A randomized controlled trial of gamification to increase physical activity among black and Hispanic breast and prostate cancer survivors: Rationale and design of the ALLSTAR clinical trial

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ABSTRACT

Background Survivors of breast and prostate cancer, especially those that are Black and/or Hispanic, are at high risk for cardiovascular events. Physical activity can reduce the risk of cardiovascular events in cancer survivors, but Black and Hispanic people are less likely to engage in routine physical activity. Concepts from behavioral economics have been used to design scalable, low-touch gamification interventions that increase physical activity in individuals at high risk for cardiovascular events, but the effectiveness of these strategies in Black and Hispanic survivors of breast and prostate cancer is uncertain.

Study Design and Objectives ALLSTAR (NCT05176756) is a pragmatic, virtual randomized controlled trial designed to evaluate the effectiveness of a gamification intervention informed by behavioral economic concepts to increase daily physical activity in Black and Hispanic breast and prostate cancer survivors who received cardiotoxic therapies and have additional risk factors for cardiovascular disease. Patients are either referred by their cancer care team or identified by electronic health record searches; contacted by letter, email, text message and/or phone; and complete enrollment and informed consent on the Penn Way to Health online platform. Patients are then provided with a wearable fitness tracker, establish a baseline daily step count, set a goal to increase daily step count by 1,500-3,000 steps from baseline, and are randomized 1:1 to control or gamification. Interventions continue for 6 months, with follow-up for an additional 3 months to evaluate the durability of behavior change. The trial has met its enrollment goal of 150 participants, with a primary endpoint of change from baseline in daily steps over the 6-month intervention period. Key secondary endpoints include change from baseline in daily steps over the 3-month post-intervention follow-up period, change in moderate to vigorous physical activity over the intervention and follow-up periods, and change in patient-reported measures of physical function, fatigue, and overall quality of life.

Conclusions ALLSTAR is a virtual, pragmatic randomized clinical trial powered to demonstrate whether gamification is superior to control in increasing physical activity in Black and Hispanic breast and prostate cancer survivors. Its results will have important implications for strategies to promote physical activity in survivors of breast and prostate cancer, specifically among minority populations.

Clinical Trial Registration clinicaltrials.gov; https://clinicaltrials.gov/study/NCT05176756 (Am Heart J 2025;280:42–51.)

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Background

Improvements in cancer treatment strategies have resulted in a growing number of long-term survivors who are expected to live well-beyond their cancer diagnosis.[1] In these survivors, the burden of *de novo* cardiovascular disease is substantial, impacting both the quality and quantity of survival.[2-9] Survivors of breast and prostate cancer, the most common noncutaneous cancers, may be at especially high risk of cardiovascular disease due to treatments that increase downstream risk of cardiovascular disease.[7,10-12] In observational studies of cancer survivors, patients who are physically active after cancer diagnosis have lower risks of cardiovascular and noncardiovascular death than sedentary patients,[13-17] and there are inverse dose-dependent associations between physical activity levels and the risk of major adverse cardiovascular events and cancer mortality.[18-21] In addition, higher physical activity levels have been demonstrated to improve cardiorespiratory fitness, physical function, fatigue and overall health-related quality of life.[9,22-25] However, the majority of breast and prostate cancer survivors are less physically active than recommended by consensus guidelines.[26,27]

Compared with non-Hispanic White cancer survivors, Black and Hispanic cancer survivors have significantly higher risk of cardiovascular mortality[28-30] and are more likely to report greater physical function limitations, emotional distress and poor health-related quality life.[31-35] Moreover, they are even more likely to be physically inactive than non-Hispanic white cancer survivors.[26,36-38]

As with many health-related behaviors, increasing individuals' physical activity has been challenging for a number of reasons. Behavioral economics is a scientific field of inquiry that uses principles from economics and psychology to understand and influence how individuals make decisions. Behavioral economists have demonstrated that people commonly make certain decision errors, leading to the concept of "bounded rationality."[39] For example, individuals are more motivated by immediate rather than delayed gratification, by losses rather than gains, and by the desire to avoid feelings of regret.[40,41] These insights can be leveraged to design interventions that effectively promote healthy behaviors. For example, rewards can be framed as losses when a goal is not achieved as opposed to gains following achievement of a goal, and individuals can be informed of what they would have received had they accomplished their goals.

In prior studies, a gamification intervention based on behavioral economic concepts substantially increased physical activity more than controls in patients without cancer but who had or were at risk for cardiovascular disease.[42-44] However, Black and Hispanic breast and prostate cancer survivors may face unique barriers to engaging in physical activity, including reduced levels of fitness, stamina, and strength related to prolonged inactivity during cancer treatment and the toxic effects of chemotherapy; the psychosocial stresses of cancer diagnosis, treatment, and recovery; and individual (eg economic resources) and structural (eg access to physical fitness facilities) social determinants of health.

We therefore designed the Randomized Controlled Trial of Strategies to Augment Physical Activity in Black and Hispanic Breast and Prostate Cancer Survivors (ALLSTAR) to test the effectiveness of behaviorally-designed gamification, compared with control, to increase physical activity over a 6-month intervention period and 3-month follow-up period in 150 Black or Hispanic breast and prostate cancer survivors at increased risk for cardiovascular disease (Figure 1).

Methods

ALLSTAR is funded by a grant from the American Heart Association to the University of Pennsylvania and is registered at clinicaltrials.gov (NCT05176756). The study protocol was approved by the University of Pennsylvania Institutional Review Board.

Study population

Black and Hispanic survivors of breast or prostate cancer who received cardiotoxic treatment for their cancer and are at an increased risk for cardiovascular disease are eligible for enrollment in ALLSTAR. Specific inclusion and exclusion criteria are presented in Table 1. Participants are recruited from oncology and cardio-oncology practices affiliated with the University of Pennsylvania Health System (UPHS), located in southeastern Pennsylvania and New Jersey, and City of Hope (COH) Comprehensive Cancer Center, located in Southern California.

Potentially eligible patients are identified in several ways: (1) using data from the electronic health record (EHR) and the health systems' clinical data warehouse; (2) from an ongoing UPHS registry of patients with breast cancer at elevated cardiovascular risk; (3) screening weekly lists of patients scheduled to be seen in breast and prostate cancer survivorship clinics; (4) by direct, in-person approach in selected breast and prostate cancer clinics; and (5) by direct referral from advanced practice providers and physicians in oncology and cardio-oncology clinics. When patients are identified by screening weekly lists of patients to be seen in survivorship clinics, the study team sends an email to their clinician asking them to briefly introduce the study to the patient, if they feel the patient's participation in the study is appropriate.

Study procedures

After potentially eligible patients are identified, they are directly contacted by email or letter, followed by a text message and a phone call from study staff. The email or letter introduces the study and provides a link

Figure 1. Summary of the design of the ALLSTAR trial. Black and Hispanic breast and prostate cancer survivors at increased risk for cardiovascular events are eligible for enrollment into ALLSTAR. Patients complete informed consent and baseline questionnaires on the Penn Way to Health platform and are mailed a Fitbit wearable fitness tracker. They wear the fitness tracker for 2 weeks to establish a baseline step count, and patients with baseline step count >7,500 are excluded. The remaining patients set a goal to increase step count by 33%-50% above baseline and are then randomized to attention control or gamification.

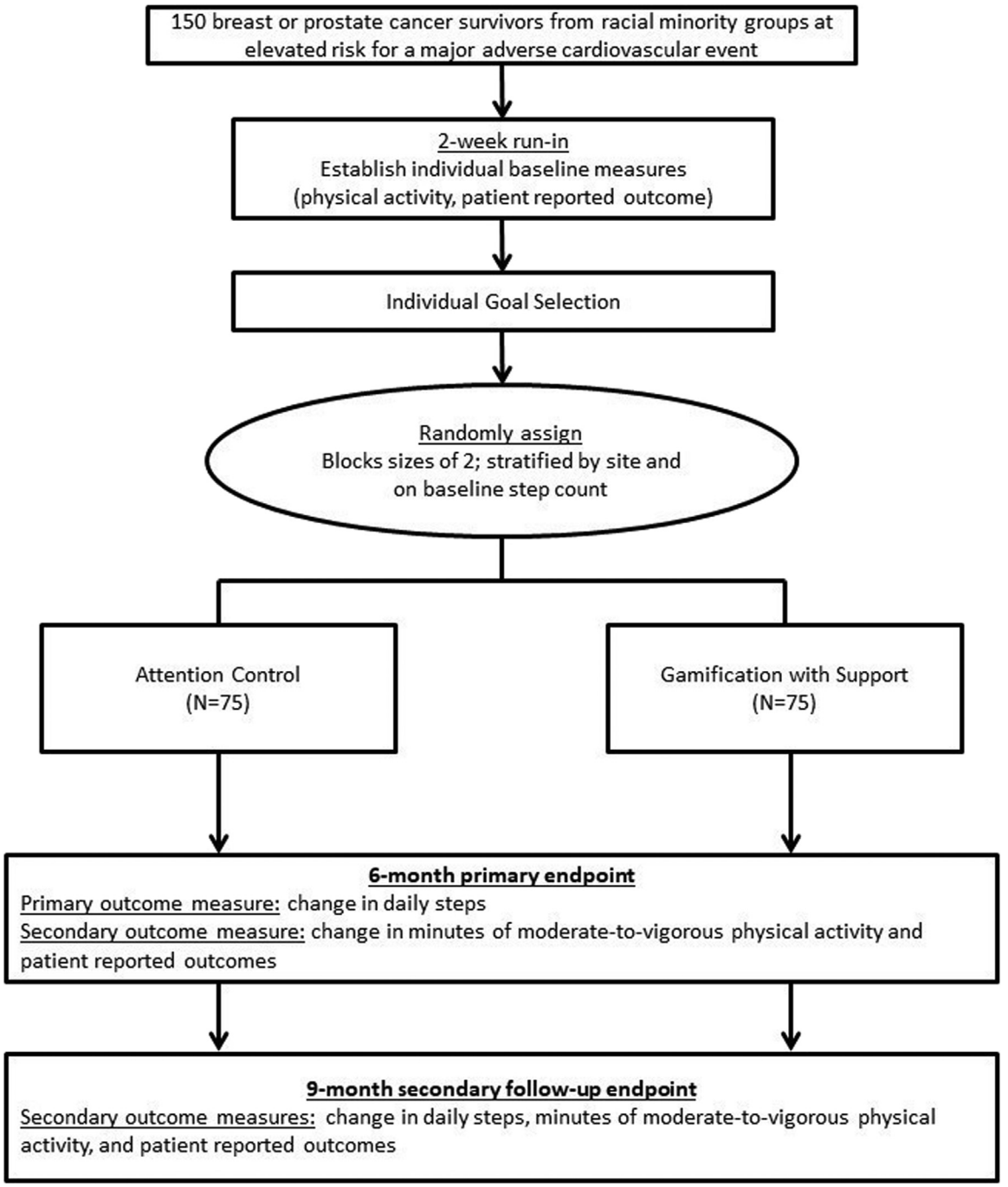

Table 1. Inclusion and exclusion criteria

Inclusion criteria
1. >18 years old
2. Self-identify as Black or Hispanic
3. Diagnosed with breast or prostate cancer ≥2 years prior
4. Treated with cardiotoxic therapies for cancer
– Anthracyclines, chest radiation, trastuzumab, aromatase inhibitors, androgen deprivation therapy
5. At least one risk factor for cardiovascular disease
– Hypertension, diabetes, dyslipidemia, obesity, age ≥65 years
6. Own a smartphone or tablet compatible with the wearable fitness tracker
7. Able to read English or Spanish
8. Able to provide informed consent
Exclusion criteria
1. Active malignancy or ongoing treatment with chemotherapy
– Individuals on long-term suppressive therapy with aromatase inhibitors or androgen deprivation therapy are permitted to enroll
2. Currently participating in another physical activity research study
3. Medical conditions prohibiting ambulation without assistance
4. Step count >7,500/day during the baseline data collection period
5. Any other reason why it is not feasible or safe to complete the entire 9-month study in the opinion of their physician or the trial investigator

to the study's webpage on Penn Way to Health,[45] a research and care delivery platform that automates the delivery of behavior change interventions. The text message also includes a link to the study webpage. On the study webpage, participants create an account, confirm their eligibility, complete the informed consent process, and answer questions regarding demographics, medical history, health status, and health-related quality of life. Most patients complete the enrollment process on their own, outside of clinical encounters, with study staff available to answer questions by phone; however, a subset of patients are able to enroll at the time of clinic appointments, with study staff available on-site to answer questions. Once patients complete the baseline questionnaire, study staff conduct chart review to confirm preliminary eligibility. If patients are still eligible, they are mailed a wrist-worn activity tracker (Fitbit Charge 5 or 6) and instructions for how to connect the device to the Way to Health platform. Participants are told to wear the device for two weeks to get comfortable using it, but are not explicitly told that baseline physical activity data are collected during this time period. During the second week of this 2-week run-in phase, baseline activity measures (daily step counts, minutes of moderate physical activity) are estimated.[44,46,47] The first week of data are ignored to diminish the potential upward bias of the estimate from higher activity during initial device use. To prevent potential mismeasurement, days with step values <1,000 are ignored, as previous studies have shown that these are unlikely to represent capture of actual activity during the entire day.[48,49] For participants with <4 days with step count ≥1,000 during the second week of the run-in period, the baseline period is extended until at least 4 valid days of data are collected. Baseline daily step count is calculated as the mean daily step count from the second week of the run-in period; days where the participant had a step count <1,000 are excluded from both the numerator (steps) and the denominator (days). Participants who do not complete the run-in phase or have baseline step counts >7,500 steps/day are not randomized into the trial and are asked to return their Fitbit device. We exclude participants with daily step count >7,500 since observational studies show minimal benefits to increasing physical activity beyond this level.[48,50-58]

Once baseline measures are established, participants are contacted via text message, given their baseline step count, and asked to set a personal goal step increase of 1,500-3,000 steps greater than their baseline. This approach was selected to give participants the option of setting their own goal, which we have shown is the most effective approach for goal-setting,[42] while nudging them to choose between different goals that are ambitious but achievable. They are then randomized 1:1 to attention control or behaviorally-designed gamification, stratified by site (Penn or City of Hope) and baseline step count (<4000, 4000-5999, 6000-7500) using an electronic number generator through the Way to Health platform. Treatment assignment is necessarily open-label, but participants are not explicitly informed about the existence or details of other treatment arms. Investigators and trial statisticians are also blinded to treatment assignment.

During the study period, participants are asked to complete questionnaires at 6 and 9 months' follow-up. Participants receive $25 for completing the baseline questionnaires, $25 for completing 6 months, and $50 for completing 9 months (total of $100). Participants who are randomized are also allowed to keep the Fitbit at the conclusion of the study.

Table 2. Behavioral economic principles used to inform the design of the interventions

Principle	Boundedly rational tendency	Implications for intervention design
Status quo bias	People avoid initiating change	Without the intervention, patients are unlikely to change their physical activity; therefore, the intervention runs automatically rather than requiring the individual to actively participate
Immediacy	Immediate rewards are more motivating than future rewards	Points are rewarded every day to create an immediate 'benefit' that links to future benefits
Loss aversion	People are more motivated when the same situation is framed as a loss rather than a gain	Points are endowed at the beginning of each week and can be lost for not achieving step counts
Social ranking	Influences from social networks impact people's behavior	Participants select a social support partner who will identify ways to help them in their journey and receive a weekly update on their progress.
Goal gradients	People try harder when goals are within reach	Participants start in the middle level and if they perform poorly, they get a fresh start every 8 weeks, and are moved back to the middle level

Study treatments

In the attention control arm, participants receive a text message each day telling them their step count on the prior day.

In the gamification arm, participants are entered into a game that leverages insights from behavioral economics to address predictable barriers to behavior change (Table 2). The components are the following: (1) Precommitment: Each participant signs a contract agreeing to try their best to achieve their daily step goal, an approach shown to motivate behavior change.[59] (2) Points: At the start of each week, the participant receives 70 points (10 for each day of the week). Participants are endowed with points rather than given points after achieving a milestone to leverage loss aversion, a concept from prospect theory that indicates that individuals are more motivated by losses than equivalent value gains.[40] Each day the participant is informed of their step count from the day prior and whether they met their goal. If the step goal was achieved, the participant retains his or her points; if the step goal was not achieved, they are informed that they lost 10 points. Points are replenished at the start of each week to leverage the "fresh start effect" – the concept that individuals are more motivated for aspirational behavior around temporal landmarks like the start of a new week.[60] (3) Levels: At the end of the week, participants with $\geq$40 points advance 1 level; participants with $<$40 points drop down a level. The levels are blue (lowest), bronze, silver, gold, and platinum (highest). Each participant begins in the silver level to create a sense of achievable goals and use loss aversion to motivate ongoing efforts not to lose status.[61] Every 8 weeks, individuals in the blue and bronze levels are restarted back at silver, and offered a chance to adjust their step goal, as long as they remain within the range of a 33%-50% increase from baseline. This allows for another "fresh start," creates a new endowment, and avoids participants becoming discouraged if they set their goals too high at the start of the study. (4) Social accountability: Each participant selects a family member or friend of their choice who receives a weekly email with the participant's progress, including accumulated points, level in the game, and average step count. The supportive sponsor creates a sense of social accountability to motivate the participant toward his or her goal. Prior to starting the study, supportive sponsors participate in a 3-way phone call with the participant and study staff to discuss the rules of the game and ways that they can help the participant reach their goals. If participants and the supportive sponsor do not find time for a phone call, they can complete this process by email. The support goals established in the initial email or phone call were included in the weekly email to support partners as a reminder. (5) Prize: At the end of the intervention period, participants in the platinum level receive a trophy (a nominal incentive of low monetary value) recognizing their achievement. The game lasts for the duration of the 6-month intervention. After 6 months, participants in the gamification arm receive a daily text message noting their step count from the day prior (as in the attention control arm) for an additional 3-month follow-up.

Study endpoints

The primary endpoint is change in mean daily steps from baseline through the 6-month intervention period. Secondary outcomes include change in mean daily steps from baseline through the 3-month follow-up period, change in mean daily minutes of moderate to vigorous physical activity (MVPA) from baseline through the 6-month intervention and 3-month follow-up periods, and change in physical function (as measured by the PROMIS physical function 6b scale), cancer fatigue (as measured by the PROMIS cancer fatigue short form), and quality of life (as measured by EQ-5D-5L) from baseline through 6- and 9-month follow-up.

Mean daily steps are captured by the Fitbit devices and automatically uploaded to the Penn Way to Health platform. Step data are transferred to the Way to Health plat-

Table 3. Consent and enrollment rates by method of recruitment

Method of recruitment (n)	Number (%) consented	Number (%) enrolled
Unsolicited outreach to patients identified by EHR algorithm (n = 868)	141 (16.2%)	55 (6.3%)
Unsolicited outreach to participants in University of Pennsylvania breast cancer registry (n = 83)	26 (31.3%)	12 (14.4%)
Outreach to patients referred by their cardiologist or oncologist (n = 55)	30 (54.5%)	13 (23.6%)
Targeted telephone outreach to patients recently seen in breast and prostate cancer survivorship clinics (n = 195)	67 (34.3%)	32 (16.4%)
Direct, in-person approach in breast and prostate cancer survivorship clinics (n = 226)	70 (31.0%)	41 (18.1%)
Total (n = 1427)	334 (23.4%)	150 (10.5%)

form every 4 hours. To identify minutes of MVPA, we use data established in previous studies validating a threshold of 100 steps per minute as the minimum level of activity to be considered MVPA.[62,63] Based on the 2018 Physical Activity Guidelines for Americans,[64] our algorithm counts any minute with a pace of at least 100 steps as MVPA.

Statistical considerations

The primary analysis will fit linear mixed effect regression models to evaluate changes in physical activity and quality of life outcomes (primary and secondary outcomes) adjusting for each participant's baseline measure, time, calendar-month fixed effects (fitted as a nominal variable), participant random effects, and accounting for repeated measures. For analyses of daily steps and MVPA, data captured during the entire study period will be used; this approach increases power by using all participant data and provides a more complete picture of daily step count over the entire study period. All analyses will be performed according to the intention-to-treat principle.

Based on our prior work,[42,43,46,65-67] we estimate a standard deviation in the primary outcome of 2,500 steps. Physical activity has a direct dose-response relationship with reduction in the risk of cardiovascular disease and events, with small increases substantially lowering risk.[68-70] We estimate that a sample of 150 participants (75 per arm), will ensure at least 90% power to detect a 1,000-step difference between the intervention arm and control, with SD of 2,000 steps, and a 6-minute/day difference in MVPA assuming SD of 10 minutes. This calculation assumes a 20% dropout rate and uses a 2-sided $\alpha = 0.05$.

As in prior studies with similar design,[42-44] our approach to handling days with missing step count data (due to participants not wearing their wearable device for that day, orthopedic injuries leading to temporary pausing of the study intervention, or participants who withdraw or are withdrawn from the study) will be to impute daily step counts for these days in our primary analysis, using an imputation model that includes study arm, calendar month (fitted as a nominal variable), week of study, baseline daily steps, age, sex, race/ethnicity, educational level, marital status, household income level, self-reported health, and participant random effect. We will also perform sensitivity analyses that use collected data without imputation. In prior studies using similar statistical methods, results of such sensitivity analyses have matched the primary analyses.[42-44] We will assess rates of missingness by arm, and if there is evidence of differential missingness, we will consider alternative modeling approaches that account for informative missingness.[71]

Trial status

The trial started enrollment in May 2022 and completed enrollment in May 2024. The last patient enrolled will finish follow up in February 2025. Overall, 1,427 patients were considered for enrollment and were contacted by study staff, including 920 patients with breast cancer and 507 patients with prostate cancer. Ultimately, 334 patients provided informed consent (23.4% of those contacted), 229 patients (16.0% of those contacted) completed enrollment and received a wearable fitness tracker, and 150 patients (10.5% of those contacted) were randomized. Consent and randomization rates differed substantially by recruitment contact type (Table 3), with the lowest rates in patients receiving unsolicited outreach after being identified through an EHR algorithm. These data should be interpreted with caution, as potential participants were not randomized to a recruitment method, and differences between the groups are likely. The lower enrollment fraction of prostate cancer patients relative to breast cancer patients (5.3% vs. 13.7% of patients approached randomized) is partly an artifact of the recruitment process, as prostate cancer patients were more likely to be recruited by unsolicited outreach after identification by EHR algorithm. However, it is consistent with our experience from previous physical activity promotion studies, in which men were less likely to enroll than women.[72]

Baseline characteristics of trial participants are shown in Table 4 . Overall, 123 participants (82.0%) are breast

Table 4. Baseline characteristics of patients enrolled in ALLSTAR

	Overall (n = 150)
Age (mean, SD)	64 (9.7)
Female sex (n, %)	122 (81.3%)
Race/ethnicity (n, %)	
Black non-Hispanic	96 (64%)
Hispanic	52 (34.7%)
Black and Hispanic	1 (0.7%)
Other	1 (0.7%)
Education (n, %)	
Some high school or less	8 (5.3%)
High school graduate	20 (13.3%)
Some college or specialized training	50 (33.3%)
College graduate	72 (48%)
Marital status (n, %)	
Single	39 (26%)
Married	74 (49.3%)
Other	37 (24.7%)
Annual household income (n, %)	
<$50,000	63 (42%)
$50,000-100,000	47 (31.3%)
>$100,000	40 (26.7%)
Self-reported health status (n, %)	
Excellent	7 (4.7%)
Very good	41 (27.3%)
Good	73 (48.7%)
Fair	26 (17.3%)
Poor	3 (2%)
Experience with wireless technology health tracking (n, %)	
None	18 (12%)
Little experience	35 (23.3%)
Moderate experience	63 (42%)
Very experienced	34 (22.7%)
BMI (mean, SD)	32.4 (7.2)
Obesity (n, %)	66 (44%)
Diabetes (n, %)	42 (28%)
Hyperlipidemia (n, %)	76 (50.7%)
Hypertension (n, %)	90 (60%)
Current smoking (n, %)	5 (3.3%)
Prior myocardial infarction (n, %)	3 (2%)
Coronary artery disease (n, %)	4 (2.7%)
Prior stroke (n, %)	2 (1.3%)
Heart failure	6 (4%)
Chronic obstructive pulmonary disease (n, %)	4 (2.7%)
Chronic kidney disease (n, %)	5 (3.3%)
Type of cancer	
Breast	123 (82%)
Prostate	27 (18%)
Years from diagnosis to enrollment (mean, SD)	7.8 (4.9)
Treatment for breast cancer	
Surgery (n, %)	121 (98.4%)
Radiation (n, %)	107 (87.0%)
Systemic therapies (n, %)	
Anthracyclines (n, %)	52 (47.3%)
Trastuzumab (n, %)	26 (23.6%)
Active cancer therapy at enrollment (n, %)	53 (43.1%)
Years from last cancer therapy to enrollment (mean, SD)	3.6 (4.5)
Treatment for prostate cancer	
Surgery (n, %)	16 (59.3%)
Nonsurgical local therapy (n, %)	
External Beam Radiation	21 (77.8%)
Brachytherapy	1 (3.7%)
Cryoablation	0 (0%)
Other Local Therapy	3 (11.1%)
None	3 (11.1%)
Androgen deprivation therapy (n, %)	27 (100%)
Active cancer therapy at enrollment (n, %)	5 (18.5%)
Years from last cancer therapy to enrollment (mean, SD)	2.7 (3.1)
Baseline daily steps (mean, SD)	4,675 (1624)
Baseline daily minutes moderate to vigorous physical activity (mean, SD)	3.8 (6.3)
Step goal increase from baseline (mean, SD)	1,743 (463)

(*continued on next page*)

Table 4. (*continued*)

cancer survivors and 27 participants (18.0%) are prostate cancer survivors. Participants' mean ± standard deviation (SD) age is 64 ± 9.7 years; 81.3% of participants are female, 64.6% are Black, 35.3% Hispanic, 28.0% have diabetes, 60.0% hypertension, and 50.7% hyperlipidemia. Among breast cancer survivors, 47.3% were previously treated with anthracyclines, 23.6% with trastuzumab, and 87.0% with chest radiation; all prostate cancer survivors had been treated with androgen deprivation therapy. Mean ± SD time from cancer diagnosis to enrollment is 7.8 ± 4.9 years, and mean ± SD time from last cancer therapy to enrollment is 3.6 ± 4.5 years; 43.1% of participants were on active cancer therapy at the time of enrollment. Mean ± SD baseline step count was 4675 ± 1624, and mean ± SD goal step count increase from baseline is 1743 ± 463. Overall, the trial population is representative of the population of Black and Hispanic breast and prostate cancer survivors at the 2 study sites.

To date, >90% of participants randomized have remained in the study through 9-month follow-up.

Conclusion

ALLSTAR, a randomized trial of an automated gamification intervention informed by concepts from behavioral economics to improve physical activity in Black and Hispanic breast and prostate cancer survivors at increased risk for cardiovascular events, will provide several important insights into clinical practice and clinical trial conduct. From the standpoint of clinical practice, the gamification intervention is effective in the general population of adults at risk for atherosclerotic vascular disease,[44] but its effectiveness is unknown in cancer survivors, who have unique barriers to engaging in physical activity related to their cancer diagnosis and treatment. Cancer survivors are at particularly high risk for adverse cardiovascular outcomes, and so represent an important population for the implementation of novel primary and secondary prevention interventions. From the standpoint of clinical research, ALLSTAR is among

the first U.S.-based virtual clinical trials to exclusively recruit non-White individuals. Virtual clinical trials with direct outreach to potential participants, self-directed informed consent, and patient-captured and-reported outcomes have the potential to overcome some of the engagement barriers faced by individuals from populations historically under-represented in clinical trials, but their design also introduces complexities that challenge representative enrollment.[72] ALLSTAR is a model for how low-cost virtual trials can answer patient-centered comparative effectiveness questions in diverse populations, and will provide important lessons for similar trials in the future.

Conflict of interest

Dr. Volpp is a co-owner of a behavioral economics consulting firm, VAL Health, and a member of the Scientific Advisory Board of THRIVE Global. Neither organization has any involvement in this study. All other authors report no relevant conflicts of interest.

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