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RESEARCH ARTICLE | Originally Publ

Loss-Framed … Personalized … Physical Activity Amo… …e Patients Using Weara… …REWARD Randomized …

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Journal of the American Heart Associatio…

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.

Clinical Perspective

What Is New?

- Despite the many benefit … tients do not participate in exercise-ba … on their own.
- We evaluated a scalable … disease patients by using insights … d goal setting to address predictable ba … remotely monitor behaviors.
- The combination of loss- … nificantly increased physical activit

What Are the Clinical Im

- Providing only wearable … to significant changes in physical activ
- Combining approaches b … can be used to deploy home-based in … ic heart disease patients.

Ischemic heart disease (IHD … United States.[1] Regular physical activity red … 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

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 he ected whether
to receive study communica ing, or a
combination of these. Eligib Misfit Shine)
and authorized access for th onstrated that
these types of devices accu

All patients received $20 for ek trial, and
were allowed to keep the we mailed a bank
check at the end of each mo

Study Sample

Recruitment occurred from I g 4 hospitals in
southeastern Pennsylvania: yterian Medical
Center, Chester County Hos ed patients
eligible for, but not yet enrol patients with a
recent cardiac catheterizatio vere contacted
by telephone or during card ipate if they
were aged ≥18 years, had a non–ST-
segment–elevation myocard rction), 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

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: Ind ns,[18] favor
immediate over delayed gra d to be more
driven for aspirational beha of the week
(the fresh start effect).[34]

After the 16-week interventi e asked to
complete self-reported surv ehabilitation,
cardiac catherization, cardic lmission) and
perceptions of the overall st

Outcome Measures

The primary outcome was c nance incentive
phase. Secondary outcome ramp-up
incentive phase and follow-

Statistical Analysis

Power calculations (a priori) ne mean step
count of 6000 steps in the c rate, and a 2-
sided α of 0.05. It was estim 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] 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] 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, 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 Ir … tistical Computing).

Results

In this trial, 105 patients witl … (SD) age of 60 (11) years, 70% were male, a … iac catheterization. Baseline pa … dy arms (Table [1]). Baseline mean dail … , 3246) in the incentive arm, which was nc

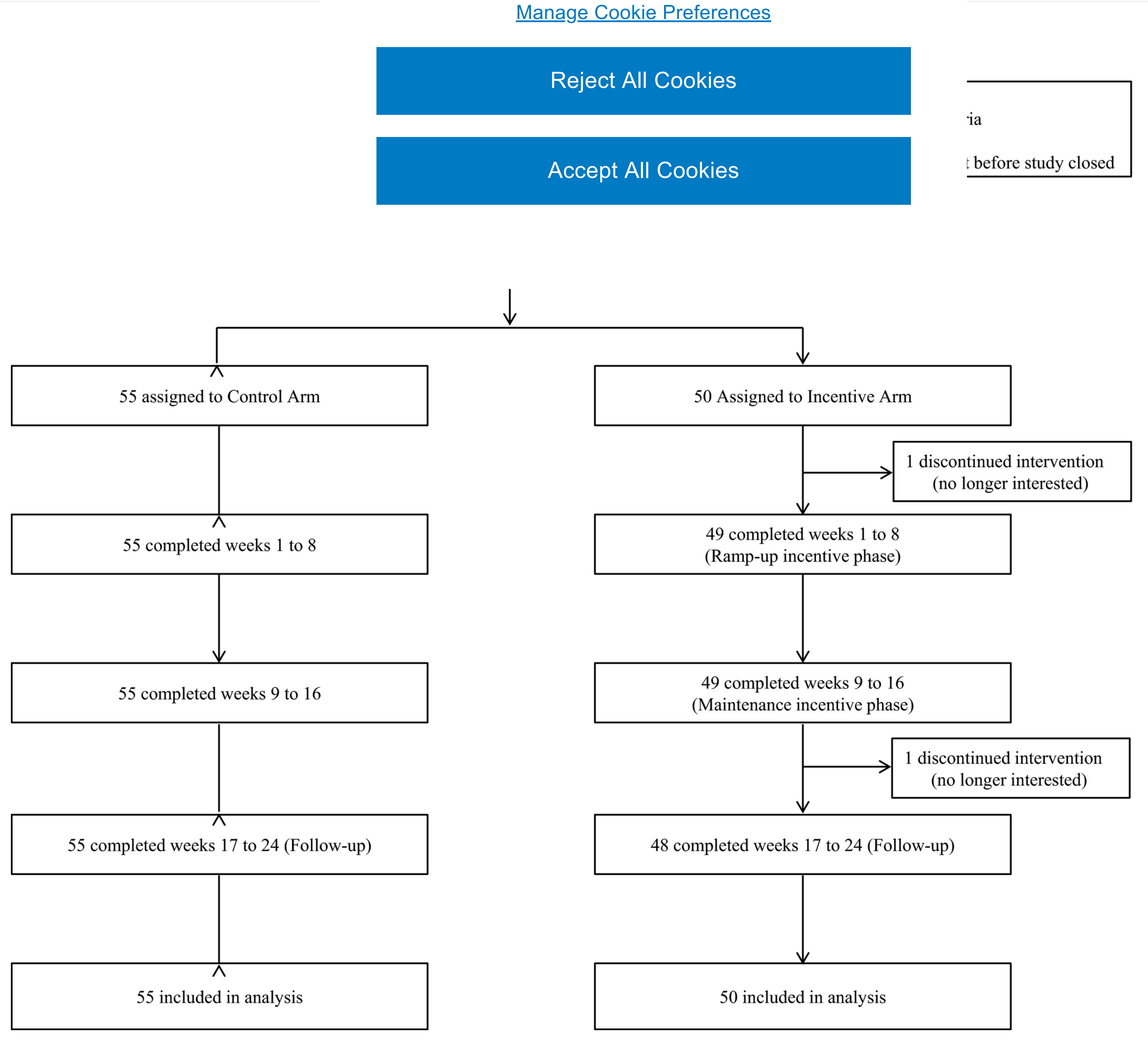

Figure 1 CONSORT diagram. Both arms used a wearable device to track daily steps. Patients in control received no other interventions. Patients in the incentive arm received a personalized step goal and daily feedback for 24 weeks. During the first 16 weeks, patients in the incentive arm also received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

Characteristic	Control Arm (n=55)	Incentive Arm (n=50)	*P* Value
Race/ethnicity, no. (%)			0.46

EXPAND TABLE

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

One hundred three patients … maintenance period, 22.0% of observatio… n 1000. In the control arm, these rates wer… step counts less than 1000 (Table S1).

In the control arm, the unad… near 500 during the first 6 weeks, but … (Figure 2). In the incentive arm, the unadj… above 1000 in week 1 and increased durin… ange in daily steps from baseline remaine… ghtly declined in the follow-up period rangi…

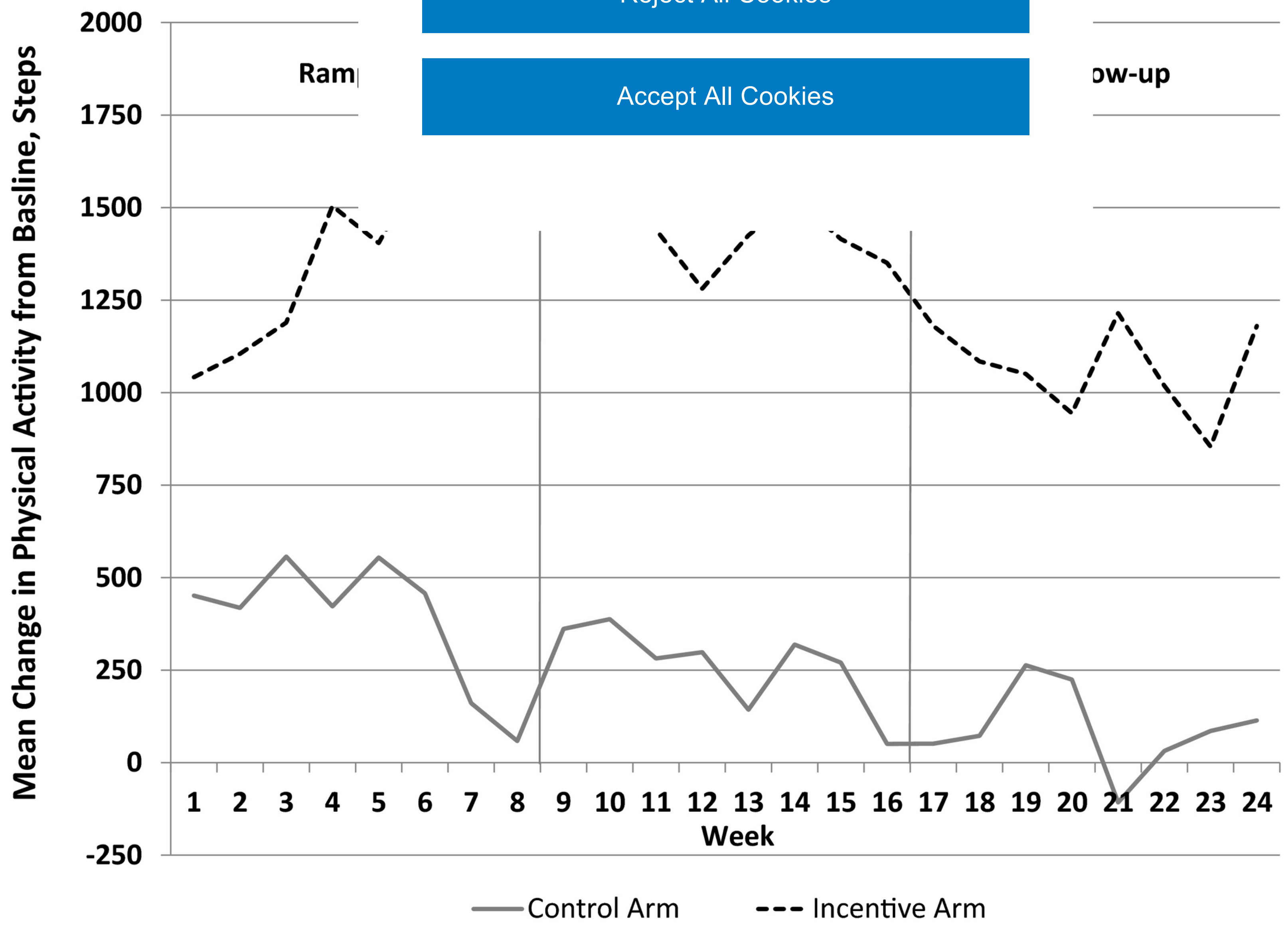

Figure 2 Central illustration, Unadjusted mean change in daily steps from baseline by study arm and week. Data presented are the difference between mean daily steps and mean baseline steps by week for each arm. Gray solid line represents patients in the control arm. Black dashed line represents patients 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	[illegible]	[illegible]	[illegible]	[illegible]271 (3003)
Main model	[illegible]	[illegible]	[illegible]	[illegible]

Models compare the incentive arr … ıs command. Main model adjusts for baseline s … djusted model also added the following covariat … ne, body mass index, days since last cardiac cat … llitus, hypertension, hyperlipidemia, sm…

Seventy-eight patients (74.3 … atheterization within the 90 days precedin … oup found that compared with control, patie … rease in mean daily steps from baseline du … 31 [95% CI, 466–1797]; *P*<0.001), mainte … 5% CI, 720–2297]; *P*<0.001), and follow- … 745–2376]; *P*<0.001; Table S4).

No adverse events were rep … 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 incentives[16]—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.

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 tc … se per week) and personalized these goal … ch mirrors that of cardiac rehabilitation prog … ate versus gradually increasing step gc … reases.

Third, this trial used a home … scaled more broadly by leveraging techn … ia for cardiac rehabilitation, but only 7.6% … ne intervention. Nationally, cardiac rehabilita … tervention does not substitute for cardiac re … physical activity in patients who are … e studies could build upon this approach to … c rehabilitation program.

Our study is subject to seve … southeastern Pennsylvania and needed ac … alizability. Second, we evaluated physi … other measures of physical activit … er, step counts are most commonly displaye … ed in interventions with small imp… 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 M

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Data S1. Study Protocol.

Table S1. Missing Data Rates by

Table S2. Physical Activity Outc

Table S3. Physical Activity Outc but Excluding Step Values Less Than 1000

Table S4. Physical Activity Outc on Within the 90 Days Preceding Enrolling in the

Table S5. Patients' Self-Reporte iod

Table S6. Patients' Self-Reporte

Table S7. Patients' Perceptions

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