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Feasibility, Acceptability, and Behavioral Outcomes from a Technology-enhanced Behavioral Change Intervention (Prostate 8): A Pilot Randomized Controlled Trial in Men with Prostate Cancer

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Abstract

Background: Increasing evidence suggests that lifestyle factors may decrease the risk of prostate cancer progression. Lifestyle guidelines and tools may support lifestyle modification after diagnosis.
Objective: To determine the feasibility and acceptability of a digital lifestyle intervention among men with prostate cancer.
Design, setting, and participants: A 12-wk pilot randomized controlled trial among 76 men with clinical stage T1–T3a prostate cancer. Eligibility included Internet access, no contraindications to aerobic exercise, and engaging in four or fewer of eight targeted behaviors at baseline.
Intervention: Website, Fitbit One, and text messaging to facilitate adoption of eight behaviors: vigorous activity, smoking cessation, and six diet improvements.
Outcome measurements and statistical analysis: Our primary outcomes were feasibility and acceptability based on recruitment and user data, and surveys, respectively. Secondarily, we evaluated the change in eight lifestyle behaviors, and also objective physical activity. Each factor was assigned one point, for an overall "P8 score" (range 0–8). Analysis of covariance (ANCOVA) was conducted. Exploratory outcomes included quality of life, anthropometrics, and circulating biomarkers after 12 wk, and behaviors after 1 yr.
Results and limitations: At baseline, men in both arms met a median of three targeted behaviors. Sixty-four men (n = 32 per arm) completed the study; 88% completed 12-wk assessments (intervention, 94%; control, 82%). Intervention participants wore their Fitbits a median of 82 d (interquartile range [IQR]: 72–83), replied to a median of 71% of text messages (IQR: 57–89%), and visited the website a median of 3 d (IQR: 2–5) over 12 wk. Median (IQR) absolute changes in the P8 score from baseline to 12 wk were 2 (1, 3) for the intervention and 0 (−1, 1) for the control arm. The estimated mean score of the intervention arm was 1.5 (95% confidence interval: 0.7, 2.3) higher than that of the

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control arm at 12 wk (ANCOVA $p < 0.001$). Changes were driven by diet rather than exercise. Limitations include self-reported diet and exercise data.
Conclusions: Overall, in this novel pilot trial, the intervention was feasible and acceptable to men with prostate cancer. Next steps include improving the intervention to better meet individuals' needs and focusing on increasing physical activity in men not meeting nationally recommended physical activity levels.
Patient summary: Tailored print materials combined with technology integration, including the use of a website, text messaging, and physical activity trackers, helped men with prostate cancer adopt healthy lifestyle habits, in particular recommended dietary changes, in the Prostate 8 pilot trial.

1. Introduction

Recent observational studies and preclinical evidence suggest that certain lifestyle behaviors may reduce the risk of prostate cancer progression [1]. Lifestyle factors that have been associated with improved clinical outcomes (ie, reduced prostate cancer mortality, metastasis, prostate-specific antigen progression, and initiation of secondary treatments) in men with prostate cancer include vigorous physical activity [2]; brisk walking [3]; not smoking [4,5]; higher intake of vegetable fat [6], cruciferous vegetables [7], tomato sauce [8], and fish [8,9]; and lower intake of processed meat [10,11] and supplemental selenium [12]. Many of these lifestyle factors also reduce the risk of cardiovascular outcomes, the leading cause of death worldwide.

Digital interventions targeting these behaviors can minimize expense and time required for phone or in-person counseling, reduce cost and burden associated with participation in on-site interventions, and scale up more readily and cost effectively for maximum reach compared with other designs. Digital interventions are promising for improving physical activity and body mass index (BMI) among cancer survivors, with mixed evidence for diet, but no studies conducted specifically for prostate cancer were found [13]. Digital health interventions have been pilot tested and shown to be effective in women with breast cancer at increasing moderate-intensity aerobic exercise and fruit and vegetable consumption over 12 wk [14], and in women at an increased risk for breast cancer at losing weight and increasing physical activity over 12 wk [15].

Therefore, we created and piloted a remote, technology enhanced lifestyle intervention for men with prostate cancer. A 12-wk pilot randomized controlled trial (RCT), Prostate 8 (NCT02470936), was conducted to determine study feasibility, acceptability, and preliminary efficacy of a digital health intervention on lifestyle behaviors. We further explored the intervention's impact on health-related quality of life (QOL), biomarkers, and body size after 12 wk and behaviors after 1 yr.

2. Patients and methods

2.1. Study design, recruitment, and eligibility

Men were randomized 1:1 to the lifestyle program or the control arm. We based our sample size on study feasibility (using an adherence measure) and behavior change. The lifestyle program included a text message component, and adherence was defined as responding to a text message each week. Our expected adherence rate was 70% (95% confidence interval [CI]: 50%, 84%). If the observed adherence rate was <50% (<16 participants responded to text messages at least weekly), the intervention would not be considered feasible. Sample size was calculated to provide 80% power if 40% of the intervention arm made at least one recommended behavior change (Table 1) in 12 wk, compared with 10% of the controls, at a two-tailed alpha level of 0.05. This required a total of 76 men, allowing for 15% dropout.

Following ethics approval at the University of California, San Francisco (UCSF), 228 men were assessed for eligibility. Potential UCSF patients were identified via (1) a list of UCSF patients who agreed to be contacted for future studies, (2) review of clinic schedules, and (3) provider referrals. We contacted men by phone or in person, who lived up to a 2-h drive from UCSF. Inclusion criteria were histologically confirmed diagnosis of clinical stage ≤T3a nonmetastatic prostate cancer within 5 yr, completion of treatment ≥3 mo prior to enrollment if not on active surveillance, ability to walk unassisted, ability to speak and read English, ability to navigate websites and email, having Internet access, and ability to travel to UCSF for pre- and poststudy blood collection. Exclusion criteria were any contraindications to moderate or vigorous aerobic exercise (eg, cardiopulmonary disease, musculoskeletal disease, and infection), psychiatric condition preventing the patient from giving informed consent or adhering to the study protocol, and reporting adherence to more than four of the eight targeted lifestyle behaviors via questionnaires at screening (Table 1). Written informed consent was obtained before all study assessments.

Table 1 – Recommendations for the Prostate 8 trial

Get active
1. Build up to 3+ h/wk of vigorous aerobic exercise. Depending on your individual fitness, vigorous aerobic exercise levels may be achieved through activities such as brisk walking, jogging, cycling, rowing, lap swimming, etc., which are done at a medium to high intensity [2,3,24].
Eat well
2. Replace solid fats with vegetable oils when cooking or baking and consume 1 serving/d of oil-based salad dressing (eg, olive or canola oil) or nuts [6] (avocados mentioned on vegetable fat web pages).
3. Consume 1 serving/d of cruciferous vegetables [7].
4. Consume 2+ servings/wk of cooked tomatoes (eg, sautéed or roasted tomatoes) or cooked tomato products (eg, tomato soup and tomato sauce) [8].
5. Consume 2+ servings/wk of fish [8,9].
6. Avoid all processed meat [10,11].
7. Do not consume single vitamin or mineral supplements unless a doctor prescribes them. Multivitamins or fish oil are ok [12].
Stop smoking
8. Avoid all tobacco products [4,5].

2.2. Randomization, stratification, and allocation concealment

Questionnaires were completed by patients independently and online, prior to the baseline visit. After baseline assessments, participants were randomly assigned to intervention ($N = 37$) or control ($N = 39$) at a ratio of 1:1 with block sizes of 1–2 using the R package blockrand (https://cran.r-project.org/web/packages/blockrand/blockrand.pdf). Patients were stratified by active surveillance or radical prostatectomy. The allocation sequences created by one investigator were concealed in sealed, opaque envelopes from the other investigators and the clinical research coordinator who assigned participants. Measurements of vital signs including weight were completed by the clinic nurse who was blinded to arm assignment, while waist/hip measurements were completed by the study coordinator using a standardized protocol.

2.3. Intervention arm

Participants received eight recommendations (see Table 1) that comprised the Prostate 8 score and were based on the literature (see Introduction). Each factor was assigned one point, for an overall "P8 score" (range 0–8). The 12-wk intervention included personalized recommendations provided in a report at baseline by the research coordinator and access to the study website with login, a Fitbit One activity tracker, and text messages. The personalized recommendations report compared self-reported diet, smoking, and physical activity habits with study recommendations, and highlighted areas of focus, classifying each reported behavior as meeting, almost meeting, or not meeting our recommendations. The website included four topic areas (get active, eat well, stop smoking, and find support) and focused on all eight factors. For details, refer to the Supplementary material. Every 2 wk, participants were emailed by the principal investigator about blog topics and recipes added on the website. We provided the Fitbit One to patients and access to a study-only community group on the Fitbit website. Lost or damaged Fitbits were replaced. Participants received four to five text messages each week, both responsive (requesting a reply) and nonresponsive. The text messages incorporated constructs/strategies from the theory of planned behavior [16] and emphasized goal setting/planning, securing social support, maintaining/enhancing self-efficacy, making healthy behaviors enjoyable, staying motivated, harms/benefits, and challenges and quizzes to reinforce and motivate adoption and continued repetition of the recommendations (see the Supplementary material).

2.4. Control arm

The control arm received their usual standard of care from baseline to 12 wk, and was given access to the study website and personalized lifestyle recommendations after the end of the study. Usual standard of care does not include distribution of print material on diet and lifestyle; however, lifestyle-related guidance/booklets developed for patients with prostate cancer are available on the department website and accessible to anyone.

2.5. Outcomes

Demographic variables collected, using online questionnaires at baseline, included race, education, relationship status, and age. The primary outcomes were feasibility, measured by recruitment rates and the use of study components, and acceptability, measured by online questionnaires in the intervention arm at 12 wk, with closed and open-ended questions. Satisfaction was measured for each component and rated as "dissatisfied," "neutral," "satisfied," and "very satisfied," and the features examined were rated as "excellent," "very good," "good," "average," "poor," and "did not notice." Usage of study components was calculated by downloading activity data from the Fitbit devices when they were returned at 12 wk, reviewing responses on the text messaging platform for each responsive text message sent, and reviewing objective website login and page view data.

Secondary outcomes included the following: (1) changes in the Prostate 8 score and individual behaviors—these changes were assessed by self-reported exercise, diet, and supplement use via online, validated surveys [17,18], at baseline and 12 wk. Men reported usual walking pace (easy, normal, brisk, and very brisk) and average time per week spent on specific activities. Vigorous activities were calculated as those with a metabolic equivalent task value of $\geq$6; (2) objective physical activity—changes in moderate and vigorous activity and daily steps from baseline to 12 wk in both arms were measured using Actigraph GTX3+ accelerometers [19]. Accelerometers were worn around the participant's waist for 7 consecutive days before the baseline visit and at 12 wk. We required at least 3 d of valid wear time, defined as $\geq$10 h/d (ActiLife v6.13.3 software). Moderate and vigorous activities were defined as 2020–5998 and 5999+ counts/min, respectively [20]. Self-reported physical activity was used in the baseline P8 score, rather than the accelerometer data, because the accelerometer was worn after patients were deemed eligible and before the baseline study visit. It would have required additional screening time to retrieve the devices before the baseline visit to determine eligibility, and participants would have had to wear the accelerometer for 7 d, without knowing whether they were eligible. Adverse events (AEs), including joint and muscle pain, shortness of breath, fatigue, surgery, and hospitalization, were collected via online questionnaires at 4, 8, and 12 wk.

Exploratory outcomes included anthropometrics, select metabolic markers (eg, fasting glucose, and hemoglobin A1c), three antioxidants (lycopene, and alpha- and gamma-tocopherol), QOL, and assessment of maintenance or adoption of behaviors after 1 yr (see the Supplementary material for details and results).

2.6. Data analysis

We described patients' demographics and baseline clinical characteristics using medians and interquartile ranges (IQRs) for continuous variables and n with percentage for categorical variables. Balance across arms was examined by appropriate statistical tests. For study feasibility, we assessed the frequency of use for tools provided in the intervention arm, and for study acceptability, we present summary statistics to describe the acceptability survey administered to men in the intervention arm. To assess preliminary efficacy, percentages of men in each arm who adopted or maintained behaviors at 12 wk were compared using two-sample proportion tests. Absolute change from baseline to 12 wk for the dietary and physical activity components were described by medians with IQR. The difference in changes from baseline to 12 wk between two groups was described by means and 95% CIs. Outcomes at 12 wk were compared between groups using analysis of covariance (ANCOVA), adjusting for the baseline assessment. To assess a difference in the absolute change of the Prostate 8 score between arms, a mixed-effect regression model was applied. Age, baseline BMI, race, clinical stage, and relationship status were considered potential covariates that may be related to behavior change and were examined using a stepwise method retaining variables with $p < 0.2$. For exploratory outcomes, we present descriptive data, medians (IQR), difference in mean changes between groups, and ANCOVA p values in the Supplementary material. Statistical analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC, USA).

3. Results

From June 5, 2015, to March 1, 2017, 76 men (mean age: 65 yr, range: 51–79 yr) were randomized to intervention ($n = 37$) and control ($n = 39$) arms. A total of 228 patients

were assessed; 33% ($n = 76$) of them were randomized (Fig. 1). Of those excluded, 24.8% were already meeting more than four of the eight study recommendations, and 28% were unwilling to travel to UCSF for the baseline and 12-wk study visits. Four patients did not receive the allocated intervention (three in the intervention arm and one in the control arm; Fig. 1). Attrition was 5.9% ($n = 2$) in the intervention arm and 15.8% ($n = 6$) in the control arm. All patients completed online surveys successfully. The post-12-mo follow-up questionnaire, added as a protocol amendment in 2017, was completed by 78% ($N = 25$) in the intervention arm and 75% ($N = 24$) in the control arm who completed the study. Median follow-up time from the end of study to the follow-up questionnaire was 16.9 mo (IQR: 13.9, 22.4) in the intervention arm and 13.4 mo (IQR: 11.5, 23.2) in the control arm. Participants were 65 yr of age on average, 84% were white, 41% were overweight (BMI $\geq$ 25 to <30), and 35% were obese (BMI $\geq$ 30). Baseline characteristics were similar for both arms (Table 2).

3.1. *Intervention use—feasibility*

Intervention arm participants wore their Fitbits for a median of 82 d (IQR: 72, 83), with 98% of days in the 12-wk period, and responded to a median of 71% (IQR: 57, 89) of 60 text messages that asked for a reply. Seventy-five percent

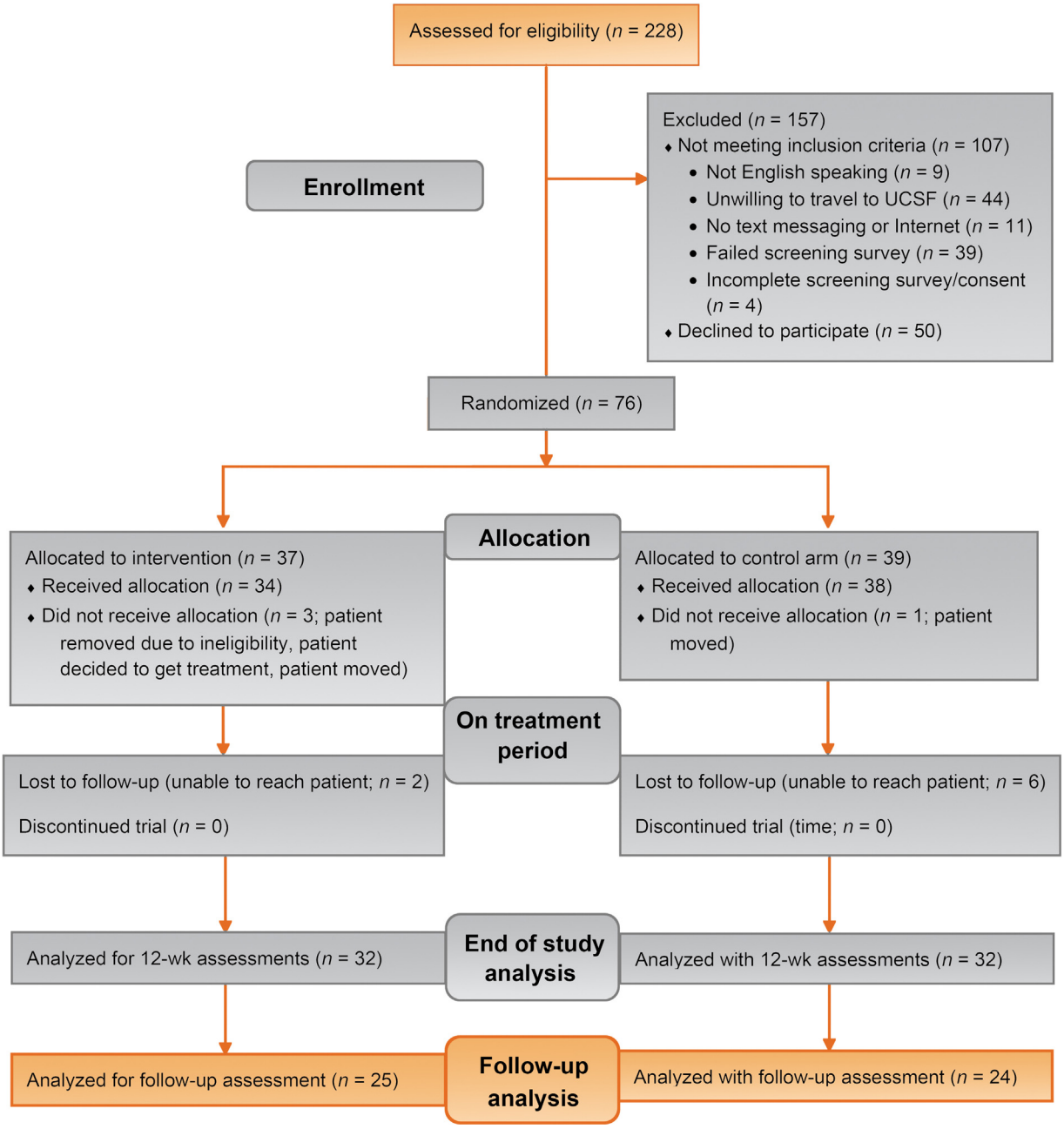

Fig. 1 – CONSORT diagram of recruitment and loss to follow-up through the trial. UCSF = University of California, San Francisco.

of patients in the intervention arm responded to at least one responsive message during each week of the 12-wk period. The total number of days that the website was visited and the total number of website visits (this could be multiple visits per day) were a median of 3 d (IQR: 2, 5) and three visits (IQR: 2, 5) over the 12-wk period, respectively, using objective login user data. Despite this, 29% of participants self-reported using the website several times a month or more frequently. The median number of total page views over all visits (counting all pages viewed using user data) was 14.5 (IQR: 0, 31.5) over the 12-wk period.

3.2. Acceptability of the intervention

The main study components were rated as follows: 60.7% of participants rated the quality of website as high or very high, 87.1% rated the Fitbits as good to excellent, 68.8% rated the text messaging as good to excellent, and 78.1% rated the baseline personalized recommendation report as good to excellent. Participant satisfaction ("satisfied" or "very satisfied") was 60% for website, 90.6% for Fitbits, and 73.3% for text messaging. Despite e-mail alerts, participants reported not noticing the following components: homepage blog (46%), recipe of the week (25%), shopping guides (50%), and weight room and home-based workouts (44%). However, based on 20 open-ended responses, the top website feature that influenced their decision to keep using the website were the recipes ($n = 7$), so among men who looked at the recipes, it was a popular item. Most participants did not request any changes to the website for improvement ($n = 24$ of 32); single participants (in open-ended question) asked for fewer website updates, specific exercise clarifications, more support for senior citizens, making posts more visible, more online events, and more in-depth pages. Additional features requested from an open-ended question included the following: clinical support geared toward treatment management, having online forums for patients to connect with one another, and personalized recommendations for exercise levels.

Table 2 – Demographics and clinical characteristics of the 76 participants who started the Prostate 8 trial

Characteristic	Median (IQR) or *N* (%)	
	Intervention	Control
No. of participants	37	39
Age (yr)	66 (61, 68)	65 (60, 69)
Body mass index (kg/m^2)	27.5 (25.2, 31.4)	29.0 (24.7, 32.2)
Weight (lbs)	187 (164, 218)	191 (169, 220)
Height (in.)	70 (67, 71)	68 (67, 70)
Waist circumference (cm)	96 (90, 103)	96 (87, 107)
Waist to hip ratio	0.9 (0.9, 1.0)	0.9 (0.9, 1.0)
Race		
White	34 (91)	27 (69)
African American	1 (3)	5 (13)
Asian	1 (3)	4 (10)
Other	1 (3)	0 (0)
Unknown	0 (0)	3 (8)
Education		
High school	3 (8)	0 (0)
2-yr college	10 (27)	6 (15)
4-yr college	8 (22)	10 (26)
Grad./prof. school	16 (43)	22 (56)
Unknown	0 (0)	1 (3)
Relationship status		
Married	29 (78)	31 (80)
Single/divorced	7 (19)	6 (15)
Unknown	1 (3)	2 (5)
Clinical stage		
T1	21 (57)	24 (62)
T2	14 (38)	12 (31)
T3a	2 (5)	3 (8)
Treatment status		
Radical prostatectomy	16 (43)	19 (49)
Active surveillance	21 (57)	20 (51)
PSA at diagnosis (ng/ml)	4.3 (0.4, 5.6)	4.6 (0.8, 6.1)
Self-reported behaviors		
Smoking status (%)		
Current	1 (3)	0 (0)
Past	16 (43)	13 (33)
Never	20 (54)	26 (67)
Moderate activity (h/wk)	3.5 (1.4, 6.5)	3.0 (1.5, 6.2)
Walking (h/wk)	1.5 (0.5, 2.5)	1.5 (0.5, 2.5)
Vigorous activity (h/wk)	0.2 (0.0, 2.5)	0.1 (0.0, 2.5)
Vigorous activity or brisk walking (h/wk)	0.2 (0.0, 3.0)	0.4 (0.0, 2.7)
Tomatoes (cooked, serv/wk)	1.5 (1.0, 3.0)	1.5 (1.0, 3.5)
Cruciferous vegetables (serv/wk)	3.0 (1.5, 5.0)	3.5 (2.0, 5.0)
Fish (serv/wk)	1.5 (0.5, 2.0)	1.5 (1.0, 2.0)
Processed meat (serv/wk)	2.0 (1.0, 3.5)	1.5 (1.0, 3.5)
Healthy vegetable fat (serv/wk)	6.5 (3.0, 12.0)	6.0 (3.5, 12.0)
Vitamin & mineral supplement use		
None	11 (30)	8 (21)
Multivitamin	1 (3)	3 (8)
Other supplements	11 (30)	15 (39)
Multivitamins & other suppls.	14 (38)	12 (32)
Prostate 8 score[a]	3 (2, 4)	3 (2, 4)

Grad. = graduation; IQR = interquartile range; prof. = professional; PSA = prostate-specific antigen; serv = servings; suppls. = supplements.
[a] Prostate 8 score: each factor was assigned one point, for an overall "P8 score" ranging from 0 to 8, with one point each for the following: ≥1 serving/d of healthy sources of vegetable fat (including oil-based salad dressing, avocado, peanut butter, other nut butter, peanuts, walnuts, and other nuts); ≥1 serving/d of cruciferous vegetables (including broccoli, cauliflower, cabbage or coleslaw, Brussels sprouts, kale, mustard, collard greens, chard, Bok choy, turnips, radish, arugula, and watercress); ≥2 servings/wk of cooked tomatoes or tomato products (including tomato or marinara sauce; tomato soup; sautéed, roasted, or other form of cooked tomatoes; picante; or taco sauce); ≥2 servings/wk of fish (canned tuna fish, breaded fish cakes, fish pieces or sticks, dark meat fish, or other fish); 0 servings of processed meat (beef or pork hot dogs, chicken or turkey hot dogs, bacon, salami, bologna, or other processed meat sandwiches, including deli lunch meat and other processed meats); no single vitamin or mineral supplements unless recommended by the doctor (multivitamins or fish oil allowed); no tobacco product use; and ≥3 h/wk of vigorous aerobic exercise (including brisk walking).

3.3. Self-reported behavior change over 12 wk

Men in the intervention arm improved on four recommendations at 12 wk compared with the controls: cooked tomatoes (75% vs 44%, $p = 0.011$), cruciferous vegetables (44% vs 19%, $p = 0.031$), fish (78% vs 28%, $p < 0.001$), and no processed meat (31% vs 9%, $p = 0.030$; Table 3). Eighty-one percent in the intervention arm met at least one new recommendation (not already met at baseline) at 12 wk

Table 3 – Proportions and counts of patients meeting each Prostate 8 recommendation at the end of study by treatment assignment and whether they met the goal at baseline

	Intervention (n = 32)				Control (n = 32)				p value[a]
	0 wk		12 wk Yes	% Adopt or maintain[b]	0 wk		12 wk Yes	% Adopt or maintain[b]	
Cooked tomatoes	No	17	10	75	No	20	7	44	0.011
	Yes	15	14		Yes	12	7		
Cruciferous vegetables	No	29	11	44	No	30	4	19	0.031
	Yes	3	3		Yes	2	2		
Fish	No	22	17	78	No	23	6	28	<0.001
	Yes	10	8		Yes	9	3		
Processed meat	No	32	10	31	No	28	2	9	0.030
	Yes	0	0		Yes	4	1		
Healthy sources of vegetable fat	No	19	11	66	No	17	3	47	0.13
	Yes	13	10		Yes	15	12		
Supplements	No	17	5	50	No	19	5	41	0.5
	Yes	15	11		Yes	13	8		
Vigorous activity or brisk walking	No	23	10	47	No	22	8	50	0.8
	Yes	9	5		Yes	10	8		
Smoking	No	1	0	94	No	0	0	100	0.2
	Yes	31	30		Yes	32	32		

[a] Two-sample proportion test that each recommendation was adopted or maintained.
[b] % Adopt or maintain is calculated by dividing those with "yes" at 12 wk by the total number in that group. For example, for cooked tomatoes in the intervention group: [(10 + 14)/32] = 75%.

versus 66% in the control arm. Median (IQR) absolute change in the P8 score from baseline to 12 wk was 2 (1, 3) in the intervention arm and 0 (−1, 1) in the control arm. The estimated mean score of the intervention arm was 1.5 (95% CI: 0.7, 2.3) higher than that of the control arm. Outcomes at 12 wk were statistically significantly improved for the overall score ($p < 0.001$) and for cooked tomatoes, cruciferous vegetables, fish, and processed meat, but not for vegetable fat and vigorous activity or brisk walking (Table 4). Median absolute changes (positive values indicate an increase, negative values indicate a decrease, and 0 indicates no change) from baseline to 12 wk comparing the intervention versus control arm were as follows: for cooked tomatoes, 1.0 versus 0 servings/wk; cruciferous vegetables, 3.0 versus 0.5 servings/wk; fish, 1.3 versus 0 servings/wk; processed meat, −1.0 versus 0.5 servings/wk; healthy sources of vegetable fat, 1.5 versus 0 servings/wk; and vigorous activity or brisk walking, 0.2 versus 0.3 h/wk (Table 4). Vegetable fat servings were near the recommended level of 7 servings/wk at baseline in both arms. In a post hoc analysis of moderate activity, there was no statistically significant difference at 12 wk ($p = 0.4$); median change was 1.1 h/wk (IQR: −0.3, 3.6) in the intervention arm and 0 h/wk (IQR: −1.1, 1.7) in the control arm. The mean differences and 95% CIs between arms for each factor are presented in Table 4. Based on mixed-effect models adjusted for age, the estimated P8 score was 1.63 higher in the intervention arm than in the control arm ($p < 0.001$). Younger men had a higher P8 score than older men (each 5-yr age increase decreased the score by 0.36, $p = 0.020$).

3.4. Accelerometer changes over 12 wk

There were no differences in 12-wk measurements for vigorous (part of the P8 score), moderate, or moderate-to-vigorous physical activity between arms (Table 5). A mean

Table 4 – Change in self-reported dietary and physical activity components[a]

Absolute change	Median (IQR)		Difference in means (95% CI)[b]	p value[b]
	Intervention (n=32)	Control (n=32)		
Cooked tomatoes (serv/wk)	1.0 (0.0, 2.8)	0.0 (−0.5, 1)	1.86 (0.32, 3.40)	0.012
Cruciferous vegetables (serv/wk)	3.0 (0.5, 7.3)	0.5 (−1.0, 2.3)	3.81 (1.14, 6.49)	0.006
Fish (serv/wk)	1.3 (0.3, 3.0)	0.0 (−0.8, 0.5)	2.38 (0.84, 3.91)	0.004
Processed meat (serv/wk)	−1.0 (−2.3, −0.5)	0.5 (0.0, 1.0)	−1.65 (−2.67, −0.64)	<0.001
Healthy vegetable fat (serv/wk)	1.5 (−1.3, 5.5)	0.0 (−2.8, 2.3)	1.19 (−1.76, 4.14)	0.4
Vigorous activity or brisk walking (h/wk)	0.2 (0.0, 4.6)	0.3 (0.0, 2.5)	0.96 (−1.60, 3.52)	0.5

ANCOVA = analysis of covariance; CI = confidence interval; IQR = interquartile range; serv = servings.
[a] For median baseline levels, see Table 2 and footnote.
[b] Difference in means is intervention arm minus control arm; ANCOVA test of difference in measures across treatment arms at the end of study.

Table 5 – Objective physical activity (all data from accelerometer) at baseline and 12 wk among men participating in a randomized controlled trial of a lifestyle intervention

Factor	Median (IQR)		Difference in means (95% CI)[a]	*p* value[a]
	Intervention (n=30)	Control (n=30)		
Average moderate to vigorous physical activity (min/d)				
Baseline	36 (26, 66)	49 (29, 71)		
End of study	45 (28, 61)	37 (20, 69)		0.5
Absolute change	1.4 (−7.0, 11.8)	−5.5 (−15.2, 3.1)	5.3 (−4.7, 15.3)	
Moderate physical activity (min/d)				
Baseline	36 (24, 59)	45 (29, 69)		
End of study	44 (27, 58)	35 (19, 69)		0.5
Absolute change	1.6 (−4.9, 10.5)	−6.1 (−16.1, 3.1)	5.2 (−4.7, 15.1)	
Vigorous physical activity (min/d)				
Baseline	0.4 (0.3, 2.4)	0.7 (0.3, 3.4)		
End of study	0.4 (0.2, 2.3)	0.5 (0.3, 2.9)		0.9
Absolute change	0.02 (−0.2, 0.9)	−0.02 (−0.6, 0.3)	0.1 (−1.8, 2.0)	
Steps (per day)				
Baseline	6909 (4569, 9046)	8887 (5338, 10 482)		
End of study	7315 (5272, 8995)	6882 (4842, 11 355)		0.085
Absolute change	849 (−367, 1595)	−978 (−1970, 270)	1212 (133, 2291)	

ANCOVA = analysis of covariance; CI = confidence interval; IQR = interquartile range.
[a] Difference in means is intervention arm minus control arm; ANCOVA test of difference in measures across treatment arms at the end of study.

difference of 1212 steps per day was observed between the intervention and the control arm, although the step count at 12 wk between arms was not statistically significantly different ($p = 0.085$).

3.5. *Adverse events*

AEs collected by arm are presented in Supplementary Table 1. In nearly all the categories relating to physical activity (eg, knee pain, joint pain, back pain, and muscle pain), the intervention arm had more AE reports, albeit not significant, despite no statistically significant difference in actual activity.

See the Supplementary material for the exploratory outcome results.

4. Discussion

In this pilot RCT, we tested a lifestyle intervention utilizing a website, Fitbit, and text messages. Fitbit use and text message responsiveness were high, and website use was low. Satisfaction with these components ranged from 60% to 91%. Intervention participants reported greater changes in certain dietary behaviors than control participants at 12 wk. The intervention did not increase objective moderate or vigorous activity by accelerometer, although we observed a 1212-step (mean) increase by accelerometer in the intervention arm. We did not observe any significant changes in anthropometric measurements, circulating biomarkers, or QOL in the 12-wk timeframe.

Few studies have reported on the feasibility and effectiveness of digital health lifestyle interventions among prostate cancer patients. Out of seven digital health RCTs conducted between 2012 and 2016 [13], one study included 27 prostate cancer patients [21] focused on a 9-wk/nine-module online program with patient exercise tracking versus usual care, and observed no significant differences in physical activity at 9 wk; however, many of the participants were already meeting activity guidelines at baseline (46%). A qualitative investigation completed in the UK among 16 men and seven partners reported that men were open to lifestyle modification programs, family support was vital to facilitate change, and e-technology could be a barrier to some [22]. Men favored individualized rather than group interventions, with added spousal or other social support [22].

In this pilot study, we observed significant improvements in dietary behavior, but no increase in vigorous activity or brisk walking. The use of Fitbits increased steps and likely promoted walking in general compared with more intense activities. The participants in our study reported high levels of moderate activity at baseline; still, we observed a median change of an additional 1.1 h/wk of moderate activity in the intervention arm versus no change in the control arm. This change was not statistically significant, but may be clinically meaningful. Together with the lack of a substantive change in vigorous activity, these results reflect that it may be harder to increase activity intensity independently, and additional support may be needed.

A recent study reported that recreational activity at levels of >13 MET-h/wk (approximately 4 h of walking or 2 h of jogging per week) was also beneficial for reducing prostate cancer death [23], while another study reported a benefit starting at 1 h of exercise per week [24]. Further research should examine how to increase physical activity in men with prostate cancer who are not meeting, at a minimum, nationally recommended physical activity levels (2.5 h/wk of moderate activity, 1.25 h/wk of vigorous activity, or combination). Additionally, future studies may wish to categorize light, moderate, and vigorous activities and sedentary behavior separately, given recent results suggesting that each of these may offer different levels of benefit, and to see whether the increase in light activity

occurs because of less sedentary activity, which has been linked with lower all-cause mortality [25]. Providing access to exercise coaches who can remotely monitor and advise on exercise during the study could be used to increase motivation and provide additional guidance to patients who are attempting to safely increase their exercise intensity level.

There are several limitations to consider when interpreting these results. Digital interventions are cost effective and scalable only if we can demonstrate that the tools are used as intended. We acknowledge that website use was low. For the pilot study, the focus of the website was education. Future interventions may wish to focus instead on behavior change strategies (eg, online goal setting and tracking). Additionally, this study may not be representative of the general US population, as most patients were white, nonsmokers, married, modestly overweight, and reported high levels of moderate activity at baseline. Future studies should incorporate diverse groups to strengthen the generalizability of the findings. Finally, this was a multicomponent intervention, so we cannot evaluate the effect of individual components on behavior change. Perhaps, asking men to make both dietary and exercise changes was too much and focusing on one or the other may be better, which we will assess in future studies.

In this novel pilot RCT, we developed and tested a digital, remote-based lifestyle intervention designed to reduce the risk of recurrence in men with prostate cancer. Our team is now conducting an NIH-funded phase II RCT among 200 men with prostate cancer at UCSF and the San Francisco Veterans Affairs Medical Center who choose radical prostatectomy. The study incorporates additional online tools, exercise equipment (heart rate monitor and resistance bands to be used in conjunction with exercise workouts), and coaches to motivate changes over 2 yr and study biological and clinical endpoints. To be eligible, men cannot already meet either the exercise national guidelines or diet recommendations.

5. Conclusions

In conclusion, a digital health lifestyle intervention was feasible and acceptable among men with prostate cancer, and preliminary data suggest that such an intervention may support at least short-term adoption of healthy diet behaviors. This work provides direction and rationale for future studies focused on biological and clinical endpoints to determine whether lifestyle change after prostate cancer reduces the risk of recurrence and mortality.

Author contributions: Stacey A. Kenfield had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Analysis and interpretation of data: Kenfield, Van Blarigan, Ameli, Cedars, Tantum, Signorell, Suh, Zhang, Chan.
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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.eururo.2018.12.040.

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