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Satisfaction and effectiveness of a digital health tool to improve health behavior counseling among adolescent and young adult cancer survivors: a randomized controlled pilot trial

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Abstract

Background This pilot study examined the preliminary effectiveness of the PREVENT digital intervention that supports health care teams in delivering health behavior counseling on cancer survivors' motivation to change behavior, their physical activity and food intake behaviors, and cardiovascular health (CVH).

Methods Clinicians (physicians, nurse practitioners) at three urban cancer survivorship clinics were trained to use PREVENT. Patients were randomized to the PREVENT intervention or a wait-list routine care control group. Eligibility criteria for patients included: between ages 12–39, overweight or obese, were at least 6-months post-active cancer treatment, and had sufficient English proficiency.

Results Fifty-five participants were enrolled; 27 were randomized to the PREVENT intervention and 28 to wait-list routine care control. The majority of the participants (82%) identified as non-Hispanic white, with an average age of 19.8 (SD ± 5.2) years. Patients that received the PREVENT intervention had greater increases in their self-efficacy, vigorous activity and number of food recommendations met than those who received routine clinical care. Changes in willingness, knowledge, and CVH outcomes were not significant.

Conclusions The PREVENT digital intervention may provide improvements in preventive behaviors among AYA cancer survivors by supporting care teams with delivering evidence-based, tailored behavior change recommendations and resources to support patient health.

Trial registration This trial (NCT04623190) was registered on 11/02/2022.

Keywords Physical activity, Nutrition, Digital health, Cardiovascular health, Feasibility

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Introduction

Cardiovascular disease (CVD) is the leading cause of death in survivors of cancer. CVD risk factors and mortality are more prevalent among adolescent and young adult (AYA) cancer survivors than the general population and childhood cancer survivors [1, 2]. The growing population of AYA cancer survivors was estimated to be more than 600,000 in 2020 [3]. This increase reflects improvements in cancer therapy, but also signals that there is a growing population of long term AYA cancer survivors who are at greater risk of treatment-related morbidity and mortality, including early onset of CVD [4]. Likewise, those who are treated for cancer during childhood have an elevated likelihood of acquiring risk factors for CVD, which are predictive of clinical disease late in life [5]. Approximately 90% of AYA diagnosed with cancer will survive and require care for long-term and late effects, including for CVD prevention [6]. AYA cancer survivors, particularly those from minoritized racial/ethnic groups or those experiencing poverty, are a growing, high-risk population, yet prevention efforts that promote healthy behaviors such as physical activity and healthy food intake to improve cardiovascular health (CVH) and prevent CVD are lacking [7, 8].

Healthy food intake and participation in regular physical activity are recommended for cancer survivors to reduce the risk of late effects, particularly CVD, and to improve quality of life [9]. The vast majority of AYA cancer survivors do not meet behavioral recommendations for physical activity and nutrition [10]. The American Cancer Society recommends that cancer survivors slowly build to 150 to 300 minutes of moderate-intensity activity, or 75–150 minutes of moderate-to-vigorous intensity each week [11]. However, in 2020 the National Cancer Institute found more than a third of cancer survivors reported inadequate levels of physical activity [12]. In addition, the American Cancer Society recommends that cancer survivors eat a variety of fruits, vegetables, and whole grains that are rich in fiber and high in nutrients [13]. There are known benefits to healthy food intake and physical activity guidelines for AYA cancer survivors and interventions that motivate patients to follow these recommendations are needed.

Clinician advice, shared decision making between patients and healthcare providers, and patient engagement can help increase physical activity and healthy eating [14–16]. AYA oncology guidelines stipulate that patients should receive physical activity and nutrition guidance during follow-up care [17]. Survivorship care teams have trusting and longstanding relationships with AYA cancer survivors that are shown to increase adherence to care plans [18]. Therefore, survivorship care teams are uniquely positioned to offer guidance

to motivate health behavior change among AYA cancer survivors.

Digital health tools have the potential to improve the quality, efficiency, and consistency of behavior change advice within survivorship care [19–22]. Digital health tools can support meaningful prevention discussions with data visualizations [23] and leverage data to deliver personalized, evidence-based behavior change within the constraints of the clinic workflow [24, 25]. The use of informatics to automate tailored behavior change recommendations into routine clinical care is novel and pragmatic [26]. Despite the rapid emergence of digital interventions for behavior change, digital health tools have not been developed to support the care team with the efficient delivery of behavior change recommendations to AYA cancer survivors [27, 28]. Furthermore, advice to promote behavior change may only be effective if the multi-level factors outside the clinic that influence health behaviors are recognized and addressed [29, 30].

The ability of AYA cancer survivors to be physically active and consume healthy foods depends on knowledge of existing resources and the built environment [31–33], including infrastructure (e.g., transportation) to access resources, particularly for marginalized racial/ethnic groups and those experiencing poverty [34–37]. Despite their importance, these factors are often not addressed at the point of care. Care teams often lack time and access to patient- and community-specific data needed to provide pertinent resources and information (e.g., parks, community centers, healthy food outlets). Clinic-based interventions linking patients to community resources have produced weight loss in adults and children in other settings [30, 38, 39]. Yet, provision of resources, coupled with evidence-based, tailored behavior change strategies that are integrated into the clinical workflow or maintained in routine practice, have not been tested in AYA cancer survivors.

Technology paired with quality patient-care team relationships may be a solution to motivate AYA cancer survivors to follow health behavior guidelines and reduce their risk of CVD and late effects. This paper presents results from a pilot randomized trial of PREVENT [40], a digital tool designed to help care teams deliver quality, patient-centered health behavior counseling and community resources at the point of care. This trial was conducted in three AYA cancer survivor clinics to determine feasibility of the intervention and examine preliminary effectiveness on patients' motivation to change behavior, their physical activity and food intake behaviors, and CVH. Detailed feasibility and implementation measures and results are presented elsewhere. This report focuses on patient outcomes.

Methods

Study overview

This study was approved by the Washington University in St. Louis Institutional Review Board (#202007026). This study took place in three urban cancer survivorship clinics affiliated with an academic medical center-based comprehensive cancer center. The research team trained clinicians (physicians, nurse practitioners) to use PREVENT and provided support during the study. The research team conducted training via a one-hour Zoom session with didactic and interactive demonstrations and discussion components. The research team also provided a detailed user manual, a brief tip sheet, and provided in-clinic support to demonstrate PREVENT's features and to troubleshoot technical challenges during the intervention delivery. Patients received a gift card after completing the baseline and follow-up surveys. Clinicians were offered a gift card after completing follow-up measures.

Eligibility and recruitment

The research team collaborated with clinical research coordinators within the cancer survivorship clinics to identify eligible patients. Patients were eligible on the day of their clinic visit if they were between ages 12–39, met the clinical threshold for overweight or obesity, were at least 6-months post-active cancer treatment, and had sufficient English proficiency. Eligible body mass index (BMI) was determined as appropriate for age: adult patients over age 19 were eligible if their BMI was $\geq 25.0 \text{ kg/m}^2$ and adolescent patients ages 12–19 years of age were eligible if their BMI was >85 th percentile for their sex, age, and height. Patients were ineligible if they needed a language interpreter during their clinic visit, had a severe physical or cognitive limitation that could make physical activity unsafe (determined by their healthcare provider), or missed their scheduled clinic visit and did not reschedule within the study period. Minor patients under the age of 18 were ineligible if they were not accompanied by a parent or legal guardian who could give consent for their participation.

The research team used several remote and in person recruitment approaches. To recruit patients prior to their clinic visit, research assistants (RAs) mailed recruitment letters and made up to three call attempts before the visit. We emailed electronic consent forms to adult patients and parents/guardians of minor patients who expressed interest via phone. The study principal investigator (PI, MMK) and an RA recruited patients on the day of their clinic visit if they did not complete the electronic consent process or phone contact was unsuccessful. Once the patient was in their exam room and vitals were taken, the study team entered and presented the study as an

opportunity to use a digital health tool to discuss physical activity and healthy food intake with their clinician.

Randomization and Enrollment

Upon adult patient consent or minor patient assent with parent/guardian consent, patients were randomized to the PREVENT intervention or a wait-list routine care control group. We used an alternating assignment approach in which the first patient was randomly assigned using an Excel randomization generator and subsequent participant assignment alternated between intervention and control to achieve balanced assignment. Blinding was not possible or appropriate as a study team member needed to inform the clinician which patients were assigned to PREVENT so that the clinician (e.g., oncologist, nurse practitioner) could deliver the intervention. Once enrolled, the PI (MMK) or RA set-up the patient profile in PREVENT adding CVH metrics from the patients electronic health record (EHR). The treating clinician used the PREVENT tool outside the EHR, described below, with intervention patients during their clinic appointment. Control patients received usual care during their routine clinic visit and received their PREVENT-generated health behavior change plan upon completion of the 3-month follow up measures.

PREVENT Intervention

The PREVENT tool and its development are described in detail in a previous publication [40]. Briefly, PREVENT is a patient-centered digital health tool designed for healthcare team members (e.g., physicians, nurses, dietitians) to use during a clinical encounter to engage patients in health behavior counseling and goal setting. In this pilot trial, PREVENT was used as a standalone website outside the EHR. PREVENT uses the American Heart Association's (AHA) *Life's Simple 7* CVH indicators and algorithm with age group-specific (pediatric and adult) standardized cut-points to create a patient CVH profile and CVH score [41]. The *Life's Simple 7* clinical indicators (BMI, blood pressure, blood glucose, and total cholesterol) were obtained from the EHR and patient behavior (physical activity, food intake) was self-reported. Each indicator is displayed in PREVENT via color-coded, interactive slider bars that indicate if the patient's data are in the poor (red), intermediate (yellow), or ideal (green) range (Fig. 1). PREVENT includes a simulation mode that allows clinicians to show how hypothetical changes in health behaviors and improvements in clinical indicators can impact overall CVH to educate patients and motivate them to engage in behavior change.

Using the patient's data and evidence-based physical activity and dietary guidelines, PREVENT generates suggested personalized goals for physical activity

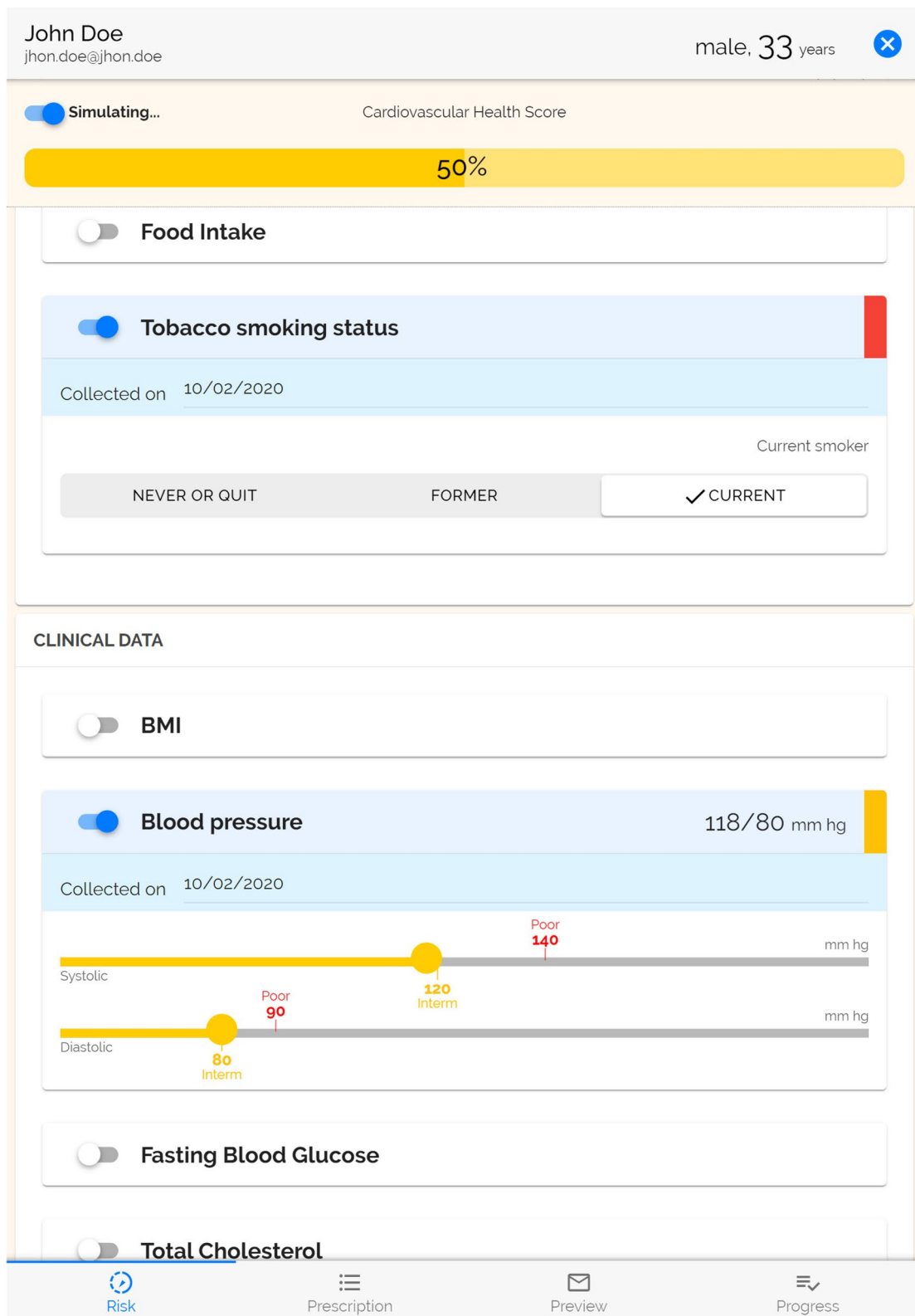


Fig. 1 PREVENT Tool CVH Profile

and the food intake that ramp up gradually over time. Goals are delivered only for behaviors when recommended targets are not met. These goals serve as a starting point for shared decision making between patients and clinicians; goals can be edited or turned on and off to narrow to an achievable set of goals based on patient needs, preferences, and motivation for change. Additionally, PREVENT contains an interactive map of community resources (e.g., farmer's markets, food pantries, parks, community centers, etc.) near the patient's home (or other preferred location) and a repository of free and low-cost digital resources (e.g., exercise videos, fitness trackers, healthy recipe websites) that patients can use to support their behavior change goals (Fig. 2). Patients are able to access the resource map and repository from any phone, computer or tablet after leaving the clinic. PREVENT creates a summary of the patient's goals, resource information, and CVH health profile into an electronic prescription delivered via text or email per patient preferences; this can also be printed with an after-visit summary. PREVENT sends brief automated surveys monthly for patients to check-in on their goal progress. PREVENT automatically provides new goals if the patient is consistently meeting their current goals or offers tailored motivational messages to encourage patients to continue working towards their current goals (Supplemental File 1). Care team members can (but are not required to) monitor patient progress in the patient's PREVENT dashboard.

Data collection

This study used multiple qualitative and quantitative data collection methods. An RA extracted patient data from the EHR at baseline and 3-months post-visit. All patients were sent a baseline demographic survey, and a health behavior survey at baseline and follow-up via email and/or text message that automatically syncs into PREVENT. For intervention patients, an additional follow-up survey was provided within 1 week of their visit to assess their experiences with PREVENT. The PI and RA observed a subset of the intervention visits ($N=6$; 24%) and completed a semi-structured observation checklist. We also collected data from providers who administered PREVENT via surveys and semi-structured interviews (provider-level findings reported elsewhere) following the intervention period.

Demographics

Patients in both age groups reported their date of birth, gender identity, and race and ethnicity. For adolescent patients only, the demographic survey also contained items to report biological parent marital status

and educational attainment of the patient's biological mother and father. The survey also contained questions on household characteristics, including household size, income and income stability, food security, neighborhood safety, transportation reliability, and health literacy (parental health literacy for minor patients). Questions were adapted from the Your Current Life Situation [42] and Accountable Health Communities Health-related Social Needs Tool [43]. As this study was conducted during the COVID-19 pandemic, we included items on household income and food security changes due to the pandemic.

Life's Simple 7 CVH indicators

We extracted height, weight, and BMI from the EHR. For adolescent patients aged 12–19, we calculated BMI z-scores based on Center for Disease Control's (CDC's) growth charts by sex and age [44]. We extracted systolic and diastolic blood pressure (mm Hg), total cholesterol (mg/dL), and fasting blood glucose (mg/dL), when available. We also determined smoking status from the EHR, categorized as never, previous (had quit >30 days ago), or current smoker.

Health behavior surveys administered at baseline and follow-up assessed physical activity and food intake behaviors. We used physical activity questions from the validated short form International Physical Activity Questionnaire [45]. We converted patient reported days and duration of physical activity to weekly minutes of moderate and vigorous activity. We adapted food intake items based on the Stoplight Diet [46] and the Rapid Eating Assessment for Participants-shortened version (REAPS) questionnaire [47] to assess how frequently patients met daily recommendations for fruits, vegetables, whole grains, sugar-sweetened beverages, and high-sugar snack food intake. Responses of usually/often meeting recommendations for each group were coded as 1, responses of sometimes or rarely/never meeting recommendations were coded as 0; these data were summed to determine total number of food intake behaviors met (range 0 to 5).

We used established methods [48, 49] to categorize AHA's *Life's Simple 7 CVH risk factors* into poor (0), intermediate (1), or ideal (2) ranges based on age group and summed these to calculate an overall CVH score (possible range 0–14). We generated an overall CVH percentile (range 0–100) by dividing the CVH score by the total number of CVH metrics available (i.e., indicators with missing data were excluded from the denominator. See Supplemental File 2 & Supplemental File 3 for additional information on the AHA's *Life's Simple 7* age group-specific cut-points and scoring.

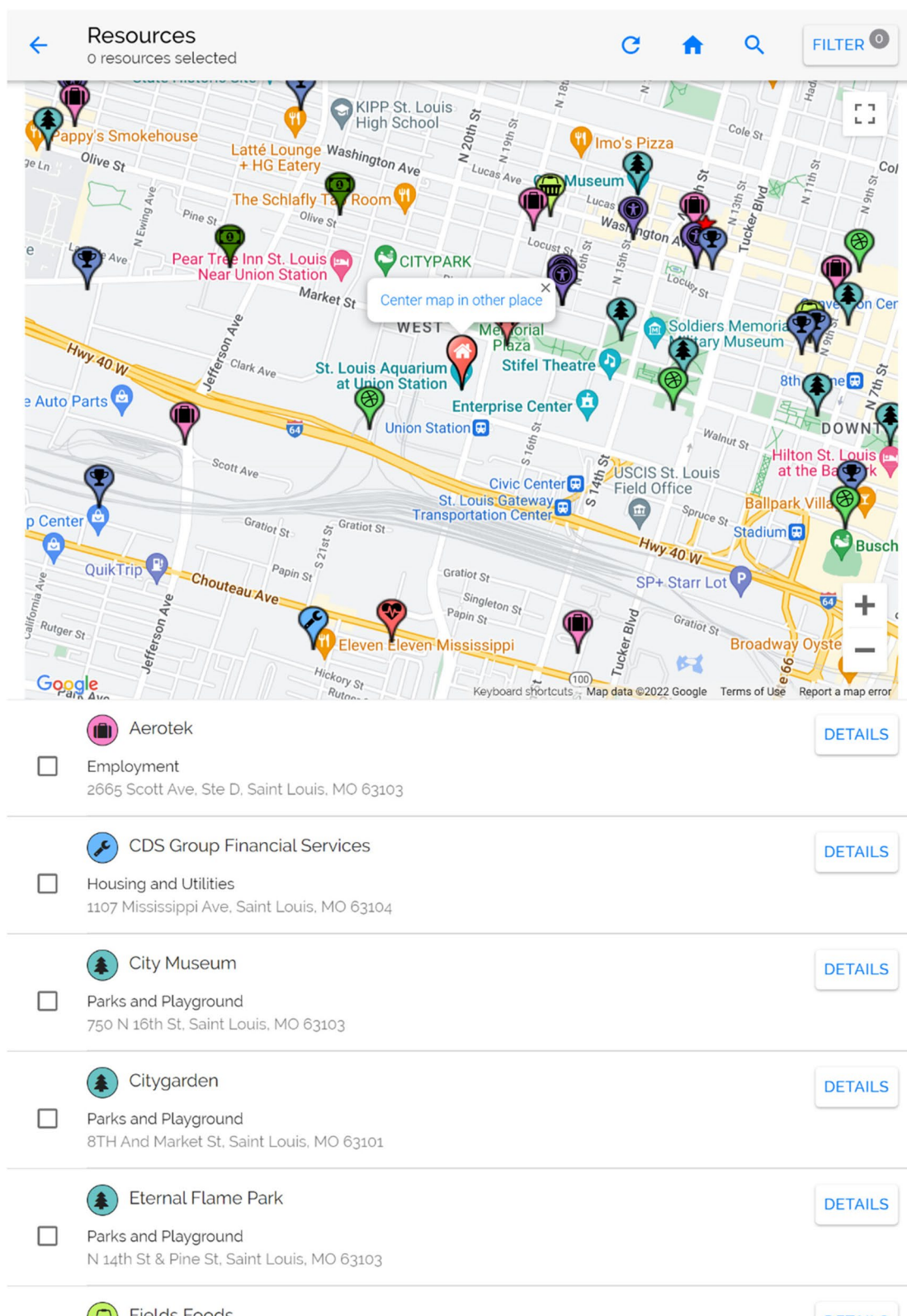


Fig. 2 PREVENT Tool Resource Map

Willingness, Self-efficacy, and Knowledge

The health behavior survey included items assessing patient willingness and self-efficacy to change physical activity and food intake behaviors, and CVH knowledge. Patient willingness to change physical activity and food intake was measured using one item for each behavior from the REAPS questionnaire rated on a 5-point Likert scale, with higher scores indicating greater willingness [47]. Self-efficacy for physical activity ($n=8$ questions) and healthy food intake ($n=8$ questions) was rated on a 5-point Likert scale using the Self-Efficacy for Healthy Eating and Physical Activity questionnaire [2]. The study team developed four items rated on a 5-point Likert scale to assess patient CVH knowledge and awareness of resources, with higher scores indicating greater knowledge.

Patient Perceptions and Implementation of Prevent

Intervention participant satisfaction with PREVENT was assessed via a follow-up survey delivered within one-week of their visit. The survey included five items rated on a 5-point Likert scale to assess patient perceptions of the PREVENT tool, with higher scores indicating greater satisfaction. During direct observation, the observer timed the duration of PREVENT's use, including number of minutes spent in each section (CVH profile, behavior change prescription, and providing resources). The observer recorded responses to fixed items assessing clinician use of PREVENT's features (e.g., using slider bars to demonstrate potential impacts of behavioral or clinical change on CVH score, showing community resource map), key conversation points (e.g., explaining physical activity and food intake recommendations), and patient- and guardian-level of engagement. The observer added open-ended field notes to include qualitative descriptions of the observation and any adaptations.

Data Analysis

We generated descriptive statistics for baseline patient demographic information using t-test to compare groups for continuous variables and Fisher's exact and Chi-squared tests for categorical variables. To examine changes in outcomes from baseline to follow-up within and across intervention and control groups, we calculated the difference of the mean (follow-up minus baseline) for continuous variables. We used Welch's unpaired t-tests for within-group significance testing. We examined differences in mean pre-post changes across groups using ANOVA tests for continuous variables (Tables 2 and 3). We performed sensitivity analyses by conducting paired significance testing only with individuals with

complete data at baseline and follow-up; results from this approach did not significantly differ from the unpaired analyses. The statistician (MZ) was not blinded and conducted all the analysis using R software.

Results

Reasons for exclusion were inability to contact the participant or deliver the consent documents ($N=32$), late arrival or missed appointments ($N=6$), or ineligibility at time of clinic visit ($N=7$; e.g., no accompanying parent, interpretation services required for limited English proficiency). We attempted to contact 92 potentially eligible patients. We enrolled 55 (60%) participants; 27 were randomized to the PREVENT intervention and 28 were assigned to wait-list control (Fig. 3). Only five of the 73 participants successfully contacted (7%) declined participation. Five patients who were enrolled and randomized prior to their baseline clinic visit missed or canceled their appointment without rescheduling, thus 23 patients received PREVENT and 27 received usual care. All 50 patients completed baseline data collection.

Baseline Characteristics (Table 1)

Table 1 shows the study sample characteristics, (overall $N=50$) and by group assignment, intervention ($n=23$) and control ($n=27$) groups. The average participant age at baseline was 19.82 (SD ± 5.17) years with 28 (56%) being adolescents 18 years of age or younger. The majority (82%) identified as non-Hispanic white; 5 (10%) identified as Black, and 4 (8%) as one or more other races and ethnicities (including Hispanic/Latino, Asian, and mixed race). Twenty-six percent lived in households below the federal poverty level; 10% of families reported unstable income, and 36% reported decreased income during the COVID-19 pandemic. Most participants (94%) reported reliable transportation to necessities for daily living in the last 12-months, sufficient health literacy (88% reported never or rarely needing help to read material from the doctor or pharmacy) and feeling safe in their neighborhood (94%). Sixteen percent of households reported being food insecure; 8% reported decreased food security during the COVID-19 pandemic. The only significant difference between groups was in literacy-level; with a higher percentage of individuals in the intervention group (26% intervention vs. 0% control) having a low health literacy level.

At baseline, most participants (64%) had intermediate CVH (overall mean CVH percentile score = 62.44 out of 100), with 22% of the sample having ideal and 14% having poor CVH. The majority (68%) were meeting physical activity recommendations based on self-report data. On average, participants met 1.50 (of 5) food intake recommendations at baseline: 22% of participants were meeting

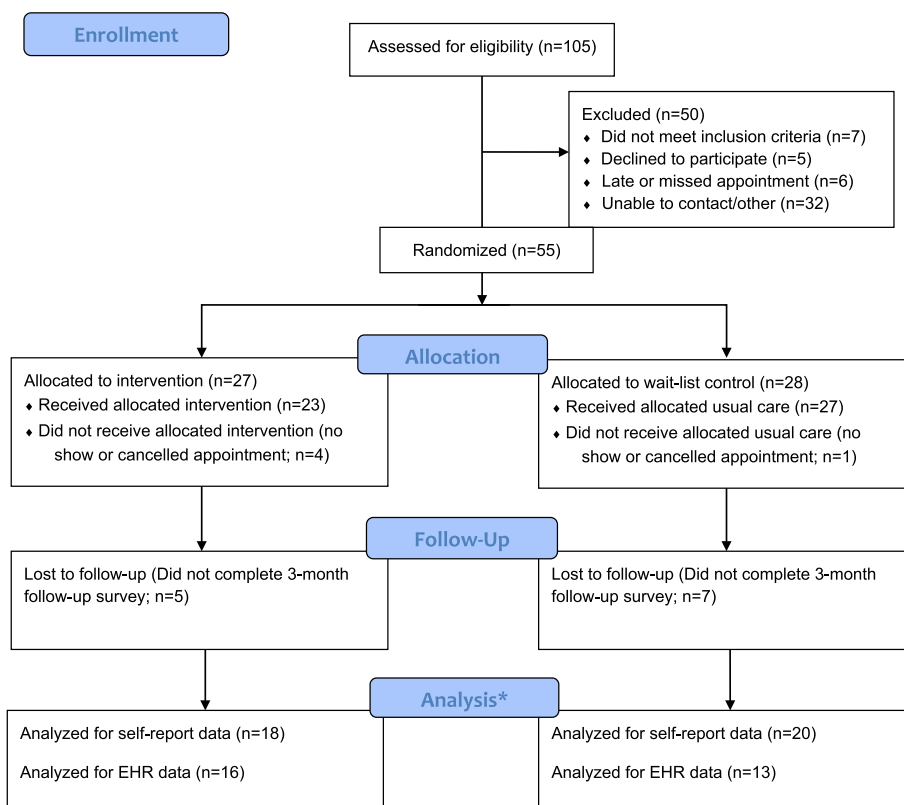


Fig. 3 Consort Flow Diagram

the recommendation for whole grain consumption, 16% fruit intake, 32.0% vegetable intake, 36.0% snacking, and 44% sugary drink consumption. Using a 5-point Likert scale, participants indicated low to moderate willingness to change their food intake (mean=2.41) and physical activity (mean=2.04) behaviors and confidence in being able to make these changes (mean=4.02). Participants understanding of their CVH was moderate (mean=3.95).

Changes in Willingness, Self-efficacy, and Knowledge (Table 2)

At 3-month follow-up, we obtained survey responses from 38 (76% follow up) patients. Female participants were 4.8 times as likely to complete the follow-up survey than male participants, with odds ratio (95% confidence interval, $p=0.046$). No other demographic variables were predictors of response. The baseline characteristics of these participants did not differ from the overall sample. Across both groups, patient willingness to change physical activity and food intake behaviors significantly increased from baseline to follow-up within both the intervention and control groups. Patients in the intervention group had a significant increase in self-efficacy for physical activity (0.47, $p=0.03$) and self-efficacy for

health food intake (0.50, $p=0.02$), whereas patients in the control group had slightly decreased self-efficacy for physical activity (-0.06) and health food intake (-0.18). These differences were not significantly different across groups ($p=0.18$). Changes in knowledge of risk for poor heart health, steps to improve heart health and resources to support heart health did not significantly change in either group.

Changes in CVH Behaviors and Outcomes (Table 3)

At baseline, all patients had BMI data in the EHR; 49 (98%) had blood pressure data; 14 (28%) had cholesterol and 33 (66%) had blood glucose data available. At 3-month follow-up, 29 (58%) patients had BMI; 28 (56%) had blood pressure; 6 (12%) had cholesterol and 14 (28%) had blood glucose. Total cholesterol data are presented in Table 3 to examine trends but due to high missingness statistical significance tests are not reported.

Moderate physical activity minutes increased in the intervention (mean=27.75) and control groups (mean=54.88); changes were not statistically significant within or across groups. Vigorous physical activity increased in the intervention (mean=50.33) and decreased (mean=-77.87) in the control group. This

Table 1 Baseline characteristics by intervention group

	Overall ^a N = 50	Intervention ^a n = 23	Control ^a n = 27	p-value ^b
Patient Characteristics				
Age (years)	19.82 (5.17)	19.83 (5.14)	19.81 (5.29)	> 0.99
Age Group				0.83
Adolescent	28 (56%)	12 (52%)	16 (59%)	
Adults	22 (44%)	11 (48%)	11 (41%)	
Sex				0.55
Male	25 (50%)	11 (48%)	14 (52%)	
Female	23 (46%)	11 (48%)	12 (44%)	
Non-binary/transgender	2 (4%)	1 (4.3%)	1 (3.7%)	
Race				0.95
Black	5 (10%)	2 (8.7%)	3 (11%)	
White	41 (82%)	19 (83%)	22 (81%)	
Other	4 (8.0%)	2 (8.7%)	2 (7.4%)	
Social Determinants of Health				
Below poverty level	13 (26%)	9 (39%)	4 (15%)	0.10
Unstable income	5 (10%)	3 (13%)	2 (7.7%)	0.88
Household income decreased during COVID	18 (36%)	10 (43%)	8 (30%)	0.47
Unreliable transportation	3 (6.0%)	1 (4.5%)	2 (7.4%)	> 0.99
Low-literacy level	6 (12%)	6 (26%)	0 (0%)	0.017
Unsafe neighborhood	3 (6.0%)	1 (4.3%)	2 (7.4%)	> 0.99
Food insecure	8 (16%)	5 (22%)	3 (11%)	0.53
Food Security decreased during COVID	4 (8.0%)	2 (8.7%)	2 (7.4%)	> 0.99

^a Mean (SD) or Frequency (%)

^b Pearson's Chi-squared test; Welch Two Sample t-test

difference (mean = 128.2) in change of vigorous activity was significantly different across groups ($p = 0.04$). The number of food recommendations increased (mean = 0.68) in the intervention and decreased (mean = -0.06) in the control group; changes were not statistically significant. Overall at follow-up, 23.7% of participants were meeting the recommendation for whole grain consumption, 26.3% fruit intake, 36.8% vegetable intake, 36.8% snacking, and 55.3% sugary drink consumption. Overall CVH percentile improved in the intervention group (mean = 7.35) and in the control group (mean = 3.95), yet these changes were not significant. Among all patients, BMI slightly increased in the intervention group (mean = 0.37) and the control group (mean = 0.49) in the control group. Among adolescents ($n = 28$), BMI z-scores decreased in the intervention group (mean = -0.02) and increased in the control group (mean = 0.08). These changes in BMI and BMI z-scores were not statistically significant within or between groups. Changes in systolic and diastolic blood pressure, total cholesterol and blood glucose were not significant within or across groups.

Patient Perceptions and Implementation of Prevent

Six intervention patients completed the follow-up satisfaction items, each rated on a 1–5 scale. Overall, patients were satisfied with PREVENT (mean = 4.2 ± 0.4). Patients found it very helpful to see their risk for poor heart health (mean = 4.6 ± 0.5). Patients found the recommendations for behavior change very easy to understand (mean = 4.8 ± 0.4) and the provided resource information to be acceptable (4.4 ± 0.9). Overall, patients were in favor of their clinician using PREVENT in future clinic visits (mean = 4.2 ± 0.4).

Detailed implementation outcomes are presented elsewhere. For interpretation purposes, we summarize key data involving patient-clinician interactions below. Clinicians spent, on average, 7.7 minutes (min = 5, max = 10 minutes) using PREVENT with patients. Approximately 3.2 minutes were spent discussing patient CVH, 2.5 minutes delivering health behavior goals, and 2.0 minutes discussing resources. Patients most frequently requested information on grocery stores, recreation centers, parks/playgrounds, and nutrition-related digital resources. On average, patients received information about 6.7 resources, including an average

Table 2 Changes in willingness, self-efficacy, and knowledge from baseline to follow-up within and across intervention groups

	PREVENT Intervention (n = 23)			Control (n = 27)			Across group difference ^c
	Baseline ^a	Follow-up ^a	Within group difference ^b	Baseline ^a	Follow-up ^a	Within group difference ^b	
Willingness to change physical activity	2.23 (0.92)	3.78 (1.00)	1.55 (0.93, 2.17)**	1.89 (1.12)	3.80 (1.11)	1.91 (1.25, 2.57)**	-0.36
missing	1	5		0	7		
Willingness to change food intake	2.55 (1.01)	3.78 (0.94)	1.23 (0.61, 1.86)**	2.30 (0.99)	3.85 (1.04)	1.55 (0.95, 2.16)**	0.64
missing	1	5		0	7		
Self-efficacy (physical activity)	3.58 (0.60)	4.05 (0.53)	0.47 (0.03, 0.91)*	3.48 (0.78)	3.42 (0.95)	-0.06 (-0.72, 0.59)	0.53
missing	0	13		0	15		
Self-efficacy (food intake)	3.66 (0.78)	4.16 (0.43)	0.50 (0.06, 0.93)*	3.68 (0.81)	3.50 (0.82)	-0.18 (-0.77, 0.41)	0.68
missing	0	13		0	15		
Understand risk for poor heart health	4.0 (0.67)	3.94 (0.64)	-0.06 (-0.47, 0.36)	4.11 (0.80)	4.25 (0.72)	0.14 (-0.31, 0.59)	0.87
missing	0	5		0	7		
Understand steps to improve heart health	3.96 (0.77)	4.00 (0.69)	0.04 (-0.42, 0.50)	4.00 (0.96)	4.05 (1.00)	0.05 (-0.54, 0.64)	0.76
missing	0	5		0	7		
Awareness of resources	3.96 (0.77)	3.78 (0.94)	-0.18 (-0.74, 0.38)	3.67 (1.30)	3.60 (1.14)	-0.07 (-0.79, 0.65)	0.83
missing	0	5		0	7		

All items scored on 5-point scale; Bold values indicate significant changes with * indicating p-value < 0.05 and **indicating p-value < 0.001

^a Mean (SD)

^b Standardized Mean Difference with 95% Confidence Interval; Welch's unpaired t-test

^c Difference in mean within-group difference (Intervention mean difference - control mean difference); ANOVA t-test

of 3.5 community resources and 3.2 digital resources. All patients and parents (accompanying a minor patient) were moderately to very engaged when using PREVENT with their clinician per observer ratings. In 5 of 6 (83%) interactions observed, providers: 1) used slider bars to show patients how changes in their behaviors and CVH risk factors would impact their overall CVH; 2) discussed the physical activity and nutrition goals to patients; and 3) answered any questions the patient asked. In one encounter, there was additional tailoring and discussion of the physical activity goal to ensure it was safe for the patient. The research team pre-selected resources near the patient's home address based on patient preferences provided via the baseline survey. Yet, in 4 of the 6 interactions observed, the provider opened the resource map to select additional resources and demonstrate functionality of the map. All patients were informed that they have access to the map after leaving the clinic.

Discussion

Physical inactivity and unhealthy food intake increase the already heightened risk of developing late effects, particularly CVD, among AYA cancer survivors. The PREVENT tool integrated tailored goals for physical activity and health food intake and resources into the

routine follow-up care of AYA cancer survivors. This approach was feasible, took relatively little time, was able to be integrated into the clinic workflow, and demonstrated short-term efficacy when implemented in three clinics among 50 AYA cancer survivors. A sample of intervention patients (n = 6) indicated they were satisfied with PREVENT, felt it was helpful, easy to understand, and were in favor of their clinician using PREVENT in the future. Results from this trial support the finding that AYA survivors may be most amenable to interventions that involve content delivered by their healthcare team [9].

Survivors who received the tailored prescription via PREVENT had greater increases in their vigorous activity and number of food intake recommendations met than those who received routine clinical care. Notably, the intervention group increased their vigorous activity by 50 minutes per week, whereas the routine care control decreased by 78 minutes per week. This was a significant difference between groups (128 minutes), which is substantial in consideration of the American Cancer Society's recommendations for cancer survivors which recommends 150 minutes per week of moderate-to-vigorous physical activity. These changes in health behaviors may be related to increases in self-efficacy

Table 3 Changes in CVH behaviors and outcomes from baseline to follow-up within and across intervention groups

	PREVENT Intervention (n = 23)			Control (n = 27)			Across group difference ^c
	Baseline ^a	Follow-up ^a	Within group difference ^b	Baseline ^a	Follow-up ^a	Within group difference ^b	
CVH Behaviors							
Moderate physical activity (min/week)	218.91 (195.38)	246.67 (273.57)	27.75 (-140.84, 196.35)	236.30 (390.77)	291.18 (360.63)	54.88 (-179.01, 288.77)	-27.13
missing	0	8		0	10		
Vigorous physical activity (min/week)	202.17 (260.00)	252.50 (201.09)	50.33 (-99.55, 200.20)	216.48 (369.26)	138.61 (176.80)	-77.87 (-244.40, 88.66)	128.2*
missing	0	7		0	9		
# of food recommendations met	1.43 (1.08)	2.11 (1.53)	0.68 (-0.19, 1.55)	1.56 (1.22)	1.50 (1.10)	-0.06 (-0.74, 0.63)	0.74
missing	0	5		0	7		
CVH Outcomes							
BMI	31.49 (4.80)	31.86(6.06)	0.37(-3.35, 4.10)	31.28(5.39)	31.77(5.27)	0.49 (-3.2, 4.19)	-0.12
missing	0	7		0	14		
Systolic blood pressure (mm hg)	119.73 (9.90)	118.50 (9.08)	-1.23 (-7.53, 5.07)	120.67 (9.99)	116.42 (8.87)	-4.25 (-10.86, 2.36)	3.02
missing	1	7		0	15		
Diastolic blood pressure (mm hg)	75.68 (10.32)	71.81 (9.54)	-3.87 (-10.47, 2.73)	73.59 (7.98)	70.75 (7.69)	-2.84 (-8.44, 2.76)	-1.03
missing	1	7		0	15		
Total cholesterol (mg/dL)	176.00 (30.11)	175.40 (41.79)	-0.60 (-52.52, 51.32)	177.14 (42.13)	165.0 (NA) ^e	NA ^e	NA ^e
missing	16	18		20	26		
Blood glucose (mg/dL)	91.59 (8.81)	91.33 (5.59)	-0.25 (-6.12, 5.61)	101.19 (12.34)	99.40 (20.79)	-1.79 (-27.11, 23.53)	1.54
missing	6	14		11	22		
CVH percentile	64.17 (12.31)	71.52 (15.46)	7.35 (-0.97, 15.66)	60.96 (12.55)	64.92 (15.29)	3.95 (-4.00, 11.90)	3.40
missing	0	0		0	3		

Bold values indicate significant changes with * indicating p-value < 0.05 and ** indicating p-value < 0.001

^a Mean (SD)

^b Standardized Mean Difference with 95% Confidence Interval; Welch's unpaired t-test

^c Difference in mean within-group difference (Intervention mean difference - control mean difference); ANOVA t-test

^d CVH percentile (range 0-100) is calculated using a published algorithm using all available data from the 7 CVH risk factors. Each risk factor is scored using criteria (0 = poor, 1 = intermediate, 2 = ideal), summed and divided by the number of variables included to generate a percentile

^e Statistical test not conducted due to high proportion with missing data

for physical activity and healthy food intake among the intervention group. Increasing self-efficacy is a key component of effective behavior change and leads to longer-term maintenance of healthy behaviors among cancer survivors [50, 51].

Lack of resources and adverse environments are two barriers to physical activity and healthy food intake for AYA cancer survivors [9]. Digital health tools can harness clinical and community data to deliver precision prevention, including tailored goals and resources that can reshape the way we care for cancer survivors, promote population health, and address health equity [52]. A strength of PREVENT was the successful delivery of

resources that were preferred and close to their home to AYA cancer survivors within their routine care clinic visit. The small sample size of this pilot feasibility trial limited our ability to examine whether this approach supports behavior change and improve CVH equitably across racial and ethnic minorities and those with poverty and low-literacy. Future studies of PREVENT will address this limitation to examine effectiveness within and across these groups to determine whether this approach generates equitable outcomes. It is reasonable to hypothesize that supporting these populations with overcoming environmental barriers will make them better able to achieve behavior change [53]. Clinicians spent

on average just under 8 minutes using PREVENT with patients. Despite demonstrating that this tool could feasibly deliver goals and resources within this time, the trial did not track patients' use of the resources and whether the resources met the patients' needs. More in-depth use including formally assessed shared decision making around goals and additional resource support and follow-up may have further benefitted patients. Yet, this type of use is limited by staff and time within the clinical encounter. One potential strategy for improving the use and scalability of PREVENT is a team-based approach that includes other care team members such as care coordinators and community health workers to support patients with resources and follow-up.

A strength of this study was the use of a randomized controlled design to test an innovative, scalable intervention approach; yet it was limited by a small sample size with limited racial and ethnic diversity (82% white). Only 7% of individuals approached to participate declined, demonstrating interest in receiving this type of physical activity and healthy food intake advice from their care team. Future studies will explore why individuals declined or enrolled but did not attend their clinic visit and whether characteristics of these individuals differed from those who completed the intervention. The study demonstrated a retention rate of 76% survivors. Follow-up was done via automated electronic email or text messages (maximum of 3 attempts) followed by up to 3 phone calls; this retention rate may have improved with in-person follow-up or in a time outside of the clinical restrictions and safety concerns of the COVID-19 pandemic. Electronic follow-up with intervention patients within 1 week of their clinic visit had low response rates. In some cases, study team members failed to deliver the survey within the intended timeframe; automated delivery or integration with existing care satisfaction surveys administered by the clinic may increase response. More data from the surveys and/or the addition of interviews would have improved our understanding of the patient's perceptions of the PREVENT tool and their preference for receiving communication (e.g., text, email, printed). This pilot trial was over a short, 3-month window which limited our ability to use routine follow-up visits (mainly occurring every 6 to 12 months) as a second time point for data collection and to demonstrate sustained changes in indices of CVH and longer-term behavior change maintenance. CVH was measured using AHA's Life's Simple 7 (now Life's Essential 8) using routine-follow-up data within the EHR, which reduced the percentage of patients with follow-up data. Future studies will extend the follow-up period to align with routine care that is generally every 6- to 12-months or utilize at-home devices (e.g., electronic scales) to increase CVH follow-up data. Furthermore, future studies will include patients' time since

diagnosis or treatment completion to better understand the intervention effect. Behavioral data was self-reported in this study which is shown to have several biases, including under-reporting unhealthy food intake and over-reporting of physical activity [54, 55]. Over-reporting may be particularly true for vigorous activities which may explain why similar increases in moderate and vigorous activity were not seen in the intervention group [56]. Integration of self-monitoring tools to objectively measure food intake (e.g., emerging food photography journals coupled with artificial intelligence systems to estimate volume and macronutrients) [57] and physical activity (e.g., activity trackers such as Fit-Bits) into the PREVENT tool and the EHR may enhance the intervention and improve patient engagement following the visit. Using these objectively measured food intake and physical activity data as inclusion criteria would limit a) the pragmatic aspect of the study and not be feasible in real world clinical settings to which we wish to generalize and b) the intervention population to those who are not currently meeting food intake and physical activity guidelines and would most benefit. Furthermore, the use of wearable devices, such as FIT-BITS would also integrate self-monitoring, which may further improve food intake and physical activity levels. In another study among AYA cancer survivors, this approach demonstrated efficacy and that clinicians will use these data to track patient progress on behavior change within the electronic medical record [58].

If these findings are replicated with other larger, more diverse samples, and results are shown to sustain at longer-follow-up points, the PREVENT digital intervention may provide improvements in preventive behaviors among AYA cancer survivors by supporting care teams with delivering evidence-based, tailored behavior change recommendations and resources to support patient health. Efforts are underway to improve the PREVENT tool based on lessons learned from this pilot study, update to AHA's Life's Essential 8, and to develop implementation plans that align even better with clinic practices and workflows to optimize implementation, patient engagement, and metrics of success. The demonstrated feasibility and preliminary efficacy of this approach is a critical step toward determining effectiveness in a subsequent fully powered randomized controlled trial in AYA cancer survivors.

Supplementary Information

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Additional file 1. Automated Monthly Patient Survey.

Additional file 2. Cardiovascular Health Score for Adolescents 12 to 19 years.

Additional file 3. Cardiovascular Health Score for Adults 20+ Years of Age.

Authors' contributions

All authors (Maura M. Kepper, Callie Walsh-Bailey, Min Zhao, Loni Parrish, Zoe M. Miller, Russell E. Glasgow, Lisa de las Fuentes, Yan Yan, Robert J. Hayashi, Ross C. Brownson, and Randi E. Foraker) contributed to the study conception and design. Material preparation, data collection were performed by Maura M. Kepper, Callie Walsh-Bailey and Zoe M. Miller. Data analysis was conducted by Min Zhao. The first draft of the manuscript was written by Maura M. Kepper and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Approval of this study was granted by institutional review board (IRB) at Washington University St Louis (202007026). All methods were carried out in accordance with relevant guidelines and regulations. All surveys created for this study were informed by validated surveys that are not under license. Informed consent was obtained from all individual participants included in the study. If the participant was a minor, the legal guardian completed the informed consent in addition to the participant.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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