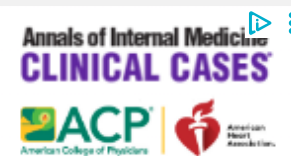




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Loss-Framed Financial Incentives and Personalized Goal-Setting to Increase Physical Activity Among Ischemic Heart Disease Patients Using Wearable Devices: The ACTIVE REWARD Randomized Trial

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Abstract

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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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.

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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.

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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?

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Providing only wearable devices to ischemic heart disease patients is unlikely to lead to significant changes in physical activity.

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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.

Ischemic heart disease (IHD) is the leading cause of morbidity and mortality in the United States.¹ Regular physical activity reduces the risk of cardiovascular events among patients with IHD.¹ For example, participation in exercise-based cardiac rehabilitation has been demonstrated to reduce mortality by up to 30%.⁴ However, the majority of eligible patients do not participate in a cardiac rehabilitation program.⁸ Recent evidence also suggests that IHD 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 However, thus far there is limited evidence of interventions that use these devices to effectively sustain behavior change among high-risk patients.¹³ Our previous work found that financial incentive-based approaches that use mobile technologies can be effective in increasing physical activity,¹⁷ 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 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 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 Patients selected whether to receive study communications by

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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 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 favor immediate over delayed gratification,²⁹ try to avoid the feeling of regret,³⁰ 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

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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 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 work¹⁷ and in this study because evidence indicates that step values less than 1000 may not represent accurate data capture.²⁶ 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 ($P=0.32$).

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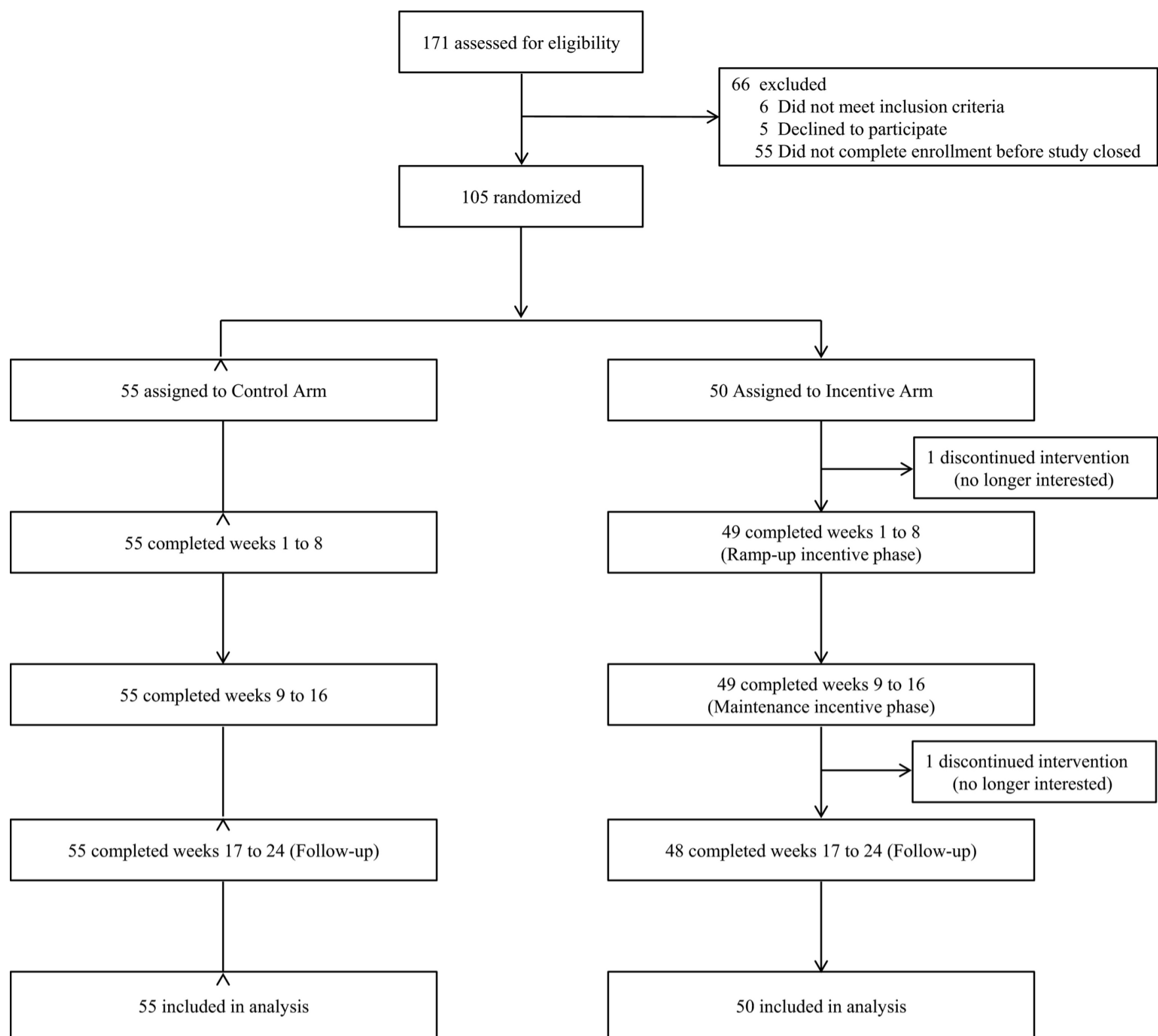


Figure 1 CONSORT diagram. Both arms used a wearable device to track daily steps. Patients in control received no other interventions. Patients in the incentive arm received a personalized step goal and daily feedback for 24 weeks. During the first 16 weeks, patients in the incentive arm also received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

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)	

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Characteristic	Control Arm (n=55)	Incentive Arm (n=50)	P Value
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.			

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](#)).

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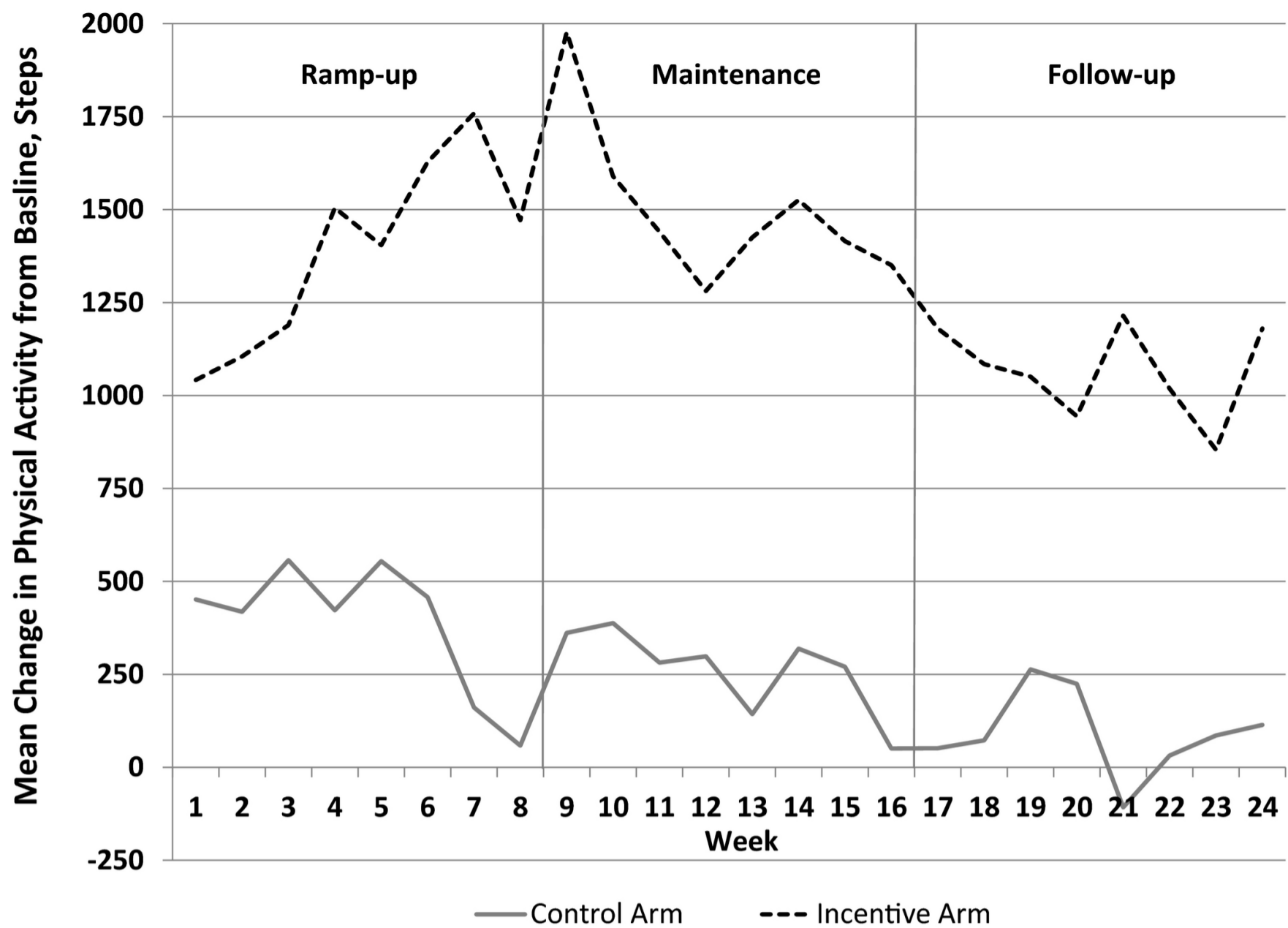


Figure 2 Central illustration, Unadjusted mean change in daily steps from baseline by study arm and week. Data presented are the difference between mean daily steps and mean baseline steps by week for each arm. Gray solid line represents patients in the control arm. Black dashed line represents patients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

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).

	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

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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.

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](#)).

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 Most previous financial incentive-based physical activity interventions have used gain-framed incentives¹⁶—individuals earn a reward after the 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 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 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 Although our intervention does not substitute for cardiac rehabilitation, it

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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

File (jah33227-sup-0001-supinfo.pdf)

Data S1. Study Protocol.

Table S1. Missing Data Rates by Arm and Study Period

Table S2. Physical Activity Outcomes Using Only Collected Data Without Multiple Imputation

Table S3. Physical Activity Outcomes Using Only Collected Data Without Multiple Imputation but Excluding Step Values Less Than 1000

Table S4. Physical Activity Outcomes for Patients That Had Their Last Cardiac Catheterization Within the 90 Days Preceding Enrolling in the Study

Table S5. Patients' Self-Reported Healthcare Utilization During the 16-Week Intervention Period

Table S6. Patients' Self-Reported Healthcare Utilization During the 8-Week Follow-up Period

Table S7. Patients' Perceptions of the Study and Wearable Device

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