Contemporary Clinical Trials Communications 22 (2021) 100768

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: http://www.elsevier.com/locate/conctc

SWOG S1820: Altering Intake, Managing Symptoms for bowel dysfunction in survivors of Rectal Cancer (The AIMS-RC intervention trial)

Virginia Sun [a, b, *], Tracy E. Crane [c, d], Kathryn B. Arnold [e], Katherine Guthrie [e], Sarah Freylersythe [d], Christa Braun-Inglis [g], Lee Jones [h], Stacey A. Cohen [i, j], Mazin Al-Kasspooles [k], Robert S. Krouse [l], Cynthia A. Thomson [d, f]

[a] Department of Population Sciences, City of Hope, Duarte, CA, USA
[b] Department of Surgery, City of Hope, Duarte, CA, USA
[c] College of Nursing, University of Arizona, Tucson, AZ, USA
[d] University of Arizona Cancer Center, Tucson, AZ, USA
[e] SWOG Statistics and Data Management Center, Fred Hutchinson Cancer Research Center, Seattle, WA, USA
[f] Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA
[g] University of Hawaii Cancer Center, Honolulu, HI, USA
[h] Research Advocate, SWOG Cancer Research Network, San Antonio, TX, USA
[i] University of Washington, Seattle, WA, USA
[j] Fred Hutchinson Cancer Research Center, Seattle, WA, USA
[k] University of Kansas, Kansas City, KS, USA
[l] Perelman School of Medicine, University of Pennsylvania and the Corporal Michael J. Crescenz Veterans Affairs Medical Center, Philadelphia, PA, USA

ARTICLE INFO

Keywords:
Rectal cancer
Survivorship
Bowel dysfunction
Diet
QOL

ABSTRACT

Objective: To describe the study protocol of SWOG S1820, a trial of the Altering Intake, Managing Symptoms intervention for bowel dysfunction in survivors of Rectal Cancer (AIMS-RC).
Design: SWOG S1820 is a multi-site, randomized trial of 94 post-treatment survivors of rectal cancer, comparing the intervention and attention control arms.
Setting: Affiliated institutions of the National Cancer Institute (NCI)-supported National Community Oncology Research Program (NCORP) and the National Clinical Trial Network (NCTN).
Participants: Survivors of rectal cancer who are between 6 and 24 months after treatment completion.
Intervention: AIMS-RC is a 17-week, 10 session telephone coaching program to help survivors of rectal cancer track their symptoms and improve their diets for better health and bowel function. It includes telephone-based coaching, resource manual, and personalized text/email messaging for motivation in between the telephone sessions.
Main outcome measures: Bowel function, low anterior resection syndrome score, quality of life (QOL), dietary quality, motivation, self-efficacy, positive/negative affect, feasibility, adherence, retention, acceptability.
Analysis: Thirty-seven participants per arm (74 total) provide 80% power to detect this 0.5 standard deviation effect size, based on a two-sample *t*-test with a 1-sided alpha = 0.1. A total of 94 randomized participants will be accrued to account for 7% ineligibility and 15% attrition at 6 months.

1. Introduction

More than 1.5 million Americans are living with a history of colorectal cancer, with an estimated 640,000 surviving a rectal cancer diagnosis and 43,340 new cases of rectal cancer diagnosed in 2020 [1,2]. Early detection and treatment advances have significantly improved survival for rectal cancer [1]. However, persistent late and long-term effects of treatments are common. A frequently reported symptom of post-treatment rectal cancer survivorship is bowel dysfunction. Symptom characteristics include the inability to control bowel movements, increased frequency in bowel movements, soiling, gas, bloating, and oscillations between diarrhea and constipation [3]. Our previous research found that bowel dysfunction occurs regardless of surgery type and ostomy status (with or without a permanent ostomy), and results in re-

* Corresponding author. Department of Population Sciences, City of Hope, 1500 East Duarte Road, Duarte, CA, 91010, USA.
E-mail address: vsun@coh.org (V. Sun).

https://doi.org/10.1016/j.conctc.2021.100768
Received 16 October 2020; Accepted 1 April 2021
Available online 8 April 2021

duced social activities, social well-being, and quality of life (QOL) [4–6]. Bowel dysfunction is a significant barrier to survivor adoption of dietary recommendations for cancer survivorship [7–9].

One promising approach for bowel symptom control is diet modifications. Empirical evidence from our team suggest that diet modification and changes in meal-related behaviors were the most consistently reported self-care strategy used by long-term (>5 years) survivors of rectal cancer [5,10]. The ability to successfully manage bowel symptoms resulted in improved QOL. However, diet modification methods varied tremendously, and were often based on a trial-and-error approach without evidence-based strategies and were not grounded in behavior change theory [11–14]. This resulted in inconsistent efficacy, unnecessary delays in symptom improvement and, for some, avoidance of cancer-preventive foods for health promotion after cancer. Our previous research suggests that consumption of fruits and vegetables often resulted in increased diarrhea, gas, and urgency [10]. For survivors that reported an increase in bowel symptoms with fruit/vegetable consumption, the elimination of these foods from their diet was a common self-care strategy [10]. While registered dietitian nutritionists (RDNs) provide the expertise to meet this challenge, evidence shows that RDN services are not readily accessible, even in comprehensive cancer centers [15]. Importantly, bowel symptoms are modifiable, but a gap exists in empirically-based interventions to manage bowel dysfunction. The aim of this paper is to describe the study protocol for SWOG S1820, a preliminary efficacy trial of the Altering Intake, Managing Symptoms intervention for bowel dysfunction in survivors of Rectal Cancer (the AIMS-RC Intervention).

2. Methods

2.1. Protocol development

SWOG S1820 full protocol development process began shortly after securing NCI funding. The core research team met weekly to discuss protocol development. The interdisciplinary core research team represented nursing science, dietary/behavioral science, medicine (surgical oncology, medical oncology), research advocacy, protocol coordination, recruitment/retention, digital engagement, biostatistics, and data operations/management. The interdisciplinary collaboration enriched the protocol development process, and the team successfully addressed critical aspects of the trial design.

2.2. Study design and objectives

SWOG S1820 is a multi-center, randomized, controlled trial of 94 post-treatment survivors of rectal cancer. The trial is designed to test the preliminary efficacy of the AIMS-RC diet modification intervention to improve bowel function, relative to an attention control. The primary endpoint is change in bowel function at 18 weeks post-randomization, as measured by the Memorial Sloan- Kettering Cancer Center Bowel Function Instrument (MSKCC-BFI). Exploratory endpoints include 1) change in total bowel function score at 26 weeks post-randomization between study arms; 2) change in bowel function subscale scores (dietary, urgency, frequency) at both 18 and 26 weeks post-randomization between study arms; 3) change in low anterior resection syndrome (LARS) scores (for anastomosis participants only), quality of life, and dietary quality at both 18 and 26 weeks post-randomization between study arms; 4) motivation, self-efficacy, and positive/negative affect at both 18 and 26 weeks post-randomization between study arms; 5) feasibility, adherence, retention, and acceptability at both 18 and 26 weeks post-randomization; and 6) variation in primary and exploratory study outcomes according to sex, and variation in intervention effects on the primary outcome according to sex.

The study is conducted within the SWOG Cancer Research Network, one of five publicly-funded, National Cancer Institute (NCI)-supported National Clinical Trial Network (NCTN) cooperative groups and also a National Community Oncology Research Program (NCORP) research base. Member institutions within SWOG can opt to participate as an accrual site.

2.3. Participant eligibility criteria and recruitment/retention

Inclusion criteria include: 1) prior history of rectosigmoid colon cancer or rectal cancer; 2) have a post-surgical permanent ostomy or anastomosis; 3) completion of most recent treatment for rectal cancer (any surgery, chemotherapy, radiation therapy) 6–24 months prior to registration; 4) anastomosis survivors must have low anterior resection syndrome (LARS) score of 21–42 (minor to major symptoms); 5) completion of baseline questionnaires within 5 days prior to registration; 6) completion of the S1820 Patient Contact form prior to registration; 7) be able to read, write and speak English; and 8) ≥ 18 years of age. Exclusion criteria include: 1) currently undergoing treatment for another cancer; and 2) diagnosis of inflammatory bowel disease (IBD), such as ulcerative colitis or Crohn's disease. The study protocol is approved by the NCI's Cancer Control and Prevention Central Institutional Review Board (CIRB).

Recruitment and retention strategies are vetted with the SWOG Cancer Research Network Recruitment and Retention Committee in accordance with established guidelines and policies. Potential participants are screened by the enrollment site staff; eligible participants who provide informed consent are registered to the study. Guided by the Recruitment and Retention Committee, engagement with national colorectal cancer advocacy groups (Fight Colorectal Cancer, Colorectal Cancer Alliance) and social media platforms are planned, following NCI CIRB approval of content. These efforts are spearheaded by the participating SWOG research advocate. In addition, an NCI CIRB approved study brochure is available for enrollment sites to use for recruitment purposes. Finally, NCI CIRB-approved templates for treatment arm-specific newsletters are used to engage and retain participants.

2.4. Participant registration and run-in period

The SWOG S1820 study schema is presented in Fig. 1. This study includes a two-step participant registration process. Step 1 registration occurs after informed consent. Participants then enroll in the study run-in that lasts 14–21 days. The run-in and related activities are designed to gauge participation and adherence to procedures in both randomization arms. At Step 1 registration, enrollment site staff gives the participant a run-in packet, which includes a 3-day food/symptom diary and postage-paid envelope. Sites inform the participant to review the materials at home and wait for a telephone call from research coordinators at the Behavior Measurement and Interventions Shared Resource (BMISR) of the University of Arizona Cancer Center.

Trained research coordinators call participants to provide instructions and support on the run-in packet. They also complete a baseline 24-h dietary recall using the USDA multi-pass dietary recall methodology and administer the baseline MSKCC-BFI. Participants are instructed to complete the 3-day food/symptom diary within 5 days of receiving the telephone call and return the diary back to the BMISR within 14 days of completion. Research coordinators determine whether a participant completed the run-in, according to protocol-defined standards of phone call compliance and questionnaire completion.

Participants who successfully complete the run-in period are registered to Step 2 and randomized. Participants who do not complete the run-in period receive a mailed or emailed resource manual containing information on healthy living after cancer treatment and have no further participation in the study.

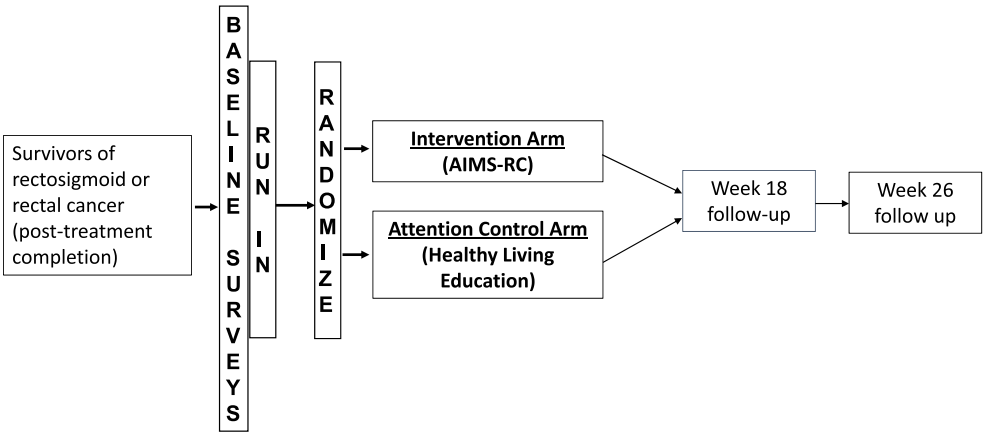

Fig. 1. Study schema.

3. Randomization

Participants are randomly assigned (1:1) to either the Intervention or Attention Control arm, using a stratified and blocked randomization. Strata are defined by sex (female vs. male) and ostomy status (permanent ostomy vs. anastomosis. Study arm assignments are provided to site research staff and communicated to the participants.

4. Study intervention

4.1. Conceptual framework

The rationale, development, and design of the AIMS-RC Intervention is described elsewhere [16]. Briefly, the intervention is a 17-week telephone coaching program to help rectal cancer survivors track their symptoms and improve their diets for better health and bowel function. The intervention draws from the Motivation and Problem-Solving (MAPS) approach, a social cognitive theory [17] driven model of behavior change [18,19]. In using the MAPS approach, skills training (coping, problem-solving) is systematically added with motivational interviewing, and adjusted based on the individuals' level of motivation and positive/negative affect [20–23]. MAPS influences self-efficacy through the removal of barriers to change, problem-solving and coping skills training, and increased motivation [24–27].

4.2. Intervention arm

The AIMS-RC Intervention arm sessions begin within 10 days after randomization and are delivered over approximately 17 weeks via 10 telephone sessions that last 30–60 min each. The Intervention is delivered in addition to standard of care for post-treatment rectal cancer. The sessions are centrally-administered via telephone by trained health coaches from the University of Arizona. The health coaches have experience with cancer survivors and are trained on rectal cancer-specific knowledge. Participants also receive an intervention resource manual, which is used during the sessions to guide health coaching discussions. Table 1 presents AIMS-RC Intervention coaching call content by session.

In addition to the coaching calls, participants receive electronic communication messaging between scheduled telephone calls. They receive three messages per week beginning with Session 6, and then messaging moves to every other week for Sessions 6–10. The messages are sent via smartphone text messaging (SMS) and/or email messaging, based on participants' preference. The messages are specific to the AIMS-RC Intervention to support participant-specific bowel symptom management goals. They are used by the health coaches to provide sup-

Table 1
AIMS-RC intervention coaching call content.

Session	Session Content	Weekly Activities
Session 1 (Within 10 days of randomization)	• Introductions • Program/coaching overview • Review food & symptom diary • Wellness Plan/goals overview	• Food and symptom diary • Reflect on Wellness Plan • Review pages in handbook • Receive welcome SMS/email
Session 2 (1 week after session 1)	• Review past week • Reflect on Wellness Plan • Review food and symptom diary • Introduction to food elimination/re-introduction trials • Introduction to SMART goals	• Food and symptom diary • Review pages in handbook
Sessions 3–6 (weekly calls)	• Review food and symptom diary • Implementation of food eliminations/re-introduction • Problem-solving diet modifications • Other symptom management strategies • Set SMART goals	• Diet modifications • Food and symptom diary • Review handbook as needed • Work on SMART goal
Sessions 7–8 (every other week calls)	• Review food and symptom diary • Elimination/re-introduction of identified foods • Problem-solving to overcome diet behavior change challenges • Review diet recommendations for cancer survivorship • Set SMART goals	• Diet modifications • Food and symptom diary • Review handbook as needed • Work on SMART goal • Receive SMS/emails (3 per week)
Sessions 9–10 (monthly calls)	• Review Wellness Plan, progress and knowledge/skills gained • Set SMART goals	• Diet modifications, as needed • Review handbook, as needed • Work on SMART goal • Receive SMS/emails (3 per week)

port, promote diet behavior change and bowel symptom management, and sustain participant engagement.

4.3. Attention control arm

The Attention Control arm sessions begin within 10 days after randomization and are delivered over approximately 17 weeks via 10 telephone sessions that last about 20–30 min each. The Attention Control arm (Healthy Living Education) content is based on our previous experience with the design of control conditions for behavioral interventions (i.e. GOG/NRG 225) [28], with 10 topics based on national survivorship guidelines on healthy living post-treatment for cancer survivors. The sessions are centrally-administered via telephone by trained health coaches from the University of Arizona. The Attention Control arm coaches are different from the Intervention arm coaches to reduce confounding and bias between arms. Participants receive a Health Education resource manual; this is used during the sessions to guide discussions. Table 2 presents Attention Control call content by sessions.

Attention Control arm participants also receive smartphone text messaging (SMS) and/or email messaging at the same frequency as those in the Intervention arm. The messages contain standard information on the 10 healthy living topics and are used for retention purposes.

4.4. Treatment fidelity

Several approaches are included to ensure intervention rigor and validity. All telephone sessions are audio-recorded and reviewed by the Study Chair and Co-Chairs. Continuous monitoring is initiated through random sampling of 15% of calls in the first week of the study and 3% monthly thereafter. Sessions are scored using as adapted version of the Motivational Interviewing Treatment Integrity (MITI) 4.2.2 guidelines [29], in addition to MAPS specific criteria related to the coaches' ability to use the MAPS approach to identify problems and capitalize on motivation to shift behaviors [30]. Intervention coaches will be expected to adhere to the MAPS approach and score consistently high on the MITI 4.2.2 scale. The Attention Control coaches will be expected to consistently score low on the MITI scale and show no evidence of utilizing a MAPS approach.

4.5. Outcome measures

Bowel Function is assessed using the MSKCC-BFI, which contains 18 items across 3 subscales (frequency, dietary, urgency/soilage) which are combined into one total score [31,32]. The Low Anterior Resection Syndrome (LARS) is a 5-item survey with a corresponding value weighted according to the impact of bowel symptoms (low anterior resection syndrome) on QOL. Scores range from 0 to 42 points; scores are categorized into three groups: no LARS (0-20), minor LARS (21–29), and major LARS (30–42) [33–37]. Quality of life is assessed using the City of Hope-Quality of Life-Colorectal Cancer (COH-QOL-CRC) survey, a validated instrument that assesses overall QOL in post-surgery colorectal cancer patients. There are separate versions for patients with ostomy (43 items) and anastomosis (35 items) [38].

Using the Nutrition Data System for Research (University of Manitoba), 24-h dietary recalls are collected at baseline, 18 weeks, and 26 weeks. Trained research staff at the BMISR use the multi-pass method to collect dietary recall data that are then entered into the NDSR database for estimation of dietary intake. Dietary quality is based on the Healthy Eating Index 2015 (HEI-2015) [39,40]. Scores are calculated from the dietary recall data according to the HEI-2015 and adapted for restriction in alcohol intake [8,41–44]. Motivation is measured using a 10-item scale assessing motivation to change dietary behaviors in survivors of rectal cancer. It was developed and adapted from the Reasons for Quitting (Intrinsic and Extrinsic Motivation) scale. Self-efficacy is measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Self-Efficacy for Managing Symptoms – Short Form. The instrument measures confidence in one's ability to successfully perform specific tasks or behaviors related to self-efficacy for managing symptoms [45]. Positive and Negative Affect is measured using the 10-item International Positive and Negative Affect Schedule Short Form (I-PANAS-SF) [46,47].

Feasibility is measured by the percentage of participants who successfully complete the run-in period, and are randomized. Adherence measures are assessed as successful completion of coaching Sessions #1–5 and at least three of Sessions #6–10 within 18 weeks after randomization. Retention is defined by completion of follow-up assessments after randomization, including those administered at follow-up site visits and the dietary recalls. Acceptability is measured for all participants using the Acceptability of Intervention measure (AIM) [48].

4.6. Data management

Data collection for this study is completed through the Medidata Rave® clinical data management system. Access to the trial in Rave is granted through the iMedidata application to all persons with the appropriate roles assigned in Regulatory Support System (RSS). Dietary recall, MSKCC-BFI, and adherence measures are tracked by the University of Arizona, with regular transfer of data to SWOG Statistics and Data Management Center.

4.7. Statistical design and analysis

The necessary sample size for this preliminary estimate of efficacy was based on a previously observed MSKCC-BFI standard deviation estimate of 9.3 points [31,32,49] and a clinically meaningful study arm difference of approximately 4.6 points as defined by the Sloan empirical rule effect size (defined as a mean difference of approximately 8% of MSKCC-BFI range) [50]. Thirty-seven participants per arm (74 total) provide 80% power to detect this 0.5 standard deviation effect size, based on a two-sample t-test with a 1-sided alpha $= 0.1$. We will accrue additional participants to account for 7% ineligibility and 15% attrition at 6 months, for a total accrual goal of 94 randomized participants.

4.8. Research/patient advocacy

Stakeholder engagement is integrated into the clinical research process. For many years, patient, caregivers, and other healthcare stakeholder engagement in research was limited; stakeholders were primarily involved in research as study participants that were consented and enrolled. As healthcare has become increasingly patient- and family-centered, stakeholders are increasingly recognized as equal partners in the planning, conduct, and dissemination of research [51]. SWOG

Table 2
Attention control call content.

Session	Session Content	Weekly Activities
Session 1 (within 10 days of randomization)	• Introductions • Program overview • Sleep	• Receive Welcome SMS/email
Sessions 2–6 (weekly calls)	• Sun safety • Food safety • Skin care • Active wear • Bone health	• None
Sessions 7–8 (every other week calls)	• ACS diet and activity recommendations • Clinical trials	• Receive SMS/emails (3 per week)
Sessions 9–10 (monthly calls)	• Understanding online resources • Screening and surveillance	• Receive SMS/emails (3 per week)

Cancer Research Network policies mandate the involvement of research advocates in all protocols. Research advocates have been consistently engaged in this study's development, from the earliest stages of study design through final protocol activation. The research advocate brings the lived experience of colorectal cancer, and is an integral member of our core research team. Their guidance, support, and feedback continue through weekly team meetings, participation in the dissemination of our study design, and future final outcomes through publications.

4.9. Quality assurance and site engagement

Given the unique design of the study, and with multiple institutions nationally accruing to the study, several strategies are integrated to maintain high quality data and minimize protocol deviations. First, clear study flow diagrams of communication and site activities are included in the study protocol. Second, enrollment site staff must view a 45-min recorded webinar of protocol specifics for study implementation and pass a brief post-test to activate the trial at their site. Third, a monthly site coordinator call led by the protocol nurse coordinator provides a regular opportunity for site-specific queries on study process, problem-solving, and study engagement. Finally, the core research team attends weekly protocol meetings via videoconferencing to discuss recruitment and enrollment progress and address any quality assurance-related questions and issues that may impede study implementation.

5. Discussion

For survivors of rectal cancer, living with persistent post-treatment bowel dysfunction and related symptoms significantly impacts QOL and likely reduces adherence to cancer survivorship dietary guidance. To our knowledge, we are the first to systematically address dietary behavior changes for symptom management in rectal cancer. Evidence-informed interventions to promote self-management of persistent post-treatment GI-related symptoms through appropriate diet behavior modifications are critical to improving the quality of survivorship in rectal cancer patients [52,53].

Recent trends suggest that rectal cancer incidence rates are increasing, particularly in adults ≤50 years; the U.S. incidence rate doubled from 14.6% to 29.5% in the last 40 years [54]. These trends suggest that the number of younger survivors of rectal cancer living with bowel symptoms requiring management will continue to rise in years to come. SWOG S1820 aims to understand the unique QOL challenges for all survivors of rectal cancer, including younger survivors, and can serve as a national model for post-treatment symptom management in rectal cancer survivorship.

Several aspects of the intervention design are innovative. The personalized approach can potentially increase adherence and uptake of the intervention by accounting for each survivor's food tolerance and preference. The AIMS-RC intervention is grounded in evidence-based behavioral change theories, with the integration of MAPS as an added approach to motivational interviewing-based interventions. Despite strong evidence for both motivational interviewing and social cognitive-based training, there are few cancer survivorship behavioral interventions that target survivors regardless of their readiness to change and respond to motivational shifts. The centralized administration of the intervention promotes intervention fidelity monitoring to ensure that SWOG S1820 is delivered as intended. It also allows for implementation across a variety of practice settings because it does not require highly skilled/trained interventionists at the individual participating site.

The AIMS-RC Intervention is expected to attenuate or alleviate persistent GI symptoms while concurrently promoting adherence to dietary guidance for cancer survivorship. The observed rise of rectal cancer incidence, particularly in younger populations, is likely partially fueled by lifestyle factors, including obesity and diet quality [55]. Evidence suggests that cancer survivors fall short in achieving national survivorship diet guidelines [39]. These trends will continue, unless effective interventions such as AIMS-RC are developed, tested, and disseminated.

The AIMS-RC Intervention builds on telehealth/telephone-based approaches that are well-grounded for behavioral interventions and dietary guideline adherence [56]. Electronic communication (including telephone) offers many advantages, including greater access, affordability, and convenience. Many health-related issues, including bowel dysfunction, can be managed appropriately via telephone. Leveraging the SWOG Cancer Research Network infrastructure (100+ enrollment sites nationally) enhances the generalizability of findings from the trial and speaks to the potential scalability of our intervention for future dissemination.

6. Conclusions

SWOG S1820 is expected to enroll participants over the next 12 months, with final data analysis to be completed by early 2022. The feasibility and preliminary efficacy findings will facilitate the design of a larger, randomized controlled Phase III trial of symptom control and healthy dietary pattern programming to support improved QOL and healthy dietary behaviors among survivors of rectal cancer. It can also potentially serve as rectal cancer survivorship clinical guidance in the future.

Author declaration

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

Acknowledgement

Research reported in this publication is supported by the National Cancer Institute of the National Institutes of Health under award number R21CA236057. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

References

[1] K.D. Miller, L. Nogueira, A.B. Mariotto, J.H. Rowland, K.R. Yabroff, C.M. Alfano, et al., Cancer treatment and survivorship statistics, CA A Cancer J. Clin. 69 (5) (2019) 363–385 2019.
[2] R.L. Siegel, K.D. Miller, A. Jemal, Cancer statistics, 2020, CA A Cancer J. Clin. 70 (1) (2020) 7–30.
[3] A. Dulskas, P. Kavaliauskas, L. Pilipavicius, M. Jodinskas, M. Mikalonis, N.E. Samalavicius, Long-term bowel dysfunction following low anterior resection, Sci. Rep. 10 (1) (2020) 11882.
[4] M. Alavi, C.S. Wendel, R.S. Krouse, L. Temple, M.C. Hornbrook, J.E. Bulkley, et al., Predictors of bowel function in long-term rectal cancer survivors with anastomosis, Ann. Surg Oncol. 24 (12) (2017) 3596–3603.
[5] V. Sun, M. Grant, C.S. Wendel, C.K. McMullen, J.E. Bulkley, A. Altschuler, et al., Dietary and behavioral adjustments to manage bowel dysfunction after surgery in long-term colorectal cancer survivors, Ann. Surg Oncol. 22 (13) (2015) 4317–4324.
[6] R.S. Krouse, L.J. Herrinton, M. Grant, C.S. Wendel, S.B. Green, M.J. Mohler, et al., Health-related quality of life among long-term rectal cancer survivors with an ostomy: manifestations by sex, J. Clin. Oncol. 27 (28) (2009) 4664–4670.
[7] S.J. Hardcastle, C. Maxwell-Smith, M.S. Hagger, M. O'Connor, C. Platell, Exploration of information and support needs in relation to health concerns, diet and physical activity in colorectal cancer survivors, Eur. J. Canc. Care 27 (1) (2018) e12679-n/a.
[8] C.L. Sardo Molmenti, S.E. Steck, C.A. Thomson, E.A. Hibler, J. Yang, N. Shivappa, et al., Dietary inflammatory Index and risk of colorectal adenoma recurrence: a pooled analysis, Nutr. Canc. 69 (2) (2017) 238–247.
[9] A.J. Vargas, M.L. Neuhouser, S.M. George, C.A. Thomson, G.Y. Ho, T.E. Rohan, et al., Diet quality and colorectal cancer risk in the women's health initiative observational study, Am. J. Epidemiol. 184 (1) (2016) 23–32.
[10] V. Sun, C.S. Wendel, W. Demark-Wahnefried, M. Grant, C.K. McMullen, J.E. Bulkley, et al., Diet and behavior modifications by long-term rectal cancer survivors to manage bowel dysfunction-associated symptoms, Nutr. Canc. 71 (1) (2019) 89–99.

[11] M. Landers, G. McCarthy, V. Livingstone, E. Savage, Patients' bowel symptom experiences and self-care strategies following sphincter-saving surgery for rectal cancer, J. Clin. Nurs. 23 (15–16) (2014) 2343–2354.
[12] M. Landers, E. Savage, G. McCarthy, J.J. Fitzpatrick, Self-care strategies for the management of bowel symptoms following sphincter-saving surgery for rectal cancer, Clin. J. Oncol. Nurs. 15 (6) (2011) E105–E113.
[13] S. Nikoletti, J. Young, M. Levitt, M. King, C. Chidlow, S. Hollingsworth, Bowel problems, self-care practices, and information needs of colorectal cancer survivors at 6 to 24 months after sphincter-saving surgery, Canc. Nurs. 31 (5) (2008) 389–398.
[14] L. Kidd, N. Kearney, R. O'Carroll, G. Hubbard, Experiences of self-care in patients with colorectal cancer: a longitudinal study, J. Adv. Nurs. 64 (5) (2008) 469–477.
[15] E. National Academies of Sciences, Medicine, Examining Access to Nutrition Care in Outpatient Cancer Centers: Proceedings of a Workshop, National Academies Press, Washington, DC, 2016.
[16] V. Sun, T.E. Crane, S.D. Slack, A. Yung, S. Wright, S. Sentovich, et al., Rationale, development, and design of the Altering Intake, Managing Symptoms (AIMS) dietary intervention for bowel dysfunction in rectal cancer survivors, Contemp. Clin. Trials 68 (2018) 61–66.
[17] A. Bandura, Social Foundations of Thought and Action: A Social Cognitive Theory, Prentice-Hall, Englewood Cliffs, NJ, 1986.
[18] G.A. Marlatt, D.M. Donovan, Relapse Prevention: Maintenance Strategies in the Treatment of Addictive Behaviors, Guilford Press, 2005.
[19] W.R.R.S. Miller, Motivational Interviewing: Helping People Change, third ed., The Guilford Press, New York, New York, 2013.
[20] C.M. Alfano, J.M. Day, M.L. Katz, J.E. Herndon 2nd, M.A. Bittoni, J.M. Oliveri, et al., Exercise and dietary change after diagnosis and cancer-related symptoms in long-term survivors of breast cancer: CALGB 79804, Psycho Oncol. 18 (2) (2009) 128–133.
[21] C.L. Park, D. Edmondson, J.R. Fenster, T.O. Blank, Positive and negative health behavior changes in cancer survivors: a stress and coping perspective, J. Health Psychol. 13 (8) (2008) 1198–1206.
[22] C.L. Park, A.E. Gaffey, Relationships between psychosocial factors and health behavior change in cancer survivors: an integrative review, Ann. Behav. Med. 34 (2) (2007) 115–134.
[23] J.M. Salsman, S.C. Segerstrom, E.H. Brechting, C.R. Carlson, M.A. Andrykowski, Posttraumatic growth and PTSD symptomatology among colorectal cancer survivors: a 3-month longitudinal examination of cognitive processing, Psycho Oncol. 18 (1) (2009) 30–41.
[24] C.E. Mosher, I. Lipkus, R. Sloane, D.C. Snyder, D.F. Lobach, W. Demark-Wahnefried, Long-term outcomes of the FRESH START trial: exploring the role of self-efficacy in cancer survivors' maintenance of dietary practices and physical activity, Psycho Oncol. 22 (4) (2013) 876–885.
[25] C.E. Mosher, B.F. Fuemmeler, R. Sloane, W.E. Kraus, D.F. Lobach, D.C. Snyder, et al., Change in self-efficacy partially mediates the effects of the FRESH START intervention on cancer survivors' dietary outcomes, Psycho Oncol. 17 (10) (2008) 1014–1023.
[26] M.L. McCarroll, S. Armbruster, H.E. Frasure, M.D. Gothard, K.M. Gil, M.B. Kavanagh, et al., Self-efficacy, quality of life, and weight loss in overweight/obese endometrial cancer survivors (SUCCEED): a randomized controlled trial, Gynecol. Oncol. 132 (2) (2014) 397–402.
[27] V.J. Strecher, B.M. DeVellis, M.H. Becker, I.M. Rosenstock, The role of self-efficacy in achieving health behavior change, Health Educ. Q. 13 (1) (1986) 73–92.
[28] C.A. Thomson, T.E. Crane, A. Miller, D.O. Garcia, K. Basen-Engquist, D.S. Alberts, A randomized trial of diet and physical activity in women treated for stage II-IV ovarian cancer: rationale and design of the Lifestyle Intervention for Ovarian Cancer Enhanced Survival (LIVES): an NRG Oncology/Gynecologic Oncology Group (GOG-225) Study, Contemp. Clin. Trials 49 (2016) 181–189.
[29] T.B. Moyers, L.N. Rowell, J.K. Manuel, D. Ernst, J.M. Houck, The motivational interviewing treatment integrity code (MITI 4): rationale, preliminary reliability and validity, J. Subst. Abuse Treat. 65 (2016) 36–42.
[30] J.I. Vidrine, L. Reitzel, P. Figueroa, M. Velasquez, C. Mazas, P. Cinciripini, et al., Motivation and Problem Solving (MAPS): Motivationally Based Skills Training for Treating Substance Abuse Cognitive and Behavioral Practice, vol. 20, 2013, pp. 501–516.
[31] L.K. Temple, J. Bacik, S.G. Savatta, L. Gottesman, P.B. Paty, M.R. Weiser, et al., The development of a validated instrument to evaluate bowel function after sphincter-preserving surgery for rectal cancer, Dis. Colon Rectum 48 (7) (2005) 1353–1365.
[32] C.S. Wendel, M. Grant, L. Herrinton, L.K. Temple, M.C. Hornbrook, C.K. McMullen, et al., Reliability and validity of a survey to measure bowel function and quality of life in long-term rectal cancer survivors, Qual. Life Res. 23 (10) (2014) 2831–2840.
[33] T. Juul, N.J. Battersby, P. Christensen, A.Z. Janjua, G. Branagan, S. Laurberg, et al., Validation of the English translation of the low anterior resection syndrome score, Colorectal Dis. 17 (10) (2015) 908–916.
[34] T.Y. Chen, K.J. Emmertsen, S. Laurberg, What are the best questionnaires to capture anorectal function after surgery in rectal cancer?, Curr. Colorect. Canc. Rep. 11 (2015) 37–43.
[35] T. Juul, M. Ahlberg, S. Biondo, K.J. Emmertsen, E. Espin, L.M. Jimenez, et al., International validation of the low anterior resection syndrome score, Ann. Surg. 259 (4) (2014) 728–734.
[36] K.J. Emmertsen, S. Laurberg, G. Rectal Cancer Function Study, Impact of bowel dysfunction on quality of life after sphincter-preserving resection for rectal cancer, Br. J. Surg. 100 (10) (2013) 1377–1387.
[37] S. Bregendahl, K.J. Emmertsen, J. Lous, S. Laurberg, Bowel dysfunction after low anterior resection with and without neoadjuvant therapy for rectal cancer: a population-based cross-sectional study, Colorectal Dis. 15 (9) (2013) 1130–1139.
[38] M. Grant, B. Ferrell, G. Dean, G. Uman, D. Chu, R. Krouse, Revision and psychometric testing of the city of Hope quality of life-ostomy questionnaire, Qual. Life Res. 13 (8) (2004) 1445–1457.
[39] C.L. Rock, C. Doyle, W. Demark-Wahnefried, J. Meyerhardt, K.S. Courneya, A.L. Schwartz, et al., Nutrition and physical activity guidelines for cancer survivors, CA A Cancer J. Clin. 62 (4) (2012) 242–274.
[40] L.H. Kushi, T. Byers, C. Doyle, E.V. Bandera, M. McCullough, A. McTiernan, et al., American Cancer Society Guidelines on Nutrition and Physical Activity for cancer prevention: reducing the risk of cancer with healthy food choices and physical activity, CA A Cancer J. Clin. 56 (5) (2006) 254–281 quiz 313-4.
[41] C.A. Thomson, M.L. McCullough, B.C. Wertheim, R.T. Chlebowski, M.E. Martinez, M.L. Stefanick, et al., Nutrition and physical activity cancer prevention guidelines, cancer risk, and mortality in the women's health initiative, Canc. Prev. Res. 7 (1) (2014) 42–53.
[42] C.A. Thomson, T.E. Crane, D.O. Garcia, B.C. Wertheim, M. Hingle, L. Snetselaar, et al., Association between dietary energy density and obesity-associated cancer: results from the women's health initiative, J. Acad. Nutr. Diet. 118 (4) (2018) 617–626.
[43] A.J. Vargas, M.L. Neuhouser, S.M. George, C.A. Thomson, G.Y.F. Ho, T.E. Rohan, et al., Diet quality and colorectal cancer risk in the women's health initiative observational study, Am. J. Epidemiol. 184 (1) (2016) 23–32.
[44] S.E. Steck, M. Guinter, J. Zheng, C.A. Thomson, Index-based dietary patterns and colorectal cancer risk: a systematic review, Adv. Nutr. 6 (6) (2015) 763–773.
[45] A.L. Gruber-Baldini, C. Velozo, S. Romero, L.M. Shulman, Validation of the PROMIS (R) measures of self-efficacy for managing chronic conditions, Qual. Life Res. 26 (7) (2017) 1915–1924.
[46] E. Thompson, Development and validation of an internationally reliable short-form of the positive and negative affect Schedule (PANAS), J. Cross Cult. Psychol. 38 (2) (2007) 227–242.
[47] D. Watson, L.A. Clark, A. Tellegen, Development and validation of brief measures of positive and negative affect: the PANAS scales, J. Pers. Soc. Psychol. 54 (6) (1988) 1063–1070.
[48] B.J. Weiner, C.C. Lewis, C. Stanick, B.J. Powell, C.N. Dorsey, A.S. Clary, et al., Psychometric assessment of three newly developed implementation outcome measures, Implement. Sci. 12 (1) (2017) 108.
[49] A.V. Bennett, K. Keenoy, M. Shouery, E. Basch, L.K. Temple, Evaluation of mode equivalence of the MSKCC bowel function instrument, LASA quality of life, and subjective significance questionnaire items administered by web, interactive voice response system (IVRS), and paper, Qual. Life Res. 25 (5) (2016) 1123–1130.
[50] J.A. Sloan, A. Dueck, Issues for statisticians in conducting analyses and translating results for quality of life end points in clinical trials, J. Biopharm. Stat. 14 (1) (2004) 73–96.
[51] S. Sheridan, S. Schrandt, L. Forsythe, T.S. Hilliard, K.A. Paez, Advisory panel on patient E. The PCORI engagement rubric: promising practices for partnering in research, Ann. Fam. Med. 15 (2) (2017) 165–170.
[52] M.J. Mohler, S.J. Coons, M.C. Hornbrook, L.J. Herrinton, C.S. Wendel, M. Grant, et al., The health-related quality of life in long-term colorectal cancer survivors study: objectives, methods and patient sample, Curr. Med. Res. Opin. 24 (7) (2008) 2059–2070.
[53] Institute of Medicine, Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis, The National Academies, Washington, DC, 2013.
[54] R.L. Siegel, S.A. Fedewa, W.F. Anderson, K.D. Miller, J. Ma, P.S. Rosenberg, et al., Colorectal cancer incidence patterns in the United States, 1974-2013, J. Natl. Cancer Inst. 109 (8) (2017).
[55] J.M. Lee, S. Pilli, A. Gebremariam, C.C. Keirns, M.M. Davis, S. Vijan, et al., Getting heavier, younger: trajectories of obesity over the life course, Int. J. Obes. 34 (4) (2010) 614–623.
[56] W. Demark-Wahnefried, L.Q. Rogers, C.M. Alfano, C.A. Thomson, K.S. Courneya, J. A. Meyerhardt, et al., Practical clinical interventions for diet, physical activity, and weight control in cancer survivors, CA A Cancer J. Clin. 65 (3) (2015) 167–189.