed from their account. Accrued winnings will be sent to the participant by check via US mail at the end of each month. There will be no financial incentive during the 2-week baseline period or 8-week follow-up period.

8. Study procedures

8.1 Consent

Upon recruitment, individuals who are interested in learning more about the study will be directed to the Way to Health web portal. Upon reaching the portal, potential participants will be asked to create an account and will then be informed of the details of the study, including its objectives, duration, requirements, and financial payments. If participants are still interested in participating, the Way to Health portal will take them through an automated online informed consent. The consent document will be divided into sections and potential participants will have to click a button to advance through each section. This is to help ensure that participants read the consent form thoroughly by breaking down the form into manageable blocks of text. Each section will have a button allowing the user to contact a researcher via email or by telephone if they have questions about the consent form. Successive screens will explain the voluntary nature of the study, the risks and benefits of participation, alternatives to participation, and that participants can withdraw from the study at any time. On the final consent screen, potential participants who click a clearly delineated button stating that they agree to participate in the study will be considered to have consented to enroll. After consenting, participants will complete an online questionnaire to determine their eligibility. Eligible participants will be randomized to one of the study arms and led through an automated description of the details specific to that arm. Participants will be provided with details regarding how to contact the research team via email or phone at any time if they subsequently wish to withdraw from the study. This contact information will remain easily accessible via the participants' individual Way to Health web portal dashboards throughout the study.

8.2 Procedures

Potentially eligible participants will be identified from one of the University of Pennsylvania Health System hospitals by the study coordinator. Participants will be recruited either in person while in the hospital or by phone after discharge. Interested participants will be directed to the online Way to Health study website to review and provide informed consent, complete eligibility and baseline questionnaires, and if eligible enroll in the study.

All participants will receive a wearable device from the study coordinator and be asked to authorize the device to electronically transmit de-identified data to the study database. Participants in this arm will be told to wear the step tracking device for the next two weeks and get used to the device. They will be provided with the study coordinator's email and phone number to contact with any questions. Participants will be told that they need to sync their wearable device with their smartphone in order for data to be transmitted to the study team. Participants will receive regular reminders during the baseline period to wear and sync their devices. If the study coordinator notices that a participant is not transmitting data during this two-week baseline period, they will contact the participant to determine the reason and offer assistance on how to use the device. After the two-week baseline period is completed, a baseline step count will be calculated using the second week of step count data and ignoring days on which the individual had less than 1,000 steps. We use the second week of data rather than both weeks in case the individual has more activity during the first week simply because they got a new device. We ignore days on which less than 1,000 steps are recorded because prior research suggests that this is unlikely to be appropriate capture of physical activity (Rowe et al. *Pediatric Exercise Science*. 2004;16:1-12. Kang et al. *Measurement in Physical Education and Exercise Science*. 2004;9(4):233-250.) and including these values may inappropriately downward bias the baseline step level for that individual. If at least four days of data are not available to calculate the baseline step count, then the period will extend until at least four days of data are available.

Once a baseline step level has been determined, participants will be sent a message to log into Way to Health to receive further instructions on their arm design as described previously in section 5.1: design.

9. Analysis plan

To compare sample characteristics between arms we will use t-tests or Wilcoxon rank-sum tests (F-tests or Kruskal-Wallis test) for continuous variables and Pearson chi square tests or Fisher's exact tests for categorical variables. In our primary analyses, we will compare the change in mean daily step count from baseline to maintenance period. In secondary analyses, we will compare the change from baseline period to ramp-up and follow-up periods. We will also compare change in sleep patterns and for those that participants change in distance in the six minute walk test. All hypothesis tests will be two-sided using a two-sided alpha of 0.05 as our threshold for statistical significance. We will use Stata and/or SAS to analyze the data. We will use multiple imputation for missing data.

10. Investigators

Mitesh Patel, MD, MBA, MS is the Principal Investigator (PI) and is an Assistant Professor of Medicine and Health Care Management at the Perelman School of Medicine and The Wharton School at the University of Pennsylvania. He has past experience leading six clinical trials using the Way to Health Platform to deploy interventions using financial and social incentives to

promote weight loss and increased physical activity. He currently spends 80% of his effort on research and 20% on clinical and teaching activities.

Neel Chokshi, MD, MBA (Co-PI) is an Assistant Clinical Professor of Medicine at the Perelman School of Medicine. He is a clinical faculty member in the Consultative Cardiology Program, Echocardiography Laboratory and the Cardiac Stress Testing Laboratory at the Hospital of the University of Pennsylvania. Clinically, he is involved in improving and facilitating physical activity in cardiac patients through the development of the Exercise and Sports Cardiology program at the University of Pennsylvania. He currently spends 90% of his effort in clinical and teaching activities.

Srinath Adusumalli, MD (Co-Investigator) is a Fellow in Cardiovascular Medicine in the Department of Medicine at the Hospital of the University of Pennsylvania. He has previously led projects using technology-based solutions to improve the appropriateness of care delivered in the inpatient and outpatient settings. He currently spends 95% of his effort on clinical and teaching activities.

The Clinical Research Coordinator has experience with administering studies involving behavioral interventions and financial incentives, and also has experience training Research Assistants to follow study protocols.

11. Human research protection

11.1 Data confidentiality

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data are secure by using passwords and encryption, because the research involves web-based surveys.

11.2 Subject confidentiality

Research material will be obtained from participant surveys, from the wearable devices, and from the 6-minute walk test. All participants will provide informed consent for access to these materials. The data to be collected include demographic data (e.g., age, sex, self-identified race), outcome data, and daily activity data collected by the wearable device. Research material that is obtained will be used for research purposes only. The same procedure used for the analysis of automated data sources to ensure protection of patient information will be used for the survey data, in that patient identifiers will be used only for linkage purposes or to contact patients. The study identification number, and not other identifying information, will be used on all data collection instruments. All study staff will be reminded to appreciate the confidential nature of the data collected and contained in these databases. The Penn Medicine Academic Computing

Services (PMACS) will be the hub for the hardware and database infrastructure that will support the project and is where the Way to Health web portal is based. The PMACS is a joint effort of the University of Pennsylvania's Abramson Cancer Center, the Cardiovascular Institute, the Department of Pathology, and the Leonard Davis Institute. The PMACS provides a secure computing environment for a large volume of highly sensitive data, including clinical, genetic, socioeconomic, and financial information. Among the IT projects currently managed by PMACS are: (1) the capture and organization of complex, longitudinal clinical data via web and clinical applications portals from cancer patients enrolled in clinical trials; (2) the integration of genetic array databases and clinical data obtained from patients with cardiovascular disease; (3) computational biology and cytometry database management and analyses; (4) economic and health policy research using Medicare claims from over 40 million Medicare beneficiaries. PMACS requires all users of data or applications on PMACS servers to complete a PMACS-hosted cybersecurity awareness course annually, which stresses federal data security policies under data use agreements with the university. The curriculum includes Health Insurance Portability and Accountability Act (HIPAA) training and covers secure data transfer, passwords, computer security habits and knowledge of what constitutes misuse or inappropriate use of the server. We will implement multiple, redundant protective measures to guarantee the privacy and security of the participant data. All investigators and research staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations. All data for this project will be stored on the secure/firewalled servers of the PMACS Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by University of Pennsylvania system managers. We will use highly secure methods of data encryption for all transactions involving participants' financial information using a level of security comparable to what is used in commercial financial transactions. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy. In addition, risk of loss of confidentiality will be minimized by storing completed paper copies of the surveys and signed informed consent forms in locked file cabinets in locked offices accessible only to trained study staff. Each subject will be assigned a unique identifier without identifying information, and data will be entered into an electronic database using only the unique identifier. Only trained study staff will have access to the code that links the unique identifier to the subject's identity. Electronic data will be stored on secure, password-protected firewalled servers at the University of Pennsylvania.

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Interested participants will be directed to the Way to Health portal where they will be asked to enter data related to eligibility and their demographic characteristics. Enrollment will include a description of the voluntary nature of participation, the study procedures, risks and potential benefits in detail. The enrollment procedure will provide the opportunity for potential participants to ask questions and review the consent form information with family and friends prior to making a decision to participate. Participants will be told that they do not have to answer any questions if they do not wish and can drop out of the study at any time, without affecting their medical care or the cost of their care. They will be told that they may or may not benefit directly from the study and that all information will be kept strictly confidential, except as required by law. Subjects will be given a copy of the consent document. All efforts will be made by study staff to ensure subject privacy.

11.4 Data disclosure

The following entities, besides the members of the research team, may receive protected health information (PHI) for this research study: -Wells Fargo, the company which processes study-related payments. Patient addresses and account balances will be stored on their secure computers. -P'unk Ave., LLC, a software development company designing the Way to Health website. P'unk Ave. will not store any of the patients' PHI, but they will have access to de-identified patient information, for the purposes of website administration and development. - Misfit Wearables, the company that designs and manufactures the wearable devices used in the study to track participant physical activity. -Twilio, Inc., the company which processes some study-related messages. Twilio will store patients' phone numbers on their secure computers. - Qualtrics, Inc., the company which processes most study-related surveys. Qualtrics will house de-identified answers to these surveys on their secure servers. -The Office of Human Research Protections at the University of Pennsylvania -Federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.

11.5 Data safety and monitoring

At the time of discharge from the hospital, all patients are given anticipatory guidance on when to seek medical attention. In addition, participants will be asked to report to the study team any episodes of chest pain, shortness of breath or other changes during periods of exercise. They will be reminded of this at the end of each week of the study. They can either call the study team or send an email. The research coordinator will call the participant to collect information regarding the issue and then the PI will review and determine whether it is ok to proceed, further investigation is needed, or the participant should stop the study. If the participant happens to also enroll in a standard cardiac rehabilitation program and is told that they should be pursuing a different step count than in the study, they will be asked to report that to the study team and their study count goal may be adjusted.

11.6 Risk/benefit

11.6.1 Potential study risks

To minimize the chance for serious and unexpected adverse events, study participants will be screened through exclusion criteria for any health conditions that may be exacerbated by participating in a physical activity study. The home-based rehab program tries to motivate a gradual step count increase that should pose little health risk to participants. Participants are given guidance on when to seek medical attention and a reporting protocol is in place to capture any changes in symptoms with physical activity. Another potential risk of this study is a breach of participant confidentiality. We will minimize this risk by linking individual identifying information with participant ID numbers only in one single secure file that will only be accessed by the study team in the case of an adverse medical event, participant dropout, or if otherwise deemed necessary by the Principal Investigator. All other identifying information will be discarded after initial contact with the Study Coordinator. Due to the financial incentives in this study, we will be collecting social security numbers so that we can complete W-9 forms for participants. Social security numbers only will be used to generate W-9 forms and will be deleted once they are no longer needed. We will also collect home addresses to mail incentive payments. This will be done through a University of Pennsylvania approved partnership with Wells Fargo. Accidental disclosure of social security numbers could lead to identity theft. We will use commercial-grade encryption to protect social security information in transit. Names and addresses will be stored in encrypted databases. These data will be viewable only by the respective participants and the study coordinator. All other members of the research team will be able to view only participant ID numbers. There will be no functionality in the web application to export a dataset with identifiable information. Even the study arms will be identified by code letters until both the statistician and PI agree that analysis is complete.

11.6.2 Potential study benefits

Through participation in this study, each participant will have the potential to increase their physical activity, which could improve their health and reduce their risk for future cardiovascular disease or other conditions such as diabetes, hypertension, and osteoarthritis. If this approach is effective, it could have tremendous benefits for society if adopted on a wide scale to help individuals increase physical activity after discharge from the cardiology service. It is expected that other people will gain knowledge from this study and that participation could help understand how to effectively motivate people to become more physically active. Participants may also receive no benefit from their participation in the study.

11.6.3 Risk/benefit assessment

Anticipated risks of this study should be minimal and the risk/benefit ratio is very favorable. To minimize the chance for serious and unexpected adverse events, study participants will be screened through exclusion criteria for any health conditions that may be exacerbated by

participating in a physical activity study. Participants that increase physical activity may improve their health and reduce their risk for future cardiovascular disease or other conditions such as diabetes, hypertension, and osteoarthritis.

Final Study Protocol

**A Randomized, Controlled Trial Evaluating Methods to
Increase Physical Activity After Hospitalization for Acute
Coronary Syndrome**

Study Protocol

June 2, 2016

Outline

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11.6 Risk/benefit

11.6.1 Potential study risks

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11.6.3 Risk/benefit assessment

1. Abstract

Cardiovascular disease is the leading cause of mortality in the United States. Among patients that survive an acute myocardial infarction (AMI), cardiac rehabilitation (CR) has been demonstrated to effectively reduce risk of re-infarction, cardiac mortality, and all-cause mortality. However, despite CR being a Class I (standard of care) recommendation in multiple American Heart Association AMI guidelines, more than 80% of eligible patients do not receive appropriate CR and much of this is due to challenges in access to these programs. Recent innovations in technology allow us to passively monitor an individual's physical activity using wearable devices. Incentives designed using insights from behavioral economics have been demonstrated to motivate device engagement and behavior change. A remotely-monitored CR program could improve access for many individuals and potentially be more cost-effective because it is less resource- and personnel-intensive. The objective of this study is to use a randomized, controlled trial to test the effectiveness of a home-based, remotely monitored program using wearable devices and financial incentives to increase physical activity. Participants will go through four phases: baseline period (weeks 1-2), ramp-up period (weeks 3-10), maintenance period (weeks 11-18), and follow-up period (weeks 19-26).

2. Overall objectives

The objective of this study is to use a randomized, controlled trial to test the effectiveness of a home-based, remotely monitored program using wearable devices and financial incentives to increase physical activity

3. Aims

3.1 Primary outcome

The primary outcome variable is the change in mean daily step count from the baseline period (weeks 1-2) to the maintenance period (weeks 11-18).

3.2 Secondary outcome

Secondary outcomes include change in mean daily steps from baseline to follow-up period, change in time slept from baseline to maintenance period, change in six minute walk test from baseline to end of maintenance period (optional for participants), and healthcare utilization during the ramp-up and maintenance period as measured by number of hospitalizations and emergency department visits.

4. Background

Cardiovascular disease is the leading cause of mortality in the United States (1). Among patients that survive an acute myocardial infarction (AMI), cardiac rehabilitation (CR) has been demonstrated to effectively reduce risk of re-infarction, cardiac mortality, and all-cause mortality

(2). Patients completing CR have also been found to have improvements in blood pressure control, lipid levels, and a reduction in smoking (3).

Despite this, more than 80% of eligible patients do not receive cardiac rehabilitation (4). Access and affordability are some of the primary factors associated with the low compliance with CR (5). Since CR centers are often located in more urban areas, patients that live in more rural locations or without transportation may have difficulty reaching these centers.

Recent innovations in technology allow us to passively monitor an individual's physical activity using wearable devices (6). These devices have been demonstrated to be accurate for tracking step counts (7) and could be utilized to deploy a home-based intervention. Recently, the concept of a remotely-monitored, internet-based CR program has been shown to be safe and superior to usual care (in terms of reducing CVD risk) in a small Canadian pilot study (8). A remotely-monitored CR program would provide access for the many individuals that cannot reach a CR center and potentially, in the future, could be more cost-effective because it is less resource- and personnel-intensive. The optimal range of steps for secondary prevention of AMI is in the range of 6500-8500 steps/day (9).

[1] Murray et al, US Burden of Disease Collaborators. The State of US Health, 1990-2010. JAMA. 2013;310(6):591-608. [2] Lawler PR, Filion KB, Eisenberg MJ. Efficacy of exercise-based cardiac rehabilitation postmyocardial infarction: a systematic review and meta-analysis of randomized controlled trials. Am Heart J 2011;162:571-84.e2.[3] Taylor RS, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. Am J Med 2004;116:682-92. [4] Menezes AR, Lavie CJ, Milani RV, et al. Cardiac rehabilitation in the United States. Prog Cardiovasc Dis 2014;56:522-9. [5] Sandesara PB, Lambert CT, Gordon NF, Fletcher GF, Franklin BA, Wenger NK, et al. Cardiac rehabilitation and risk reduction. Time to "rebrand and reinvigorate." JACC. 2015;65(4):389-395. [6] Patel MS, Asch DA, Volpp KG. Wearable devices as facilitators, not drivers, of health behavior change. JAMA. 2015;313(5):459-460. [7] Case MA, Burwick HA, Volpp KG, Patel MS. The accuracy of smartphone applications and wearable devices for tracking physical activity data. JAMA. 2015;313(6):625-626. [8] Lear S, Singer J, Banner-Lukaris D, et al. Randomized Trial of a Virtual Cardiac Rehabilitation Program Delivered at a Distance via the Internet. Circ Cardiovasc Qual Outcomes. 2014;7(6):952-959 [9] Ayabe M, Brubaker PH, Dobrosielski D, Miller HS, Kiyonaga A, Shindo M, Tanaka H. Target step count for the secondary prevention of cardiovascular disease. Circ J. 2008;72(2):299-303.

5. Study design

5.1 Design

We will conduct a two-arm randomized, controlled trial comparing a control group that uses a wearable devices to track physical activity and sleep data to an intervention group that uses the same wearable devices and receives a financial incentive to adhere to a step goal program. Patients will be randomized to one of the two arms using a block size of four. To account for

possible differences in reimbursement for CR among patients with and without Medicare, we will stratify the randomization by age (less than 65 years vs. 65 years and older). Since referral to a standard health system CR program is recommended for all patients after an acute myocardial infarction, we will not attempt to modify current referral and adherence patterns to these programs. However, data suggest that more than 80% will not actually obtain this type of cardiac rehabilitation. During the study, we will ask all patients whether or not they participated in a standard cardiac rehabilitation program.

All participants will receive \$20 for enrolling and \$30 for completing the 26 week study. All participants will be given the option to have an in-person visit with the study coordinator at the beginning and after the maintenance period to conduct the six minute walk test. If a participant chooses to participate they will receive \$30 for each visit.

Participants in all arms will be informed of the CDC/federal recommendation guidelines for physical activity and receive additional interventions as follows:

Arm 1. Control: use a wearable device to track physical activity and sleep data. Receive reminders to use their device and sync their data.

Arm 2. Financial incentive-based program: Participants will be given a wearable device to monitor daily step counts and sleep patterns with automated feedback on physical activity goal attainment via text message, automated interactive voice call or email (based on participant communication choice). Based on recommendations for the optimal step count for secondary prevention of AMI, we will establish a baseline step count for each participant (weeks 1-2) and then recommend a 15 percentage point increase in daily step goal each week during the 8-week ramp-up phase (weeks 3-10) with a maximum goal of 10,000 steps. After the ramp-up phase, participants will be asked to maintain that daily step goal for the maintenance period (weeks 11-18). After 18 weeks, financial incentives will be stopped and the participants will be followed for an additional 8 weeks with the same step goal as the maintenance period (weeks 19-26). Participants will be given daily feedback on whether or not they achieved their daily step goal on the prior day, for the entire intervention and follow-up period. Participants will be told at the beginning of each week during the ramp-up and maintenance phases that \$14 has been placed in a virtual account for them. Each day during the week that the participant does not meet their daily step goal, \$2 will be removed from their account. Accrued winnings will be sent to the participant by check via US mail at the end of each month. There will be no financial incentive during the 2-week baseline period or the 8-week follow-up period.

5.2 Study duration

This is an 26-week study with rolling enrollment beginning in January 2016.

5.3 Target population

Adults age ≥ 18 years with a history of acute coronary syndrome or history of undergoing coronary catheterization for suspected coronary artery disease.

5.4 Accrual

The study population will be drawn from adults at one of the University of Pennsylvania Health System hospitals or clinics. We will aim to enroll 150 participants. We estimate that a sample size of at least 148 participants (74 per arm) will provide 80% power to detect a difference of 1000 steps in the change in mean daily step count from baseline to maintenance phase between intervention and control, using a 2-sided α of 0.05, assuming a baseline mean step count of 6000 steps in the control group with a standard deviation of 2000 steps, and accounting for a 15% dropout rate.

5.5 Key inclusion criteria

1) Age ≥ 18 years; 2) ability to read and provide informed consent to participate in the study; 3) history of a) acute coronary syndrome (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); or b) patients having undergone coronary catheterization for suspected coronary artery disease.

5.6 Key exclusion criteria

1) Inability to provide informed consent; 2) does not have daily access to a smartphone compatible with the wearable device and not willing to use a device that we can provide them; 3) unable or unwilling to participate in a 26-week physical activity program 4) already enrolled in an exercise cardiac rehabilitation program prior to hospital admission; 5) hemodynamic instability or NYHA III-IV heart failure; 6) any other medical conditions that would prohibit participation in an 26-week physical activity program; 7) if admitted and not being discharged to home.

6. Subject recruitment

Potentially eligible participants will be identified from data requests to Penn Data Store and EPIC, and from the cardiology services or clinics at one of the University of Pennsylvania Health System hospitals by the study coordinator. Participants will be recruited either in person or by phone. Interested participants will be directed to the online Way to Health study website to review and provide informed consent, complete eligibility and baseline questionnaires, and if eligible enroll in the study.

7. Subject compensation

All participants will receive \$20 for enrolling and \$30 for completing the 26-week study. Participants that choose to attend the optional in-person visit for the six minute walk test will receive \$30 for each visit.

Participants randomized to Arm 2 (financial incentive program) will be told at the beginning of each week during the ramp-up and maintenance phases that \$14 has been placed in a virtual account. Each day that the participant does not meet their daily step goal, \$2 will be removed from their account. Accrued winnings will be sent to the participant by check via US mail at the end of each month. There will be no financial incentive during the 2-week baseline period or 8-week follow-up period.

8. Study procedures

8.1 Consent

Upon recruitment, individuals who are interested in learning more about the study will be directed to the Way to Health web portal. Upon reaching the portal, potential participants will be asked to create an account and will then be informed of the details of the study, including its objectives, duration, requirements, and financial payments. If participants are still interested in participating, the Way to Health portal will take them through an automated online informed consent. The consent document will be divided into sections and potential participants will have to click a button to advance through each section. This is to help ensure that participants read the consent form thoroughly by breaking down the form into manageable blocks of text. Each section will have a button allowing the user to contact a researcher via email or by telephone if they have questions about the consent form. Successive screens will explain the voluntary nature of the study, the risks and benefits of participation, alternatives to participation, and that participants can withdraw from the study at any time. On the final consent screen, potential participants who click a clearly delineated button stating that they agree to participate in the study will be considered to have consented to enroll. After consenting, participants will complete an online questionnaire to determine their eligibility. Eligible participants will be randomized to one of the study arms and led through an automated description of the details specific to that arm. Participants will be provided with details regarding how to contact the research team via email or phone at any time if they subsequently wish to withdraw from the study. This contact information will remain easily accessible via the participants' individual Way to Health web portal dashboards throughout the study.

8.2 Procedures

Potentially eligible participants will be identified from data requests to Penn Data Store and EPIC, and from the cardiology services or clinics at one of the University of Pennsylvania Health System hospitals by the study coordinator. Participants will be recruited either in person or by phone. Interested participants will be directed to the online Way to Health study website to review and provide informed consent, complete eligibility and baseline questionnaires, and if eligible enroll in the study.

All participants will receive a wearable device from the study coordinator and be asked to authorize the device to electronically transmit de-identified data to the study database.

Participants in this arm will be told to wear the step tracking device for the next two weeks and get used to the device. They will be provided with the study coordinator's email and phone number to contact with any questions. Participants will be told that they need to sync their wearable device with their smartphone in order for data to be transmitted to the study team. Participants will receive regular reminders during the baseline period to wear and sync their devices. If the study coordinator notices that a participant is not transmitting data during this two-week baseline period, they will contact the participant to determine the reason and offer assistance on how to use the device. After the two-week baseline period is completed, a baseline step count will be calculated using the second week of step count data and ignoring days on which the individual had less than 1,000 steps. We use the second week of data rather than both weeks in case the individual has more activity during the first week simply because they got a new device. We ignore days on which less than 1,000 steps are recorded because prior research suggests that this is unlikely to be appropriate capture of physical activity (Rowe et al. *Pediatric Exercise Science*. 2004;16:1-12. Kang et al. *Measurement in Physical Education and Exercise Science*. 2004;9(4):233-250.) and including these values may inappropriately downward bias the baseline step level for that individual. If at least four days of data are not available to calculate the baseline step count, then the period will extend until at least four days of data are available.

Once a baseline step level has been determined, participants will be sent a message to log into Way to Health to receive further instructions on their arm design as described previously in section 5.1: design.

9. Analysis plan

To compare sample characteristics between arms we will use t-tests or Wilcoxon rank-sum tests (F-tests or Kruskal-Wallis test) for continuous variables and Pearson chi square tests or Fisher's exact tests for categorical variables. In our primary analyses, we will compare the change in mean daily step count from baseline to maintenance period. In secondary analyses, we will compare the change from baseline period to ramp-up and follow-up periods. We will also compare change in sleep patterns and for those that participants change in distance in the six minute walk test. All hypothesis tests will be two-sided using a two-sided alpha of 0.05 as our threshold for statistical significance. We will use Stata and/or SAS to analyze the data. We will use multiple imputation for missing data.

10. Investigators

Mitesh Patel, MD, MBA, MS is the Principal Investigator (PI) and is an Assistant Professor of Medicine and Health Care Management at the Perelman School of Medicine and The Wharton School at the University of Pennsylvania. He has past experience leading six clinical trials using the Way to Health Platform to deploy interventions using financial and social incentives to promote weight loss and increased physical activity. He currently spends 80% of his effort on research and 20% on clinical and teaching activities.

Neel Chokshi, MD, MBA (Co-PI) is an Assistant Clinical Professor of Medicine at the Perelman School of Medicine. He is a clinical faculty member in the Consultative Cardiology Program, Echocardiography Laboratory and the Cardiac Stress Testing Laboratory at the Hospital of the University of Pennsylvania. Clinically, he is involved in improving and facilitating physical activity in cardiac patients through the development of the Exercise and Sports Cardiology program at the University of Pennsylvania. He currently spends 90% of his effort in clinical and teaching activities.

Srinath Adusumalli, MD (Co-Investigator) is a Fellow in Cardiovascular Medicine in the Department of Medicine at the Hospital of the University of Pennsylvania. He has previously led projects using technology-based solutions to improve the appropriateness of care delivered in the inpatient and outpatient settings. He currently spends 95% of his effort on clinical and teaching activities.

The Clinical Research Coordinator has experience with administering studies involving behavioral interventions and financial incentives, and also has experience training Research Assistants to follow study protocols.

11. Human research protection

11.1 Data confidentiality

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data are secure by using passwords and encryption, because the research involves web-based surveys.

11.2 Subject confidentiality

Research material will be obtained from participant surveys, from the wearable devices, and from the 6-minute walk test. All participants will provide informed consent for access to these materials. The data to be collected include demographic data (e.g., age, sex, self-identified race), outcome data, and daily activity data collected by the wearable device. Research material that is obtained will be used for research purposes only. The same procedure used for the analysis of automated data sources to ensure protection of patient information will be used for the survey data, in that patient identifiers will be used only for linkage purposes or to contact patients. The study identification number, and not other identifying information, will be used on all data collection instruments. All study staff will be reminded to appreciate the confidential nature of the data collected and contained in these databases. The Penn Medicine Academic Computing Services (PMACS) will be the hub for the hardware and database infrastructure that will support the project and is where the Way to Health web portal is based. The PMACS is a joint effort of the University of Pennsylvania's Abramson Cancer Center, the Cardiovascular Institute, the

Department of Pathology, and the Leonard Davis Institute. The PMACS provides a secure computing environment for a large volume of highly sensitive data, including clinical, genetic, socioeconomic, and financial information. Among the IT projects currently managed by PMACS are: (1) the capture and organization of complex, longitudinal clinical data via web and clinical applications portals from cancer patients enrolled in clinical trials; (2) the integration of genetic array databases and clinical data obtained from patients with cardiovascular disease; (3) computational biology and cytometry database management and analyses; (4) economic and health policy research using Medicare claims from over 40 million Medicare beneficiaries. PMACS requires all users of data or applications on PMACS servers to complete a PMACS-hosted cybersecurity awareness course annually, which stresses federal data security policies under data use agreements with the university. The curriculum includes Health Insurance Portability and Accountability Act (HIPAA) training and covers secure data transfer, passwords, computer security habits and knowledge of what constitutes misuse or inappropriate use of the server. We will implement multiple, redundant protective measures to guarantee the privacy and security of the participant data. All investigators and research staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations. All data for this project will be stored on the secure/firewalled servers of the PMACS Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by University of Pennsylvania system managers. We will use highly secure methods of data encryption for all transactions involving participants' financial information using a level of security comparable to what is used in commercial financial transactions. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy. In addition, risk of loss of confidentiality will be minimized by storing completed paper copies of the surveys and signed informed consent forms in locked file cabinets in locked offices accessible only to trained study staff. Each subject will be assigned a unique identifier without identifying information, and data will be entered into an electronic database using only the unique identifier. Only trained study staff will have access to the code that links the unique identifier to the subject's identity. Electronic data will be stored on secure, password-protected firewalled servers at the University of Pennsylvania.

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participants to ask questions and review the consent form information with family and friends prior to making a decision to participate. Participants will be told that they do not have to answer any questions if they do not wish and can drop out of the study at any time, without affecting their medical care or the cost of their care. They will be told that they may or may not benefit directly from the study and that all information will be kept strictly confidential, except as required by law. Subjects will be given a copy of the consent document. All efforts will be made by study staff to ensure subject privacy.

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11.5 Data safety and monitoring

At the time of discharge from the hospital, all patients are given anticipatory guidance on when to seek medical attention. In addition, participants will be asked to report to the study team any episodes of chest pain, shortness of breath or other changes during periods of exercise. They will be reminded of this at the end of each week of the study. They can either call the study team or send an email. The research coordinator will call the participant to collect information regarding the issue and then the PI will review and determine whether it is ok to proceed, further investigation is needed, or the participant should stop the study. If the participant happens to also enroll in a standard cardiac rehabilitation program and is told that they should be pursuing a different step count than in the study, they will be asked to report that to the study team and their study count goal may be adjusted.

11.6 Risk/benefit

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To minimize the chance for serious and unexpected adverse events, study participants will be screened through exclusion criteria for any health conditions that may be exacerbated by participating in a physical activity study. The home-based rehab program tries to motivate a gradual step count increase that should pose little health risk to participants. Participants are given guidance on when to seek medical attention and a reporting protocol is in place to capture any changes in symptoms with physical activity. Another potential risk of this study is a breach of participant confidentiality. We will minimize this risk by linking individual identifying information with participant ID numbers only in one single secure file that will only be accessed by the study team in the case of an adverse medical event, participant dropout, or if otherwise deemed necessary by the Principal Investigator. All other identifying information will be discarded after initial contact with the Study Coordinator. Due to the financial incentives in this study, we will be collecting social security numbers so that we can complete W-9 forms for participants. Social security numbers only will be used to generate W-9 forms and will be deleted once they are no longer needed. We will also collect home addresses to mail incentive payments. This will be done through a University of Pennsylvania approved partnership with Wells Fargo. Accidental disclosure of social security numbers could lead to identity theft. We will use commercial-grade encryption to protect social security information in transit. Names and addresses will be stored in encrypted databases. These data will be viewable only by the respective participants and the study coordinator. All other members of the research team will be able to view only participant ID numbers. There will be no functionality in the web application to export a dataset with identifiable information. Even the study arms will be identified by code letters until both the statistician and PI agree that analysis is complete.

11.6.2 Potential study benefits

Through participation in this study, each participant will have the potential to increase their physical activity, which could improve their health and reduce their risk for future cardiovascular disease or other conditions such as diabetes, hypertension, and osteoarthritis. If this approach is effective, it could have tremendous benefits for society if adopted on a wide scale to help individuals increase physical activity after discharge from the cardiology service. It is expected that other people will gain knowledge from this study and that participation could help understand how to effectively motivate people to become more physically active. Participants may also receive no benefit from their participation in the study.

11.6.3 Risk/benefit assessment

Anticipated risks of this study should be minimal and the risk/benefit ratio is very favorable. To minimize the chance for serious and unexpected adverse events, study participants will be screened through exclusion criteria for any health conditions that may be exacerbated by participating in a physical activity study. Participants that increase physical activity may improve their health and reduce their risk for future cardiovascular disease or other conditions such as diabetes, hypertension, and osteoarthritis.

Table S1. Missing data rates by arm and study period.

	Ramp-up (Weeks 1-8)	Maintenance (Weeks 9-16)	Follow-up (Weeks 17-24)
Control arm			
Missing data	422/3080 (13.7%)	1189/3080 (38.6%)	1504/3080 (48.8%)
Step values < 1000	51/3080 (1.7%)	42/3080 (1.4%)	39/3080 (1.3%)
Total	473/3080 (15.4%)	1231/3080 (40.0%)	1543/3080 (50.1%)
Incentive arm			
Missing data	311/2800 (11.1%)	616/2800 (22.0%)	1060/2800 (37.9%)
Step values < 1000	14/2800 (0.5%)	53/2800 (1.9%)	25/2800 (0.9%)
Total	325/2800 (11.6%)	669/2800 (23.9%)	1085/2800 (38.8%)

Data is presented at the patient-day level. For example, in the control arm there were 55 patients in an 8-week ramp-up period. So 55 patients x 8 weeks x 7 days/per week = 3080 patient-days for that period.

Table S2. Physical activity outcomes using only collected data without multiple imputation.

Original Data Including Step Values Less than 1000	Baseline	Ramp-up (Weeks 1-8)	Maintenance (Weeks 9-16)	Follow-up (Weeks 17-24)
Steps Per Day, Mean (SD)				
Control arm	6577 (3084)	6820 (3521)	6698 (3679)	6646 (3890)
Incentive arm	7205 (3246)	8423 (3400)	8724 (3444)	8017 (3959)
Main Model				
Difference adjusted for baseline (95% CI)	-	1069 (340, 1798)	1543 (526, 2561)	994 (-372, 2360)
<i>P</i> value	-	<.01	<.01	0.15
Fully Adjusted Model				
Difference adjusted for baseline (95% CI)	-	613 (-223, 1449)	1370 (162, 2577)	853 (-856, 2562)
<i>P</i> value	-	0.15	0.03	0.33

Abbreviations: SD, standard deviation; CI, confidence interval

Table S3. Physical activity outcomes using only collected data without multiple imputation but excluding step values less than 1000.

Original Data Excluding Step Values Less than 1000	Baseline	Ramp-up (Weeks 1-8)	Maintenance (Weeks 9-16)	Follow-up (Weeks 17-24)
Steps Per Day, Mean (SD)				
Control arm	6577 (3084)	7056 (3436)	7016 (3617)	7115 (3605)
Incentive arm	7205 (3246)	8564 (3275)	8945 (3262)	8425 (3524)
Main Model				
Difference adjusted for baseline (95% CI)	-	988 (289, 1688)	1407 (488, 2327)	965 (-208, 2139)
<i>P</i> value	-	<.01	<.01	0.11
Fully Adjusted Model				
Difference adjusted for baseline (95% CI)	-	608 (-197, 1414)	1216 (101, 2332)	859 (-716, 2434)
<i>P</i> value	-	0.14	0.03	0.29

Abbreviations: SD, standard deviation; CI, confidence interval

Table S4. Physical activity outcomes for patients that had their last cardiac catheterization within the 90 days prior to enrolling in the study.

Imputed data for patients with cardiac catheterization within 90 days prior to study enrollment	Baseline	Ramp-up (Weeks 1-8)	Maintenance (Weeks 9-16)	Follow-up (Weeks 17-24)
Steps Per Day, Mean (SD)				
Control arm	5979 (2787)	6255 (2753)	6122 (2431)	5983 (2360)
Incentive arm	6707 (3167)	8037 (3247)	8152 (3060)	7932 (3142)
Main Model				
Difference adjusted for baseline (95% CI)	-	1131 (466, 1797)	1509 (720, 2297)	1455 (557, 2354)
<i>P</i> value	-	<.001	<.001	<.001
Fully Adjusted Model				
Difference adjusted for baseline (95% CI)	-	854 (80, 1628)	1469 (610, 2328)	1561 (745, 2376)
<i>P</i> value	-	0.03	<.001	<.001

Abbreviations: SD, standard deviation; CI, confidence interval

Table S5. Patients' self-reported health care utilization during the 16-week intervention period.

		Patients Reporting Health Care Utilization During 16-Week Intervention Period, No. (%)				
Arm	Response	Clinic Visit with Cardiologist	Emergency Room Visit	Hospital Admission	Cardiac Catheterization	Participated in Formal Cardiac Rehabilitation Program
Control Arm	0	10/37 (27.0)	27/37 (73.0)	28/37 (75.7)	32/37 (86.5)	34/37 (91.9)
	1	8/37 (21.6)	6/37 (16.2)	6/37 (16.2)	5/37 (13.5)	3/37 (8.1)
	2	13/37 (35.1)	4/37 (10.8)	2/37 (5.4)	0/0 (0.0)	NA
	3+	6/37 (16.2)	0/37 (0.0)	1/37 (2.7)	0/0 (0.0)	NA
Incentive Arm	0	3/40 (7.5)	32/40 (80.0)	34/40 (85.0)	37/40 (92.5)	35/40 (87.5)
	1	24/40 (31.2)	6/40 (15.0)	6/40 (15.0)	2/40 (5.0)	5/40 (12.5)
	2	11/40 (27.5)	1/40 (2.5)	0/0 (0.0)	0/0 (0.0)	NA
	3+	2/40 (5.0)	1/40 (2.5)	0/0 (0.0)	1/40 (2.5)	NA

Table S6. Patients' self-reported health care utilization during the 8-week follow-up period.

		Patients Reporting Health Care Utilization During 8-Week Follow-Up Period, No. (%)				
Arm	Response	Clinic Visit with Cardiologist	Emergency Room Visit	Hospital Admission	Cardiac Catheterization	Participated in Formal Cardiac Rehabilitation Program
Control Arm	0	9/34 (26.5)	31/34 (91.2)	30/34 (88.2)	34/34 (100.0)	30/34 (88.2)
	1	21/34 (61.8)	2/34 (5.9)	2/34 (5.9)	0/0 (0.0)	4/34 (11/8)
	2	2/34 (5.9)	1/34 (2.9)	2/34 (5.9)	0/0 (0.0)	NA
	3+	2/34 (5.9)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	NA
Incentive Arm	0	17/37 (46.0)	32/37 (86.5)	33/37 (89.2)	35/37 (94.6)	35/37 (94.6)
	1	17/37 (46.0)	3/37 (8.1)	4/37 (10.8)	2/37 (5.4)	2/37 (5.4)
	2	3/37 (8.1)	2/37 (5.4)	0/0 (0.0)	0/0 (0.0)	NA
	3+	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	NA

Table S7. Patients’ perceptions of the study and wearable device.

Arm	Response	I enjoyed participating in this study	This exercise program was manageable	This study has helped increase my physical activity	This study has helped to improve my cardiac health	I was satisfied with my experience using the Way to Health Platform online	After the study is complete, I will continue to use the activity monitoring device
Control Arm	Strongly agree	62.2%	NA	43.2%	52.9%	29.7%	2.9%
	Agree	35.1%	NA	37.8%	35.3%	43.2%	2.9%
	Neutral	0.0%	NA	13.5%	8.8%	27.0%	11.8%
	Disagree	2.7%	NA	5.4%	0.0%	0.0%	29.4%
	Strongly disagree	0.0%	NA	0.0%	2.9%	0.0%	59.9%
Incentive Arm	Strongly agree	52.5%	67.5%	67.5%	46.0%	32.5%	59.5%
	Agree	27.5%	12.5%	12.5%	37.8%	47.5%	24.3%
	Neutral	12.5%	17.5%	17.5%	13.5%	15.0%	8.1%
	Disagree	2.5%	2.5%	2.5%	0.0%	2.5%	8.1%
	Strongly disagree	0.0%	0.0%	0.0%	2.7%	2.5%	0.0%