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Original Paper

Associations Among Wearable Activity Tracker Use, Exercise Motivation, and Physical Activity in a Cohort of Cancer Survivors: Secondary Data Analysis of the Health Information National Trends Survey

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Abstract

Background: Cancer survivors who meet physical activity (PA) recommendations (≥150 minutes of moderate-to-vigorous physical activity [MVPA] per week) experience better health outcomes. With the growing availability of wearable activity trackers (WATs), it may be easier to track PA. However, it is unknown what motivates survivors to use these devices.

Objective: The aim of this study is to investigate the associations among motivations for exercise, previous WAT use for tracking a health goal or activity, and meeting the recommended amount of PA among a cohort of cancer survivors.

Methods: Data on WAT users who reported having a previous cancer diagnosis were analyzed from the National Cancer Institute's Health Information National Trends Survey 5 Cycle 3. All survivors with complete information on demographics, exercise motivations (internal guilt, external pressure, physical appearance, and exercise enjoyment), previous WAT use (yes or no), and minutes of MVPA per week (N=608) were included. Multivariate logistic regression models were used to test these associations. A separate cluster analysis was conducted to identify the profiles of exercise motivation that were associated with reporting WAT use.

Results: The mean age of the cohort was 66.9 years (SD 12.1). The majority were non-Hispanic White (473/608, 78.8%) and female (322/608, 54.9%), and skin cancer was the most commonly reported diagnosed cancer (154/608, 27.8%). Survivors who reported using WATs to track a health goal or activity were 1.6 times more likely to meet MVPA recommendations than those who did not use WATs (odds ratio [OR] 1.65, 95% CI 1.03-2.65; *P*=.04). When exercise motivations were assessed independently, survivors who reported not feeling any internal guilt as an exercise motivation were 73% less likely to report having used a WAT than those who felt any internal guilt (OR 0.27, 95% CI 0.14-0.54; *P*<.001). A total of 3 distinct motivational profiles emerged from the cluster analysis. WAT users had an increased probability of membership in profile 3, which was characterized as being strongly motivated to exercise by internal guilt, physical appearance, and exercise enjoyment (OR 4.5, 95% CI 2.1-9.7; *P*<.001).

Conclusions: Among this cohort, survivors who reported using WATs to track a health goal or activity were significantly more likely to report meeting PA recommendations. Survivors who reported feeling internal guilt as an exercise motivation were significantly more likely to report using WATs to track a health goal or activity. When examining clusters of motivation, survivors who reported previous WAT use were more likely to report being motivated to exercise by a mix of intrinsic and extrinsic motivations, including internal guilt, exercise enjoyment, and physical appearance. Given the health benefits of PA for cancer

survivors, technology-focused interventions that use WATs and target exercise motivation may aid in cancer survivors meeting the level of recommended PA.

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KEYWORDS

mHealth; mobile health; cancer survivors; exercise; physical activity; motivation; wearable electronic devices; fitness trackers

Introduction

Background

There are more than 16.9 million cancer survivors living in the United States, and this number is expected to reach more than 22.1 million by 2030 [1]. From 1997 to 2014, obesity increased more rapidly among adult cancer survivors than in the general population [2]. Furthermore, there is a higher prevalence of obesity among cancer survivors from underrepresented populations, such as Hispanics, compared with White cancer survivors [3-8]. In addition, Hispanic breast cancer survivors tend to have lower levels of physical activity (PA) than their non-Hispanic White counterparts [9]. Obesity has several negative health consequences that affect cancer survivors. Obesity puts survivors at a greater risk for cardiovascular disease, diabetes, and cancer recurrence [10-14]. In addition, accumulation of adipose tissue can inhibit effective cancer treatment [15].

PA plays an important role in reducing obesity and increasing quality of life among breast, colorectal, prostate, and multiple site cancer survivors [16-18]. PA can help reduce morbidity and mortality and alleviate the negative side effects of chemotherapy, including fatigue, nausea, disturbed sleep, decreased activity, and impaired quality of life [19-22]. Thus, guidelines from the American Cancer Society recommend that cancer survivors engage in at least 150 minutes per week of moderate-to-vigorous physical activity (MVPA) [23]. However, only 17% to 37% of breast cancer survivors in the United States adhere to these recommendations and most tend to exercise less after treatment [24-27].

Cancer survivors have unique health-related physical and psychological challenges resulting from the acute and long-term effects of cancer, including declines in physical functioning, decreased exercise motivation, and increased levels of anxiety and fatigue [28-31]. Innovative approaches are required to address these challenges. Wearable activity trackers (WATs) are promising tools for addressing these barriers. As of 2020, approximately 1 in 5 US adults (21%) say they regularly wear a smart watch or wearable fitness tracker [32]. WATs that monitor PA act as a motivational tool for increasing awareness of sedentary behavior and are useful for measuring and tracking activity at home or any location [33]. One of the benefits of WATs is that they have the ability to measure a variety of activity-related outcomes, including steps, distance, heart rate, active minutes, calories, and sleep, with high validity and reliability [34,35]. A large systematic review found that using WATs significantly increased the daily step count (P<.001), MVPA (P<.001), and energy expenditure (P=.03) in adult populations [36]. Owing to the rapid advances and relatively low cost of WATs, a growing amount of research has successfully incorporated WATs into interventions to increase PA, reduce obesity, and manage chronic conditions such as breast cancer [22,37]. Results from a qualitative study of breast cancer survivors found that survivors reported acceptance of using WATs, confidence, and comfort in using them, and that using WATs increased their motivation for PA [38]. WATs may also be helpful for promoting PA among cancer patients who are still receiving primary therapy for the disease [39,40]. In addition, WATs have been shown to increase self-awareness of PA and reinforce progress toward meeting PA goals [41]. WATs also show promise as a tool to reduce disparities among patients with cancer and cancer survivors by overcoming barriers such as access to health care providers and health monitoring [42]. WATs are cost-effective, can be widely distributed, have the potential to minimize user burden, and provide immediate feedback in an enjoyable experience for users [43].

Overall, WATs may overcome some limitations of traditional in-person programs for PA and weight management for cancer survivors, such as overcoming travel barriers, decreasing user burden, and addressing time or schedule constraints [30,44,45].

To aid in interpreting the underlying behavior regulations associated with motivation, we examined exercise motivation through the lens of self-determination theory (SDT) [46]. SDT distinguishes between two sources of motivation that regulate a person's behavior: intrinsic (internal) and extrinsic (external). Intrinsic motivation is defined as engaging in an activity or behavior because of the inherent satisfaction a person gets. An intrinsically motivated person experiences enjoyment, accomplishment, and excitement when engaging in the behavior or action. Extrinsic motivation refers to engaging in a behavior to obtain an outcome outside of what is inherently achieved through doing a behavior. This can include social rewards, such as praise, disapproval avoidance, or monetary incentives.

Furthermore, SDT distinguishes between different types of extrinsic motivation by their style of regulation on behavior. For example, controlled regulation is the least autonomous form of extrinsic motivation. In this regulation style, behavior is primarily driven by externally administered rewards and punishments. Individuals operating from this type of motivation typically experience externally regulated behavior as controlling or alienating, leading to an externally perceived locus of causality or control [47]. In another regulation type, introjected regulation, people will perform actions to avoid feeling guilty or anxious or to satisfy their ego or pride. Although this style is still strongly externally controlled, introjection represents a type of regulation that is also contingent on ego and self-esteem. Although this regulation style is internal to the person, introjected behaviors are not experienced as fully self-determined and still operate from an external locus of control [47]. SDT conceptualizes these motivations as a constant

continuum moving between amotivation, or having no motivation, to fully self-determined motivation [46,48]. SDT postulates that meeting goals and changing behavior are more likely to occur if motivation is self-determined or autonomous [24]. Previous studies have demonstrated the efficacy of adapting and mapping SDT concepts to exercise motivations in understanding health behavior [49], particularly mapping guilt onto introjected regulation [48,50,51].

There is still a lot of uncertainty around understanding what motivates cancer survivors to engage in PA. One of the challenges to PA engagement among survivors is that they tend to have lower exercise motivation after diagnosis and treatment [24]. However, some studies have examined exercise motivation among cancer survivors, specifically through the framework of SDT. One study found that breast cancer survivors who meet PA recommendations have higher scores of intrinsic motivation and autonomous regulation, similar to exercise enjoyment as a motivation in this study, than those who did not reach PA guidelines [52]. Other research also indicates that intrinsic motivation is significantly associated with greater long-term exercise adherence [48].

Objectives

Cancer survivors who meet PA recommendations experience better health outcomes. With the growing availability and implementation of WATs, it may be easier to track PA, but it is still unknown what motivates cancer survivors to wear these devices. Therefore, the purpose of this study is to investigate the relationship among motivations for exercise (internal guilt, pressure from others, physical appearance, and exercise enjoyment), reported previous use of WATs to track health goals, and meeting the recommended amount of PA (≥150 minutes of MVPA per week) among a cohort of cancer survivors.

Methods

Data Source

First administered in 2002-2003 by the National Cancer Institute, the Health Information National Trends Survey (HINTS) is a biennial, cross-sectional survey of a nationally representative sample of noninstitutionalized American adults aged 18 years and older that is used to assess the context in which people access and use health information. There are 13 iterations of HINTS, and this study uses the 13th iteration released in January 2020, HINTS 5 Cycle 3, which represents data collected from January to April 2019. Each HINTS iteration has been approved through an expedited review by the Westat Institutional Review Board and deemed exempt by the US National Institutes of Health Office of Human Subjects Research Protections. A total of 5438 people participated in HINTS 5 Cycle 3. In this cycle, the overall response rate was 30.3%. For descriptive analysis, sample weighting was used to provide nationally representative US estimates. The HINTS survey uses weights that are designed to provide population level estimations utilizing a modified Horvitz-Thompson estimator and Jackknife replication method [53].

Participants

In this study, all cancer survivors who completed a survey for cycle 3 in 2019 with complete information on demographic variables, WAT use, exercise motivation, and minutes of MVPA per week were included (N=608).

Measures

Demographics

Demographic variables included participants' age (years), BMI, gender (male or female), marital status (married or divorced), household income range, education (less than high school, high school graduate, some college education, college graduate, or more), health insurance status (yes or no), English-speaking proficiency (very well or not very well), self-rated health (excellent, very good, good, fair, or poor), ability to take care of one's health (completely confident, very confident, somewhat confident, a little confident, or not confident at all), rural or urban designation, cancer type (breast, cervical, prostate, colorectal, skin, other, or more than one type), and time since cancer diagnosis (in years). Race or ethnicity was examined using a dichotomized variable representing survivors from a White racial or ethnic background and those from a non-White racial or ethnic background, including Hispanics, Asians, and African Americans. BMI was used to classify participants as obese (≥30), overweight (29.9-26), or normal weight or underweight (<26).

Use of WATs

Participants' responses to the question, "In the past 12 months, have you used an electronic wearable device to monitor or track your health or activity? For example, a Fitbit, AppleWatch or Garmin Vivofit..." were used to characterize the distribution of subjects who used WATs (yes or no).

Exercise Motivation

To assess motivation, we used participants' responses to questions that asked "Why the participant starts or continues exercise regularly" with separate questions asking if the reason was "pressure from others (external pressure), concern over the way you look (physical appearance), feeling guilty when you stop exercising (internal guilt), or getting enjoyment from exercise (exercise enjoyment)." Answer choices included "A lot," "Some," "A little," or "Not at all." For regression modeling, we dichotomized the response variable into *not at all* versus *any*.

Physical Activity

To investigate the association between WAT use and PA, we created a binary outcome variable derived from a composite of combining responses to questions which asks, "In a typical week, how many days do you do any physical activity or exercise of at least moderate intensity, such as brisk walking, bicycling at a regular pace, and swimming at a regular pace (do not include weightlifting)?" with option choices from *1 day per week* to *7 days per week*, and another question, which asks, "On the days you do physical activity for exercise of at least moderate intensity, how long do you typically do these activities?" and allowed participants to answer with any positive number up to 3 digits in length. To develop the outcome

variable, the number of days per week reported was multiplied by the number of minutes to obtain the average time per week of MVPA. We then created a binary variable with either *yes* or *no* options based on whether the participant met recommended weekly minutes of MVPA (yes ≥150 or no <150).

Statistical Analyses

Before the analysis, data were screened for normality, outliers, and patterns of missing data. Missing data were screened and tested in Statistical Access Software (SAS) version 9.4 using PROC MI to examine the distribution of missing values. No distinct patterns of missing data were found; therefore, the data were approached as missing at random. As no patterns in missing data were found, participants who completed the survey for cycle 3 in 2019 with complete information on demographics, exercise motivations, WAT use, and minutes of moderate-to-vigorous PA (MVPA) per week were included in the study (N=608). Descriptive data for continuous variables were reported as weighted means and SDs, and categorical variables were reported as weighted frequencies and percentages.

To assess the relationship between exercise motivation variables and WAT use, multivariable logistic regression models were used. In addition, we examined the interaction between individual exercise motivations and race or ethnicity to explore differences in motivations by race or ethnicity. A separate multivariable logistic model was used to assess the relationship between WAT use and meeting the recommended amount of PA. A cutoff of $P<.05$ was used to determine statistical significance for all analyses.

A cluster analysis was conducted to generate motivational profiles based on responses to exercise motivation questions using the PROC LCA procedure in SAS 9.4. In PROC LCA, parameters are estimated using an expectation-maximization algorithm to obtain the maximum likelihood. In addition, this procedure incorporates the Newton-Raphson method for the estimation of regression coefficients. The convergence index used in this procedure is the maximum absolute deviation (MAD). The estimation procedure continues to iterate until either a specified criterion value of MAD (the convergence criterion) is met or the maximum number of iterations is reached. Finally, LCA parameter estimates and standard errors are found by inverting the Hessian matrix to obtain the log likelihood [54]. Using this method, we tested the best-fit model as either a 2-, 3-, 4-, or 5-cluster solution. These options were then assessed further using goodness-of-fit statistics, Akaike information criterion, Bayesian information criterion, G-squared, entropy, and interpretability. Once profiles were formed, differences in WAT use were assessed using logistic modeling and chi-square tests. SAS version 9.4 was used for all data modeling and analyses carried out in this study.

Results

Demographic Characteristics of the Cohort

Multimedia Appendix 1 describes the cancer cohort. The mean age of the cohort was 66.9 years (SD 12.1), and the mean BMI was 28.3 (SD 6.1). The majority of cancer survivors were non-Hispanic White (473/608, 78.7%), female (322/608, 54.9%), married (328/608, 62.9%), and spoke English very well (546/608, 89.8%). The most frequently reported cancer was skin cancer (154/608, 27.8%), followed by more than one type of cancer (110/608, 18.1%) and breast cancer (79/608, 12.4%), which are among the most prevalent types of cancer in the general population [55]. A large proportion of the cohort completed some college or more (489/608, 71.5%) and frequently reported being in good (228/608, 38.3%) or very good health (194/608, 29.4%) and being very confident that they could take care of their health (279/608, 43.3%). In addition, the cohort overwhelmingly reported having health insurance (596/608, 96.8%). Regarding PA, the majority of this cancer cohort did not meet the recommended amount of PA (396/608, 67.9%) and most only reported between 0 and 74 minutes of MVPA per week (282/608, 49.9%). One-fifth of cancer survivors reported using a WAT device in the past month (119/608, 20.9%). The complete breakdown of exercise motivations reported by WAT users and non-WAT users in provided in Table 1.

Table 1. Exercise motivations (wearable activity tracker users vs nonwearable activity tracker users; N=608).

Characteristic and category	WAT[a] users (n=119), n (%)		Non-WAT users (n=489), n (%)	
	Participants	Participants (weighted)	Participants	Participants (weighted)
Internal guilt				
No	17 (9.6)	330,710 (9.6)	198 (42.9)	5,572,690 (42.9)
Yes	102 (90.4)	3,106,554 (90.4)	291 (57.1)	7,422,694 (57.1)
Exercise enjoyment				
No	20 (12.5)	428,160 (12.5)	123 (23.7)	3,086,204 (23.7)
Yes	99 (87.5)	3,009,105 (87.5)	366 (76.3)	9,909,181 (76.3)
Physical appearance				
No	12 (6.3)	215,926 (6.3)	110 (19.3)	2,503,455 (19.3)
Yes	107 (93.7)	3,221,338 (93.7)	379 (80.7)	10,491,930 (80.7)
Pressure from others				
No	77 (63.6)	2,184,454 (63.6)	323 (67.6)	8,784,210 (67.6)
Yes	42 (36.4)	1,252,810 (36.4)	166 (32.4)	4,211,175 (32.4)

[a]WAT: wearable activity tracker.

Exercise Motivation and WAT Use—Regression Modeling

When exercise motivations were assessed independently, adjusting for all covariates in a multivariate logistic regression model, cancer survivors who did not report internal guilt as a motivation for exercise were 73% less likely to use WATs (odds ratio [OR] 0.27, 95% CI 0.14-0.54; *P*<.001). This model was adjusted by participant's age, BMI, time since cancer diagnosis, gender, marital status, household income range, level of educational attainment, race or ethnicity, self-rated health, self-efficacy for health, region, urban or rural status, health insurance status, English-speaking ability, and type of cancer diagnosis. In addition, several demographic variables were found to be significantly associated with WAT use in this model. An increase in age was associated with a decreased likelihood of using WATs (OR 0.95, 95% CI 0.93-0.97; *P*<.001). In addition, survivors with higher income (US $75,000-$199,000 vs US $0-$34,000; OR 2.84, 95% CI 1.22-6.59; *P*=.02) and those with better health (fair or poor vs excellent; OR 0.2, 95% CI 0.07-0.61; *P*=.004) were more likely to use WATs. The time since cancer diagnosis was included as a control variable in this model and was found to be not statistically significantly associated with WAT use (*P*=.93). Finally, when testing for interactions between individual exercise motivations and race or ethnicity, we found no significant interactions. The results are presented in Table 2.

Table 2. Results from multivariable regression modeling of exercise motivations and previous wearable activity tracker use (N=608).

Variable[a]	Odds ratio (95% CI)	*P* value
Pressure from others[b]	1.17 (0.70-1.97)	.54
Physical appearance[c]	0.67 (0.30-1.53)	.35
Internal guilt[b]	0.27 (0.14-0.54)	<.001
Exercise enjoyment[c]	0.82 (0.40-1.60)	.55
Age	0.95 (0.93-0.97)	<.001
Income[d]	2.84 (1.22-6.49)	.02
Self-rated health[e]	0.20 (0.07-0.61)	.004

[a]Adjusted for age, BMI, time since cancer diagnosis, gender, marital status, household income range, level of educational attainment, race or ethnicity, self-rated health, self-efficacy for health, region, urban or rural status, health insurance status, English-speaking ability, and type of cancer diagnosis.

[b]None versus any motivated.

[c]Any versus not motivated.

[d]US $75,000-$199,000 versus US $0-$34,000.

[e]Fair or poor versus excellent.

Exercise Motivation and WAT Use—Cluster Analysis

Figure 1 displays the 3 motivational profiles that emerged from the cluster analysis. The profiles differed significantly across motivation and class membership.

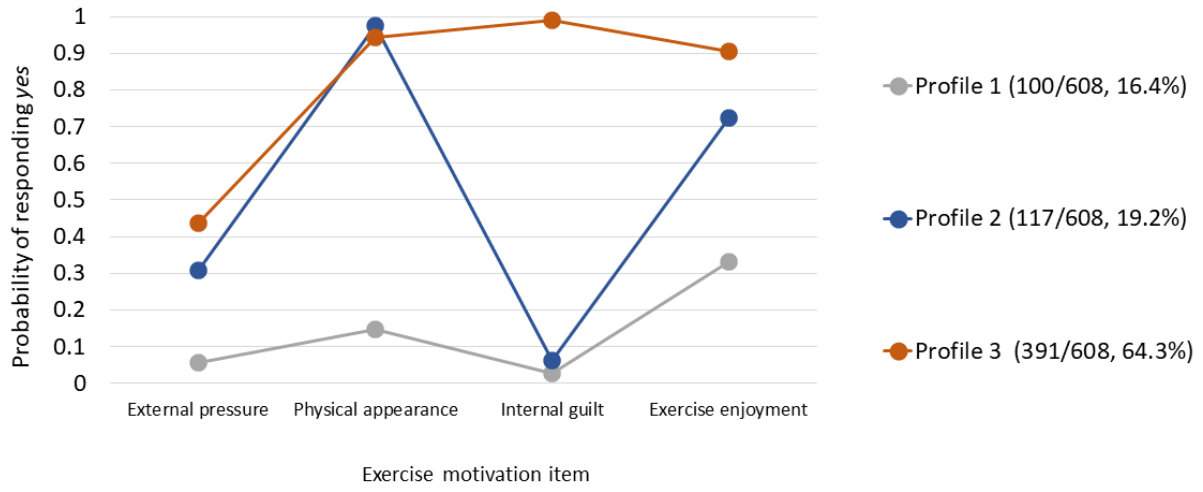
Profile 1 (100/608, 16.4%) is characterized by cancer survivors who did not report being influenced to exercise by any of these motivations (internal guilt, pressure from others, physical appearance, and exercise enjoyment).

Profile 2 (117/608, 19.2%) profile is characterized by cancer survivors who reported exercising because of exercise enjoyment (intrinsic motivation with autonomous regulation) and physical appearance (extrinsic motivation with introjected regulation).

Profile 3 (394/608, 64.4%) is characterized by cancer survivors who reported being motivated by exercise enjoyment (intrinsic with autonomous regulation) and strongly by both physical appearance and internal guilt (extrinsic motivation with introjected regulation).

WAT users had an 86% probability of membership in profile 3 (gamma=0.86; SE 0.04; *P*<.001) versus profile 1, whereas non-WAT users only had a 58% (gamma=0.58; SE 0.04; *P*<.001) chance of being in this profile. When assessed in a logistic regression model, profile 3 was also the only cluster that was significantly associated with WAT use (OR 4.5, 95% CI 2.1-9.7; *P*<.001) after adjusting for participants' age, BMI, time since cancer diagnosis, gender, marital status, household income range, level of educational attainment, race or ethnicity, self-rated health, self-efficacy for health, region, urban or rural status, health insurance status, English-speaking ability, and type of cancer diagnosis.

Figure 1. Latent class analysis of motivation profiles (N=608), adjusting for age.



Association Between WAT Use and PA

Cancer survivors who used WATs were 1.6 times more likely to meet PA recommendations than those who did not use WATs (OR 1.65, 95% CI 1.03-2.65; *P*=.04). In addition, in this model, we found that survivors who had lower BMI (OR 0.92, 95% CI 0.89-0.96; *P*<.001), had higher household income (US $200,000+ vs US $0-$35,000; OR 2.62, 95% CI 1.11-6.19; *P*=.03), and were in better health (fair or poor vs excellent; OR 0.18, 95% CI 0.07-0.44; *P*<.001) were more likely to meet weekly PA recommendations. The results can be found in Table 3.

Table 3. Association between wearable activity tracker use and meeting the recommended amount of physical activity (N=608).

Variable[a]	Odds ratio (95% CI)	*P* value
Previous wearable activity tracker use[b]	1.65 (1.03-2.65)	.04
BMI	0.92 (0.89-0.96)	<.001
Household income[c]	2.62 (1.11-6.19)	.03
Self-rated health[d]	0.18 (0.07-0.44)	<.001

[a]Adjusted for age, BMI, time since cancer diagnosis, gender, marital status, household income range, level of educational attainment, race or ethnicity, self-rated health, self-efficacy for health, region, urban or rural status, health insurance status, English-speaking ability, and type of cancer diagnosis.

[b]Yes versus no wearable activity tracker use.

[c]US $200,000+ versus US $0-$35,000.

[d]Fair or poor versus excellent.

Discussion

Principal Findings

One of our primary objectives was to examine the associations of internal guilt, exercise enjoyment, pressure from others, and physical appearance as motivations for exercise with reporting having used WATs to track a health goal among a cohort of cancer survivors. The second objective was to examine clusters of exercise motivations associated with reporting previous WAT use. When exercise motivations were assessed independently, only internal guilt was significantly associated with WAT use among this cohort of cancer survivors. However, in the cluster analysis, 3 distinct motivational profiles emerged with distinctly different class memberships. WAT users were significantly more likely to be in profile 3, a group characterized by being motivated by internal guilt, physical appearance, and exercise enjoyment (autonomous with high introjected regulation). The cluster analysis provided a unique examination on not only how a single exercise motivation is associated with reporting WAT use but also how a combination of motives can be identified.

In both analyses, external guilt as a motivation for exercise emerged as being significantly associated with reporting previous WAT use. There is concern that guilt as a motivation can be harmful to healthy behavior adherence and that using WATs can cause additional stress or induce negative affect [56]. However, in this study, we observed a significant relationship between health-related internal guilt and reporting using WATs to track a health goal or activity. Health-related guilt in this context is a negative feeling about a person's own behavioral shortcomings related to health, often through self-blame. For example, a person may feel guilty when they have not exercised, although having been given recommendations from a health provider to do so. This experience typically involves a sense of anxiety or regret [50]. However, the experience of guilt is typically in response to a specific behavior, unlike shame, which is a negative feeling about oneself or global self-blame. Therefore, the experience of guilt is typically less painful than shame [50]. This may explain why previous studies have found an association between guilt and higher levels of MVPA among breast cancer survivors [51].

Understanding exercise motivation through a framework of SDT helps us to identify and differentiate sources of exercise motivation (internal vs external) and allows us to conceptualize different forms of control or behavior regulation within extrinsic motivation (eg, introjected regulation and controlled regulation). In this context, we can think of health-related guilt as an emotion. However, considering the underlying behavior regulation associated with guilt, we apply an SDT framework, specifically mapping guilt onto extrinsic motivation with introjected regulation [48,50,51].

Understanding the type of behavioral regulation linked with guilt can inform the planning and design of technology-based mobile health (mHealth) interventions that focus on addressing the behavioral regulation aspect of health-related guilt while not directly leveraging or increasing the emotional aspect that may negatively impact healthy behavior adherence.

Given that motivation in the context of SDT exists on a continuum, viewing the results of this study through an SDT framework can potentially inform the development of interventions that focus on moving survivors from extrinsically motivated regulations such as introjected regulation (eg, guilt) to more autonomous forms of motivational control (eg, enjoyment). One approach is to design intervention components such as motivational messages that avoid guilt- or shame-inducing language and instead aid the user in becoming more accountable for meeting MVPA recommendations while creating enjoyable experiences. This can potentially be achieved by using mHealth intervention components such as gamification and motivational affordances (eg, leaderboards, badges, and challenges), which help to foster more autonomous forms of regulation and motivation (eg, enjoyment and mastery). Clinicians may also play a role in guiding their patients toward making more positive cognitive appraisals directed at managing feelings of guilt. This process distinguishes between health-related guilt and engaging in self-blaming behavior (eg, failure and shame), which has been found to be associated with negative health consequences and decreased PA motivation [51].

On the basis of these findings, motivational regulation is likely to be an important factor linking body-related emotions and MVPA. WAT interventions typically contain behavior change techniques that include monitoring and tracking but rarely address extrinsic motivation with introjected regulation (eg, guilt). There is a need to recognize that health- and body-related guilt exists among cancer survivors and consider the implications of the relationship between guilt and health behaviors among this population.

Another objective of this study is to examine the association between WAT use and meeting the recommended amount of weekly MVPA among this cohort of cancer survivors. Reporting previous WAT use for tracking health goals was statistically significantly associated with meeting MVPA recommendations. Given the health benefits of PA for cancer survivors and the potential barriers to in-person PA programs, interventions aimed at aiding cancer survivors in meeting MVPA recommendations could leverage WATs to help survivors reach these goals.

Comparison With Previous Work

Similar to previous findings, we found that enjoyment (intrinsic motivation), a more autonomous form of behavioral regulation, was found to play a role in reporting WAT use when looking at clusters of motivation [57]. However, contrary to previous work, we did not find that external pressure from others to exercise was associated with WAT use [58].

Although previous studies have investigated the relationships among demographic, health, and lifestyle variables associated with meeting PA guidelines in cancer survivors, few have investigated the role of reporting previous WAT use in meeting PA guidelines among cancer survivors [49]. A large systematic review found that cancer survivors showed an increase in PA when using WATs and that increased PA played an important role in alleviating the adverse health effects of breast cancer therapy [22]. Another study found that WATs motivated breast cancer survivors to be physically active and created more

awareness of their sedentary lifestyle [37]. Results from a qualitative study found similar findings in that WATs increased self-awareness and motivation among breast cancer survivors [38].

Future Considerations

Findings from this study can provide insights into the relationship between reporting internal guilt as an exercise motivation and reporting meeting MVPA recommendations for cancer survivors. The results can also provide some insights into possible ways to interpret guilt as an exercise motivation and potentially understand the underlying behavior regulation of this emotion through a framework of SDT. There remains an opportunity for future researchers to address questions regarding the intensity of WAT use among cancer survivors and the amount of PA. There also remains uncertainty as to whether WATs act as a facilitator of PA or a primary driver of health behavior [59]. In addition, there are technological difficulties to consider (initial setup, troubleshooting, etc) that can create barriers to PA adherence in home-based PA interventions among cancer survivors [59]. In addition, there is concern that WATs can cause stress or induce negative effects on healthy behavior, which can also be problematic [56]. However, studies have shown successful integration of WATs into interventions with no reported increase in negative affect or causing unwanted stress [60]. This study will also serve to inform a follow-up paper focused on the intensity of WAT use, exercise motivation, and PA.

Limitations

Although HINTS is designed to be nationally representative, the data were collected through a self-report, cross-sectional survey. Thus, we are unable to analyze trends in WAT use, motivations, and PA over time and must rely on a person's recollection of events and behaviors. In addition, because this is a cross-sectional survey, we were limited to the questions and variables that were included in the survey, such as being limited to examining only the range of the exercise motivations included in the survey and being unable to know what specific health measures or activities the participants were tracking on their wearable devices. There is also the possibility of unmeasured confounding, which might be associated with mHealth engagement that would influence the interpretation of these results. Although our analyses showed a statistically significant association, it does not indicate a causal relationship, and we cannot address the issue of temporality, given the cross-sectional nature of the study. For example, we cannot determine whether a motivation leads to WAT use or if WAT use leads to motivation. Our goal was to determine associations among motivations for exercise, WAT use, and meeting PA recommendations among this cohort of cancer survivors; thus, our results should not be generalized to populations outside of survivors. Finally, because of smaller data cell counts, we had to examine interactions for race using a dichotomized variable derived from cancer survivors reporting if they were from a White racial or ethnic background or if they were from a non-White racial or ethnic background. Due to this dichotomization, we may have been unable to detect more subtle but significant differences in motivations by race. Finally, we need to consider that those who used WATs had more access to devices based on higher socioeconomic status (SES) and must consider the implications for cancer survivors with lower SES. Although this study was a secondary analysis of cross-sectional data, the results add to the literature supporting the notion that previous WAT use among cancer survivors is associated with reported meeting MVPA guidelines.

Conclusions

When assessed individually, internal guilt as an exercise motivation (extrinsic motivation with introjected regulation) was found to be significantly associated with reporting previous WAT use among a cohort of cancer survivors. In a cluster analysis, WAT users were more likely to be in a profile that reported being motivated to exercise by internal guilt, exercise enjoyment, and physical appearance, demonstrating a combination of intrinsic and extrinsic motivations (autonomous with high introjected regulation). This provides us with insights on not only how one motivation but how a confluence of motivations was found to be associated with reporting previous WAT use for tracking health goals among a cohort of cancer survivors. However, in both analyses, we found that internal guilt was consistently reported as an exercise motivation associated with reported WAT use. We can also apply an SDT framework to better understand the underlying behavioral regulation that underlies health-related guilt. In addition, among this cohort of cancer survivors, WAT use was significantly associated with meeting the PA recommendation guidelines. The results of this study can aid in identifying which cancer survivors are more or less likely to use WATs and the potential underlying motivations and behavior regulations that are associated with their use. Given the health benefits of PA for cancer survivors, technology-focused interventions targeting exercise motivation may aid cancer survivors in meeting MVPA recommendation guidelines.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Descriptive characteristics of the cancer cohort (wearable activity tracker users vs nonwearable activity tracker users; N=608).
[PDF File (Adobe PDF File), 175 KB - cancer_v7i2e24828_app1.pdf]

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Abbreviations

HINTS: Health Information National Trends Survey
MAD: maximum absolute deviation
mHealth: mobile health
MVPA: moderate-to-vigorous physical activity
OR: odds ratio
PA: physical activity
SDT: self-determination theory
SES: socioeconomic status
WAT: wearable activity tracker

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Original Paper

A Novel Behavioral Intervention for Rural Appalachian Cancer Survivors (weSurvive): Participatory Development and Proof-of-Concept Testing

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Abstract

Background: Addressing the modifiable health behaviors of cancer survivors is important in rural communities that are disproportionately impacted by cancer (eg, those in Central Appalachia). However, such efforts are limited, and existing interventions may not meet the needs of rural communities.

Objective: This study describes the development and proof-of-concept testing of *we*Survive, a behavioral intervention for rural Appalachian cancer survivors.

Methods: The Obesity-Related Behavioral Intervention Trials (ORBIT) model, a systematic model for designing behavioral interventions, informed the study design. An advisory team (n=10) of community stakeholders and researchers engaged in a participatory process to identify desirable features for interventions targeting rural cancer survivors. The resulting multimodal, 13-week *we*Survive intervention was delivered to 12 participants across the two cohorts. Intervention components included in-person group classes and group and individualized telehealth calls. Indicators reflecting five feasibility domains (acceptability, demand, practicality, implementation, and limited efficacy) were measured using concurrent mixed methods. Pre-post changes and effect sizes were assessed for limited efficacy data. Descriptive statistics and content analysis were used to summarize data for other domains.

Results: Participants reported high program satisfaction (acceptability). Indicators of demand included enrollment of cancer survivors with various cancer types and attrition (1/12, 8%), recruitment (12/41, 30%), and attendance (median 62%) rates. Dietary (7/12, 59%) and physical activity (PA; 10/12, 83%) behaviors were the most frequently chosen behavioral targets. However, the findings indicate that participants did not fully engage in action planning activities, including setting specific goals. Implementation indicators showed 100% researcher fidelity to delivery and retention protocols, whereas practicality indicators highlighted participation barriers. Pre-post changes in limited efficacy outcomes regarding cancer-specific beliefs and knowledge and behavior-specific self-efficacy, intentions, and behaviors were in desired directions and demonstrated small and moderate effect sizes. Regarding dietary and PA behaviors, effect sizes for fruit and vegetable intake, snacks, dietary fat, and minutes of moderate-to-vigorous activity were small (Cohen *d*=0.00 to 0.32), whereas the effect sizes for change in PA were small to medium (Cohen *d*=0.22 to 0.45).

Conclusions: *we*Survive has the potential to be a feasible intervention for rural Appalachian cancer survivors. It will be refined and further tested based on the study findings, which also provide recommendations for other behavioral interventions targeting rural cancer survivors. Recommendations included adding additional recruitment and engagement strategies to increase demand and practicality as well as increasing accountability and motivation for participant involvement in self-monitoring activities through the use of technology (eg, text messaging). Furthermore, this study highlights the importance of using a systematic model (eg, the ORBIT framework) and small-scale proof-of-concept studies when adapting or developing behavioral interventions, as

doing so identifies the intervention's potential for feasibility and areas that need improvement before time- and resource-intensive efficacy trials. This could support a more efficient translation into practice.

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KEYWORDS

cancer survivors; quality of life; behavior change; rural; feasibility; Appalachia

Introduction

Cancer survivors comprise approximately 5% of the US population, and the number of cancer survivors is expected to increase by almost 30% over the next 10 years [1]. Although cancer survivors live longer, evidence suggests that they continue to engage in behaviors that increase their risk for recurrence, new cancers after treatment, and other chronic diseases that could impair survivorship outcomes [2,3]. Health behaviors that are recommended for cancer survivors to engage in include healthy diet and weight, being physically active, avoiding or stopping tobacco use, limiting alcohol consumption, and practicing sun safety [4,5]. Cancer survivors may be primed to change their health behaviors, as the cancer diagnosis and treatment may serve as *teachable moments* that motivate them to improve health behaviors. Therefore, addressing the health behaviors of cancer survivors has been identified as a priority in both clinical and community settings [6].

Addressing the health behaviors of cancer survivors is particularly important in health disparate communities, such as those in rural Central Appalachia. These communities are disproportionately impacted by cancer, as indicated by higher cancer mortality rates than those of nonrural communities [7]. There are also high rates of low educational attainment and low socioeconomic status in this region [8], and these social determinants of health are associated with a greater likelihood of engaging in unhealthy behaviors after treatment [2]. In addition, these communities often have a high prevalence of other chronic health conditions, such as type 2 diabetes, obesity, and heart disease [9-12], which can adversely impact cancer outcomes and mortality. Importantly, the development and management of these health conditions can be impacted by changing health behaviors. However, efforts to address the health behaviors of cancer survivors in Appalachia, similar to other rural areas, have been limited [13].

Increasing efforts to integrate interventions for cancer survivors that target modifiable health behaviors may be a strategic way to reduce cancer disparities in this region and others. Although there are existing behavioral interventions for cancer survivors, most of them are designed for survivors of a specific type of cancer and use one mode of delivery [14-17]. In addition, few of these existing interventions have been specifically developed for the needs of rural cancer survivors. Therefore, existing interventions would need to be adapted or a new intervention would need to be developed to meet the needs of cancer survivors in Appalachia.

Using a systematic process to develop or adapt an intervention allows for the assessment of the intervention's potential relevance, clinical efficacy, and sustainability. This information is particularly vital for interventions that have the ultimate goal of being translated into real-world settings. The Obesity-Related Behavioral Intervention Trials (ORBIT) model presents a systematic process of translating basic and clinical behavioral science findings into behavioral interventions [18]. Although initially designed for the development of obesity-focused trials, the systematic steps of the ORBIT model are applicable for the design of behavioral interventions targeting other health conditions. This paper describes how researchers affiliated with the University of Virginia (UVA) Cancer Center and community stakeholders from its rural Appalachia catchment area in southwest Virginia employed phase 1 and phase 2 of the ORBIT model to adapt or develop and pilot test a behavioral intervention for cancer survivors.

Methods

Design

This two-phase mixed methods study describes the development and initial pilot testing of a behavioral intervention for rural cancer survivors. The process, guided by the ORBIT model [18] and feasibility framework by Bowen et al [19], provides a conceptual framework for the evaluation of a proof-of-concept study. The ORBIT model includes 4 phases—phase 1: define and refine basic elements, phase 2: preliminary testing, phase 3: efficacy testing, and phase 4: effectiveness testing. This study focused on the first 2 phases. The feasibility framework by Bowen et al [19] identifies 8 key domains to measure during feasibility trials at both the participant and organizational levels. This study measures indicators for the 5 domains that are appropriate for the early proof-of-concept trial phase: acceptability, demand, implementation, practicality, and limited efficacy testing. The domains are listed in Table 1.

Table 1. Summary of measures used in the feasibility trial of *we*Survive.

Feasibility domain, definition, indicator, and measure	Baseline	Postassessment	Process evaluation
Acceptability: extent to which the intervention is judged as suitable, satisfying, or attractive to recipients			
Organizational perceptions			
Recruitment memos	—[a]	—	✓[b]
Participant satisfaction			
Summative evaluation	—	✓	—
Demand: extent to which the intervention is likely to be used			
Organizational adoption			
Recruitment memos	—	—	✓
Recruitment rates			
Recruitment logs	—	—	✓
Participant engagement			
Attendance logs	—	—	✓
Class and call memos	—	—	—
Class or call artifacts	—	—	—
Behavioral target chosen by participants			
Summative evaluation	—	✓	✓
Class or call artifacts	—	—	—
Practicality: extent to which the intervention can be carried out with intended participants using existing means, resources, and circumstances and without outside intervention			
Barriers and facilitators of participant engagement			
Summative evaluation	—	✓	—
Implementation: extent the intervention can be successfully delivered to intended participants			
Recruitment execution			
Recruitment memos	—	—	✓
Recruitment logs	—	—	—
***we*Survive delivery**			
Class or call memos	—	—	✓
Limited efficacy: the promise of the intervention to be successful with the intended population			
Changes in cancer-related beliefs			
Cancer belief questions from HiNTS[c]	✓	✓	—
Changes in diet and physical activity self-efficacy			
Scaled survey questions	✓	✓	—
Changes in diet and physical activity intentions			
Scaled survey questions	✓	✓	—
Changes in dietary behaviors			
NCI[d] multifactor screener	✓	✓	—
Changes in physical activity behaviors			
Modified Godin	✓	✓	—
L-CAT[e]	—	—	—
Changes in social network size			
Cancer survivor social networks measure	✓	✓	—

Feasibility domain, definition, indicator, and measure	Baseline	Postassessment	Process evaluation
Changes in quality of life			
Quality of life patient or cancer survivor version	✓	✓	—

[a]Related data were not collected.

[b]Related data were collected.

[c]HiNTS: Health Information National Trends Survey.

[d]NCI: National Cancer Institute.

[e]L-CAT: Stanford Leisure-Time Activity Categorical Item.

ORBIT Model Phase 1: Define and Refine Basic Elements

Intention of Phase

The purpose of phase 1 of the ORBIT model is to develop a hypothesized pathway through which behavioral intervention could impact health and determine components, duration, mode of delivery, and tailoring needs [18]. For our study, the intention for this phase was to identify and adapt an existing intervention or, if needed, develop a novel intervention using best practices. We approached this phase by (1) conducting literature searches and (2) engaging an advisory team of local stakeholders in a participatory development process.

Literature Search

We conducted a search of those listed in the National Cancer Institute's (NCI) Research Testing Intervention/Program website [20] and through PubMed to identify existing behavioral interventions for cancer survivors. The identified interventions were reviewed during participatory processes.

Participatory Process

This process was guided by a comprehensive participatory planning and evaluation process [21] (described below). It incorporated the Putting Public Health Evidence in Action training [22] and focused on the sessions related to identifying, selecting, and adapting evidence-based interventions.

To recruit advisory team members, the study was presented to all members of the Cancer Center Without Walls Southwest Virginia Community Advisory Board (CAB) during a quarterly CAB meeting. The CAB consists of representatives from local health care systems and other organizations that work on cancer-related issues, community members, and the UVA Cancer Center faculty and staff. The CAB members who were interested in joining the advisory team contacted the research team. The resulting advisory team consisted of 10 members: 6 community stakeholders, 1 UVA Cancer Center Outreach and Engagement staff member, and 3 interdisciplinary UVA faculty members with expertise in behavioral interventions, oncology, and community engagement. Community stakeholders represented local health systems (n=2), the social services sector (n=2), and higher education (n=2). The 3 members were cancer survivors.

The advisory team engaged in 6 meetings over 6 months, three 1-hour in-person meetings, and three 1-hour conference calls. The intention of these meetings was to identify key recommendations for what the intervention should address and to use these recommendations to identify and either adapt or develop a behavioral intervention. Planned activities included sharing previous experiences with behavioral interventions for cancer survivors and perceptions of needed and acceptable components, reviewing and commenting on existing behavioral interventions for cancer survivors, and deciding upon the intervention and identifying adaptations. Notes and reflection worksheets completed during meetings were reviewed, summarized, and used to identify key action steps between meetings. During this process and based on the literature review, it became evident that existing interventions did not meet local needs and that a novel intervention would need to be developed.

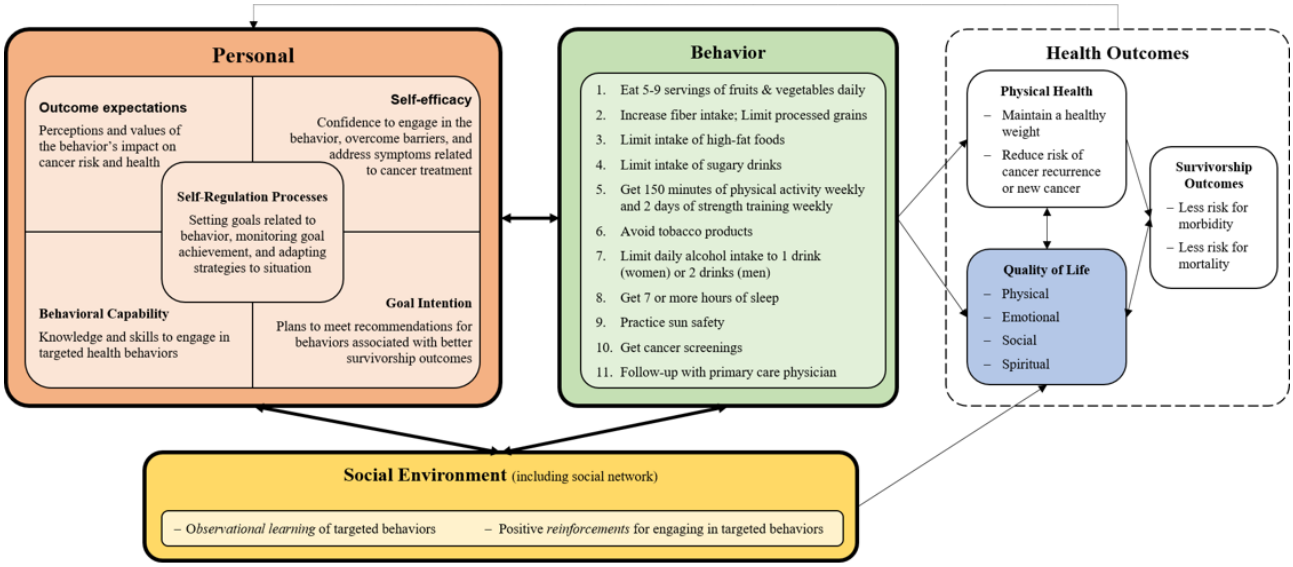
Through the participatory process, the advisory team identified 4 key recommendations that an ideal behavioral intervention for rural Appalachian cancer survivors would need to take into account: (1) incorporation of both in-person and telehealth components so that participants could engage even if they had barriers to one delivery mode; (2) utilization of strategies that promoted action planning and storytelling; (3) addressing multiple behaviors; and (4) opening the program to all adult cancer survivors regardless of gender or cancer type. A conceptual model and program design were developed using these recommendations and a review of the best practices (Figure 1).

The resulting intervention, *we*Survive, was rooted in Social Cognitive Theory (SCT) [23] and targeted improving participant quality of life (QoL) through the improvement of 11 health behaviors associated with better cancer survivorship outcomes, including dietary and physical activity (PA) behaviors (Figure 1) [4,5]. Participants self-selected 1 or 2 behaviors they wanted to focus on in the first in-person group class. To make this selection, participants engaged in a guided reflection through which they assessed their level of engagement with each healthy behavior, whether they wanted to improve upon it, and their confidence in making the improvements or changes.

Participants received 10 hours of contact over 13 weeks. There were 3 in-person group classes, 4 group telehealth calls, and 2 individualized telehealth calls. Telehealth activities were assessed using Zoom (Zoom Video Communications Inc) [24]. Each component was led by KP. The activities in each component addressed 6 SCT constructs: outcome expectations, behavioral capability, self-efficacy, goal intention, self-regulation, and supportive environment [23]. Behavior change techniques, including self-monitoring [25], that tapped into the theory constructs and addressed aspects of QoL were included in each component. To support the execution of the components and behavior change, participants received a

physical workbook that included class and call content, action planning materials, and evidenced-based resources (eg, exercise DVDs). Group components also provided avenues for discussion about participants' experiences as a cancer survivor to extend social networks to include other cancer survivors.

Figure 1. *we*Survive program conceptual model and component design. SCT: Social Cognitive Theory.



Component	Time	Week	Behavior/Content Focus	SCT Constructs	Behavior Change Technique	Other Activities
In-person group classes	2 hours	1	Healthy behaviors for survivors (overview all)	• Outcome expectations • Behavioral capability • Self-efficacy • Goal intention • Self-regulation • Supportive environment	• Comparison of the behavior • Comparison of outcomes • Sharing knowledge • Self-belief • Goals and planning • Feedback and monitoring • Social support • Restructuring social environment	• Storytelling • Shared meal • Discussion of other concerns • Evidence-based behavior change resources
		5	Physical activity (and healthy weight)			
		13	Relaxation & sleep			
Group telehealth	1 hour	3	Tobacco & alcohol & ultraviolet (UV) light exposure			
		4	Healthy weight 101			
		7	Nutrition behaviors (and healthy weight)			
		11	Health care provider visits & communication			
Individual telehealth	20 minutes	2	Target behavior of participant			
		9	Target behavior of participant			

ORBIT Framework Phase 2: Preliminary Testing

Intention of Phase

The goal of phase 2 of the ORBIT model is to determine the potential of the intervention to produce clinically significant findings and evaluate intervention feasibility. A hallmark of this phase is the establishment of a clearly articulated intervention protocol (eg, curriculum, protocols for recruitment, retention, and data collection). This phase consists of proof-of-concept studies, followed by pilot studies. Proof-of-concept studies aim to determine whether the intervention warrants more rigorous testing or whether modifications are needed before additional testing. Proof-of-concept studies are usually conducted using quasi-experimental designs and usually have small sample sizes. Small sample sizes are acceptable, as the intention is to identify clinically significant impacts, not statistically significant ones.

The *we*Survive proof-of-concept study used a single-group pre-post design and a concurrent mixed methods approach [26]. All study procedures were approved by the UVA Institutional Review Board (IRB). As study measures were completed over the telephone to reduce participant burden, participants provided verbal informed consent. They received US $25 in gift cards to complete each of the baseline assessments and postassessments. Participants also received a US $5 gas card for each in-person class attended to assist with cover transportation costs.

Recruitment

Recruitment strategies were executed at the organizational and participant levels. At the organizational level, 2 local health care organizations that provide clinical care to cancer survivors were approached to be a part of this study. Importantly, a member of the advisory team worked for one of these organizations. To recruit the organizations, we presented the intention and design of the *we*Survive intervention and the proof-of-concept trial to key clinical staff. After the organizational staff expressed interest, we reviewed the participant recruitment protocol with them and tailored the recruitment strategy, including a communication plan, to their needs. As needed, we obtained approval from the IRB of the organizations.

Following organization recruitment, *2* cohorts of participants were recruited from 2 recruited organizations. To be eligible, participants had to be cancer free, had to have completed primary treatment within the past 5 years, and be English speaking. Inclusion was not limited by cancer type or gender. The initial recruitment protocol involved selecting clinical staff who interacted with cancer survivors during their follow-up appointments to directly present the *we*Survive intervention to eligible survivors and solicit their interest. Then, for interested survivors, the clinician would securely share their contact information with the research team or show the prospective participant how to contact us. This strategy was expanded to include other active (eg, direct communication with research staff during follow-up appointments, booths at survivorship dinners, Relay-4-Life events) and passive (eg, flyers in waiting rooms) recruitment strategies.

Data Collection and Measures

Participant-level data were collected at baseline and postassessment. Process data were collected during the execution of the proof-of-concept trial. Table 1 describes the measures used to assess the indicators for the assessed feasibility domains.

During recruitment, research and organizational staff maintained recruitment logs and kept recruitment memos of interactions with prospective participants. These logs included the gender, age, and decision of all prospective participants with whom staff members spoke about joining *we*Survive as well as where and by whom they were approached. The research staff also kept notes during meetings with the organizational staff.

Research staff maintained attendance logs, recording attendance for each component.

Class artifacts, including action plans during the first group class, were photographed. The research staff also kept delivery memos of how each component went and the completeness of each activity. Tracking sheets were also used to monitor adherence to the intervention protocols (eg, sending reminder messages, contacts for individual calls).

To measure limited efficacy measures, participants completed a survey packet at baseline and postintervention. The packet was completed over the phone with a trained research staff member. The included measures were validated, cancer survivor specific, and/or successfully used in the region before. A total of 2 questions from the Health Information National Trends Survey were used to identify beliefs about cancer [27]. Single-item questions were used to assess self-efficacy and behavioral intentions to change dietary and PA behaviors [28]. The targeted dietary and PA health behaviors were assessed using scales from the NCI Multifactor Screener [29], Stanford Leisure-Time Activity Categorical Item (L-CAT) [30], and modified Godin [28]. Although behaviors, intentions, and self-efficacy were also assessed for other health behaviors, they were not reported in this paper because of the infrequency with which they were selected by participants. The Cancer Survivor Social Networks Measure [31] was used to assess participants' social networks. QoL was measured using the Quality of Life Patient/Cancer Survivor version [32]. Additional details regarding the measures can be found in Table 2.

Following completion of the postassessment survey, participants completed a *summative evaluation*. This semistructured interview assessed indicators of acceptability (ie, satisfaction), demand (ie, chosen behavioral target, reasons for choosing the behavioral target), and practicality (ie, barriers and facilitators of attendance) [33].

Participant *demographics* (ie, gender, age, race or ethnicity, income, educational attainment) and cancer experience (ie, type, staging, type of treatment, date of primary treatment completion) were collected at baseline. Health literacy was also measured using a validated 3-item brief questionnaire [34].

Table 2. Limited efficacy-related outcomes.

Variable type and specific variable	Scale	Preassessment (n=11), mean (SD)	Postassessment (n=11), mean (SD)	Direction of change	*t* statistic (*P* value)	Cohen *d*
Cancer beliefs and knowledge						
There are so many recommendations about preventing cancer, it's hard to know which ones to follow	5-point Likert scale (1=strongly disagree; 5=strongly agree)	4.0 (1.34)	3.6 (1.51)	↓[a]	1.102 (.30)	−0.28
Cancer is most often caused by a person's behavior or lifestyle	5-point Likert scale (1=strongly disagree; 5=strongly agree)	2.6 (1.63)	3.3 (1.62)	↑[b]	1.295 (.22)	0.43
Self-efficacy						
Self-efficacy to eat 5-9 servings of fruits and vegetables a day	10-point Likert scale (1=not at all confident; 10=totally confident)	6.7 (2.65)	6.6 (1.63)	↓	0.118 (.91)	−0.05
Self-efficacy to eat a diet with less saturated fat	10-point Likert scale (1=not at all confident; 10=totally confident)	7.6 (1.92)	7.4 (1.96)	↓	0.319 (.76)	−0.10
Self-efficacy to be physically active for 150 min a week	10-point Likert scale (1=not at all confident; 10=totally confident)	6.5 (3.39)	6.8 (2.79)	↑	0.498 (.63)	0.10
Behavior-specific intentions						
Eat 5-9 servings of fruits and vegetables a day	5-point scale (1=no intention to engage in at all; 5=already doing)	3.2 (1.40)	3.6 (1.29)	↑	1.174 (.27)	0.30
Eat a diet with less saturated fat	5-point scale (1=no intention to engage in at all; 5=already doing)	3.9 (1.38)	4.0 (1.18)	↑	0.289 (.78)	0.08
Be physically active for 150 min a week	5-point scale (1=no intention to engage in at all; 5=already doing)	3.2 (1.32)	3.9 (1.14)	↔[c]	2.667 (.02)	0.57
Health behaviors						
Fruit and vegetables	Daily portions	1.8 (1.38)	1.8 (.92)	↔	0.096 (.93)	0.00
Snack foods	Daily portions	1.1 (.84)	1.0 (1.58)	↓	0.178 (.86)	−0.08
Dietary fat	Daily portions	5.3 (6.53)	3.5 (4.45)	↓	1.402 (.19)	−0.32
Moderate-vigorous physical activity	Minutes per week	115.0 (137.20)	158.6 (237.78)	↑	0.889 (.40)	0.22
Self-reported frequency of physical activity	6-point scale (1=very little physical activity; 6=30 min of vigorous activity 5 or more times a week)	2.4 (.84)	2.8 (.92)	↑	1.809 (.10)	0.45
Social network						
Cancer-specific social support network size	Score of 0-15	9.6 (2.01)	10.5 (2.50)	↑	1.423 (.19)	0.40
Quality of life						
Overall	11-point Likert scale (0=extremely negative; 10=extremely positive)	8.1 (1.39)	7.8 (1.78)	↓	1.055 (.32)	−0.19
Physical	11-point Likert scale (0=extremely negative; 10=extremely positive)	8.6 (1.47)	7.8 (2.43)	↓	1.173 (.27)	−0.40
Emotional	11-point Likert scale (0=extremely negative; 10=extremely positive)	7.7 (1.77)	7.3 (2.26)	↓	1.303 (.22)	−0.20

Variable type and specific variable	Scale	Preassessment (n=11), mean (SD)	Postassessment (n=11), mean (SD)	Direction of change	*t* statistic (*P* value)	Cohen *d*
Social	11-point Likert scale (0=extremely negative; 10=extremely positive)	7.8 (2.40)	7.6 (2.33)	↓	0.578 (.58)	−0.08
Spiritual	11-point Likert scale (0=extremely negative; 10=extremely positive)	8.4 (1.74)	8.4 (2.17)	↔	0.120 (.91)	0.00

[a]Decrease in score from pre to postassessment.

[b]Increase in score from pre to postassessment.

[c]No change in score from pre to postassessment.

Data Analysis

Descriptive statistics (frequencies, means, medians, and ranges) were used to summarize participant demographics, participant satisfaction, recruitment and engagement rates, and selected behavioral targets. Limited efficacy measures were scored using standard procedures, and paired, two-tailed *t* tests were used to compare baseline and posttest responses for limited efficacy measures for program completers (n=11). Cohen *d* was calculated for each limited efficacy outcome. Open-ended data related to participant satisfaction, facilitators and barriers to engagement, component execution, and perceptions of organizations were content coded by one researcher and reviewed by another. Quantitative and qualitative data for each indicator were triangulated [26].

Results

Participants

A total of 12 participants were enrolled in 2 sequential pilot cohorts (n=5 and n=7). The participants were 75% (8/12) female and 100% (12/12) White. The average age of participants was 64 (SD 6.37) years, and 75% (9/12) were married. Half (6/12, 50%) of the participants were employed full-time, 33% (4/12) had a high school degree or less, and 25% (3/12) made under US $25,000 a year. All participants had medical insurance, either private (5/12, 42%) or Medicare (7/12, 58%). The majority of the participants (n=11) had adequate health literacy.

The participants were survivors of 6 types of cancer: breast (6/12, 50%), prostate (3/12, 25%), skin (2/12, 17%), colon (1/12, 8%), cervical cancer (1/12, 8%), and large B-cell lymphoma (1/12, 8%). Two participants (2/12, 17%) had multiple cancers. The participants had completed chemotherapy (8/12, 67%), radiation (5/12, 42%), surgery (8/12, 67%), and stem cell treatment (1/12, 8%). Over half of the participants (7/12, 58%) received multiple treatment types. On average, participants had completed primary treatment for 13.8 months (SD 13.5; range 1-40 months) before joining the trial.

Feasibility Indicators

The outcomes for acceptability, demand, practicality, and implementation are presented in Table 3, whereas limited efficacy outcomes are presented in Table 2.

Table 3. Findings related to the feasibility domains of acceptability, demand, practicality, and implementation.

Feasibility domain and indicator	Quantitative findings	Qualitative findings
Acceptability		
Organizational perceptions	—[a]	Staff from the 2 organizations that were approached to host *we*Survive felt it would be beneficial to their patients
Participant satisfaction	Overall rating, mean 10.0/10.0 (SD 0.00) • Group classes, mean 9.7/10.0 (SD 0.65) • Group calls, mean 9.5/10.0 (SD 0.87) • Individualized calls, mean 9.7/10.0 (SD 0.53)	Perceived program benefits: • Knowledge gained • Opportunity to share their experiences and learn about others' experiences • Felt the program was an important wakeup call • Saw the program as an opportunity to improve their lives or give back to others • No facets of the program identified as "unacceptable"
Demand		
Organizational adoption	• The 2 (100%) health care organizations approached agreed to take part in the *we*Survive proof-of-concept trial	—
Recruitment rates	• Recruitment rate=30% (12/41) • 59% (17/29) of nonenrolment was due to lack of ability to follow up with prospective participant to schedule or complete the survey • 38% (11/29) of nonenrolment was due to lack of interest	—
Participant participation	• Attrition=8% (1/12) Overall attendance: median 62% (average 56%): • Group class attendance: median 84% (average 72%) • Group call attendance: median 50% (average 42%) • Individual call attendance: median 50% (average 50%) • Of the 8 participants who attended group calls, only 3 (38%) used the video portion of the telehealth platform	• When completing action plans, participants often only partially completed them or just discussed their plans without writing them down. Participants appeared hesitant to set SMART[b] goals • During individual calls, 3 participants asked for and received support for specific dietary matters beyond what was in the standard curriculum
Behavioral target chosen by participants	100% (12/12) selected diet or PA[c]: • 83% (10/12) selected PA • 59% (7/12) selected a dietary behavior • 42% (5/12) chose both PA and diet • 50% (6/12) chose a behavior other than diet or PA: sleep (3/12, 25%), stress reduction (4/12, 33%)	Reasons for choosing behaviors: • Priority for personal or disease-specific reasons • Perceived as easier to address
Practicality		
Barriers and facilitators of participant engagement	—	Barriers to attendance: • Personal and work obligations Facilitators of attendance: • Participants found reminder texts helpful • Expanded texting reminder system in cohort 2 to include reminder day before and 2 hours before
Implementation		

Feasibility domain and indicator	Quantitative findings	Qualitative findings
Recruitment execution	Eligible participants (n=41) were approached through office visits (25/41, 61%), community events (13/41, 32%), and word of mouth (3/41, 7%): • 100% of office visit referrals were executed jointly by site and research staff • 100% of community event referrals were completed by research staff • 100% of word-of-mouth referrals were completed outside of the clinic by site staff	• At one of the 2 sites, a provider (MD or NP) introduced *we*Survive to an eligible participant. If the participant was interested, they invited the research team member to come in to speak with the participant. This process did not occur at the other site due to the distance to the site and inconsistent communication between research and site staff • Organization staff were very interested in the idea of the program but were unable to follow the recruitment protocol on their own (ie, refer eligible patients without the presence of a research team member) but were able to execute when working in conjunction with research staff
*we*Survive delivery	• 100% fidelity (of researchers) to the execution of intervention components and the participant retention protocol	—

[a]Quantitative or qualitative data was not collected for the feasibility domain indicator.

[b]SMART: specific, measurable, attainable, relevant, time-based.

[c]PA: physical activity.

Acceptability

Participants who completed the intervention (n=11) reported high satisfaction with the program (mean 10, SD 0.0) and with the individual components: group classes (mean 9.7, SD 0.65), group calls (mean 9.5, SD 0.87), and individual calls (mean 9.7, SD 0.53). Participants described benefits related to knowledge attainment, feeling that *we*Survive was a *wakeup call* to improve their health, sharing their cancer experiences and hearing others' cancer experiences, and knowing that by being in the trial they were helping future cancer survivors. In addition, staff from the participating organizations expressed positive reactions to the program and viewed it as having the potential to be beneficial to their patients.

Demand

The 2 local health care organizations approached to participate in the proof-of-concept trial agreed to participate. The participant recruitment rate for the trial was 30%, with 12 of 41 eligible individuals approaching enrolment in the program. Among individuals who did not enroll, 38% (11/29) expressed a lack of interest in the program or prohibitive barriers (eg, language difficulties, transportation) and 59% (17/29) had barriers that limited scheduling surveys or completed the web-based presurvey.

Intervention attrition for the program was low, with only 1 participant (1/12, 8%) not completing the program. The median participation rate for all activities was 62%, with the medians for class, group call, and individual being 84%, 50%, and 50%, respectively. Of the 8 participants who completed group calls, only 3 (38%) used the video portion of the telehealth platform. The other 5 called into the platform using the telephone number and did not use the phone, tablet, or computer application that would have allowed for video.

Research staff noted that participants did not fully engage in self-monitoring activities, such as setting a specific behavioral goal and writing SMART (specific, measurable, attainable, relevant, time-based) goals, even with prompting. For example, a participant would broadly describe their target behavior (ie, "eat healthy" instead of "eat 5 fruits and vegetables 3 days a week day") and would not include a plan for how they would make the change.

Although participants could choose among 11 behaviors, 100% chose either a diet (7/12, 59%) or PA behavior (10/12, 83%) and 42% (5/12) chose both. Of the 6 nondiet or PA behaviors, only 2 were selected: stress (n=3) and sleep (n=4).

Practicality

Participants identified personal and work obligations as their primary barriers to participate in intervention activities. They identified the reminder texts as facilitators of attendance.

Implementation

Staff from both organizations were unable to follow the original recruitment protocol and did not refer participants to the program without on-site support from the research staff. Therefore, it was necessary to adapt the recruitment protocol to provide on-site research staff support at the clinic and recruit through community events. Eligible participants were identified in 3 ways: during office visits (25/41, 61%), at community events (13/41, 32%), and word of mouth (3/41, 7%). Organizational staff made all word-of-mouth referrals, whereas research staff made referrals through community events. All office visit referrals occurred with the organizational and research staff working together. Organizational staff would introduce *we*Survive to an eligible participant and, if interested, a research team member provided further detail and collected their contact information to complete the surveys.

There was 100% fidelity to the delivery and retention protocols by the research staff. All planned activities for the components were executed as designed, and participant retention strategies (eg, reminder texts) were adhered to as intended.

Limited Efficacy

Regarding behavior-related psychosocial variables, participants changed their beliefs about cancer with respect to knowing

which recommendations to follow (Cohen *d*=0.28) and the impact of lifestyle behaviors on cancer risk (Cohen *d*=0.43) in the desired direction. Self-efficacy to meet the PA guidelines changed in the desired direction, whereas changes in self-efficacy to reduce dietary fat and increase fruits and vegetables were in the undesired direction (ie, lower self-efficacy). The effect sizes for the behavioral self-efficacy variables were very small (≤0.10). Although not statistically significant, behavioral intentions to eat more fruits and vegetables, eat less fat, and meet PA guidelines changed in the desired direction. The change in intentions specific to PA was statistically significant (*P*=.02) and demonstrated a medium effect size (Cohen *d*=0.57).

Baseline to postassessment changes in dietary and PA behaviors were in the desired directions but were not statistically significant. Effect sizes for fruit and vegetable intake, snack foods, dietary fat, and minutes of moderate-vigorous activity were small (Cohen *d*=0.00 to 0.32), whereas the effect size for L-CAT score was medium (Cohen *d*=0.45).

Participants' social networks specific to their cancer support networks increased. Although not significant, this change had a small-to-medium effect size of 0.40.

Regarding QoL indicators, there were nonsignificant decreases (ie, worsening of QoL) in all indicators. The magnitude of these changes was small for overall QoL, emotional QoL, social QoL, and spiritual QoL (Cohen *d*=0.00 to 0.20); However, the change in physical QoL from baseline to postassessment was small or medium (Cohen *d*=0.40).

Discussion

Principal Findings

Taken together, our results suggest that the *we*Survive intervention has the potential to be feasible. Our findings also highlight how the design and execution of the intervention and its components could be improved to further enhance its feasibility, including increasing efficacy among cancer survivors. Furthermore, outcomes also provide support for using a participatory process and a systematic planning model, such as the ORBIT model, to inform the design of behavioral interventions for cancer survivors.

Implications for *we*Survive's Feasibility

Our findings suggest high feasibility related to indicators of acceptability (ie, high satisfaction), demand (ie, high adoption rate by organizations, diversity of cancer survivors by cancer type and gender, low attrition rate, recruitment, and component engagement rates similar to other behavioral interventions for rural participants and/or cancer survivors [28,35-38]), and implementation (ie, high researcher fidelity to protocols). However, findings related to indicators of practicality (eg, consistent barriers to participation), implementation (eg, ability of organizational staff to follow intended delivery, retention, and recruitment protocols), and limited efficacy highlight opportunities to adjust aspects of the intervention design and delivery protocols that could improve feasibility.

Although our results do not fully confirm the feasibility of *we*Survive, they identify areas where modifications to *we*Survive's design and protocols could strengthen feasibility. As proof-of-concept studies focus on the feasibility of the intervention, the evidence collected provides integral preliminary data not only about its clinical efficacy but also its relevance and potential sustainability. This preliminary evidence can help build an intervention that is both effective and more readily translated into practice. This is particularly important for behavioral interventions for rural cancer survivors, as efforts to address the health behaviors of cancer survivors in rural regions are limited [13].

Recommendations to Improve Feasibility of *we*Survive and Other Behavioral Interventions for Rural Cancer Survivors

A total of 6 recommendations that impact all measured feasibility domains from this proof-of-concept study were identified. In addition to being directly relevant to the *we*Survive intervention, many of these recommendations are broadly applicable and can be used to inform future behavioral interventions for cancer survivors.

Tighten the Behavioral Focus of weSurvive (Demand and Efficacy)

Including a wide array of behaviors important for positive survivorship outcomes was suggested by the advisory team to ensure the applicability of the program to regional cancer survivors. However, demand findings clearly demonstrated that diet and PA were the most popular choices, with all participants choosing one or the other. In addition, limited efficacy outcomes suggest that *we*Survive impacted these behaviors and related psychosocial variables in the desired direction, with some of the PA outcomes having small-to-moderate effects. Making this adjustment would streamline *we*Survive's behavioral focus, potentially impacting the magnitude of effects for the targeted behaviors. Although the recommendation to include a variety of behaviors may have hindered feasibility, incorporating this suggestion from the advisory team during this initial phase allowed us to better ascertain the wants of regional cancer survivors. Importantly, although the behavioral focus of *we*Survive will shift to energy-balance–related behaviors, the program will still include content related to stress reduction and sleep.

Add Additional Recruitment Strategies (Demand)

Although we recruited a diverse group of participants with regard to gender and cancer experience, the overall group sizes were small, and the recruitment rate of 30% was modest. During the trial, we added and adapted strategies to maximize the recruitment efforts. Successful strategies included having an on-site research staff recruit in tandem with organizational staff and promoting *we*Survive at community events targeting cancer survivors. For future trials of *we*Survive, these strategies should be incorporated into recruitment from the start.

An additional recruitment strategy was to promote *we*Survive during survivorship care plan meetings. Survivorship care plans are a highly recommended part of survivorship care [39], and more clinics are systematically using them. Suggestions for

behavioral changes may be included [40], but not all clinics have the resources to facilitate behavioral changes, including those related to diet, PA, and weight change behaviors. Therefore, aligning *we*Survive with cancer care survivorship plans could make the intervention more relevant for organizations and provide a natural place for it within the workflow, which could motivate organizational staff to promote *we*Survive. Although this seems to be a logical connection, few known behavioral interventions for cancer survivors reported tying their intervention in survivorship care plans [41]. If future behavioral interventions were designed to address needs highlighted by their participants' survivorship care plans, this could increase the demand for the program from both the participant and organizational sides and could help cancer survivors better execute their plans.

Recruitment into behavioral interventions can be one of the most difficult aspects of executing an intervention, and underaccrual of participants hinders many interventions. Past lifestyle interventions for cancer survivors have reported a range of recruitment rates ranging from 4% to 70%. Although this difficulty is prevalent in densely populated regions, it may be even greater in rural regions, such as Appalachia, which have smaller populations and lack large academic medical centers and large cancer centers. Therefore, using preliminary data to create a tailored, adaptable, and multi-faceted approach to recruitment may aid in the successful recruitment of other behavioral interventions as well [42].

Incorporate Strategies to Support Program Engagement (Demand and Practicality)

The participation rates from our trial were similar to those of other behavioral interventions for cancer survivors [28,35-38]. However, these rates can be improved by addressing the barriers to attendance identified by the participants (eg, conflicts with personal and work scheduling, forgetting). Future strategies include (1) having at least 2 formal day or time opportunities to participate in all group activities, (2) sending reminder texts the day before and 2 hours before the scheduled call time for virtual components, and (3) offering virtual makeup sessions. These changes could improve feasibility related to participant perceptions of acceptance and practicality for *we*Survive and could be applicable strategies for similar interventions.

In addition to overall participation rates, findings show that engagement with the video portion of the teleconferencing platform was underused. Most of the 8 participants who attended at least one group call only used the audio capabilities of the platform (82.5%), and none of the participants used the video feature for all group calls they completed. We suspect that reasons include unfamiliarity with the technology and poor internet or cellular access and/or quality. During the proof-of-concept trial, participants received a written instruction sheet, and the researcher delivered the first group class talked through the instructions. Additional activities to encourage use could include a platform demonstration, a formal system for troubleshooting barriers to using the teleconferencing platform, and structured conversations about the benefits of participation in virtual components. Providing this additional support may be valuable for rural participants in lifestyle programs, as previous studies have shown that they may hesitate to use teleconferencing platforms due to low digital literacy, privacy concerns, and fear that it might limit group connection [43]. Importantly, as found in other studies with rural populations, the video portion of teleconferencing calls enabled participants to experience greater engagement and feelings of support than they would have if these components were absent [43]. Importantly, as this study was conducted before the COVID-19 pandemic, during which the general public started regularly using Zoom and other teleconferencing platforms, this experience may make future participants more comfortable with the video feature.

Improve Engagement in Behavioral Self-Monitoring Strategies by Creating More Accountability and Motivation (Implementation)

Behavioral self-monitoring encompasses vital behavior change techniques, such as goal setting and self-monitoring activities, which are linked to better behavioral changes [44]. Action planning, sharing goals, and discussing progress and struggles were included in each component of *we*Survive. However, participants in this trial did not fully engage in self-monitoring activities, particularly action plans. The behavior change literature suggests that this is common and that strategies can be employed to increase engagement with action planning, such as sending motivational messages, sending text messages or email reminders, and providing feedback [45,46]. In this proof-of-concept trial for *we*Survive, personalized approaches to keep participants motivated toward and accountable for their goals were not included, as our focus was on solidifying the curriculum content and recruitment, retention, and data collection protocols. Adding accountability structures appropriate to rural populations could increase engagement with behavioral self-monitoring activities. It might also be necessary to create norms within the group activities to make participants feel comfortable to share their goals, progress, and struggles and to help one another troubleshoot their issues. Employing this recommendation will not only increase the implementation of behavioral self-monitoring activities but also limit the behavioral targets of the program and impact the intervention's efficacy on behavioral outcomes and QoL.

Capture the Overall Health Experiences of the Participants During the Trial Timeline

For this proof-of-concept study of *we*Survive, there were no statistically significant yet undesired changes in QoL indicators. This undesired change is not unusual, as postassessment scores on QoL measures sometimes go in the *wrong* direction due to participants rating themselves higher at baseline, potentially because they are primed to have higher expectations for QoL. In addition, through informal conversations with participants, we learned that 3 of them had substantial negative health experiences unrelated to the trial (ie, hospitalization, injury that required surgery, negative reaction to adjuvant therapy). When they were removed from the analyses, the changes either moved in the desired direction or the magnitude of the undesired changes was reduced. If captured systematically during interventions, these participant experiences could be factored into the actual outcome analyses or provide context to their

interpretation. This will allow for more context from which to interpret QoL outcomes and identify whether they are unintended consequences of the intervention.

Use a Participatory Process to Engage Stakeholders During Intervention Development or Adaptation Interventions (Demand)

Engaging stakeholders identified the key features that aided feasibility. Features identified by the *we*Survive advisory team impacted indicators of demand and included suggestions to blend group and individual activities and were not limited by cancer type or gender. In addition, these considerations informed the decision to measure social networks, which were found to moderately, though not significantly, increase. Interestingly, 4 of the 5 participants who did not include survivors or support groups as part of their network at baseline did at postassessment. This measurement of social networks along with broad inclusion criteria added innovative features to *we*Survive, which may aid in its future translation to practice. Although there is evidence that stronger social networks are linked to improved cancer survivorship outcomes [47] and that rural cancer survivors may be less connected than survivors in other regions [48], measuring and seeking to enhance social networks is not a common feature of behavioral interventions for cancer survivors. In addition, the advisory team recommended that the intervention allow participants to have authentic opportunities to share their stories and hear from others. Although storytelling is a noted cultural tradition in Appalachia [49] and has been used in cancer-focused interventions to transfer knowledge and address emotional and existential or spiritual concerns [50], it most likely would not have been included at this early stage of development of *we*Survive if not for the advisory team. Finally, our first site was identified by one of our community stakeholders. Stakeholder participation can strengthen the design and execution of behavioral interventions by identifying unique needs or resources within the community. Although not all the comments from the advisory team aided feasibility (ie, focusing on multiple behaviors), without our stakeholder's input and support, many of these other features would not have been included.

Limitations

When interpreting this study's conclusions, it is important to consider these limitations. The participant sample for the proof-of-concept trial was small. Although this impacts statistical power and interprets limited efficacy outcomes, it was still adequate to identify effect sizes and inform other feasibility indicators. The sample was not racially diverse; however, the racial makeup of the study reflects the geographical region, which is approximately 95% non-Hispanic White [8]. In addition, the sample was diverse in terms of gender and cancer experience and represented an underserved rural population. Finally, data were primarily collected at the participant level and, as such, findings are limited to feasibility at the organizational level. Future trials of *we*Survive will need to include a more robust evaluation of organizational-level indicators, including acceptability, practicality, and feasibility at this level and the potential for integration and penetration [19], to more fully understand

feasibility and identify modifications to protocols, particularly those related to recruitment.

Conclusions

Findings from our study will inform changes to the *we*Survive intervention's conceptual model, program design, and recruitment and delivery protocols. The recommendations identified through our study will be incorporated into the next version of *we*Survive. Engagement in the participatory development process and initial proof-of-concept testing strengthens *we*Survive and will lead to the development of a behavioral intervention that could positively impact the health of cancer survivors in rural Appalachia and be more readily translated into practice. Importantly, the findings also stress the importance of using a model, such as the ORBIT framework, when developing or adapting behavioral interventions for cancer survivors. By conducting small-scale proof-of-concept studies, the feasibility of the novel or adapted intervention can be assessed relatively quickly and inexpensively, and the necessary revisions can be made before larger-scale testing.

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Conflicts of Interest

None declared.

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Abbreviations

CAB: Community Advisory Board
IRB: Institutional Review Board
L-CAT: Stanford Leisure-Time Activity Categorical Item
NCI: National Cancer Institute
ORBIT: Obesity-Related Behavioral Intervention Trials
PA: physical activity
QoL: Quality of Life
SCT: Social Cognitive Theory
SMART: specific, measurable, attainable, relevant, time-based
UVA: University of Virginia

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Original Paper

A Home-Based Mobile Health Intervention to Replace Sedentary Time With Light Physical Activity in Older Cancer Survivors: Randomized Controlled Pilot Trial

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Abstract

Background: Older cancer survivors are at risk of the development or worsening of both age- and treatment-related morbidity. Sedentary behavior increases the risk of or exacerbates these chronic conditions. Light-intensity physical activity (LPA) is more common in older adults and is associated with better health and well-being. Thus, replacing sedentary time with LPA may provide a more successful strategy to reduce sedentary time and increase physical activity.

Objective: This study primarily aims to evaluate the feasibility, acceptability, and preliminary efficacy of a home-based mobile health (mHealth) intervention to interrupt and replace sedentary time with LPA (standing and stepping). The secondary objective of this study is to examine changes in objective measures of physical activity, physical performance, and self-reported quality of life.

Methods: Overall, 54 cancer survivors (aged 60-84 years) were randomized in a 1:1:1 allocation to the tech support intervention group, tech support plus health coaching intervention group, or waitlist control group. Intervention participants received a Jawbone UP2 activity monitor for use with their smartphone app for 13 weeks. Tech support and health coaching were provided via 5 telephone calls during the 13-week intervention. Sedentary behavior and physical activity were objectively measured using an activPAL monitor for 7 days before and after the intervention.

Results: Participants included survivors of breast cancer (21/54, 39%), prostate cancer (16/54, 30%), and a variety of other cancer types; a mean of 4.4 years (SD 1.6) had passed since their cancer diagnosis. Participants, on average, were 70 years old (SD 4.8), 55% (30/54) female, 24% (13/54) Hispanic, and 81% (44/54) overweight or obese. Malfunction of the Jawbone trackers occurred in one-third of the intervention group, resulting in enrollment stopping at 54 rather than the initial goal of 60 participants. Despite these technical issues, the retention in the intervention was high (47/54, 87%). Adherence was high for wearing the tracker (29/29, 100%) and checking the app daily (28/29, 96%) but low for specific aspects related to the sedentary features of the tracker and app (21%-25%). The acceptability of the intervention was moderately high (81%). There were no significant between-group differences in total sedentary time, number of breaks, or number of prolonged sedentary bouts. There were no significant between-group differences in physical activity. The only significant within-group change occurred within the health coaching group, which increased by 1675 daily steps (95% CI 444-2906; *P*=.009). This increase was caused by moderate-intensity stepping rather than light-intensity stepping (+15.2 minutes per day; 95% CI 4.1-26.2; *P*=.008).

Conclusions: A home-based mHealth program to disrupt and replace sedentary time with stepping was feasible among and acceptable to older cancer survivors. Future studies are needed to evaluate the optimal approach for replacing sedentary behavior with standing and/or physical activity in this population.

Trial Registration: ClinicalTrials.gov NCT03632694; https://clinicaltrials.gov/ct2/show/NCT03632694

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KEYWORDS

light-intensity physical activity; physical activity; sedentary behavior; mobile health; cancer survivors; consumer wearable; activity monitor; mobile phone

Introduction

Background

By 2030, there will be 22.1 million cancer survivors living in the United States, and two-thirds of them will be more than 65 years old [1]. Older cancer survivors are faced with both age- and treatment-related morbidity that increase their risk of physical function impairment and other comorbidities, including cardiovascular disease, diabetes mellitus, and osteoporosis [2-5]. These comorbidities further increase the risk of functional limitations. Compared with individuals without a history of cancer, cancer survivors have a 2- to 5-fold increased risk of having one or more functional limitations [5]. These chronic conditions are associated with diminished quality of life (QoL), premature death, and substantial financial costs [6-11]. Physical inactivity and sedentary behavior (too much sitting, which is distinct from too little exercise [12]) can increase the risk of or exacerbate these chronic conditions [13-19].

Recent research suggests that sedentary behavior has molecular and physiological effects distinct from a lack of exercise [20,21]. Sedentary behavior is defined as any waking behavior (ie, not sleep) characterized by minimal energy expenditure (≤1.5 metabolic equivalents [METs]) while in a sitting, lying, or reclining position [22]. Sedentary behavior is associated with an increased risk of cardiovascular disease [23,24], premature all-cause mortality [23,25-27], greater fatigue [28,29], and decreased physical function [11,29,30]. Furthermore, how sedentary time is accumulated throughout the day is important, as frequent short breaks in sedentary time can attenuate the negative physiological response associated with prolonged, uninterrupted periods of inactivity [31-34].

Among cancer survivors, less than 2% of waking hours are spent in moderate-to-vigorous physical activity (MVPA), up to 70% of waking hours are spent in sedentary activities, and the remaining time is spent in light-intensity physical activity (LPA) [35]. LPAs are associated with better physical health [36,37], including better physical function [37-40], reduced risk of incident disability [39,41], and better emotional well-being [36,40,42,43], independent of MVPA. The association between LPA and health outcomes is either only apparent or appears stronger in older adults and adults who are less physically active or have impaired lower extremity function [41,44-47]. Thus, disrupting and replacing sedentary time with LPA, rather than MVPA, are likely a more feasible approach to reducing sedentary behavior in older cancer survivors.

Behavior change interventions based on theory are generally more effective than atheoretical approaches [48-50]. Recent reviews suggest that goal setting, feedback, self-monitoring, problem solving, and social support are the most promising behavioral change techniques for interventions designed to reduce sedentary behavior [51-53]. Unlike simple pedometers, consumer wearable activity trackers include multiple behavior change techniques [54,55]. The ability to provide feedback in real time is particularly salient for sedentary behavior, as it is a largely subconscious behavior [51]. Furthermore, wearable activity trackers are readily available and low cost and, if effective, represent a scalable option for expanding the reach to a large number of cancer survivors, including in rural areas.

Given the deleterious effects of sedentary behavior on health, including cardiovascular disease and diabetes mellitus, conditions that are commonly observed in older cancer survivors, or for which they are at an elevated risk [56], the role of sedentary behavior in cancer survivorship has been identified as a research priority [35,57]. However, to date, few interventions have been designed to reduce sedentary time among cancer survivors [51]. Recently, several mobile health (mHealth) pilot or feasibility interventions have evaluated text messaging or wearable activity trackers as an intervention tool to decrease sedentary behavior in breast, prostate, and colorectal cancer survivors [58-60]. These interventions encouraged standing and stepping to replace sedentary behavior, with a primary focus on moderate-intensity activity. Preliminary results suggest that mHealth interventions are feasible and acceptable in this population and have the potential to replace sedentary behavior with physical activity, at least in the short term. However, additional research is needed to further evaluate effective strategies to reduce sedentary time by either replacing it with standing, stepping, or both.

Objectives

The purpose of this study is to examine the feasibility, acceptability, and preliminary efficacy of an mHealth intervention for disrupting (frequent breaks) and replacing sedentary time with intermittent bouts of LPA (standing and stepping). The 13-week intervention used the Jawbone UP2 activity monitor and associated smartphone app to promote awareness and enable self-monitoring of both physical activity and inactivity. We evaluated 2 versions of the mHealth intervention: a low-touch approach providing only tech support and a higher resource approach that included health coaching in addition to the tech support. This would allow us to determine whether a low-cost, consumer-based technology (wearable activity tracker plus smartphone app) is effective in meeting the goals or whether health coaching is needed to cover additional behavior change techniques not provided in the wearable activity tracker. Our primary objective is to determine the feasibility and acceptability of the 2 versions of the mHealth intervention by assessing recruitment, retention, and adherence rates; monitoring adverse events; and evaluating satisfaction with the program. In addition, we examined the preliminary

efficacy of the intervention on changes in objective measures of daily total sedentary time and the number of breaks in sedentary time. Our secondary objective is to explore changes in objective measures of physical activity, physical performance, and self-reported QoL.

Methods

Study Design

This study was a 3-arm pilot randomized controlled trial (RCT). Older cancer survivors were randomized in a 1:1:1 allocation to the tech support intervention group, the tech support plus health coaching intervention group, or a modified waitlist control group. The intervention used a consumer wearable activity tracker (Jawbone UP2 wristband) that was paired with a smartphone app to promote awareness and enable self-monitoring of both inactivity (band gently vibrates after a specified time of inactivity) and physical activity (eg, steps per day). We evaluated 2 versions of the intervention: a low-touch approach providing only tech support and a higher resource approach that included health coaching in addition to the tech support. Each intervention group was compared with the waitlist control group. Recruitment for the trial began in June 2016, and data collection was completed in July 2017.

Eligibility

Eligibility criteria for the feasibility study included (1) men and women aged 60 years and older (reduced from 65 years to increase the number of participants who own a smartphone); (2) those who were diagnosed as having an invasive, local or regionally staged cancer within the past 7 years (time frame increased the likelihood that address and phone number in cancer registry were still current) and completed primary treatment (surgery, radiation, and chemotherapy); (3) those who owned a smartphone capable of running the Jawbone UP2 smartphone app; (4) those who were willing to be randomized to any of the 3 study arms, attend 2 clinic visits, and wear activity monitors; (5) those who were able to read, speak, and understand English; (6) those who were living independently and were capable of walking 3 blocks (approximately 1/4 mile or 1300 steps) without an assistive device (eg, cane and walker); (7) self-reported sedentary time (during waking hours) of ≥6 hours/day (Longitudinal Aging Study Amsterdam Sedentary Behavior Questionnaire: hours and minutes in a day spent in 10 activities, on average, during a weekday [61]); (8) those who were not currently participating in a program to decrease sedentary time or increase physical activity and not currently using a fitness tracker; (9) those who had no paid employment or volunteer position for more than 20 hours per week (to avoid potential confounding by occupational activity/inactivity); (10) those who had no severe impairments (in seeing or hearing) or preexisting medical limitations for engaging in daily LPA (eg, severe orthopedic conditions, pending hip/knee replacement, dementia, and oxygen dependent); (11) those who had residence within 60 miles of the research clinic (to reduce travel burden and improve retention and compliance); and (12) those who had a wrist size of 14 cm to 20 cm to wear the Jawbone UP2 activity wristband during the intervention. Individuals who met the physical activity guidelines (150 minutes per week of MVPA) [17,62] were eligible because sedentary behavior is a risk factor for morbidity and mortality independent of MVPA.

Recruitment

The population-based New Mexico Tumor Registry, a founding member of the Surveillance, Epidemiology, and End Results Program [63], was used as the primary source for identifying potential study participants. Additional sources included posting flyers at selected locations, including senior centers and libraries. After identifying potentially eligible study participants, the New Mexico Tumor Registry mailed a letter that introduced the study and gave potentially eligible participants the opportunity to decline further contact. Contact information for individuals not refusing further contact was provided to the study team after a 3-week waiting period. Potential participants were then mailed a letter explaining the study and a consent form. One week later, the staff telephoned to discuss the study, answer questions, begin the consent process, and verify eligibility. Up to 3 attempts (later expanded to 4) were made to reach individuals who had a valid telephone number. A written informed consent for the interested and eligible participants was obtained during the baseline clinic visit.

Randomization

After a 1-week run-in period, a member of the research team opened the next sequentially numbered sealed envelope (created by a biostatistician) to reveal the randomization status. Participants were block randomized with equal allocation to 3 arms (tech support, tech support plus health coaching, or modified waitlist control) according to obesity status (BMI <30 vs ≥30 kg/m^2).

mHealth Intervention

Theoretical Framework

The theoretical framework used to guide this intervention was the social cognitive theory [64,65]. The intervention primarily targeted the theoretical constructs of knowledge, behavioral skills, behavioral capability, and self-efficacy. Wearable activity trackers, such as Jawbone, include a number of behavioral change techniques associated with decreasing sedentary behavior and increasing physical activity (eg, goal setting, graded tasks, and self-monitoring) [54,55]. However, some of the key techniques are missing and were supplemented with educational materials and technology support. Additional behavior change techniques were provided by the health coaches for the health coaching intervention, such as the identification of barriers and problem solving. Health coaches also provided encouragement and support and encouraged positive support from family and friends. A list of the behavior change techniques, theoretical constructs, and examples of strategies to promote behavior change in this mHealth intervention is presented in Table 1.

Table 1. Behavior change techniques and strategies to promote behavior change via educational materials, the Jawbone tracker and app, or tech support coaching or health coaching.

Behavior change technique	Theoretical construct	Examples of strategies	TS[a] group			HC[b] group		
			EM[c]	JB[d]	TS	EM	JB	HC
Information on consequences of behavior	Knowledge	Educational materials on harms of physical inactivity and sedentary behavior; also discussed with health coach	✓[e]			✓		✓
Goal setting (behavior)	Behavioral skills; self-efficacy	Set weekly short-term and long-term step goals; tech support for changing goal settings on app; idle alert goal (every 30 min) and step goal (graded increase in steps)		✓	✓		✓	✓
Barrier identification and problem solving	Barrier self-regulatory efficacy	Work with health coach to assess barriers and identify solutions to breaking up sedentary time and getting more steps throughout the day						✓
Set graded tasks	Self-efficacy	Encourage incremental and achievable sedentary (breaks) and step goals		✓			✓	
Review of behavioral goals	Behavioral skills	Using Jawbone app to review daily progress and weekly patterns for longest idle time and steps		✓			✓	
Generalization of a target behavior	Behavioral capability	Educational materials with suggestions for breaking up sedentary time in different ways and locations; additional support from health coach	✓			✓		✓
Self-monitoring of behavior	Behavioral skills	Using Jawbone app to review daily progress and weekly patterns and provide immediate feedback (idle alert and longest idle time)		✓			✓	
Feedback on behavior	Behavioral skills	Jawbone tracker and app provide immediate feedback; health coach to discuss whether goals were met		✓			✓	✓
Information on where and when to perform behavior	Behavioral capability	Education materials to suggest tips for disrupting SB[f]; Jawbone idle alert to prompt when to stand up and move	✓	✓		✓	✓	
Instructions on how to perform the behavior	Self-efficacy; behavioral skills	Print materials and coaching provide instructions on setting up and using the Jawbone tracker and app	✓		✓	✓		✓
Social support	Social support	Health coach provides support and encouragement; provide information and suggestions when asked; encourage enlisting positive support from family members and friends to take more steps throughout the day						✓
Use prompts/cues; prompt practice	Cues to action	Jawbone idle alert will prompt user to disrupt sitting with standing or stepping; Jawbone alerts will prompt more steps to reach daily goal		✓			✓	

[a]TS: tech support.

[b]HC: health coaching.

[c]EM: educational material.

[d]JB: Jawbone tracker and app.

[e]Primary source for the behavior change technique.

[f]SB: sedentary behavior.

Components of the Intervention

The mHealth intervention consisted of educational materials; a Jawbone (in)activity tracker; a free, commercially available smartphone app; and support via 5 telephone calls. The only difference between the 2 intervention groups was the level of telephone support. One group received only support related to the use of technology (tracker and app, tech support group), whereas the other group received additional health coaching to meet the study goals (tech support plus health coaching group).

Educational Materials

Upon randomization, both intervention groups received brief educational materials by mail. These materials explained the negative consequences of sedentary behavior, especially prolonged periods of sitting, and included suggestions for how to disrupt and replace sedentary time with LPA. Examples of suggestions provided included walking around the house during television commercial breaks, standing while talking on the telephone, and parking the car further away from the entrance [66]. The summary graph representing the most active and least active days from the week-long collection of objectively measured sedentary time, standing, and stepping (output from the activPAL3 monitor) was mailed to study participants (for later discussion with their coach; Multimedia Appendix 1). The waitlist control group received educational materials at the

postintervention follow-up when they received their activity tracker and smartphone app.

Jawbone UP2 Activity Tracker

Upon randomization to either of the 2 intervention groups, participants were mailed the Jawbone UP2 activity wristband and provided detailed instructions for installing the free, commercially available app on their smartphone and for using the wristband with the app. At the time the study was designed (2015), this was one of the few consumer wearable activity trackers that had the ability to alert the wearer after a specified time of inactivity. For the Jawbone monitor, this feature was known as an *idle alert*, which notified the user of inactivity via a gentle vibration of the wristband (eg, users select time in increments of 15 minutes). The assigned coach telephoned participants to assist with the installation and setup of the activity tracker and smartphone app.

The goal was to decrease daily total sedentary time and increase the number of breaks in sedentary time by replacing/disrupting sedentary time with intermittent bouts of LPA (standing and stepping). The key message for the activity prescription was to "sit less, stand more, and move more, throughout the day, every day." This message was included in the educational materials and was repeated during each of the 5 support telephone calls. Participants were encouraged to stand up and move at least once every 30 minutes. To encourage more movement than standing, participants were provided with a graduated steps per day goal of adding 3000 steps per day above their baseline level by week 9 (schedule in Figure 1). This target represents approximately 40 extra minutes of leisurely paced walking [67] and is associated with health benefits [36,68]. When combined with 20 minutes of standing, this would result in replacing 1 hour of sedentary time with 1 hour of LPA per day. A minimum intensity and a minimum bout duration for stepping were not provided, thus allowing the participant to self-select how to accumulate their extra daily steps.

The participants were instructed to wear the Jawbone during waking hours and were encouraged to track their activity at least once a day by viewing their results on the app. A commercially available app was used without any modifications by the research team. The app included a daily summary of total steps, total and longest active time, and longest idle time (longest time spent sedentary). To promote gradual and sustained change in LPA, participants were asked to increase the number of steps per day (above their individual baseline level), during weeks 1 to 9, and then work to maintain their goal during weeks 10 to 13 (Figure 1). Similarly, the *idle alert* setting began at 1 hour, decreased to 45 minutes, and then every 30 minutes. Participants in both intervention groups received guidance from their coaches on how to change the settings in their app.

Figure 1. Weekly schedule for the tech support and health coaching intervention groups.

	Intervention schedule			
Week	Telephone support calls	Idle alert setting (min)	Steps per day above baseline	Minimum days per week
-2		baseline clinic visit activPAL 1-week data collection		
-1		Randomization Mail Jawbone UP2		
0	Call #1	Setup Jawbone UP2 Establish baseline steps/day		
1	Call #2	60	1000	4
2		60	1000	7
3	Call #3	45	1500	4
4		45	1500	7
5		45	2000	4
6		45	2000	7
7	Call #4	30	2500	4
8		30	2500	7
9	Call #5	30	3000	4
10		30	3000	7
11		30	3000	7
12		30	3000	7
13		30	3000	7
		activPAL 1-week data collection follow-up clinic visit		

Tech Support and Health Coaching Calls

The coaches were graduate students who received study-specific training, including 4 practice calls with staff members before calls to study participants. One coach was assigned to each intervention group participant based on their type of phone, for example, iPhone vs android or other mobile operating system. Phone scripts were used to guide the coaches to deliver only tech support versus tech support plus health coaching. During the first telephone call (week 0; Figure 1), coaches helped the participants to set up their Jawbone monitor. During the second telephone call (week 1), each coach reviewed the activPAL3 baseline summary data (total and percentage of time spent sedentary, standing, and stepping for best and worst days) with the participant and discussed the importance of reducing sedentary time, especially prolonged periods of inactivity.

Additional telephone calls (15-20 minutes) were made during weeks 3, 7, and 9 to verify completion or to assist participants with changing the steps per day goal and *idle alert* setting on their app (if needed). Tech support coaches provided support related only to the technology (Jawbone UP2 activity tracker and/or smartphone app), including troubleshooting technical issues. In contrast, health coaches provided additional support to help their participants identify a list of LPAs to replace/disrupt sedentary time and to achieve the ≥3000 steps per day goal, review the importance of goal setting and self-monitoring, and help troubleshoot problems and find solutions to meet their goals.

Problems With Jawbone UP2 Monitors

During the intervention, the Jawbone UP2 wristbands started to fail (ie, losing settings, losing connection with app, and not syncing data), affecting 13 of 36 intervention group participants. New Jawbone UP2 wristbands were purchased by the study team through other sources (Amazon website), but many of these wristbands also failed. We were able to buy and test UP2 wristbands to replace the failed units for the intervention group participants. Given these major issues and lack of support from Jawbone, waitlist control participants enrolled later in the study were provided with a Fitbit Alta (Fitbit Inc) at the end of the 13-week study. This product was similar to the Jawbone UP2 in that it provided an inactivity alert (reminder to move every hour) and allowed the user to set a step goal and track their steps.

Waitlist Control Group

Upon completion of the study, the control group received a shortened version of the intervention, that is, education materials, tracker, and smartphone app, and instructions for use to track their activity/inactivity. During the postintervention clinic visit, a study team member helped the participant to install the app on their smartphone; pair the tracker to their phone; and select settings for the idle alert and step goal. Each participant in this group was also offered up to 2 telephone calls with one of the coaches to receive tech support or other support to meet their personal goals for reducing sedentary behavior and increasing their activity via steps.

Procedures

Baseline Assessment

Pre- and postintervention clinic visits were conducted at the University of New Mexico Clinical and Translational Science Center. Assessments were conducted primarily by study team members not involved in intervention delivery; however, occasionally, there was overlap owing to limited resources. The baseline assessment included obtaining written informed consent, simple anthropometric measurements (height and weight), and objective physical function measures (physical tests of lower extremity function and mobility). At the end of the visit, study participants were instructed on how to attach the activPAL3 research-grade activity monitor and then observed to verify correct placement. Participants were instructed to wear the activPAL3 monitor for 24 hours/day for 1 week and on how to remove and return (via self-addressed stamped mailer) the monitor to study staff at the end of that week.

Follow-Up Assessment

At the end of the intervention, the activPAL3 research-grade monitor, attachment supplies, and instructions were mailed to all participants to collect 1 week of sedentary behavior and physical activity data. The project manager called to review the instructions for use and answer any questions. Additional postintervention outcome measures were collected at the clinic visit at the end of week 13. Participants received US $50 gift cards to complete the baseline and follow-up assessments and to help cover the costs of accessing the app on their smartphone. In addition, participants were allowed to keep the Jawbone UP2 activity tracker at the end of the study.

Device-Based Measures

Sedentary behavior and physical activity were measured using an activPAL3 research-grade monitor (PAL Technologies Ltd). activPAL3 is a lightweight device worn on the thigh and includes both an inclinometer (to detect changes in position) and a triaxial accelerometer. activPAL is the gold standard in sedentary behavior research and provides accurate measures of sitting (or lying), standing, and stepping [69-72]. Participants wore the device for 24 hours per day for 7 days, before and after the intervention. The device was only removed for bathing or swimming or if an adverse reaction occurred to the Tegaderm dressing used to attach the device. Participants recorded in their diary, the day/time when the device was attached, each time it was removed and reattached, and the time they went to bed at night and woke up in the morning.

Outcomes and Measurements

Feasibility and Acceptability Outcomes

The feasibility and acceptability of the mHealth intervention were determined by achieving the following goals: (1) to recruit 60 older cancer survivors; (2) to retain 80% of the sample; (3) to achieve 80% adherence to the intervention; (4) to have no serious adverse events attributable or possibly attributable to the intervention, defined as any condition that is life threatening and results in overnight hospitalization or a physical or cardiac event serious enough to require medical attention; and (5) to achieve high satisfaction (acceptability) rates with the intervention; to have 75% or more of participants report agree or strongly agree on a 5-point Likert scale.

Retention was calculated as the percentage of participants who completed the follow-up clinic visits and accelerometer assessment. Adherence to wearing the Jawbone UP2 tracker, checking the app daily, and acting on the *idle alert* was assessed with 4 questions. Response items included never, rarely, sometimes, often, or very often. For adherence to the intervention, we calculated the percentage of intervention group participants who responded *often* or *very often* to the 4 questions regarding their use of the Jawbone tracker and app. In addition, the completion of telephone support calls was tracked. Acceptability and evaluation of the Jawbone UP2 technology (UP2 tracker and app) were assessed using 7 questions. Response items included strongly disagree, disagree, neutral, agree, or strongly agree. For acceptability, we calculated the percentage of respondents who responded *agree* or *strongly agree* to the 7 questions regarding ease of use, motivation,

intention for continued use, and recommendations of this technology. Adherence and acceptability were stratified based on whether participants received a replacement Jawbone tracker owing to severe malfunctioning.

Primary Preliminary Efficacy Outcomes

The primary behavioral outcomes of interest were changes in total sedentary time (average minutes per day) and number of breaks from sitting (average breaks per day). As the opportunity to interrupt sitting while standing or stepping is dependent on the amount of sedentary time, the break ratio was also calculated. The break ratio was defined as the number of absolute breaks divided by total sedentary time.

Secondary Preliminary Efficacy Outcomes

Device-Based Measures of Sedentary Behavior and Physical Activity

activPAL was also used to assess changes in total minutes spent in prolonged sedentary bouts, minutes per day spent standing, number of steps per day, and minutes of light- and moderate-intensity physical activity (reported separately). A prolonged sedentary bout was defined as 30 or more continuous minutes in a seated or lying position [73]. LPA was defined as stepping at a cadence equivalent to 1.5 to 3.0 METs [73]. A MET is a multiple of resting energy expenditures. With resting (sitting quietly) energy expenditure defined as 1 MET, a 3-MET activity expends the energy of rest by 3 times, whereas a 5-MET activity expends the energy of rest by 5 times. Standing is also considered an LPA and has been reported separately from light stepping. Moderate-intensity physical activity was similarly defined, but with MET values from 3.0 to 5.9. Vigorous-intensity physical activity was defined as MET values of ≥6.0 or higher. As the guidelines at the time this intervention were designed specified that MVPA be accumulated in minimum bouts of 10 minutes, we also evaluated guideline bouts of MVPA [17,62]. The activPAL monitor provides accurate and precise categorization of sedentary time, LPA, and MVPA in a free-living setting (96.2% accuracy compared with direct observation) [73].

Objectively Measured Physical Performance

The emphasis on frequent interruptions of sedentary behavior with standing and stepping has the potential to improve lower extremity physical function. This was measured using the Short Physical Performance Battery (SPPB). The SPPB includes tests of standing balance, walking speed (timed 8-ft walk at usual speed), and lower body strength (time to rise from a chair 5 times) [6,74]. Scores range from 0 (not attempted) to 4 (highest score) for each test, with a total score ranging from 0 to 12. This battery has strong predictive validity and is responsive to changes [6,74].

Subjective Measures

Given the inverse association reported between sedentary behavior and QoL [29,75,76], we evaluated changes in QoL as a secondary outcome. The Medical Health Outcomes Study Short Form 36-item survey (SF-36, version 2) was used to assess health-related QoL. The SF-36 includes 8 individual scale scores and 2 component summary scores for physical and mental health and well-being. This instrument is valid and reliable for use in healthy and chronically ill adults [77,78]. Surveys were scored using QualityMetric [79]. Raw scores range from 0 to 100, with higher scores indicating better functioning and well-being. T-scores represent a linear transformation, normed to the US population, with a mean of 50 (SD 10). Pain and fatigue were assessed using the patient-reported outcomes measurement information system (PROMIS) Pain Interference Short Form 8A and the functional assessment of chronic illness therapy (FACIT)-Fatigue scale (version 4) [80,81]. The pain interference survey included 8 questions on whether and the degree to which pain interfered with various activities during the past 7 days. The fatigue scale included 13 questions on whether fatigue affected a person's life during the past 7 days and the degree to which fatigue affected a person's life during the past 7 days.

Other Measures

In addition, sociodemographics, cancer-related data, comorbidities, and simple anthropometrics were ascertained via paper surveys to characterize the study population. Sociodemographic data were assessed via questionnaires at baseline, including age, sex, race/ethnicity, education, income range, and marital status. Smoking status (current, former, or never smoker) was also assessed at baseline. Cancer data were obtained from the New Mexico Tumor Registry (cancer type, stage, and date of diagnosis) and from self-reported surveys (treatment [yes/no]: surgery, chemotherapy, radiation, hormone therapy, and date primary therapy completed). The Self-Administered Comorbidity Questionnaire [82] was used to assess the number of conditions and their impact on usual activities. The number of comorbidities and whether they limited activities were summed and categorized as 0 or 1 comorbidity (activities not limited), 1 comorbidity (activities limited), and 2 or more comorbidities (activities limited). Height (nearest 0.5 cm) was measured at the baseline clinic visit. Weight (nearest 0.1 kg) was measured at both the baseline and follow-up clinic visits. BMI (kg/m^2) was calculated and categorized as normal weight (18.5 kg/m^2-24.9 kg/m^2), overweight (25.0 kg/m^2-29.9 kg/m^2), and obese (≥30 kg/m^2).

Data Processing and Statistical Analysis

Processing of activPAL Data

activPAL3 data were downloaded using activPAL software (version 7; PAL Technologies Limited). The event files (start/stop time for sitting/lying, standing, and stepping) were processed using the activPALProcessing R package (version 1.0.2) [73,83]. After converting the event file into a second-by-second data file (second-by-second R function), other R functions were used to calculate the sedentary behavior and physical activity metrics. Only days with 10 or more hours of wear per awake time were included, and only the first 7 valid days were included (extra days were excluded). To be included in the analyses, a participant needed at least one valid day of activPAL3 data from baseline, which is consistent with the intention-to-treat principle and similar to other recent trials [58,84]. Owing to the large variability in the within- and between-person average number of awake per wear hours, all activPAL metrics were standardized to a 15-hour awake per

wear day (average in this study sample). Additional details of the activPAL data collection and processing are included in Multimedia Appendix 2 [69-73,83,85], similar to other studies [59,85].

Efficacy Outcomes

Baseline descriptive characteristics (mean, SD or frequency, %) were used to characterize the study population. Intent-to-treat analyses were conducted to evaluate changes in sedentary behavior metrics and secondary outcomes. Linear mixed methods were used to estimate the within- and between-group differences for each outcome. Each model included a fixed effect for group (tech support, health coaching, and waitlist control), time (before and after the intervention), and group by time interaction. A subject-level random effect was included to account for the correlation between repeated measurements of the same individuals over time. Statistical analyses were performed using SAS (version 9.4) and R (v.3.4.3).

Complete case analyses were conducted that only included individuals with complete data (12 tech support, 17 health coaching, and 18 controls). A sensitivity analysis was conducted that excluded individuals with fewer than 4 valid days of activPAL data (3 participants from the tech support only group). In addition, a sensitivity analysis was conducted by excluding the 12 intervention participants who experienced major problems with their Jawbone tracker (ie, required 1 or more tracker replacements, excluding 6 participants in each intervention group). For this sensitivity analysis, the control group was restricted to control participants who completed their baseline visit during the same period as the intervention participants, to account for potential seasonality effects (ie, before mid-February 2017, excluding 6 controls).

The proposed pilot intervention was a feasibility and acceptability intervention and thus was not powered to detect small effect sizes for change in any outcome. However, for sedentary time, with 20 people per group, assuming a 2-sided alpha level of 0.05 and an SD of 1.4 hours, there was 80% power to detect a difference of 1.3 hours in sedentary time between 2 groups [86,87].

Results

Feasibility

The New Mexico Tumor Registry identified 421 potentially eligible participants and, after accounting for a 3-week opt-out period, forwarded contact information on 354 individuals to study staff. Of the 364 individuals (including 10 self-referrals) we attempted to contact by telephone, 76 refused to participate, 101 were ineligible, and 118 were considered passive refusals after 3 to 4 attempts to contact via telephone (Figure 2; see Multimedia Appendix 3 for CONSORT [Consolidated Standards of Reporting Trials] checklist). The overall response rate was 20.5%. The top 3 reasons for ineligibility included not owning a smartphone, volunteering or working for more than 20 hours per week, and mobility limitations. The top 2 reasons for refusal included a lack of interest and feeling that they were already active enough. An additional 15 individuals were eligible and interested but were unable to begin the intervention before the end of the enrollment period. Owing to the major malfunctions with the Jawbone UP2 monitors during the second half of the study, enrollment was stopped early with a final enrollment of 54 participants.

Retention in this 13-week intervention for older cancer survivors was moderately high (47/54, 87%). All of the dropouts occurred in the intervention groups, with the majority in the tech support group (6 of 7). The reasons included personal or severe family illness (n=2), move out of state (n=1), inconvenience (n=1), frustration with technology (n=1), and loss to follow-up (n=2). Notably, 3 of the 7 dropouts occurred among individuals who experienced malfunctioning with their Jawbone monitor (tech support group). Individuals who dropped out or were lost to follow-up were more likely to be female (5/7, 71% vs 25/47, 53%), have a higher BMI (34.4 kg/m^2 vs 29.5 kg/m^2), and report poor or fair health at baseline (3/7, 43% vs 5/47, 11%) compared with individuals who completed the study.

The characteristics of the 54 cancer survivors enrolled in this study are presented in Table 2. The mean age at study enrollment was 69.6 years (SD 4.8, range 60-84 years), 44% (24/54) were male, 24% (13/54) were Hispanic, and 57% (31/54) had graduated from college. Most study participants (44/54, 81%) were overweight or obese, 44% (24/54) reported very good or excellent general health, and 50% (27/54) reported 1 or more comorbidities that limited their general activity. There were no significant differences between groups. Among the participants, 39% (21/54) had been diagnosed as having breast cancer, 30% (16/54) had prostate cancer, and 31% (17/54) had a variety of other cancer types. Most patients (40/53, 75%) had been diagnosed as having local-stage disease. The mean age at diagnosis was 65.2 (SD 4.8) years, and the mean number of years between diagnosis and study enrollment was 4.4 (SD 1.6) years.

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) diagram.

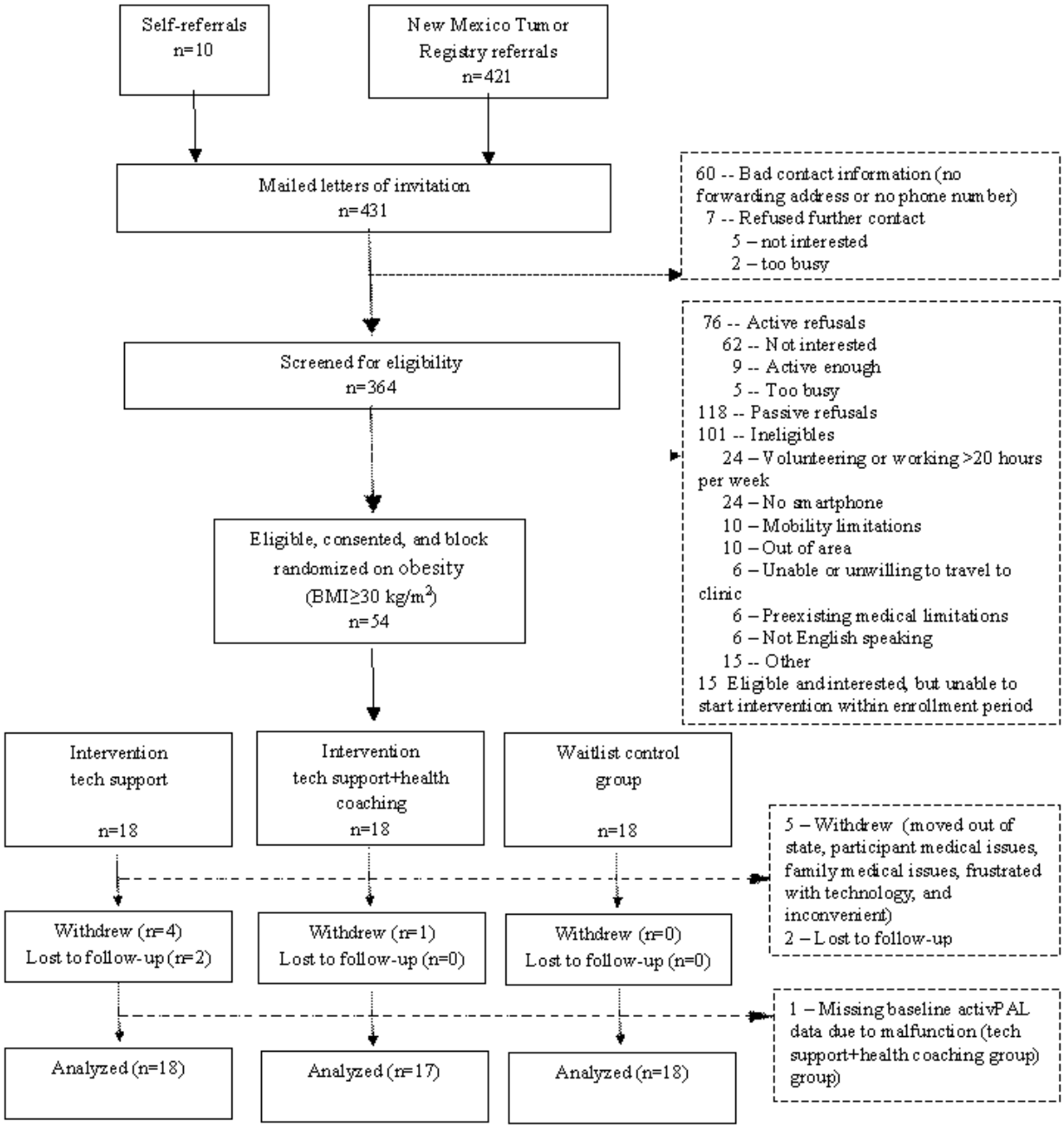


Table 2. Baseline characteristics of the mobile health intervention study participants.

Characteristic	Combined groups (N=54)	Intervention group: tech support (n=18)	Intervention group: tech support+health coaching (n=18)	Waitlist control group (n=18)
Sociodemographic characteristics				
Age (years), mean (SD)	69.6 (4.8)	69.6 (4.5)	69.1 (4.0)	70.2 (5.9)
BMI, mean (SD)	30.1 (5.7)	30.2 (6.0)	29.8 (4.8)	30.4 (6.5)
BMI, n (%)				
Normal weight	10 (18)	4 (22)	2 (11)	4 (22)
Overweight	21 (39)	6 (33)	9 (50)	6 (33)
Obese	23 (43)	8 (44)	7 (39)	8 (44)
Male, n (%)	24 (44)	10 (56)	6 (33)	8 (44)
Ethnicity, n (%)				
Hispanic	13 (24)	5 (28)	4 (22)	4 (22)
Non-Hispanic	41 (76)	13 (72)	14 (78)	14 (78)
Race, n (%)				
Non-White	4 (7)	1 (6)	2 (11)	1 (6)
White	50 (93)	17 (94)	16 (89)	17 (94)
College degree, n (%)	31 (57)	11 (61)	11 (61)	9 (50)
Household income, n (%)				
<US $50,000	19 (35)	7 (39)	8 (44)	4 (22)
≥US $50,000	32 (59)	10 (56)	9 (50)	13 (72)
Missing or refused	3 (6)	1 (6)	1 (6)	1 (6)
Health and physical functioning				
Ever smoker, n (%)[a]	24 (44)	8 (44)	7 (39)	9 (50)
General health status, n (%)				
Fair or poor	8 (15)	4 (22)	2 (11)	2 (11)
Good	22 (41)	9 (50)	6 (33)	7 (39)
Very good or excellent	24 (44)	5 (28)	10 (56)	9 (50)
Number of comorbidities, n (%)				
0-1; does not limit activities	27 (50)	10 (56)	8 (44)	9 (50)
1-2; limits activities	16 (30)	6 (33)	5 (28)	5 (28)
≥3; limits activities	11 (20)	2 (11)	5 (28)	4 (22)
Self-reported physical function, mean (SD)				
Raw score (0-100)	73.7 (20.7)	68.1 (22.4)	77.5 (15.4)	75.6 (23.2)
T-score[b]	47.5 (7.9)	45.3 (8.6)	48.9 (5.9)	48.2 (8.9)
Short Physical Performance Battery (0-12), mean (SD)	10.7 (1.6)	10.4 (2.2)	11.1 (0.9)	10.7 (1.5)
Clinical characteristics				
Cancer type, n (%)				
Breast	21 (39)	7 (39)	9 (50)	5 (28)
Prostate	16 (30)	7 (39)	3 (17)	6 (33)

Characteristic	Combined groups (N=54)	Intervention group: tech support (n=18)	Intervention group: tech support+health coaching (n=18)	Waitlist control group (n=18)
Other[c]	17 (31)	4 (22)	6 (33)	7 (39)
Stage at diagnosis[d], n (%)				
Local	40 (75)	14 (78)	14 (78)	12 (71)
Regional	13 (25)	4 (22)	4 (22)	5 (29)
Treatment received[e], n (%)				
Surgery	42 (78)	13 (72)	13 (72)	14 (78)
Chemotherapy	10 (18)	3 (17)	3 (17)	4 (22)
Radiation	30 (56)	12 (67)	10 (56)	8 (44)
Hormone therapy	12 (22)	2 (11)	6 (33)	4 (22)
Time since diagnosis (years), mean (SD)	4.4 (1.6)	4.3 (1.4)	4.2 (1.9)	4.6 (1.4)
Other characteristics				
Comfort level with using smartphone, n (%)				
Very or extremely comfortable	38 (70)	11 (61)	13 (72)	14 (78)
Slightly or not comfortable	16 (30)	7 (39)	5 (28)	4 (22)
activPAL data, mean (SD)				
Number of valid wear days[f]	6.7 (0.7)	6.6 (1.0)	6.8 (0.4)	6.7 (0.5)
Average awake hours	14.5 (1.0)	14.1 (1.1)	14.6 (0.6)	14.6 (0.9)

[a]Only 1 participant was currently smoking at baseline.

[b]T-scores represent a linear transformation, normed to the US population, with a mean of 50 (SD 10).

[c]Other cancers include bladder, cervical, colon, endometrium, kidney, lymphoma, or melanoma cancers.

[d]Stage at diagnosis is missing for 1 participant.

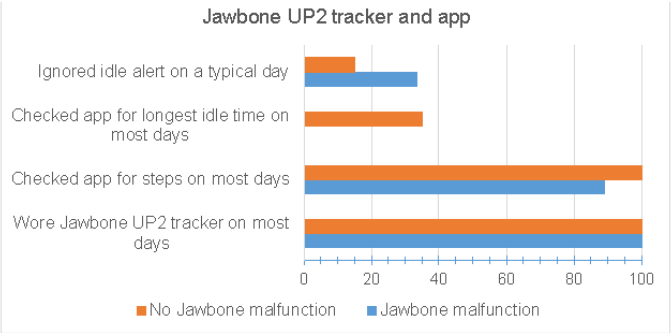
[e]Percentages do not add up to 100% because participants may have had more than 1 type of treatment.

[f]Up to the first 7 days of 10 hours or more of awake/wear time were included in the analyses; additional days of wear beyond the first 7 days were excluded.

Adherence

Adherence during the intervention was moderately high for wearing the Jawbone activity monitor most days of the week (100% very often) and checking the app daily for the number of steps taken (23/29, 79% very often and 5/29, 17% often; Figure 3). However, few participants checked the app for the longest *idle time* (aka longest sedentary bout; 7/29, 24% often or very often), and on a typical day, most participants ignored the vibration on their tracker and remained seated when reminded to stand up and move (18/29, 62% sometimes and 6/29, 21% often or very often). As indicated in Figure 3, adherence related to the sedentary features of the tracker and app was lower in participants who experienced malfunctions with their initial Jawbone UP2 monitor. Among the participants who completed the trial, 93% (27/29) completed all 5 coaching calls.

Figure 3. Adherence to wearing the Jawbone UP2 activity tracker and using the smartphone app, stratified by whether the intervention participant experienced malfunctions with the Jawbone UP2 tracker.



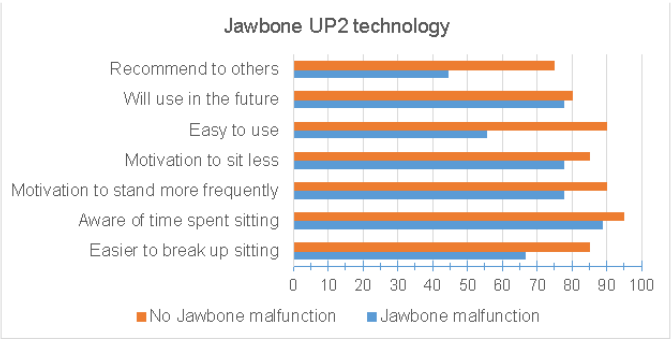
Adverse Events

There were no serious adverse events attributable or possibly attributable to the intervention.

Acceptability

Despite initial Jawbone UP2 malfunctions among one-third of the intervention group, the acceptability of the intervention was moderately high (Figure 4). Overall, 79% (23/29) of the participants agreed or strongly agreed that the Jawbone UP2 technology (monitor plus app) was easy to use and the same percentage indicated that they would use the Jawbone UP2 in the future. Despite the lack of tracking of sedentary data, most participants agreed or strongly agreed that this technology made them more aware of how much time they spent sitting and motivated them to decrease their sedentary time (27/29, 93% and 24/29, 83%, respectively). Participants who started with a malfunctioning Jawbone tracker reported lower acceptability scores than those with properly functioning trackers, with the greatest difference related to ease of use and recommending the tracker and app to others.

Figure 4. Acceptability and participant evaluation of the mobile health intervention using the Jawbone UP2 activity tracker and smartphone app to sit less, stand more, and move more, throughout the day, and every day. Results are stratified by whether the intervention participant experienced malfunctions with the Jawbone UP2 tracker.



Efficacy Primary Outcomes

Of the 54 cancer survivors enrolled in the study, data for the primary and secondary outcomes for sedentary behavior and physical activity were available for 53 participants (1 monitor malfunction at baseline). On average, participants wore the activPAL monitor for 6.7 days (SD 0.7, range 3-7 days), for an average of 14.5 (SD 1.0) awake/wear hours per day. During a standardized 15 hour awake/wear day, study participants spent 9.6 hours (SD 1.7 h) in sedentary (sitting/lying) activities. Approximately half (5.1, SD 1.7 h) of the number of sedentary minutes were spent in prolonged bouts (30 minutes or longer). The average number of breaks from sitting was 46.6 (SD 14.0) per 15 hour day. Standing accounted for one-quarter of the awake hours (3.8, SD 1.5 h). The remaining time was spent in light- and moderate-intensity stepping (36.8, SD 14.8 minutes and 56.5, SD 25.5 min, respectively; zero minutes in vigorous-intensity stepping). At baseline, only 5 participants met the physical activity guidelines that were recommended at the time the study began (150 minutes per week of moderate-intensity or 75 minutes of vigorous-intensity physical activity, minimum bout duration of 10 min) [17]. On the basis of current guidelines, which no longer require that activity occurs in bouts of at least 10 minutes, 46 participants met the minimum recommendation of at least 150 minutes per week of moderate-intensity activity [88,89].

Between- and within-group comparisons of changes in sedentary behavior are presented in Table 3. The tech support and the tech support plus health coaching groups did not reduce their daily sedentary time compared with the control group (least square means 8.5 min, 95% CI −50.5 to 67.5; *P*=.77 and least square means 10.4 min, 95% CI −43.5 to 64.3; *P*=.70, respectively). There were no significant differences between the intervention and control groups in the daily number of breaks from sitting (least square means −0.1, 95% CI −7.6 to 7.4; *P*=.97 and least square means −2.2, 95% CI −9.0 to 4.7; *P*=.52, respectively). There were no significant or meaningful changes in these sedentary behavior outcomes within any of the 3 groups.

Table 3. Between- and within-group comparisons of change in sedentary behavior and physical activity after a 13-week mobile health intervention.[a,b]

Sedentary behavior and physical activity metrics	Baseline, least square mean (95% CI)	Follow-up, least square mean (95% CI)	Within-group change, least square mean difference (95% CI)	*P* value	Between-group change[c], least square mean difference (95% CI)	*P* value
Sedentary, minutes per 15 hours awake						
Tech support	598.5 (550.1 to 646.9)	604.6 (549.1 to 660.0)	6.0 (−39.5 to 51.6)	.79	8.5 (−50.5 to 67.5)	.77
Health coaching	567.7 (517.9 to 617.5)	575.6 (525.0 to 626.1)	7.9 (−30.8 to 46.6)	.68	10.4 (−43.5 to 64.3)	.70
Control	555.4 (507.0 to 603.8)	552.9 (503.8 to 602.0)	−2.5 (−40.0 to 35.0)	.89	N/A[d]	N/A
Prolonged sedentary bouts (≥30 min), minutes per 15 hours awake						
Tech support	319.8 (258.8 to 380.8)	331.9 (263.8 to 400.0)	12.1 (−38.2 to 62.4)	.63	4.7 (−60.3 to 69.7)	.88
Health coaching	287.0 (224.2 to 349.7)	305.5 (242.0 to 369.0)	18.5 (−23.9 to 61.0)	.38	11.2 (−48.0 to 70.3)	.71
Control	289.7 (228.7 to 350.7)	297.1 (235.4 to 358.8)	7.4 (−33.8 to 48.6)	.72	N/A	N/A
Breaks from sitting, number per 15 hour awake						
Tech support	50.6 (44.2 to 57.1)	50.5 (43.2 to 57.9)	−0.1 (−5.9 to 5.8)	.97	−0.1 (−7.6 to 7.4)	.97
Health coaching	48.8 (42.2 to 55.4)	46.6 (39.9 to 53.4)	−2.2 (−7.1 to 2.7)	.38	−2.2 (−9.0 to 4.7)	.52
Control	46.2 (39.7 to 52.6)	46.2 (39.6 to 52.7)	0.0 (−4.7 to 4.8)	1.00	N/A	N/A
Break ratio, number of breaks per sedentary hour						
Tech support	5.4 (4.5 to 6.2)	5.4 (4.5 to 6.4)	0.06 (−0.66 to 0.77)	.87	−0.08 (−1.00 to 0.85)	.87
Health coaching	5.3 (4.4 to 6.2)	4.9 (4.0 to 5.8)	−0.39 (−0.99 to 0.21)	.20	−0.52 (−1.36 to 0.32)	.22
Control	5.1 (4.2 to 5.9)	5.2 (4.3 to 6.0)	0.13 (−0.45 to 0.72)	.65	N/A	N/A
Standing, minutes per 15 hours awake						
Tech support	213.9 (174.2 to 253.7)	202.8 (157.6 to 248.0)	−11.2 (−47.4 to 25.0)	.54	−8.7 (−55.6 to 38.2)	.71
Health coaching	243.0 (202.1 to 283.9)	220.4 (178.9 to 261.8)	−22.6 (−53.3 to 8.1)	.14	−20.1 (−62.9 to 22.6)	.35
Control	241.9 (202.2 to 281.6)	239.4 (199.2 to 279.7)	−2.5 (−32.3 to 27.3)	.87	N/A	N/A
Steps per 15 hour awake						
Tech support	6686 (5166 to 8206)	7339 (5594 to 9085)	654 (−794 to 2101)	.37	420 (−1456 to 2297)	.65
Health coaching	6663 (5099 to 8227)	8338 (6749 to 9926)	1675 (444 to 2906)	.009[e]	1441 (−273 to 3156)	.10
Control	7898 (6378 to 9418)	8132 (6590 to 9674)	233 (−961 to 1428)	.70	N/A	N/A
Light-intensity physical activity, minutes per 15 hours awake						
Tech support	34.4 (27.2 to 41.5)	33.1 (25.4 to 40.9)	−1.2 (−6.0 to 3.6)	.61	−4.2 (−10.4 to 2.0)	.18
Health coaching	37.3 (29.9 to 44.7)	36.9 (29.5 to 44.4)	−0.3 (−4.4 to 3.7)	.86	−3.3 (−8.9 to 2.3)	.24
Control	38.8 (31.6 to 45.9)	41.7 (34.5 to 49.0)	3.0 (−0.9 to 6.9)	.13	N/A	N/A
Moderate-intensity physical activity (MPA), minutes per 15 hours awake						
Tech support	53.2 (40.2 to 66.1)	59.5 (44.5 to 74.6)	6.4 (−6.6 to 19.3)	.33	4.6 (−12.2 to 21.4)	.58
Health coaching	52.1 (38.8 to 65.4)	67.2 (53.7 to 80.8)	15.2 (4.1 to 26.2)	.008[e]	13.4 (−2.0 to 28.8)	.09
Control	64.0 (51.0 to 76.9)	65.7 (52.6 to 78.9)	1.8 (−9.0 to 12.5)	.74	N/A	N/A

Sedentary behavior and physical activity metrics	Baseline, least square mean (95% CI)	Follow-up, least square mean (95% CI)	Within-group change, least square mean difference (95% CI)	*P* value	Between-group change[c], least square mean difference (95% CI)	*P* value
MPA (guideline bouts), minutes per 15 hours awake						
Tech support	5.8 (−3.2 to 14.8)	13.0 (2.2 to 23.8)	7.3 (−3.1 to 17.6)	.17	7.1 (−6.4 to 20.6)	.30
Health coaching	3.0 (−6.3 to 12.2)	19.7 (10.2 to 29.1)	16.7 (7.8 to 25.7)	<.001[e]	16.6 (4.1 to 29.0)	.01[e]
Control	12.1 (3.1 to 21.1)	12.3 (3.1 to 21.4)	0.2 (−8.5 to 8.8)	.97	N/A	N/A

[a]Intent-to-treat analyses.

[b]All variables were standardized to a 15-hour awake per wear day before calculating the pre- to postintervention changes.

[c]Comparisons are between each intervention group and the control group.

[d]N/A: not applicable.

[e]Statistically significant (*P*<.05) results.

Secondary Outcomes

Between- and within-group comparisons of changes in daily steps and time spent stepping are presented in Table 3. Although time spent standing is considered an LPA, it was evaluated separately from the time spent stepping at a light intensity. There were no significant between-group changes in the time spent standing for either intervention group compared with controls (tech support vs control: least square means −8.7 min, 95% CI −55.6 to 38.2; *P*=.71 and health coaching vs control: least square means −20.1 min, 95% CI −62.9 to 22.6; *P*=.35). There were no significant changes in daily steps between the intervention groups and the control group (tech support vs control: least square means 420 steps, 95% CI −1456 to 2297; *P*=.65 and health coaching vs control: least square means 1441 steps, 95% CI −273 to 3156; *P*=.10). There was a borderline significant difference between moderate-intensity stepping in the health coaching group compared with the control group (least square means 13.4 min, 95% CI −2.0 to 28.8; *P*=.09), but there was no difference between the tech support and control groups (least square means 4.6 min, 95% CI −12.2 to 21.4; *P*=.58). The between-group differences for moderate-intensity stepping accumulated in guideline bouts of 10 minutes or longer were least square means of 16.6 minutes (95% CI 4.1-29.0; *P*=.01) and 7.1 minutes (95% CI −6.4 to +20.6; *P*=.30), respectively, for health coaching group vs controls and tech support group vs controls.

The only significant within-group change occurred in the health coaching group. There was a significant increase of 1675 daily steps (95% CI 444-2906; *P*=.009). Although there was no appreciable change in light-intensity stepping, there was a significant increase in moderate-intensity stepping overall and guideline bouts among the health coaching group (least square means 15.2 extra minutes per day, 95% CI 4.1-26.2; *P*=.008 and least square means 16.7 extra minutes per day, 95% CI 7.8-25.7; *P*<.001). There was neither a significant decrease in sedentary time (least square means 7.9 min, 95% CI −30.8 to 46.6; *P*=.68) nor increase in standing (least square means −22.6 min/day, 95% CI −53.3 to 8.1; *P*=.14). There were no significant within-group changes for either the tech support group or the control group.

QoL Analysis

There were no significant between-group changes in subjectively measured health-related QoL (Multimedia Appendix 4). However, between-group differences of 4 or more points, representing the minimally clinically significant difference for the SF-36 QoL survey [90], occurred in several subscales. For health coaching compared with controls, these scales included general health, role physical, social functioning, and vitality. For tech support compared with controls, these scales included physical function and social functioning (favoring tech support) and mental health and role emotional (favoring controls). No significant or meaningful between- or within-group differences were observed for the FACIT-Fatigue or the PROMIS pain scales.

Physical Performance

The average baseline scores on the SPPB were relatively high at baseline for each of the 3 groups (tech support: 10.4, health coaching: 11.2, and control: 10.7). There were no significant between-group changes (*P*>.4); the difference between the health coaching and control groups was at the lower limit of the minimally meaningful change for this scale (0.3-0.8 points) [91].

Additional Analyses

The results of the complete case analyses, including participants with both baseline and follow-up data, did not differ substantially from the intent-to-treat analyses regarding sedentary behavior and physical activity (data not shown). The results of a sensitivity analysis excluding people with fewer than 4 days of valid activPAL data were not appreciably different from the intention-to-treat analyses (data not shown). No significant between-group differences were found in a sensitivity analysis, excluding participants who experienced issues/failures with the Jawbone tracker. The results for tech support versus controls were as follows (least square mean, 95% CI): sedentary time (−28 min, −99 to 43), standing (17 min, −42 to 76), total daily steps (1290 steps, −403 to 2982), and moderate-intensity stepping (13 min, −2 to 28). The results for health coaching versus controls were as follows: sedentary time (10 min, −56 to 76), standing (−18 min, −72 to 36), total daily steps (1102 steps, −460 to 2663), and moderate-intensity stepping (11 min, −3 to 25).

Discussion

Principal Findings

This study explored the feasibility, acceptability, and preliminary efficacy of a home-based mHealth intervention to disrupt and replace sedentary time with LPA (standing and stepping) among older cancer survivors. Despite technical issues with one-third of the Jawbone UP2 activity trackers, an mHealth intervention in older cancer survivors was feasible (high retention and adherence) and acceptable. However, although participants reported that the mHealth intervention increased their awareness of sedentary behavior, this did not translate into a reduction in total sedentary time, prolonged sedentary time, or an increase in breaks from sitting in either intervention group.

The lack of a reduction in total sedentary time was an unexpected finding, given ample room for improvement (nearly 10 hours of sedentary time per day at baseline). In contrast, this group of older, primarily retired, cancer survivors was already taking frequent breaks from sitting, averaging 3 breaks per hour. However, despite the average number of hourly breaks, the amount of time spent in prolonged sedentary bouts (≥30 min) was not reduced, suggesting that there is room for improvement in this metric. Only a few studies have reported a significant increase in the number of breaks from sitting [66]. A large proportion of our study participants reported ignoring the *idle alert* on a typical day. Whether this represented a valid opportunity to stand up and move (eg, alerted while watching television) or an inopportune time (eg, eating, driving, or in a social setting) is unknown. Other studies using the Jawbone tracker reported overall acceptability, including the usefulness or interest in continued use of the *idle alert* [92,93]; however, other studies noted that some participants found the *idle alert* very irritating and inaccurate [94].

In our study, both the postintervention evaluation and comments received from many participants during coaching calls support their focus on the step goal. Similar to other activity tracker apps, the predominant tracking features of the Jawbone apps are related to daily steps rather than sedentary behavior, which may have reinforced the step goal. More support for replacing rather than merely disrupting sedentary time with a suggested minimal bout duration may have been more helpful for individuals already taking frequent breaks from sitting. In addition, research suggests that given the automaticity of sedentary behavior, different and more effortful strategies are required to break existing habits compared with forming new habits [95-97].

Additional unexpected findings were the 6-fold higher time spent standing compared with light-intensity stepping (both before and after intervention) and the suggested decrease in standing, especially in the health coaching group (22 fewer minutes per day). Interventions that report LPA separately indicate that cancer survivors spend 2 to 5 hours per day in these activities [59,60,98,99]. In comparison, our study measured, on average, only 30 to 40 minutes per day. This likely involves measurement differences. Importantly, many interventions have not been able to determine the amount of time spent standing, and standing still is often combined with sedentary time. The activPAL monitor, which is worn on the upper thigh and includes both an inclinometer and accelerometer, provides a more accurate measure of sedentary time (sitting or lying) and standing compared with the ActiGraph accelerometer [70,72], which is the gold standard in MVPA research.

Another research challenge is measuring daily steps in a free-living population (vs in a controlled lab setting), especially if all steps are of interest rather than just higher intensity steps (ie, MVPA). In a free-living population measured during awake hours, stepping ranges from slow, intermittent stepping to fast, continuous stepping. The accuracy of step accumulation by research-grade monitors varies according to walking speed (less accurate at slower speeds) and intermittent (less accurate) versus continuous (more accurate) stepping [100,101]. Therefore, slow or intermittent stepping may be classified as standing rather than light-intensity stepping [100,101]. In our study, overall, there was no reduction in sedentary time, which was measured with high accuracy. Instead, the increased step accumulation among each group, especially the health coaching group, likely represents a shift from standing and slow or intermittent stepping to moderate-intensity and continuous stepping.

There was much flexibility allowed to achieve the goals of the study, that is, no minimum bout duration (standing or stepping) or intensity level (stepping) was provided to participants. The results suggest that most of the intervention group participants focused on the step goal rather than standing more frequently. Furthermore, participants self-selected to accumulate steps in longer bouts and at a moderate versus light intensity. However, only the intervention group with additional health coaching (vs only tech support) achieved significant and meaningful increases in the total daily steps and number of moderate-intensity steps. Although the average number of additional daily steps was below the 3000 goal, it is similar to that reported from meta-analyses using consumer wearable activity trackers, which report 400 to 475 additional daily steps [52,102].

Comparison With Previous Work

On the basis of recent reviews, interventions with a sedentary behavior focus were more effective (greater reduction in sedentary time) than interventions with a focus on increasing MVPA or both increasing MVPA and reducing sedentary time [103,104]. Reviews of interventions with device-based measurement of sedentary behavior (eg, activPAL and ActiGraph) report, on average, a decrease of 35 minutes per day of sedentary time; however, there was significant heterogeneity detected [51,52,102]. Although device-based measures of sedentary behavior are more accurate than self-report measures, there are also differences in accuracy between device-based measures. For example, hip-worn accelerometers estimate sedentary behavior based on lack of movement (eg, <100 counts per minutes on an ActiGraph), whereas thigh-worn monitors base their estimation on posture (eg, activPAL) [105]. As a result, a hip-worn accelerometer cannot distinguish between standing and sedentary time and can overestimate the change in sedentary time if both sitting and standing are reduced.

To date, few interventions have been designed specifically to decrease sedentary behavior in cancer survivors [106]. In

contrast to our findings, several studies have reported a reduction in sedentary time among breast, prostate, and colorectal cancer survivors [58-60]. However, our study compares favorably with the increase in daily steps, especially moderate-intensity stepping. Lynch et al [58] designed an RCT to both reduce sedentary behavior and increase MVPA using the Garmin Vivofit activity tracker among 80 breast cancer survivors (mean age 62 years, SD 6.4). They reported a 37 minutes per day decrease in sitting (95% CI −72.0 to −2.0), which was primarily replaced with standing (27 minutes; 95% CI −2 to 56), and an increase of 933 steps per day (95% CI −215 to 2082). Gomersall et al [59] designed a text-message enhanced clinical exercise intervention (RCT) to reduce sitting time and increase activity among 36 participants, representing several cancer types, primarily colorectal and prostate cancer. The significant decrease in total daily sitting (mean difference −48 minutes/16 h awake day; 95% CI −90 to −6) was primarily replaced with standing (mean difference 42 minutes; 95% CI −4 to 88) and light-intensity stepping (mean difference 7.0 minutes; 95% CI 0.4-14). The RiseTx web-based program designed by Trinh et al [60] included 46 prostate cancer survivors (mean age 73.2 years, SD 7.3) who were given a Jawbone UP 24 activity monitor (model preceding the UP2). The goal was to increase daily steps by 3000 and to reduce sedentary time over a 12-week period in a single-arm trial. There was a significant decrease in sitting time (−455.4 minutes per week; 95% CI −766.6 to −144.2), a nonsignificant decrease in LPA (−91.0 minutes per week; 95% CI −236.4 to 54.4), and a significant increase in MVPA (44.1 minutes per week; 95% CI 11.1-77.0; all measured with the hip-worn ActiGraph). There was also an increase in daily steps (1535; P<.001), which was measured using the Jawbone wearable activity tracker rather than a research-grade accelerometer.

Limitations and Strengths

The limitations of our feasibility study include the potential for selection bias because smartphone ownership was an eligibility criterion. Individuals not familiar with a smartphone (if provided with a loaner phone) may have had more difficulty with adherence or uptake of an mHealth intervention. In addition, individuals who were enrolled were likely more motivated to change their inactivity. The results of this study may not be generalizable to cancer survivors who are less healthy, less physically active, or less comfortable with smartphones than those enrolled in the study. Recruitment was more challenging than anticipated, resulting in a low response rate. Another limitation is the lack of fidelity measures to ensure that the intervention components were delivered as intended. The use of a consumer activity monitor, in this case the Jawbone UP2, is both a limitation and a strength. We experienced substantial technical issues/failures with the device, affecting one-third of the intervention group, as the manufacturing company quit the production, stopped providing support, and eventually closed. While adversely affecting intervention delivery (starting over with tech support/health coaching calls) and possibly retention (3 of 7 dropouts had issues with their Jawbone UP2 monitor; all tech support group), the intervention acceptability scores were moderately high. Most importantly, as reported during follow-up interviews, many intervention participants switched to a different consumer activity monitor to track their steps (Fitbit or Garmin), suggesting a transfer of knowledge and skills gained during the intervention. The strengths of this study include the RCT design and a diverse study sample in terms of sociodemographics, cancer type, and health characteristics. Another strength is the measurement of sedentary behavior with the activPAL research-grade monitor, which is the gold standard for distinguishing between sitting, standing, and stepping [69-72].

Several lessons were learned from this pilot study. First, despite the tremendous growth in the consumer wearable activity tracker market, the disadvantages of using these devices for research studies include technical issues/failures, changes in availability, changes in the user interface or algorithms behind the app, and the potential lack of support from the manufacturer. However, this mHealth approach has been popular among researchers because of its low cost, the ability to reach a large number of participants, and the potential for maintenance of behavior change. The advantages for participants include receiving feedback in real time to prompt change and reducing the burden of tracking weekly/monthly steps (eg, participant recording steps in diary vs automated recording and tracking with app).

Second, sedentary behavior is a strongly ingrained habit that is mostly initiated subconsciously [94]. Research suggests that, given the automaticity of sedentary behavior, different and more effortful strategies are required to break existing habits compared with forming new habits [95-97]. This may require different or multiple behavioral theories to inform the intervention. Although many consumer activity trackers have several behavioral change techniques built into the tracker and/or the app, including Jawbone [54,55,107], accumulating evidence suggests that additional behavior change techniques are needed to achieve meaning change [92,102]. Until activity tracker apps advance to provide features for tracking daily sedentary behavior, researchers will need to provide participants with other strategies. Finally, the daily step goal (+3000 steps above baseline) may have been too high, although participants were able to self-select the minimum bout duration and intensity level for stepping. Nevertheless, the step goal may have competed with messaging to reduce sedentary time.

Conclusions

This low-touch, home- and technology-based intervention designed to disrupt and replace sedentary time with LPA (standing and stepping) was feasible and acceptable for a diverse group of older cancer survivors. Future studies are warranted to evaluate strategies for replacing sedentary time with standing and/or physical activity.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
An example of the activPAL monitor summary data from baseline discussed with intervention group participants in an mHealth study.
[PNG File , 22 KB - cancer_v7i2e18819_app1.png]

Multimedia Appendix 2
activPAL3 data collection and processing details.
[DOCX File , 31 KB - cancer_v7i2e18819_app2.docx]

Multimedia Appendix 3
CONSORT (Consolidated Standards of Reporting Trials)-EHEALTH checklist (v 1.6).
[PDF File (Adobe PDF File), 1566 KB - cancer_v7i2e18819_app3.pdf]

Multimedia Appendix 4
Effects of mHealth intervention on health-related Quality of Life.
[DOCX File , 22 KB - cancer_v7i2e18819_app4.docx]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
LPA: light-intensity physical activity
MET: metabolic equivalent
mHealth: mobile health
MVPA: moderate-to-vigorous physical activity
NIH: National Institutes of Health
QoL: quality of life
RCT: randomized controlled trial
SF-36: Short Form 36-item survey
SPPB: Short Physical Performance Battery

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Original Paper

Data Integration to Improve Real-world Health Outcomes Research for Non–Small Cell Lung Cancer in the United States: Descriptive and Qualitative Exploration

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Abstract

Background: The integration of data from disparate sources could help alleviate data insufficiency in real-world studies and compensate for the inadequacies of single data sources and short-duration, small sample size studies while improving the utility of data for research.

Objective: This study aims to describe and evaluate a process of integrating data from several complementary sources to conduct health outcomes research in patients with non–small cell lung cancer (NSCLC). The integrated data set is also used to describe patient demographics, clinical characteristics, treatment patterns, and mortality rates.

Methods: This retrospective cohort study integrated data from 4 sources: administrative claims from the HealthCore Integrated Research Database, clinical data from a Cancer Care Quality Program (CCQP), clinical data from abstracted medical records (MRs), and mortality data from the US Social Security Administration. Patients with lung cancer who initiated second-line (2L) therapy between November 01, 2015, and April 13, 2018, were identified in the claims and CCQP data. Eligible patients were 18 years or older and received atezolizumab, docetaxel, erlotinib, nivolumab, pembrolizumab, pemetrexed, or ramucirumab in the 2L setting. The main analysis cohort included patients with claims data and data from at least one additional data source (CCQP or MR). Patients without integrated data (claims only) were reported separately. Descriptive and univariate statistics were reported.

Results: Data integration resulted in a main analysis cohort of 2195 patients with NSCLC; 2106 patients had CCQP and 407 patients had MR data. The claims-only cohort included 931 eligible patients. For the main analysis cohort, the mean age was 62.1 (SD 9.27) years, 48.56% (1066/2195) were female, the median length of follow-up was 6.8 months, and for 37.77% (829/2195), death was observed. For the claims-only cohort, the mean age was 66.6 (SD 12.69) years, 52.1% (485/931) were female, the median length of follow-up was 8.6 months, and for 29.3% (273/931), death was observed. The most frequent 2L treatment was immunotherapy (1094/2195, 49.84%), followed by platinum-based regimens (472/2195, 21.50%) and single-agent chemotherapy (441/2195, 20.09%); mean duration of 2L therapy was 5.6 (SD 4.9, median 4) months. We describe challenges and learnings from the data integration process, and the benefits of the integrated data set, which includes a richer set of clinical and outcome data to supplement the utilization metrics available in administrative claims.

Conclusions: The management of patients with NSCLC requires care from a multidisciplinary team, leading to a lack of a single aggregated data source in real-world settings. The availability of integrated clinical data from MRs, health plan claims, and other sources of clinical care may improve the ability to assess emerging treatments.

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KEYWORDS

non–small cell lung cancer; cancer; data aggregation; real-world data; administrative claims data; medical records; electronic health record; retrospective study; population health; health services research

Introduction

Background

Real-world health outcomes research is often challenged by data insufficiency resulting from studies using a single data source and/or short durations [1-3]. For example, medical records (MRs) generally do not contain details of care outside of the point of service of the single health care provider, claims data contain few variables related to clinical outcomes, and registries often do not contain complete longitudinal data [4-7]. The integration of clinical data from different sources such as MRs [8], disease registries, or quality initiatives with large administrative claims repositories has been shown to increase the volume and quality of available data [9-12]. For example, integrated data allow the inclusion of important clinical factors when analyzing health care utilization and costs, as recorded in claims [13]. Such integrated observational data sets have also been used to generate predictive algorithms to better identify patients with cancer [14-17] and their disease characteristics [18-20].

Lung cancer is the second most common cancer in the United States, with approximately 230,000 new diagnoses in 2020 [21]. It is the leading cause of cancer-related deaths in the United States, projected at 136,000 in 2020 [22]. Non–small cell lung cancer (NSCLC) accounts for approximately 85% of all lung cancer cases [23]. Treatment modalities for advanced and/or metastatic NSCLC include radiotherapy, chemotherapy, targeted therapy, or a combination therapy [24]. Over the last few years, second-line (2L) treatment options have expanded rapidly with the introduction of immune checkpoint and epidermal growth factor receptor inhibitors and associated predictive biomarkers [25].

Treatment sequencing in the setting of NSCLC is not well characterized, largely because of the sparseness of applicable studies, which tend to be limited by inadequate data. This study was designed based on the rationale that a combination of retrospective data from multiple sources, such as MRs, administrative claims, and care quality initiatives, would provide a solid foundation for observing and characterizing real-world treatment outcomes at a lower cost than a traditional site-based prospective approach.

Objectives

The central objective of this study is to create an integrated database from several complementary sources and to assess the feasibility and effectiveness of these integrated observational data for health outcomes research. Patient characteristics and outcomes were described to evaluate the enrichment attained through integration. This analysis presents a descriptive summary of the final study cohort that was obtained for the study.

Methods

Study Design

RESOUNDS (Real-World Treatment Sequences and Outcomes Among Patients With Non-Small Cell Lung Cancer) was a retrospective, observational cohort study that integrated data from 4 sources: administrative claims from the HealthCore Integrated Research Database (HIRD), clinical data from a quality initiative called the Cancer Care Quality Program (CCQP), clinical data extracted from patients' MRs obtained from treating providers, and all-cause mortality data from the Death Master File of the US Social Security Administration. Details of the RESOUNDS study design and each of these data sources have been published previously [26]. The study protocol was approved by the New England Institutional Review Board before the commencement of data collection activities. This study was conducted in full compliance with the relevant provisions of the Health Insurance Portability and Accountability Act.

Patient Identification

Patients diagnosed with lung cancer who initiated 2L therapy between November 01, 2015, and April 13, 2018, were identified in the HIRD and CCQP data. Patients were required to receive 1 of the following 2L therapies alone or in combination: atezolizumab, docetaxel, erlotinib, nivolumab, pembrolizumab, pemetrexed, or ramucirumab. This subset of the original set of therapies listed in the protocol [26] was selected based on treatment guidelines and observed frequency of use during the study period, to ensure sufficient sample sizes to evaluate treatment patterns. Patients aged under 18 years at the start of 2L therapy were excluded. Due to the absence of specific International Classification of Diseases, Ninth and Tenth Revision, Clinical Modification codes for NSCLC, cancer type was confirmed via CCQP or MR data. Follow-up for all-cause death events was conducted through March 31, 2019.

Integrated Database Development

Patients were first identified in the CCQP data, where information on the type of lung cancer (NSCLC or not) was available, and information for patients with a record of 2L therapies of interest was retained. All cancer stages were included in the analyses. Second, lung cancer diagnosis and treatment claims were used to identify patients with 2L treatment in the HIRD. Patients who also had claims for other primary cancers were retained. All patients identified in the CCQP data were also included in the HIRD sample; patients who appeared in the HIRD but not the CCQP were retained. Third, copies of MRs were obtained from selected patients' 2L prescribers (focusing on oncologists, as identified in the HIRD) and screened for qualification (presence of evidence for NSCLC and that the index treatment was used as therapy for NSCLC). Regulatory and operational requirements for inclusion in this process consisted of patients having a fully insured status (vs administrative services only) and presence of complete contact

information for the 2L prescriber. Once obtained and screened, clinical information was abstracted from each record by trained health information management technicians using a standardized form. The target sample size for MR abstraction was 398 patients, based on the expected feasible accrual over the 2.5-year patient identification period.

Data from each source were accumulated in 3 consecutive waves to continuously build the database. After each MR abstraction wave was complete, the claims and CCQP data were refreshed to the most current date at that point to obtain additional follow-up outcomes. The integrated data were used to establish the main analysis cohort, consisting of patients with both claims and either CCQP or MR data (or both). Eligible patients from the HIRD who did not appear in the CCQP and for whom no MRs were obtained were included in the claims-only cohort (these patients could have any type and stage of lung cancer).

Patient Characteristics and Outcomes

Demographic and clinical characteristics, treatment patterns, and survival outcomes were recorded. Baseline was defined as the 6 months before the index date (start of 2L therapy). The Quan-Charlson Comorbidity Index (QCI) was calculated, excluding lung cancer and metastatic carcinoma [27]. A patient was considered to be on the same line of therapy until new agents were added (except for maintenance and platinum agent switching), a gap of >90 days between treatments, end of follow-up, or (for 2L and higher) discontinuation. The percentage of patients flagged as deceased (for all causes) was calculated using a combination of the Death Master File, a hospitalization discharge code of *deceased* from claims, and mortality recorded from the health plan enrollment files.

Statistical Analysis

Univariate statistics including means, SDs, and medians for continuous variables and relative frequencies and percentages for categorical variables were reported. No hypothesis testing was performed. Statistical analysis was performed using SAS version 9.3 (SAS Institute Inc).

Results

Data Integration and Patient Selection

Following data integration, the main analysis cohort consisted of 2195 patients. All patients had claims data, 2106 patients had CCQP data, and 407 patients had MR data (Table 1).

Approximately 47.14% (997/2115) of patients fulfilled regulatory and operational requirements for their MRs to be requested from their 2L-prescribing providers; for 54.5% (543/997) of those, the records were obtained. A large number of MRs were not obtained as outreach was stopped after the planned sample size (n=398) was achieved; others could not be obtained because the provider did not have a record of the particular patient or because of inability to contact the provider. Among the obtained records, the most frequent reason for exclusion was the absence of confirmation of NSCLC (43/543, 7.9% of the obtained records). The claims-only cohort comprised 931 patients. Table 2 details what variables were obtained from which source.

Table 1. Patient selection.

Criteria	First wave sample (patients, n)	Second wave sample[a] (patients, n)	Third wave sample (patients, n)	Final sample[b] (patients, n)
Step A: Patients identified from CCQP[c]				
Step 1: Patients with non–small cell lung cancer	295	760	1428	—[d]
Step 2: From step A1, patients with 2L[e] therapy[f]	174	469	863	—
Step B: Patients identified from claims				
Step 1: Patients with lung cancer claim before start of first-line therapy	640	1058	2187	—
Step 2: From step B1, patients with 2L therapy	368	600	1127	—
Step C: Combined patients from CCQP and claims				
Step 1: From A2 and B2, unique patients with 2L therapy	423	756	1732	2115
Step D: Patients considered for MR[g] review				
Step 1: Patients used for MR outreach	149	279	718	997
Step 2: Number of patient MRs obtained	102	194	349	543
Step 3: Number of failed MRs[h]	15	20	45	65
Step 4: Not used (target had been met previously)	—	—	62	62
Step 5: Final MRs used	87	174	242	416
Step E: Main analysis cohort (patients with claims and either CCQP or MR data)	272	791	1446	2195[i]
Step 1: Patients with CCQP data	223	748	1399	2106
Step 2: Patients with MR data	85	168	239	407
Step F: Claims-only cohort (patients with claims data only, no CCQP or MR data)	377	243	659	931[i]

[a]Second wave included all patients from the first wave.

[b]The final sample removed duplicates that were included in >1 wave. For those patients, information from the most recent wave was used for analysis.

[c]CCQP: Cancer Care Quality Program.

[d]Not available.

[e]2L: second-line therapy.

[f]2L medications of interest included atezolizumab, docetaxel, erlotinib, nivolumab, pembrolizumab, pemetrexed, or ramucirumab.

[g]MR: medical record.

[h]Medical records excluded due to one or more of the following: no documentation of lung cancer, no documentation of non–small cell lung cancer, and patient mismatch (missing or unmatched name, sex, or date of birth; wrong timeframe; inconsistent clinical information).

[i]These are the final sample sizes for the 2 cohorts of interest.

Table 2. Variable sourcing by database type.

Variable	HealthCore Integrated Research Database (claims)	Cancer Care Quality Program	Medical record
Length of follow-up	✓[a]	—[b]	—
Age	✓	—	✓
Gender	✓	—	✓
Health plan type	✓	—	—
Geographic region of patient residence	✓	—	—
Race/ethnicity	—	—	✓
Weight, height, and BMI	—	—	✓
Histology	—	✓	✓
Staging	Y[c]	✓	✓
Treating physician specialty	✓	—	—
Smoking status	—	—	✓
Performance status (Eastern Cooperative Oncology Group)	—	✓	✓
Comorbidities	✓ (Quan-Charlson Comorbidity Index, secondary cancers)	—	—
Mortality	Z[d]	—	—

[a]Indicates variable was sourced from the data set listed in the column header.

[b]Variable was not sourced from the data set listed in the column header.

[c]Indicates the presence of claims for metastatic disease.

[d]This was based on the Death Master File data from the US Social Security Administration.

Demographic Characteristics at Baseline

In the main analysis cohort, mean age was 62.1 (SD 9.27) years and 48.56% (1066/2195) were female (Table 3), whereas in the claims-only cohort, mean age was 66.6 (SD 12.69) years and 52.1% (485/931) were female. More than two-thirds (1498/2195, 68.25%) of the main analysis cohort were from the Midwest and South, and 23.01% (505/2195) had Medicare Advantage or Supplemental and Part D coverage. In the claims-only cohort, patients were almost equally distributed across the West, Midwest, and South, with a smaller proportion (164/931, 17.6%) from the Northeast; almost half (457/931, 49.1%) had Medicare Advantage coverage. Treating physician specialty based on claims listed oncologists for 67.52% (1482/2195) of the main analysis population and for 30.7% (286/931) of the claims-only sample; this difference is by design as only patients whose 2L-prescribing providers were listed as oncologists were included in the MR phase. Among the 407 patients with MR data, 45.7% (186/407) were White, 3.7% (15/407) were Black, 3.2% (13/407) were other races, and 47.4% (193/407) had no race information. Race was not available in patients without MRs.

Table 3. Demographic characteristics at baseline (on or close to second-line therapy initiation date).

Variables	Main analysis cohort (n=2195)	Claims-only cohort (n=931)
Age at second-line therapy initiation (years), mean (SD)	62.1 (9.27)	66.6 (12.69)
Age categories (years), n (%)		
18-39	22 (1.0)	33 (3.5)
40-64	1509 (68.7)	343 (36.8)
65-74	412 (18.8)	278 (29.9)
≥75	252 (11.5)	277 (29.8)
Female, n (%)	1066 (48.6)	485 (52.1)
Health plan type, n (%)		
Health maintenance organization	769 (35.0)	225 (24.2)
Preferred provider organization	1126 (51.3)	628 (67.5)
Consumer-driven health plan	300 (13.7)	78 (8.4)
Medicare Advantage[a], n (%)	505 (23.0)	457 (49.1)
Affordable Care Act exchange plan, n (%)	550 (25.1)	106 (11.4)
Geographic region of patient, n (%)		
Northeast	344 (15.7)	164 (17.6)
Midwest	815 (37.1)	262 (28.1)
South	683 (31.1)	274 (29.4)
West	353 (16.1)	231 (24.8)
Treating physician specialty, n (%)		
Oncology	1482 (67.5)	286 (30.7)
Pulmonary medicine	34 (1.5)	18 (1.9)
Primary care provider	77 (3.5)	36 (3.9)
Other	481 (21.9)	133 (14.3)
Missing	121 (5.5)	458 (49.2)

[a]Includes Supplemental and Part D plans.

Clinical Characteristics at Baseline

In the main analysis cohort, the mean QCI was 1.6 (SD 1.59). The most frequent comorbidities were dyspnea (1417/2195, 64.56%), chronic pulmonary disease (1125/2195, 51.25%), hypertension (1073/2195, 48.88%), anemia (880/2195, 40.09%), and dyslipidemia (792/2195, 36.08%; Table 4). More than half of the main analysis cohort (1224/2195, 55.76%) had claims for additional or secondary malignancies and 79.41% (1743/2195) had claims for metastatic disease. In the claims-only cohort, the mean QCI was 1.8 (SD 1.69). The most frequently occurring comorbidities were hypertension (565/931, 60.7%), dyspnea (542/931, 58.2%), and dyslipidemia (403/931, 43.3%). Almost three-quarters (681/931, 73.1%) had codes for other malignancies and 67.9% (632/931) had codes for metastatic disease.

In the main analysis cohort, additional clinical information was available via CCQP and/or MRs (Table 5). Among the 407 patients with MR data, 59.2% (241/407) were former smokers, 16.5% (67/407) were current smokers, 14.3% (58/407) were never smokers, and 10.1% (41/407) had no documentation. Height and weight were available for the majority (341/407, 83.8% height; 371/407, 91.2% weight) of patients; mean BMI was 26.1 (SD 6.36). The most common cancer histology was adenocarcinoma (271/407, 66.6%); for most of the remainder, histology was not documented. Metastasis was noted in MRs for 95.1% (387/407) of the patients, most commonly to the lymph nodes (289/407, 71.0%). Eastern Cooperative Oncology Group (ECOG) performance status was available for 96.26% (2113/2195) of the sample, and an ECOG score ≥2 was observed in 21.20% (448/2113) of patients.

Table 4. Clinical characteristics from claims at baseline (over 6 months before second-line therapy initiation date).

Variables	Main analysis cohort (n=2195)	Claims-only cohort (n=931)
QCI[a], mean (SD)	1.6 (1.59)	1.8 (1.69)
QCI categories, n (%)		
0	570 (26.0)	230 (24.7)
1	705 (32.1)	271 (29.1)
2	414 (18.9)	185 (19.9)
3-5	444 (20.2)	212 (22.8)
6+	62 (2.8)	33 (3.5)
QCI comorbidities, n (%)		
Myocardial infarction	112 (5.1)	46 (4.9)
Congestive heart failure	195 (8.9)	111 (11.9)
Peripheral vascular disease	357 (16.3)	186 (20.0)
Cerebrovascular disease	255 (11.6)	100 (10.7)
Dementia	18 (0.8)	10 (1.1)
Chronic pulmonary disease	1125 (51.2)	390 (41.9)
Connective tissue/rheumatic disease	57 (2.6)	32 (3.4)
Peptic ulcer disease	31 (1.4)	13 (1.4)
Mild liver disease	421 (19.2)	162 (17.4)
Moderate or severe liver disease	10 (0.5)	<10[b]
Paraplegia and hemiplegia	50 (2.3)	<10[b]
Renal disease	172 (7.8)	127 (13.6)
Diabetes with chronic complications	96 (4.4)	75 (8.1)
Diabetes without chronic complications	380 (17.3)	211 (22.7)
Malignancy (excluding lung cancer)	1224 (55.8)	681 (73.1)
Metastatic carcinoma	1743 (79.4)	632 (67.9)
AIDS/HIV	<10[b]	<10[b]
Other comorbidities of interest, n (%)		
Anemia (any)	880 (40.1)	376 (40.4)
Anemia due to chemotherapy	323 (14.7)	92 (9.9)
Asthma	166 (7.6)	88 (9.5)
Cardiac dysrhythmias	375 (17.1)	199 (21.4)
Coronary heart disease	410 (18.7)	209 (22.4)
Depression	338 (15.4)	139 (14.9)
Dyslipidemia	792 (36.1)	402 (43.2)
Dyspnea	1417 (64.6)	542 (58.2)
Hypertension	1073 (48.9)	565 (60.7)
Idiopathic fibrosis of the lung	15 (0.7)	<10[b]
Interstitial lung disease	29 (1.3)	<10[b]
Peripheral vascular disease	361 (16.4)	187 (20.1)
Pneumonia	508 (23.1)	151 (16.2)
Pneumonitis	29 (1.3)	16 (1.7)
Pulmonary fibrosis	112 (5.1)	<10[b]

Variables	Main analysis cohort (n=2195)	Claims-only cohort (n=931)
Stroke	255 (11.6)	100 (10.7)
Thyroid disease	272 (12.4)	165 (17.7)
Tuberculosis	<10[b]	<10[b]

[a]QCI: Quan-Charlson Comorbidity Index.

[b]Values <10 have not been reported for patient confidentiality.

Table 5. Clinical characteristics from Cancer Care Quality Program and/or medical records at baseline (on or close to second-line therapy initiation date).

Variables	Main analysis cohort
Information from MRs[a]; valid N=407	
Smoking status, n (%)	
Current smoker	67 (16.5)
Former smoker	241 (59.2)
Never smoker	58 (14.3)
Not documented	41 (10.1)
Presence of number of years smoked, n (%)	201 (49.4)
Number of years smoked, mean (SD)	36.1 (13.48)
Presence of weight, n (%)	371 (91.2)
Weight (pounds), mean (SD)	165.0 (44.48)
Presence of height, n (%)	341 (83.8)
Height (inches), mean (SD)	66.5 (3.88)
Presence of BMI, n (%)	339 (83.3)
BMI, mean (SD)	26.1 (6.36)
Histology, n (%)	
Adenocarcinoma	271 (66.6)
Large-cell carcinoma	9 (2.2)
Bronchioloalveolar carcinoma	2 (0.5)
Mixed	3 (0.7)
Unspecified nonsquamous	2 (0.5)
Other	4 (1.0)
Unknown/not documented	116 (28.5)
Presence of metastasis, n (%)	387 (95.1)
Lymph nodes (thoracic region)	289 (71.0)
Supraclavicular nodes	87 (21.4)
Superior mediastinal nodes	201 (49.4)
Aortic nodes	64 (15.7)
Inferior mediastinal nodes	132 (32.4)
Hilar, lobar, and/or (sub)segmental nodes	199 (48.9)
Bone	190 (46.7)
Other respiratory systems (not trachea)	163 (40.0)
Brain	121 (29.7)
Liver	72 (17.7)
Adrenal gland	59 (14.5)
Number of metastases sites, mean (SD)	3.2 (1.90)
Information from Cancer Care Quality Program and/or MRs; valid N=2195	
Eastern Cooperative Oncology Group performance status, n (%)	2113 (96.26)
0	464 (21.96)
1	1201 (56.84)
2	364 (17.23)
3	74 (3.50)

Variables	Main analysis cohort
4	10 (0.47)
5	0 (0)
TNM[b] stage classification, n (%)	2146 (97.77)
0	0 (0)
1	<10
2	32 (1.49)
3	167 (7.78)
4	1935 (90.17)
Unknown or not documented	<10

[a]MR: medical record.

[b]TNM: tumor/lymph nodes/metastasis cancer staging system.

Length of Follow-Up and Mortality

The mean length of follow-up in months was 7.9 (SD 5.77) for the main analysis cohort (median 6.8) and 9.1 (SD 6.06) for the claims-only cohort (median 8.6). Death (for all causes) was observed in 37.77% (829/2195) of the main analysis cohort and 29.3% (273/931) of the claims-only cohort.

Treatment Patterns

Among the 1974 patients with first-line (1L) treatment information, 69.50% (1372/1974) used platinum-based regimens, 37.69% (744/1974) used pemetrexed-containing regimens, and 16.51% (326/1974) used single-agent chemotherapy (treatment groups are not mutually exclusive; Table 6). The mean duration of 1L therapy was 128 (median 90) days; 56.84% (1122/1974) switched to 2L therapy with a gap ≤90 days and 43.16% (852/1974) had a gap of >90 days before initiating 2L. The most frequent 2L treatment was immunotherapy (1094/2195, 49.84%), followed by platinum-based regimens (472/2195, 21.50%). The mean duration of 2L therapy was 169 (median 121) days; this variable was right-censored due to loss of follow-up. For patients with third- and/or fourth-line therapy (n=731 and 265, respectively), platinum-based regimens were used most frequently (418/731, 57.2% of third-line patients and 139/265, 52.5% of fourth-line patients), and 21.6% (158/731) of third-line patients and 20.4% (54/265) of fourth-line patients also used immunotherapy. Among the 269 patients who received radiation therapy after the initial diagnosis of NSCLC, 46.1% (124/269) patients received radiation therapy as a palliative treatment.

Table 6. Treatment patterns from Cancer Care Quality Program and claims, measured from the initiation of first-line treatment to the end of follow-up.

Therapy	Main analysis cohort (N=2195)
1L[a] therapy, n (%)	1974 (89.9)
Chemotherapy, n (%)	
Platinum-based regimen	1372 (69.5)
Nonplatinum-based regimen	90 (4.6)
Pemetrexed-containing regimen	744 (37.7)
Single-agent chemotherapy	326 (16.5)
Immunotherapy, n (%)	
PD-1/PD-(L)1[b] inhibitor–containing regimen	241 (12.2)
Targeted therapy, n (%)	
EGFR[c] TKIs[d]-containing regimen	98 (5.0)
EGFR mAb[e]-containing regimen	11 (0.6)
VEGF[f] mAb-containing regimen	308 (15.6)
ALK[g] inhibitor	21 (1.1)
Duration of time (days) between initial lung cancer diagnosis and 1L treatment, mean (SD)	134.6 (380.98)
Duration (days) of 1L therapy, mean (SD)[h]	127.7 (142.75)
Treatment change, n (%)	
Gap of ≤90 days before 2L[i]	1122 (56.8)
Gap of >90 days before 2L	852 (43.2)
2L therapy, n (%)	2195 (100.0)
Chemotherapy	
Platinum-based regimen	472 (21.5)
Nonplatinum-based regimen	221 (10.1)
Pemetrexed-containing regimen	344 (15.7)
Single-agent chemotherapy	441 (20.1)
Immunotherapy	
PD-1/PD-L1 inhibitor–containing regimen	1094 (49.8)
Targeted therapy	
EGFR TKIs-containing regimen	36 (1.6)
EGFR mAb-containing regimen	10 (0.5)
VEGF mAb-containing regimen	141 (6.4)
ALK inhibitor	<10[j]
Duration (days) of 2L therapy, mean (SD)[k]	168.6 (148.4)
Radiation therapy following initial diagnosis of non-small cell lung cancer, n (%)	269 (12.3)
Intent of radiation therapy, n (%)	
Curative	21 (7.8)
Palliative	124 (46.1)
Both curative and palliative (separate instances)	15 (5.6)
Unknown	109 (40.5)

[a]1L: first-line therapy.

[b]PD-(L)1: programmed death-(ligand) 1.
[c]EGFR: epidermal growth factor receptor.
[d]TKI: tyrosine kinase inhibitor.
[e]mAb: monoclonal antibodies.
[f]VEGF: vascular endothelial growth factor.
[g]ALK: anaplastic lymphoma kinase.
[h]Median 90.0.
[i]2L: second-line therapy.
[j]Values <10 have not been reported for patient confidentiality.
[k]Median 121.0.

Discussion

Principal Findings

This study combined 3 data sources for the analysis of real-world outcomes in patients with NSCLC, conducting data integration on a large scale across disparate but complementary sources. It was designed to simulate a prospective observational study by identifying patients upfront within large preexisting databases and then following them within the data set to examine outcomes. One of the potential strengths of this approach is the development of a database that includes demographic, clinical, and health care resource utilization data that can more accurately assess health outcomes.

The use of big data from multiple sources, such as health plan enrollment, disease registries, and scanned image repositories, among others, is becoming more important for the accurate determination of patient outcomes, particularly in the setting of NSCLC [28-31]. With the current availability of a wide range of newer, more effective systemic therapies, including several novel biologic agents, the use of diverse provider, institutional, and registry databases is increasingly necessary to evaluate outcomes due to the gaps in administrative claims data alone [32-35]. As treatments in oncology have improved, patients with lung cancer are living longer with the ability to personalize care with novel targeted therapies. This approach, coupled with more effective treatment, means that treatment strategies are increasingly complex, and factors influencing these strategies and their resultant outcomes are not fully identifiable in administrative claims data. As a result, the effective evaluation of treatment outcomes increasingly draws on data from multiple sources across lines of treatment, providers, and institutions.

Real-world evidence (RWE), which is largely derived from big health care data, has increasingly been driven by important technological advances, including machine learning, natural language processing improvements in electronic medical systems, and the ability to link clinical and health claims data in private and public systems [9]. As RWE grows and gains value, especially for pragmatic clinical trials (PCTs), the traditional gold standard of a randomized clinical trial (RCT) is facing major hurdles: low recruitment rates, small patient populations, long durations, and high costs. This evolving environment, along with growing interest in PCTs, is increasing the importance of big data and RWE as a complement to RCTs [36,37].

Furthermore, a bigger role for RWE is developing in decision making across the health care system, including regulators, payers, providers, and patients. Part of the reason is that although RCTs have internal validity, which is essential for safety and efficacy determinations, results from clinical studies may have limited external validity. At the same time, RWE studies using big data are able to explore key clinical questions that are outside the scope of RCTs. Such studies are well suited for investigations seeking safety and effectiveness outcomes data for broader target populations. This is especially valuable for the evaluation of fast-tracked medical products, which typically gain regulatory approval based on limited data. In addition, large RWE studies are invaluable in detecting the side effects of treatments over longer periods. Other circumstances in which RWE is valuable include exploration of rare diseases, assessing the impact of treatment adherence, when rapid retrospective results are needed, comparing multiple treatments that have not been explored in trials, and focusing on population subsets of interest, given more heterogeneity and larger population sizes in real-world data compared with clinical trials [36-38].

Due to the frequency of onset of NSCLC later in life, our study sample included patients with an average age greater than 60 years, with females constituting about half of the study population, which is consistent with other real-world US outcomes studies that examined patients with NSCLC [39-48]. All prior studies, to our knowledge, that focused on the United States used 1 or 2 of the following data sources: administrative claims, registry data, or MR. Limitations of these studies fall into 2 categories: (1) missing data on potential confounders and/or outcomes of interest (eg, claims data can assess utilization outcomes but lack disease characteristics; MR data have a rich set of clinical characteristics but lack longitudinality and utilization or cost data) and (2) limited generalizability (eg, the SEER-Medicare linked data in the United States capture claims and cancer registry data only for patients aged 65 years or older).

The ability of our study to integrate data across 3 sources to create a cohort of NSCLC patients with rich clinical and economic data offers an important addition to the comparatively small body of data on the performance of data integration methods and the determination of health outcomes based on these data for patients with NSCLC. To the extent that our study sample reflects the larger national population affected by lung cancer and with commercial insurance, these data could be instructive for a range of decisions made by multiple health care stakeholders including providers and patients requiring insights into the allocation of resources and overall disease management that cannot be completely ascertained from a single data source alone. One example would be the interaction of biomarker testing, treatment choice, and health outcomes. Integrated data

sets such as RESOUNDS that can be refreshed regularly also offer many opportunities for future research, such as treatment sequencing, disease progression, and health care resource utilization and costs.

Data Integration Challenges

Our study also highlighted some challenges in the creation, maintenance, and analysis of large integrated data sets. Integration of data sets in the midst of a rapid shift in the treatment landscape (such as the introduction of immune checkpoint inhibitors for oncology) may impact the value of data sets that are large and deep, but that include periods of time that are no longer relevant to current standards of care. The maintenance of these data sets requires constant refresh and update, so that the periods of interest to the investigator can be current and available for analysis. The wealth of data available in MRs presents challenges in identifying the trade-offs between generating a limited set of relevant but reasonably quickly available data versus a broader set of data that is potentially available but more difficult to obtain and prepare for analysis. Methods of data integration and data extraction may be improved with machine learning or natural language processing to reduce the manual extraction via data collection forms that was used in this study. Patient sample sizes available for analysis diminish when multiple data sources are required. Finally, there were specific data integration challenges in our study that resulted in additional effort needed by the project team to understand and address (eg, the estimated 2L therapy start date for a given patient sometimes differed between the data sources, plan enrollment changes entailed patients leaving or entering the data set multiple times, and conflicts between data sources for a given variable had to be resolved).

Study Limitations

Results based on integrated data must also be viewed with some limitations. The data quality and content will depend on the underlying data selected for integration. Specific to the data used for this project, limitations include the following: CCQP data were collected at the time of the prior authorization request, not at diagnosis. CCQP offers incentives to physicians for treating according to evidence-based guidelines created by the health plan, which could have influenced treatment choices. MR data may be underreported or missing due to vague, incomplete, or illegible entries; the inability to locate the required information; or missing patient files. ECOG performance status, a standard data item in cancer trials, is not always assessed in real-world patient care settings (in our study, this variable was available for 96.26% (2113/2195) of the sample, mostly from the CCQP), and information on race/ethnicity is often missing in claims data. Similarly, tumor growth and progression information is collected in various formats and levels of detail outside of a clinical trial setting. As a result, some of our research questions of interest had underpopulated data. Efforts by payers to tie provider reimbursement to the collection of key data points, for example, through quality improvement initiatives, may over time alleviate some of the missing data issues. Data collected during MR abstraction may have measurement errors linked to inconsistent coding, transcription, and data transfer errors. The typical limitations of claims data also apply. For example, a diagnosis code on a medical claim (eg, for secondary malignancies) does not guarantee the presence of a disease. Similarly, a claim for a prescription fill does not indicate that the medication was consumed or taken as prescribed. The generalizability of claims-based results is confined to similarly insured populations (eg, commercial, US-based in this study).

Conclusions

The care of patients with NSCLC requires a range of resources in a variety of settings in the real world. NSCLC and other forms of cancer are increasingly being managed like chronic diseases with a broad range of increasingly effective treatments. The assessment of real-world data to evaluate outcomes among patients with NSCLC will require the integration of a broad range of clinical data with health plan claims data. Overcoming data integration and completeness challenges will allow better informed decision making by all stakeholders of the health care system.

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Conflicts of Interest

MG is an employee of HealthCore, Inc, an independent research organization that received funding from Eli Lilly and Company for the conduct of this study. CM, KW, ZC, and LH are employees and stockholders of Eli Lilly and Company. GC was an employee of Eli Lilly and Company at the time the study was conducted. LW was an employee of HealthCore at the time the study was conducted.

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Abbreviations

1L: first-line
2L: second-line
CCQP: Cancer Care Quality Program
ECOG: Eastern Cooperative Oncology Group
HIRD: HealthCore Integrated Research Database
MR: medical record
NSCLC: non–small cell lung cancer
QCI: Quan-Charlson Comorbidity Index
RCT: randomized clinical trial
RESOUNDS: Real-World Treatment Sequences and Outcomes Among Patients With Non-Small Cell Lung Cancer
RWE: real-world evidence

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