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Authors

Kenfield, Stacey
Philip, Errol
Phillips, Siobhan
et al.

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Optimizing intervention tools to improve nutrition and physical activity for colorectal cancer survivors (Tools To Be Fit): Study protocol of a randomized factorial experiment

Stacey A. Kenfield[a,b,1], **Errol J. Philip**[c,1], **Siobhan M. Phillips**[d], **Jeffrey A. Meyerhardt**[e], **June M. Chan**[a,b], **Chloe E. Atreya**[f,g], **Mi-Ok Kim**[b,f], **Quincy Harris**[f], **Paige Steiding**[f], **Greta Macaire**[f], **Marjorie L. McCullough**[h], **Sorbarikor Piawah**[f,g], **Wenora Y. Johnson**[i], **Florence A. Kurttila**[i], **Wendy L. Lewis**[i], **Curtis Pesmen**[i], **Yasmeem Watson**[i], **Erin L. Van Blarigan**[a,b,*]

[a]Department of Urology, University of California, San Francisco, CA, United States of America

[b]Department of Epidemiology and Biostatistics, University of California, San Francisco, CA, United States of America

[c]UCSF School of Medicine, University of California, San Francisco, CA, United States of America

[d]Department of Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL, United States of America

[e]Dana-Farber Cancer Institute, Boston, MA, United States of America

[f]Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco, CA, United States of America

[g]Department of Medicine, University of California, San Francisco, CA, United States of America

[h]Department of Population Science, American Cancer Society, Atlanta, GA, United States of America

[i]Fight Colorectal Cancer Research Advocate, Springfield, MO, United States of America

Abstract

Background: Colorectal cancer (CRC) is the 2nd leading cause of cancer death in the United States. The American Cancer Society (ACS) Nutrition and Physical Activity Guidelines are associated with longer survival among CRC survivors, but few report behaviors consistent with the guidelines.

Methods: The Tools To Be Fit study, based on the Multiphase Optimization Strategy (MOST) framework, is a full factorial experimental to optimize a remotely delivered 48-week diet and physical activity intervention for non-metastatic CRC survivors. The intervention includes a core

*Corresponding author at: UCSF Box 0560, 550 16th St 2nd Floor, San Francisco, CA 94158, United States of America. erin.vanblarigan@ucsf.edu (E.L. Van Blarigan).

[1]Equal contribution.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

component (booklet and personal report). CRC survivors ($N = 400$) are additionally randomly assigned to one of 16 combinations of four candidate components, each with 2 options: 1) text messaging (on/off); 2) self-monitoring modality (digital/paper); 3) health coaching (on/off); and 4) support person coaching (on/off).

Outcomes: Our primary outcome is adherence to the ACS guidelines after 48 weeks using a score that includes physical activity from accelerometers, dietary intake from a food frequency questionnaire, and body mass index (BMI) measured by a technician. Secondary outcomes include the ACS score after 24 weeks and score components at 24 and 48 weeks. Exploratory outcomes include adherence and change in Social Cognitive Theory constructs. We will explore moderation by sociodemographic, clinical, and psychological/behavioral factors; and change in the ACS score in relation to change in levels of insulin, insulin sensitivity, inflammation, gut microbiome structure, fatigue, depression, and sleep disturbance.

Discussion: The proposed study aims to inform a randomized controlled trial to determine whether an optimized intervention reduces risk of recurrence among CRC survivors.

Keywords

Physical activity; Nutrition; Weight loss; Colorectal cancer; Survivorship; Multiphase optimization strategy framework (MOST)

1. Introduction

Over 1.5 million Americans currently live with colorectal cancer (CRC), the 2nd leading cause of cancer death in the United States [1]. The American Cancer Society (ACS) has published guidelines to improve health among cancer survivors, which include: avoid obesity and maintain or increase muscle mass, engage in regular physical activity, and follow a healthy eating pattern (i.e., rich in a variety of vegetables, fruits, whole grains) [2,3]. Health behaviors consistent with these guidelines are associated with longer survival among CRC survivors, but few survivors report behaviors consistent with the guidelines [4–7]. Thus, interventions that improve health behaviors among CRC survivors could have great public health impact.

Prospective cohort studies have reported that increasing adherence to the 2012 ACS Guidelines, assessed using a composite score [4,5,8], after CRC diagnosis is associated with lower mortality. For example, individuals who increased their adherence to the ACS nutrition guidelines pre-diagnosis to post-diagnosis had a 29% lower risk of CRC-specific mortality compared to those who did not [5]. In an independent study by our team, patients with stage III colon cancer who made behavior changes that aligned with the ACS guidelines from 3 to 15 months post-diagnosis had a 33% lower risk of overall mortality compared to patients who did not change [4]. These studies are supported by prospective studies on individual health behaviors and CRC mortality [9–15]. Together, data strongly suggest that physical activity and a healthy diet can reduce the risk of recurrence and mortality in CRC survivors.

Yet, adherence to such recommendations remains sub-optimal among CRC survivors. For example, among 1011 individuals with stage III colon cancer in a nationwide chemotherapy

trial, only 9% reported health behaviors consistent with the 2012 ACS Guidelines [4]. In another cohort study of 1321 stage I-III CRC survivors, the mean (SD) ACS Nutrition score was 4.3 (2.0) out of a possible 9 points [4–7].

Few randomized controlled trials (RCTs) with behavioral interventions have included CRC survivors. Additionally, to date, most studies have tested multi-component interventions simultaneously as "bundled" packages and compared them to usual care in a RCT [16]. Whereas the RCT design is the gold standard for determining the effect of an intervention package on an outcome, it does not provide information about which intervention components contribute to the desired effect and which do not, as all components are turned "on" in the treatment group and "off" in the control group [17]. Such insight is critical to improving intervention effectiveness and efficiency, and ultimately, to the identification of an impactful, scalable, and sustainable behavioral intervention to reduce CRC mortality.

To address this need, we are applying the Multiphase Optimization Strategy (MOST) framework, an engineering-based approach for efficiently optimizing behavioral interventions [17,18]. The MOST framework includes three phases: preparation, optimization, and evaluation. In this optimization study, we aim to identify which of four candidate intervention components, independently or combined, increase moderate-to-vigorous physical activity (MVPA), and improve diet and BMI in CRC survivors. The four intervention components we are testing (health coaching, support person coaching, a digital health toolkit, and text messages) were chosen because they can be remotely delivered, have been established to be feasible and acceptable, and likely affect health behaviors among cancer survivors [19–29]. Our primary outcome is a composite score that combines accelerometer-measured physical activity, diet assessed via validated food frequency questionnaires (FFQ), and technician-measured BMI to measure adherence to the ACS Guidelines [30]. The findings from the proposed study will lead to a better understanding of which intervention components are most effective for improving adherence to the ACS guidelines among CRC survivors and guide the development of an optimized intervention for reducing risk of CRC recurrence.

2. Methods

2.1. Study design

The Tools To Be Fit study is a multicenter 48-week randomized factorial experiment among 400 CRC survivors (ClinicalTrials.gov Identifier: NCT05056077). The objectives of the study are to determine the individual and interaction effects of four candidate intervention components on change in the ACS Guideline score after 24 and 48 weeks of intervention. In exploratory analyses, mediators, and moderators of the components' effects and whether change in the ACS guideline score is associated with change in levels of insulin, insulin sensitivity, inflammation, the gut microbiome, fatigue, depression, and sleep disturbance will be examined.

The factorial design will allow the identification of individual and interaction effects of the candidate intervention components efficiently, while balancing individual characteristics across the conditions and ensuring good statistical power for all aims. This design is distinct

from a multi-arm RCT; all 400 participants contribute data to each effect estimate. All participants receive a core intervention that includes a study booklet with the ACS Nutrition and Physical Activity Guidelines for Cancer Survivors and tips on how to increase exercise safely and a personalized report comparing their diet, physical activity, and BMI to the ACS guidelines. Participants are then randomized to one of 16 possible combinations of four candidate intervention components, ranging from none to all four (n = 25 per condition, N = 400) (Table 1). The four candidate intervention components, each with 2 options, are: 1) text messaging (on/off); 2) self-monitoring modality (digital/paper); 3) health coaching (on/off); and 4) support person training (on/off). All four intervention components are delivered remotely; no aspect of the intervention is delivered in-person.

2.2. Recruitment

The study aims to randomize 400 CRC survivors. This will include additionally consenting 400 support people, of whom 200 will receive support person training. We will recruit CRC survivors and ask them to nominate a support person to participate with them. Participants will be recruited through the University of California, San Francisco (UCSF), Dana-Farber Cancer Institute (DFCI), and advertising on the web and through social media.

At UCSF, we will use MyChart for recruitment along with cohort identification and direct mail for recruitment of patients who are not enrolled in MyChart. People who meet clinical eligibility criteria based on their UCSF medical record will receive a MyChart message or paper letter inviting them to participate in the study. We will also approach participants in past studies who have consented to be recontacted and patients in the Gastrointestinal Oncology Survivorship Clinic. At DFCI, people receiving care will be approached about the study in the Gastrointestinal Oncology clinics; participants in past studies who have consented to be recontacted will also be sent information about the study. Lastly, we will advertise the study on social media.

2.3. Eligibility and screening

The study inclusion criteria are as follows: ≥18 years of age, diagnosis of stage I-III colon or rectal cancer, undergone curative-intent complete surgical resection (patients who have received non-operative management for rectal cancer may be eligible), completed all neoadjuvant and adjuvant cytotoxic chemotherapy or radiation (if indicated), own a smartphone that has access to the Internet and can receive text messages, and able to speak and read English or Spanish. Further, participants need to have a support person ≥18 years of age who can speak English or Spanish and is willing to provide informed consent. We will not restrict participants based on time since diagnosis, because improving health behaviors may be beneficial for CRC survivors regardless of time since diagnosis.

The study exclusion criteria are as follows: people with potential contraindications to exercise based on the Physical Activity Readiness Questionnaire (PAR-Q) [31] for whom we are unable to obtain physician clearance, ACS guideline score of >4 out of 6 at enrollment based on self-reported diet, BMI, and physical activity; used a physical activity tracker AND a diet tracking app for 1 week or longer in the past 3 months; planned major surgery during the study period; scheduled to receive any form of cancer therapy during the study period;

concurrent, actively treated other cancer (except non-melanoma skin cancer, in situ cervical cancer or localized prostate cancer treated with surveillance only); self-reported history of severe cardiovascular, respiratory, musculoskeletal disease, or joint problems that preclude moderate physical activity; self-reported history of psychiatric disorders that would preclude participation in the study intervention or prevent the patient from giving informed consent; concurrent participation in another weight loss, physical activity, or dietary intervention clinical trial; currently pregnant or trying to become pregnant during the study period; and living outside the US during the study period.

2.4. Informed consent

Potentially eligible cancer survivor participants are asked to provide informed consent electronically using DocuSign. The consent form asks individuals for permission to contact their providers to request their medical records and confirm clinical eligibility, and for permission to contact their support person. No contact with the study team is required for potential participants to take the online screening survey and complete the consent form; the consent form provides contact information for the study investigators. Following consent of the cancer survivor participant, the UCSF team sends an email via Research Electronic Data Capture (REDCap) to the cancer survivor's support person that includes an invitation to participate. If interested and eligible, the support person is asked to complete an informed consent form via DocuSign.

2.4.1. Study procedures—Self-reported survey data are collected online on a website hosted on the Eureka platform (toolstobefit.eurekaplatform.org). Participants securely log in to complete the screening survey and the consent form. After consent and confirmation of eligibility, participants are asked to return to the study website to complete surveys at 0, 12, 24, 36, and 48 weeks.

2.5. Randomization

Eligible consented participants are randomized to 1 of 16 intervention conditions, using block randomization of size 16 stratified by sex and age (<50 vs. ≥50 years). The randomization scheme was created by the study biostatistician and uploaded to the Eureka randomization tool. Once participants complete enrollment procedures and are confirmed eligible, the Eureka platform's randomization tool is used to determine their assigned intervention condition.

2.6. Conceptual model

The Tools To Be Fit's conceptual model (Fig. 1) was based on Social Cognitive Theory (SCT), previous literature, and pilot data [17,20,21,32,33]. Arrows in our framework indicate hypothesized relations between each candidate intervention component and its primary target mediator (SCT construct), proximal behavioral outcomes (diet, physical activity, BMI), the ACS Guideline score, and biological outcomes. Dashed lines indicate effect modification.

2.7. Intervention components

Following randomization, all participants receive a core intervention which includes access to a study booklet with the ACS Nutrition and Physical Activity Guidelines for Cancer Survivors and tips on how to increase exercise safely and a personalized report comparing their diet, physical activity, and BMI to the ACS Guidelines. Participants are additionally randomized to receive 1 of 16 combinations of the four candidate intervention components for 48 weeks. The cost of each component will be tracked throughout the study period.

2.7.1. Text messaging—Half of the participants receive text messages "on" for 48 weeks (4 per week) and half receive no text messages ("off"). Message content targets outcome expectations, but also incorporates the study recommendations, informational facts, self-efficacy, social support, goals, barriers/facilitators, and self-monitoring. Details of our text messages, including samples, have been published [20,21,34,35].

2.7.2. Self-monitoring modality—Half of the participants are asked to self-monitor their behavior using a Digital Health Toolkit. The Digital Health Toolkit includes a 2021 Fitbit Inspire (or equivalent model) and instructions to download and install the free Fitbit™ and MyFitnessPal™ apps. Instructions to set up the apps are provided in print and video. The other half will self-monitor their diet and exercise using a study logbook. All participants, regardless of condition will be asked to track their physical activity and diet daily initially, and for at least 1 week per month throughout the study. Self-monitoring has been established as an effective behavior change technique in behavioral interventions [36]; therefore our research question is whether technology-based monitoring is superior to standard paper monitoring. With the participants' permission, their Fitbit and MyFitnessPal data sync with the study website, so all recorded data are automatically stored. Participants assigned to the logbooks are asked every 12 weeks about their tracking behavior and asked to upload photos of their logbooks.

2.7.3. Health coaching—Half the participants receive 15 coaching sessions (weekly for the first 3 weeks, semi-weekly at week 5 and 7, then every 4 weeks there-after) and half receive no coaching. The study has a team of four female health coaches, including one bilingual health coach who is a native Spanish speaker. All coaches have extensive experience with health coaching and are Wellcoaches® Certified Lifestyle Medicine Coaches. Coaching is done by video calls (i.e., Zoom) or phone, recorded, and takes approximately 30–45 min per session. Coaches use motivational interviewing techniques to increase the participant's self-efficacy related to diet and exercise.

2.7.4. Support person training—All participants identify a support person at enrollment. In the online screening survey, participants are asked: "*Do you have a person in your life who would be willing to support you during this study? This individual must be 18 years of age or older, speak English or Spanish, and be someone who you interact with at least once per week. This person may be asked to participate in four coaching calls over 1 year (approximately 1 call every 3 months).*" Half of the participants' support people receive quarterly semi-scripted 30–45 min 1-on-1 telephone sessions with a health coach (4 calls: 1 every 12 weeks). The coaches will use motivational interviewing techniques to primarily

target social support for the cancer survivor. Additional behavior change techniques such as problem-solving, role modeling, and prompts/cues to action are also included [37].

2.8. Intervention fidelity

The health coaching for CRC survivors and support persons will be done by a team of certified, experienced health coaches. As part of the MOST framework, it is important that coaching be as uniform as possible regardless of the participants' assigned intervention condition. Coaches will be trained and supported with scripts so that the coaching is delivered the same way across conditions. Coaches will refer participants to the UCSF study team if they have questions about other intervention components (e.g., Fitbit, diet tracking app). Coaching calls will be audio recorded and 10% will be reviewed annually for fidelity. Checklists that specify appropriate session content will be developed for the 12 conditions that include coaching. Feedback will be provided to coaches based on the recorded calls and checklists.

2.9. Outcome measures

2.9.1. Body size—Body mass index (BMI; kg/m^2) will be calculated from weight (kg) and height (m) at 0, 24, and 48 weeks. Weight and height will be self-reported at all study time points (0, 12, 24, 36, 48 weeks) and measured by blinded staff at LabCorp or Quest Diagnostics Patient Service Centers at 0 and 48 weeks. Points (0 or 2) are assigned for BMI (Table 2).

2.9.2. Diet assessment—Diet factors used to calculate the ACS score and points assigned are in Table 2. All patients complete the 2021 version of the validated Harvard FFQ for external investigators at 0, 24, and 48 weeks, modified to ask about usual diet in past 6 months [38]. Participants are also asked to complete a brief diet survey that asks about intake of food groups in the ACS guidelines at 12 and 36 weeks (same questions on the screening survey).

2.9.3. Physical activity—Physical activity will be assessed with 7 consecutive days of Actigraph GT3X+ accelerometers at 0, 24, and 48 weeks [32,39,40]. Participants are mailed the device, wristband, a paper log to record wear, and a prepaid addressed envelope to return the accelerometer at each time point. Patients are required to have at least 4 days with 10-h of valid wear time to be considered a valid source of data. The Troiano 2007 default settings in Actilife v 6.13.4 are used to assess wear time; non-wear is defined as at least 60 min of consecutive 0 counts, allowing for 1–2 min epochs between 0 and 100. If an accelerometer is returned with insufficient valid wear time, the participant is asked to re-wear the accelerometer one time. If insufficient data are returned twice at enrollment (prior to randomization), the participant is considered a screen fail. For the ACS score, we will calculate total MVPA (min/wk.) from the accelerometer data [32] (see Table 2). Participants are also asked to complete a modified Godin Leisure-Time activity survey at 0, 12, 24, 36 and 48 weeks [40].

2.9.4. ACS Guideline score—A score to combine physical activity, diet, and BMI into one continuous measure at 0, 24, and 48 weeks will be used as the primary study outcome

(Table 2) [4,8]. Participants are assigned 0–6 points based on their BMI, accelerometer based total MVPA (min/wk.), daily intake of fruits and vegetables, percentage of grains that are whole, and weekly intake of red and processed meat from the FFQ. Higher scores indicate healthier behaviors and body size. Each factor (BMI, physical activity, diet) is equally weighted from 0 to 2 points. In the original score developed for cohort data, diet points were calculated using percentile distributions for grains and meat. To operationalize the score for this trial, the cut-points for diet items are based on a standardized score for cancer prevention from the American Institute for Cancer Research [41]. The three diet sub-factors are weighted to maintain 0–2 possible points for diet. Observational data from stage III colon cancer indicate that nearly two-thirds of survivors changed their ACS score by at least 1 point (up or down) from 3 to 15 months post-diagnosis, supporting that this outcome is sensitive to changes in behaviors over time [4].

2.9.5. Cancer survivor questionnaires—Sociodemographic and clinical factors are assessed via online surveys at enrollment, including age, gender, race/ethnicity, marital status, education, income, tobacco/alcohol use, residence (e.g., zip code, state), health literacy, cancer site, stage, and time since diagnosis. Additional surveys are administered online at 0, 24, and 48 weeks to measure SCT constructs and aspects of quality-of-life [32,42,43]. These include the Social Support for Exercise Survey, Exercise Goal Setting Scale, Exercise Planning Scale, Exercise Self-Efficacy Scale, Multidimensional Outcome Expectations for Exercise Scale, and a modified Food Beliefs Survey to assess self-efficacy, self-monitoring, and social, self-evaluative, and physical outcome expectations for a healthy diet [32,44–51]. Depression, fatigue, and sleep disturbance are assessed at 0, 24, and 48 weeks using the 4-item sub-sections of the PROMIS-29 Profile v2.0 [52–54].

2.9.6. Support person questionnaires—The 200 support persons randomized to receive support person training are asked to complete a brief online survey using REDCap at 0 and 48 weeks. At enrollment, the support persons are asked about their sociodemographic factors, relationship and contact with the cancer survivor, health literacy, height, weight, and diet and physical activity in the past 3 months. At 48 weeks, support persons are asked if they currently live in the same household as the participant and, if not, how often they had contact with the participant in the past 3 months; they are also asked to update their body weight, diet, and physical activity data.

2.9.7. Adherence to assigned intervention—Adherence will be measured using number of replies to text messages that ask for a response, number of days with data recorded in MyFitnessPal (≥600 kcal/d for women, ≥650 kcal/d for men based on 5th percentile from NHANES data) [55], number of days the Fitbit™ was worn (>1500 steps/d), number of days the logbook was used, number of health coaching calls completed, and number of support person training calls completed.

2.10. Compensation

All participants will receive a Fitbit™ and up to $50. Participants will receive $25 for completion of the assessments at 24-weeks and 48-weeks. Participants' support persons will receive $20 at the end of the study for completing the four support person training calls.

2.11. Optional biological outcome sub-studies

2.11.1. Insulin and inflammatory markers—A subset of 240 participants will be asked to complete a fasting blood draw at 0 and 48 weeks. Fasting insulin, glucose, hs-CRP, TNF-a, and IL-6 will be measured. Insulin resistance will be assessed using the HOMA-IR index [fasting insulin (μIU/mL) × fasting glucose (mmol/L)/405]. Blood will be drawn at LabCorp or Quest Diagnostics patient service centers. The technicians will be blinded to the participants' assigned intervention condition.

2.11.2. Gut microbiome—Participants will be consecutively invited to participate in an optional sub-study in which they are asked to donate stool samples at up to five time points: 0, 12, 24, 36, and 48 weeks; 30 people will be asked to provide stool samples at all five time points and 70 additional participants will be asked to provide baseline stool samples only. These data will be used to describe the gut microbiome structure of colorectal cancer survivors and explore changes over time that occur in response to changes in health behaviors.

2.12. Adverse events

Study participants are encouraged to report any 'emergencies or events' by calling a study doctor, coordinator, or investigators. Participants are also asked to complete a survey on "Your Recent Health" every 12 weeks. The survey asks about changes to regular medications, treatments for colon or rectal cancer, and hospitalizations. It also includes questions from the National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™) on the frequency and severity of nausea, heartburn, flatulence, bloating of the abdomen, constipation, diarrhea, pain in the abdomen, numbness or tingling in hands or feet, aching muscles, aching joints, and up to five other symptoms that they wish to report [56].

2.13. Statistical considerations for primary outcome

This is a randomized factorial experiment; all 400 participants contribute data to the analyses. The primary outcome is change in ACS guideline score from 0 to 48 weeks. Change in ACS score assessed at baseline, 24 weeks, and 48 weeks will be modeled as repeated measures using a generalized linear mixed effect model. This will begin as a saturated model including coefficients for main effects, interactions up to 3-way, and stratification variables (gender and age). We will reduce the model via backward variable selection with a 0.05 significance level ($\alpha = 0.05$) to identify the intervention components, and combinations of components, associated with change in ACS Guideline score.

To choose these components, we will first identify the significant main effects and interactions of the components on ACS score. Components that are empirically demonstrated to be efficacious for improving ACS score will be considered candidates for inclusion in the optimized intervention. All combinations of components will be considered and the combination with the largest effect retained. There is the possibility that no components will emerge as effective. In this case, we will follow the continuous optimization principle of MOST and return to the preparation phase and revise the most promising components and, if warranted, identify potential new components to test.

2.14. Power and sample size

With 400 participants, anticipating 0 [standard deviation (SD): 1.2] mean change in ACS score among people who do not receive a component based on cohort data [4], $\alpha = 0.05$, and accommodating up to 20% dropout, a *t*-test for the primary objective will have ≥80% power to detect a significant main effect if one component is effective with a mean difference ≥ 0.22 SD. An ANOVA test will have ≥80% power for individual components if 2 components are effective and each increases the mean ACS score at 48 weeks by ≥0.3 SD. If there are two effective components, each increasing the ACS score by 0.22 SD, an ANOVA test will have ~70% power for a 2-way interaction between the components if the interaction increases the ACS score by an additional ~0.55 SD. Note, the proposed mixed effects models include all 400 participants under the assumption of missing at random. Thus, there will be sufficient power to detect smaller effect sizes. Further, due to the orthogonal study design, estimation of each effect is independent and adjustment for multiple testing is not indicated [17].

3. Discussion

Growing evidence suggests that nutrition and physical activity are associated with survival among CRC survivors. However, adherence to nutrition and physical activity guidelines is poor [4–7], and the most effective intervention to promote such behavior remains to be elucidated. In Tools To Be Fit, we aim to identify the optimal set of intervention components to improve CRC survivors' ACS guideline score. This study will guide the development of an effective and scalable intervention for CRC survivors.

While previous trials focused on health promotion among cancer survivors have demonstrated effects, the complex interventions have had limited sustainability, reach and scalability. For example, previous studies used in-person visits for education and data collection; focused on education rather than engagement with the web-based intervention; tested multi-component interventions without the ability to examine the effectiveness of individual components; enrolled already highly active individuals or those with appropriate dietary practices already in place; relied upon self-report for physical activity tracking; and/or excluded support persons and caregivers [20,57–59]. These limitations guided the development of Tools To Be Fit, which ultimately aims to move the field of patient-centered health promotion in cancer survivorship forward. As previously noted, our factorial design was selected to determine the effectiveness of individual intervention components, thus providing critical insight into which aspects of intervention should be carried forward in the development of a scalable and sustainable survivorship program.

3.1. Limitations

Limitations of the Tools To Be Fit study include requiring participants to have Internet access, potential measurement error in diet and body size data, and anticipated inability to verify self-reported clinical information for a portion of participants. While approximately 85% of people in the US have smart phones, there remains a digital divide in Internet access. Additionally, we acknowledge the limitation of using self-reported dietary behavior to assess change in diet. However, this is standard in the field and recommended by the

NCI [30]. No validated objective measures are available to assess usual intake of percent of total grains that are whole or red and processed meat intake. Body height and weight will be measured by technicians blinded to the participants' assigned intervention; however, this will occur at LabCorp and Quest locations of the participants' choosing. The scales used may not have been recently calibrated and there may be some variation in the Patient Service Center's instructions to patients regarding removal of clothing layers or shoes. This may introduce nondifferential error in measurement of body weight. Lastly, we initially planned to verify all self-reported clinical information to confirm eligibility, prior to randomization. However, in the first few months of enrollment for this study, obtaining medical records from outside institutions (not UCSF or DFCI) caused significant delays. To eliminate this barrier to participation, we dropped the requirement for medical record verification prior to enrollment for people who pass the PAR-Q. We still request provider information and seek to obtain medical records for all participants but anticipate a small portion of enrolled individuals will not have their self-reported clinical information confirmed.

4. Conclusion

The Tools To Be Fit intervention is a novel approach to health promotion in CRC survivorship. The findings from this study will inform a definitive randomized controlled trial to determine whether an optimized intervention (including tailoring if indicated) versus usual care reduces the risk of CRC recurrence among survivors.

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JMC: Husband is a full-time employee of Adela, Inc.

WYJ: Blue Note Therapeutics (Patient Advocate Member).

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EVB: Dr. Van Blarigan is on the Medical Advisory Board for Fight Colorectal Cancer (Fight CRC).

Data availability

No data was used for the research described in the article.

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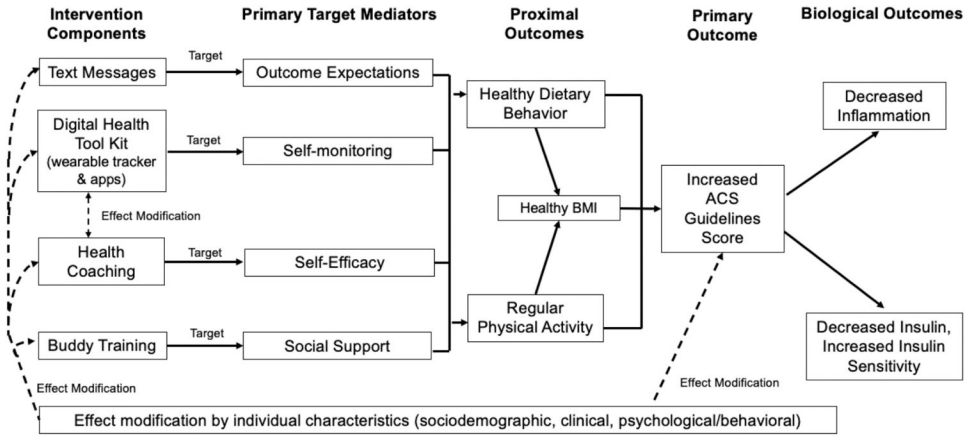

Fig. 1.

Conceptual framework for the Tools To Be Fit study[a].

[a] Target mediators are drawn from social-cognitive theory (Bandura, 1986). This model adheres to the MOST framework, which recommends specifying one mediator per component (Collins, 2018). Components may affect other behavior change techniques not shown and mediators may be synergistic.

Table 1

Intervention conditions in the Tools To Be Fit study. All 400 participants contribute to each effect estimate; in each column, shading indicates which participants' data are combined to determine that component's effect. For example, to determine the effect of text messages, participants assigned to conditions 1–8 will be compared to participants assigned to conditions 9–16.

Condition	Study Booklet	Text Messages	Digital Health Tool Kit[a]	Health Coaching	Support Person Training
1	Yes	Yes	Yes	Yes	Yes
2	Yes	Yes	Yes	Yes	No
3	Yes	Yes	Yes	No	Yes
4	Yes	Yes	Yes	No	No
5	Yes	Yes	No	Yes	Yes
6	Yes	Yes	No	Yes	No
7	Yes	Yes	No	No	Yes
8	Yes	Yes	No	No	No
9	Yes	No	Yes	Yes	Yes
10	Yes	No	Yes	Yes	No
11	Yes	No	Yes	No	Yes
12	Yes	No	Yes	No	No
13	Yes	No	No	Yes	Yes
14	Yes	No	No	Yes	No
15	Yes	No	No	No	Yes
16	Yes	No	No	No	No

[a] "Yes" groups: Wearable and instructions to use physical activity and diet tracking apps; "No" groups: paper log for tracking diet and exercise.

Table 2

Calculation of the ACS nutrition and physical activity guidelines score (range: 0–6).[a]

Recommendation	Possible Points
Avoid obesity *As lean as possible without being underweight*	0: BMI ≥30 or < 18.5 kg/m^2 2: BMI 18.5 – <30 kg/m^2
Engage in regular physical activity *Exercise ≥ 150 min/wk.*	0: <75 min/wk. MVPA 1: 75 – <150 min/wk. MVPA 2: ≥150 min/wk. MVPA *0-2 points for 3 diet factors: Fruits & Vegetables* 0: <3 servings/day 1/3: 3 to <5 servings/day 2/3: ≥5 servings/day
Consume a healthy diet, with an emphasis on plant foods *≥ 2.5 cups/d of non-starchy vegetables and fruits (not including juice)* *Choose whole instead of refined grain products Limit processed and red meat*	*% Grains that are Whole* 0: <50% 1/3: 50 – <75% 2/3: ≥75% *Red and Processed Meat* 0: >2 servings/wk. red *OR* ≥ 1 serving/wk. proc. meat 1/3: ≤2 servings/wk. red & 1–3 servings/mo. proc. meat 2/3: ≤2 servings/wk. red & never or < 1/mo. proc. meat

MVPA, moderate-to-vigorous physical activity.

[a]Specific cut-points for physical activity, fruits and vegetables, and red and processed meat based approximately on the 2018 WCRF/AICR guidelines for cancer prevention scoring criteria [41].