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SWOG S1820: A Pilot Randomized Trial of the Altering Intake, Managing Bowel Symptoms Intervention in Survivors of Rectal Cancer (AIMS-RC)

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Structured Abstract

Background: Survivors of rectal cancer experience persistent bowel dysfunction following treatments. Dietary interventions may be an effective approach for symptom management and post-treatment diet quality. SWOG S1820 was a pilot randomized trial of the Altering Intake, Managing **S**ymptoms in Rectal Cancer (AIMS-RC) intervention for bowel dysfunction in survivors of rectal cancer.

Methods: Ninety-three post-treatment survivors were randomized to the AIMS-RC group (N=47) or the Healthy Living Education attention control group (N=46), following informed consent and completion of a pre-randomization run-in. Outcomes measures were completed at baseline, 18 and 26 weeks post-randomization. Primary endpoint was total bowel function score, and exploratory endpoints included low anterior resection syndrome (LARS) score, quality of life (QOL), dietary quality, motivation, self-efficacy, and positive/negative affect.

Results: Most participants were White and college educated, with a mean age of 55.2 years and median time since surgery of 13.1 months. There were no statistically significant differences in total bowel function score by group, with the AIMS-RC group demonstrating statistically significant improvements in the exploratory endpoints of LARS (p=0.01) and the frequency subscale of the bowel function index (p=0.03). The AIMS-RC group reported significantly higher acceptability of the study.

Conclusions: SWOG S1820 did not provide evidence of benefit from the AIMS-RC intervention relative to attention control. Select secondary endpoints did demonstrate improvements. The study was highly feasible and acceptable for participants in the National Community Oncology Research Program (NCORP). Findings provide strong support for further refinement and effectiveness testing of the AIMS-RC intervention.

Precis

In this feasibility and preliminary efficacy randomized trial, the AIMS-RC diet modification intervention did not significantly improve total bowel function among survivors of rectal cancer but demonstrated improvements in frequency of bowel movements and low anterior resection syndrome (LARS). SWOG S1820 and the AIMS-RC intervention was highly feasible and acceptable for participants enrolled through the National Community Oncology Research Program (NCORP).

Keywords

rectal cancer; bowel dysfunction; LARS; quality of life

Introduction

Multimodality therapy (chemotherapy/radiation/surgery) has significantly improved long-term survival for men and women with rectal cancer.[1,2] However, long-term treatment effects such as bowel dysfunction are common. For survivors with anastomosis, postoperative bowel dysfunction and the associated constellation of symptoms are known as low anterior resection (LAR) syndrome. Survivors with permanent ostomies also experience poor bowel function. Syndrome characteristics include frequent and erratic bowel movements, fecal incontinence, gas, bloating, and oscillations between diarrhea and constipation.[3–5] Previous research suggests that bowel symptom characteristics vary tremendously, and that 27% to 56% of survivors report moderate to severe bowel dysfunction at 1-year post-treatment.[6,7] Bowel dysfunction results in reduced social activities, poor social well-being, and decrements in quality of life (QOL).[7–11] Additionally, bowel dysfunction is a significant impediment to survivor adoption of dietary guidance for cancer survivorship.[12]

Bowel symptom management is challenging for survivors and oncology care teams, and there is a lack of consensus and evidence-based management guidelines.[13] One promising approach for bowel symptom control is diet modification.[14] In our previous research, diet modification was the most consistently reported self-care strategy used by long-term (>5 years) survivors of rectal cancer.[7] The ability to successfully manage bowel symptoms results in improved QOL; however, the choice of diet modifications varied tremendously, and was often based on a trial-and-error approach without structured coaching that is grounded in theory-based strategies.

To address survivors' unmet bowel symptom management needs, SWOG S1820 was conducted as a pilot randomized trial to assess the preliminary efficacy, feasibility and acceptability of the Altering Intake, Managing Symptoms Intervention in Survivors of Rectal Cancer (AIMS-RC) for the management of post-treatment bowel dysfunction, compared to attention control in 93 survivors with rectal cancer. We hypothesized that survivors randomized to receive AIMS-RC (anastomosis and ostomy) would show improvements in bowel function, LARS score and QOL compared to those receiving attention control. We also hypothesized that the intervention would be feasible and acceptable to participants.

Methods and Methods

Trial Design

The trial protocol has been previously described.[15] SWOG S1820 was a multisite, randomized (1:1), controlled pilot trial of 93 participants assigned to two groups: the AIMS-RC group (intervention) or the Heathy Living Education group (attention control).

Participants and Settings

Eligible survivors had a prior history of cancers of the rectosigmoid colon or rectum; were within 6–24 months of primary treatment completion (including ileostomy reversal); had either a post-surgical permanent ostomy or an anastomosis with LAR syndrome score of 21–42 (minor to major symptoms); were able to read, write and speak English; and were

over 18 years of age. Survivors that were undergoing treatment for a second primary cancer or had a diagnosis of inflammatory bowel disease (ulcerative colitis, Crohn's disease) were excluded.

The trial was conducted through the National Cancer Institute (NCI) Community Oncology Research Program (NCORP) research base of the SWOG Cancer Research Network, an NCI-supported National Clinical Trial Network (NCTN). A total of 39 NCORP/NCTN member institutions (30 community and 9 academic institutions) from 17 states and the U.S. territory of Guam contributed to overall enrollment. At each participating institution, site investigators and site research staff screened and identified eligible survivors that met the trial eligibility criteria. Eligible survivors were met by site research staff at regular clinic visits and consented for participation. The study was approved by the NCI's Cancer Control and Prevention Central Institutional Review Board (CIRB), and all participants provided signed informed consents. Following informed consent, baseline assessments were completed by participants prior to registration.

Pre-Randomization Run-In Activity

Consented participants that completed baseline assessments started a 14-to-21-day run-in period prior to randomization. The run-in activities were designed to evaluate and enhance adherence to the post-randomization study activities. Participants received a run-in packet with instructions, a 3-day food/symptom diary, and a postage-paid envelope to return the diary. Study coordinators from the University of Arizona Cancer Center completed an introductory telephone call within 48 hours of registration. During the call, coordinators instructed participants to complete the 3-day food/symptom diary and return the completed diary to them by mail or email within 7 seven days of completion. Trained research assistants at the Behavior Measurement and Interventions Shared Resource (BMISR) of the University of Arizona Cancer Center also completed the Memorial Sloan-Kettering Bowel Function Instrument (MSK-BFI) questionnaire[16,17] and a 24-hour dietary recall (USDA multi-pass dietary recall methodology) by telephone interview.[18]

Randomization and Group Assignment

Consented participants who did not sufficiently complete the run-in activities did not participate in any further trial activities and were given a resource manual with information on healthy living after cancer treatment. Those who successfully completed all run-in activities were randomized to either the AIMS-RC (intervention) or Healthy Living Education (attention control) arm.

Participants were registered by site staff after consent. The unblinded intervention assignment (AIMS-RC or Healthy Living Education) was computer generated at registration in the SWOG database using a dynamic balancing algorithm[19] to randomly assign participants (1:1) to either AIMS-RC or Healthy Living Education, balancing on sex (female vs. male) and ostomy status (permanent ostomy vs. anastomosis).

Study Conditions

Study arm activities were centrally administered by trained health coaches from the BMISR at the University of Arizona Cancer Center via telephone to all randomized participants nationally. This model has demonstrated efficacy to support dietary behavior change in cancer survivors from across the U.S.[20] The health coaches participated in a 6-week training program on the basics of rectal cancer, cancer survivorship lifestyle guidelines[12], and delivery of the study conditions. Fidelity for both study arms was monitored via audio-recording of sessions; participants provided informed consent for all sessions to be recorded. Continuous fidelity monitoring was initiated through random sampling of 15% of intervention calls in the first week of the study and 3% monthly thereafter. Control calls were monitored at random for 3% of all calls sampled throughout the study.

AIMS-RC Group

AIMS-RC is a social cognitive theory-driven intervention, guided by the Motivation and Problem-Solving (MAPS) model of behavior change.[21–24] The model suggests that even with adequate self-efficacy, an individual may fail to make desired changes without motivation for change.[23] An internal motivational shift may prompt an individual to decide and commit to long-term behavior change.[24] Similarly, in using the MAPS approach, skills training (coping, problem-solving) is systematically added with motivational interviewing, and adjusted based on the individual's level of motivation.

AIMS-RC group participants received ten centrally administered telephone sessions over a 17-week period. The average length of the sessions was 27 minutes (range 4–93 minutes). Prior to session initiation, participants received an AIMS-RC resource manual that was used during the sessions to guide discussions between the health coach and participants. Session 1 began within 10 days of randomization; during this session, the health coach provided an introduction of the overall program and overview of the AIMS-RC resource manual. Throughout the sessions, the health coach considered potential psychosocial dynamics (e.g. employment and impact on eating, eating patterns/preferences, food preferences based on ethnic dietary habits) to personalize the diet behavior change approach.

Session 2 was administered approximately one week following Session 1. Using the food and symptom diary, participants were coached to accurately document their food intake and note any symptoms associated with the foods. SMART (Specific, Measurable, Attainable, Relevant, Timely) goals for diet behavior change in relation to bowel symptom management were identified by the participants.

Sessions 3–6 were weekly calls. During these calls, the health coach reviewed the food/symptom diary and SMART goals with the participants. The diary information was used to guide discussions on the elimination/substitution process of possible troublesome foods for bowel symptoms. The health coach problem-solved with the participant on integration of other symptom management strategies beyond diet modifications (e.g., sitz baths, fiber supplements).

After Session 6, and between each telephone session thereafter, intervention participants received short message service (SMS) text messages or email messages. The messages were

specific to the intervention and designed to support participant-specific bowel symptom management goals. The health coach used the messages to provide support, promote bowel symptom management and diet behavior change, and to sustain participant engagement. Participants received three messages per week after Session 6 through the end of the intervention sessions.

Sessions 7–8 were every other week calls. Here, the health coach focused on reintroducing, on a 3-day schedule, patient-identified foods. The elimination/re-introduction diet process was designed to coach participants on identifying the main food "culprits" that caused bowel symptoms, and provided the skills needed to re-introduce other foods that were tolerable and beneficial. Participants were coached to use problem-solving skills for overcoming diet behavior change challenges. Evidence-based diet recommendations for cancer survivorship were also introduced.

In Sessions 9–10 (monthly calls), the health coach reviewed progress that the participants made and the skills they had gained to re-enforce self-efficacy for long-term application of AIMS-RC. The health coach also revisited the resource manual and reviewed using SMART goals for appropriate diet behavior change.

Additionally, participants received quarterly newsletters during the 17 weeks of telephone sessions. The newsletters were designed to sustain patient engagement. The content varied and contained information to support diet modification skills.

Healthy Living Education Group

The Healthy Living Education (attention control) group participants received 10 centrally administered telephone sessions over 17 weeks. The average length of sessions was 12.5 minutes (range 4–37 minutes). Prior to session initiation, participants received a Health Education resource manual that was used during the sessions to guide discussions between the health coach and participants. Session 1 began within 10 days of randomization. The ten health promotion topics covered national cancer survivorship guidelines on healthy living post-treatment: regular exercise, sun safety, sleep, food safety, skin care, active wear, bone health, clinical trials, online resources, and screening/surveillance. Sessions 2–6 were weekly calls, sessions 7–8 were every other week calls, and sessions 9–10 were monthly calls.

After Session 6, participants received, based on their preference, SMS text messages or email messages with standard information on the 10 healthy living topics; the messaging occurred between scheduled telephone sessions. Participants also received quarterly newsletters during the 17 weeks that contained standard information on the ten healthy living education topics.

Outcome Measures

All participants completed questionnaires at baseline and at weeks 18 (after sessions completion) and 26 weeks post-randomization. Questionnaires were completed at clinic visits, at home by participants, or through phone interviews based on participant preference.

Primary outcome measure

Bowel function was measured by total bowel function score of the Memorial Sloan-Kettering Bowel Function Instrument (BFI). The BFI's total scores range from 18 to 90; higher scores indicate better bowel function. All responses are measured on a 5-point Likert scale, apart from the frequency of bowel movements item.[16,17] There are separate versions for patients with ostomy and anastomosis.[16,17] A newly derived eight-item BFI total score that excludes frequency items was used for analysis of combined ostomy and anastomosis groups.[25]

Exploratory outcome measures

Bowel function subscale scores were measured by the BFI's four-item Dietary subscale (score range of 4–20), a four-item Urgency subscale (4–20), and a 6-item Frequency subscale (6–30); higher scores indicate better bowel function.[16,17] Low anterior resection syndrome (for anastomosis participants only) was measured using the LARS Score, a validated 5-item instrument with score range from 0 to 42 points. Scores were categorized into three groups: no LARS (0–20), minor LARS (21–29), and major LARS (30–42).[26–30] Quality of life was assessed using the City of Hope-Quality of Life-Colorectal Cancer (COH-QOL-CRC) questionnaire, 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).[31] Dietary quality was assessed by the Healthy Eating Index 2015 (HEI-2015).[32,33] Scores were calculated from the repeat dietary recall data and ranged from 0–100 with higher scores indicating higher (better) diet quality.[34–38]

Several potential mediating variable measures were also collected. Motivation was measured using the total score of the adapted version of the Intrinsic and Extrinsic Motivation scale.[39] Items were scored on a 5-point Likert scale, with higher scores indicating higher motivation. Self-efficacy was measured by the 4-item Patient-Reported Outcomes Measurement Information System (PROMIS) Self-Efficacy for Managing Symptoms – Short Form 4a; higher scores indicated greater self-efficacy.[40] Affect was measured using the 10-item International Positive and Negative Affect Schedule Short Form (I-PANAS-SF).[41,42] Scores range from 5 to 25, with higher scores indicating greater positive affect or negative affect.

Feasibility was defined as the percentage of consented participants who successfully completed the run-in period and were randomized. Retention was defined by the percentage of consented participants who completed follow-up assessments after randomization (weeks 18, 26, and dietary recalls). Adherence was defined by the percentage of randomized participants who completed coaching Sessions 1–5 and at least three of Sessions 6–10 within 18 weeks post-randomization. Finally, acceptability was measured for all participants using the Acceptability of Intervention measure (AIM).[43]

Data Analysis

The primary outcome for the trial was the change in bowel function at 18 weeks post-randomization, as measured by the BFI total score. Thirty-seven patients per arm (74 total)

provided 80% power to detect an effect size of 0.5, based on a two-sample t-test with a 1-sided alpha=0.1.[15] We planned to accrue 94 randomized patients to account for 7% ineligibility and 15% attrition at 6 months.

The analysis of the primary endpoint was conducted in all eligible participants randomized to the study with 18-week BFI data regardless of adherence to the coaching calls, according to a modified intention-to-treat principle. Study arm differences in BFI at 18 weeks were assessed by a linear regression model as a function of randomization assignment, BFI baseline value, and stratification factors. Study arm differences in BFI at 26 weeks were also assessed by a linear regression model as a function of randomization assignment, BFI baseline value, and stratification factors.

Other continuous exploratory outcomes at both 18 and 26 weeks (BFI subscales, LARS, quality of life, dietary quality, motivation, self-efficacy, and positive/negative affect) were assessed by a repeated measures linear regression model as a function of randomization assignment, baseline value of the outcome, stratification factors, and visit. Robust standard errors were estimated via generalized estimating equations to adjust for correlation between repeated outcome measures. Study arm differences in adherence and retention were assessed by chi square tests and study program acceptability was compared across arms via t-test.

Results

SWOG S1820 opened to accrual on December 9, 2019, and closed to randomization on April 28, 2022. CONSORT flow diagram is presented in Figure 1. A total of 117 participants were consented to the pre-randomization run-in step. Of those who were consented, 19% (N=22) were ineligible for randomization. Reasons included not completing run-in activities (N=10), consent withdrawal (N=8), treatment less than 6 months prior to registration (N=2), and disease progression (N=2). Out of the 117 participants who registered to the run-in period, 95 were randomized. However, two participants ineligible at run-in were randomized in error. Thus, 93 eligible participants successfully completed the run-in period and were randomized, with 47 allocated to the AIMS-RC (intervention) group and 46 to the Healthy Living Education (attention control) group.

Sample Characteristics

The majority of the 93 participants were female, White, and college educated (Table 1). Most participants in both randomization groups were diagnosed with rectal cancer and underwent low anterior resection (Table 2; Supplement). Most participants, regardless of randomization assignment, reported that they had made some adjustment to their diet post-operatively. There were no significant differences in participant sociodemographic, clinical and treatment characteristics according to randomization assignment.

Primary and Exploratory Outcomes

No statistically significant difference was observed in the primary endpoint of total bowel function score from the BFI at week 18 between the AIMS-RC and Health Living Education groups (Table 3); nor did these scores differ at week 26.

The MSK-BFI frequency subscale score, available in anastomosis participants only, improved significantly more from baseline to week 26 in the AIMS-RC group than in the control group (Table 4). In participants with anastomosis, the AIMS-RC group also showed significantly better improvement on the LARS score from baseline to week 26. There were no significant differences on other MSK-BFI subscales (dietary, urgency), QOL, dietary quality, motivation, self-efficacy, and positive/negative affect.

Feasibility and Acceptability

Overall, feasibility and acceptability for the trial were high, and met the definitions for success (Table 5). Of the 117 consented, 81% (N=95) of participants successfully completed the run-in and were randomized. Demographic characteristics of those enrolling versus those completing run-in suggested the groups were of similar age, sex and educational distribution. More than 95% of participants in both groups completed Sessions 1–5 and at least three of Sessions 6–10 within 18 weeks post-randomization, meeting goals for adherence. For retention, greater than 97% of participants in both groups completed follow-up assessments (at least one PRO or dietary recall) following randomization and at weeks 18 and 26. Finally, acceptability was high for participants at both weeks 18 and 26, with the AIMS-RC group reporting significantly higher acceptability compared to the Healthy Living Education group.

Discussion

The AIMS-RC intervention is one of the first and few to use diet modification for bowel symptom management. Overall, SWOG S1820 was a highly feasible trial, with significantly higher acceptability for the AIMS-RC intervention compared to the attention control. While we did not observe a significant change in the primary endpoint of total bowel function score by group, we did observe significant differences in two exploratory outcomes, the frequency subscale of the MSK-BFI and the LARS score. Of note, these questionnaire items were completed by participants with anastomosis only, which made up 84% of the study population. The significant difference observed in the frequency subscale may be due to the high number of bowel movements, which is a common bowel symptom characteristic for LARS. Recent reported findings from the PROSPECT trial that compared neoadjuvant fluorouracil and oxaliplatin (FOLFOX) to the North American standard of neoadjuvant pelvic chemoradiation with fluorouracil (5FUCRT) found that preop FOLFOX was noninferior to chemoradiotherapy in clinical outcomes.[44] Patients in the neoadjuvant FOLFOX arm reported lower rates of diarrhea and overall bowel function during treatment, but symptoms did not vary by arm after surgery.[45] The potential changes in rectal cancer treatment based on PROSPECT trial findings may impact characteristics of acute bowel function impairments, and future studies should address the impact of neoadjuvant treatment regimen on bowel symptom severity.

The inclusion of survivors that were 6–24 months post-primary treatment completion (including anastomosis surgery) may have resulted in a wide range of bowel function adjustments among participants. While the eligibility criteria for anastomosis participants included a report of minor or major LARS, there was no comparable criterion for ostomy

participants. Thus, may have been less consistency in the initial level of comfort and adjustment to bowel dysfunction among the latter group. Future studies may consider moving the AIMS-RC intervention closer to treatment completion when bowel dysfunction may still be relatively new to survivors. Previous research suggests that survivors may desire bowel symptom management support soon after treatment completion.[46] Additionally, the run-in protocol for diet tracking may have increased awareness of diet modification for bowel symptom control for all participants prior to randomization resulting in modest increases in scores on the MSK-BFI score in both groups over time (Table 3).

The behavioral constructs used in the AIMS-RC intervention (MAPS with motivational interviewing, goal setting, problem solving) had minimal impact on supporting participants in modifying their diet for bowel control. Future studies should more purposefully address the use of these behavioral constructs for health coaching and diet modifications. In terms of diet quality, the scores overall were worse than those reported on other cancer survivorship populations, although there were some improvements seen in both groups, with slightly greater improvements in the intervention group. Future studies may consider increasing the timing and dose of the AIMS-RC intervention (e.g., more sessions over a longer time). Healthy eating coaching can be introduced in earlier sessions and balanced with diet changes for symptom management to achieve higher, more sustainable effects on bowel control and diet quality.

This study had several strengths that can guide the design of future trials. First, the use of an attention control condition with balanced treatment contact and encounters helped provided a clearer test of the hypothesized active ingredient of the AIMS-RC intervention. Second, the inclusion of a run-in step helped with assessing level of adherence to the intervention activities and likely contributed to high feasibility and retention rates. The study is limited by its relatively small sample size, although the study was powered appropriately for a randomized pilot trial. The study did not enroll a racially or economically diverse population, but the overall cohort was evenly distributed with regards to sex; future studies should incorporate more effective and intentional strategies to ensure recruitment of a more representative population. This assessment of the AIMS-RC intervention was an important first step in determining the feasibility and acceptability of diet behavioral change strategies for bowel symptom management for post-treatment survivors of rectal cancer.

In conclusion, SWOG S1820 and the AIMS-RC intervention were highly feasible and acceptable for participants in the NCORP setting, with improvements in LARS and frequency of bowel function. The lessons learned from this multisite pilot randomized trial will help with further refinement of the AIMS-RC intervention and contribute to the design of evidence-based interventions for rectal cancer survivorship and Phase III effectiveness trials. Specific refinements include focusing on anastomosis patients, increasing the dose (number of calls) of the intervention, and increasing specific emphasis on healthy eating during coaching sessions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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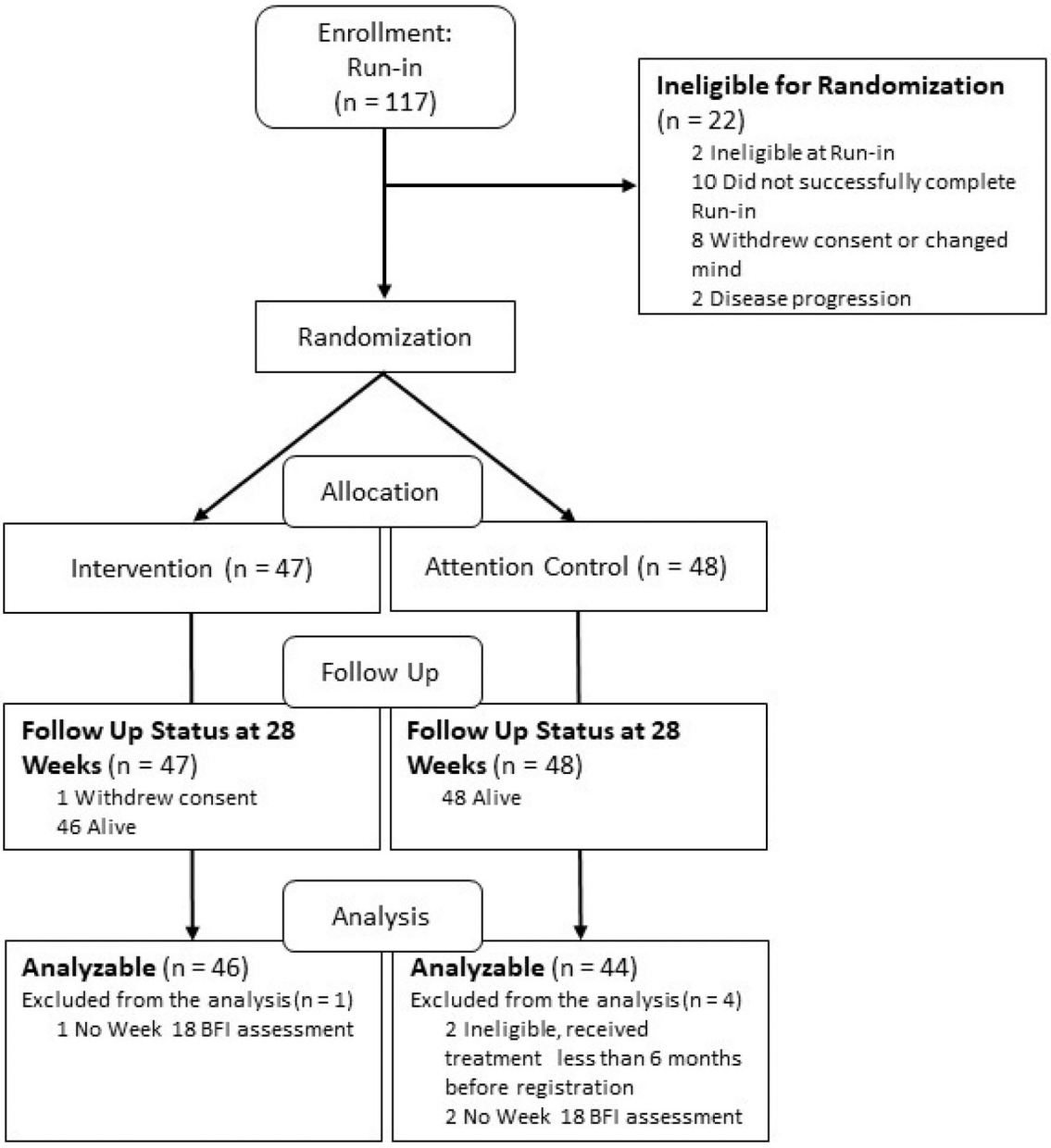

Figure 1.
CONSORT flow diagram for enrollment, assignment to study conditions, follow-up status, and primary analysis.

Table 1.

Baseline sociodemographic and health status characteristics

Characteristic	Intervention N=47 n (%)	Attention Control N=46 n (%)
Age		
Median (range)	54.6 (30.3, 81.2)	56.9 (26.7, 86.7)
Sex		
Female	27 (57)	24 (52)
Male	20 (43)	22 (48)
Race		
American Indian/Alaska Native	2 (4)	2 (4)
Asian	4 (9)	3 (7)
Black or African American	1 (2)	1 (2)
Native Hawaiian or other Pacific Islander	0 (0)	1 (2)
Unknown	2 (4)	0 (0)
White	38 (81)	39 (85)
Ethnicity		
Hispanic	3 (6)	4 (9)
Non-Hispanic	42 (89)	40 (87)
Unknown	2 (4)	2 (4)
Highest level of education		
Did not complete high school	2 (4)	0 (0)
Completed high school/ GED/ vocational/ secretarial/ business	7 (15)	10 (22)
Any college	23 (49)	24 (52)
Any graduate school	15 (32)	12 (26)
Body Mass Index (BMI)		
Median (range)	27.3 (17.1, 52.3)	27.6 (19.1, 66.3)
<18.5 (Underweight)	2 (4)	0 (0)
18.5 - <25 (Normal weight)	13 (28)	12 (26)
25 - <30 (Overweight)	16 (34)	18 (39)
>=30 (Obese)	16 (34)	16 (35)
Smoking status		
Current	1 (2)	1 (2)
Former	9 (19)	15 (33)
Never	35 (74)	28 (61)
Unknown	2 (4)	2 (4)
Current marital status		
Divorced	7 (15)	6 (13)
Married or partnered	34 (72)	31 (67)
Single	5 (11)	7 (15)

Characteristic	Intervention N=47 n (%)	Attention Control N=46 n (%)
Widowed	1 (2)	2 (4)
Any change in marital status since diagnosis		
Yes	1 (2)	5 (11)
No	46 (98)	41 (89)
Adjusted diet because of surgery/ostomy		
Yes	35 (74)	35 (76)
No	12 (26)	11 (24)
Time to comfort with diet after your surgery/ostomy		
Less than 1 month	6 (13)	6 (13)
1 to 12 months	15 (32)	12 (26)
More than 12 months	3 (6)	3 (7)
I am still not comfortable	22 (47)	25 (54)
Not answered	1 (2)	0 (0)

Table 2.

Baseline clinical and treatment characteristics

Characteristic	Intervention N=47 n (%)	Attention Control N=46 n (%)
Time since diagnosis (months)		
Median (range)	23.6 (8.1, 56.7)	22.3 (10.5, 36.0)
Type of cancer		
Rectal	39 (83)	38 (83)
Rectosigmoid colon	8 (17)	7 (15)
Other	0 (0)	1 (2)
Prior treatments		
Any chemotherapy	41 (87)	42 (91)
Any radiation therapy	33 (70)	38 (83)
Prior surgery related to this cancer		
Anastomosis	24 (51)	16 (35)
Ostomy	6 (13)	9 (20)
Temporary ostomy and re-anastomosis	17 (36)	21 (46)
Time since surgery (months)		
Median (range)	15.9 (6.2, 51.9)	13.6 (6.4, 29.7)
Type of low anterior resection surgery		
Abdominoperineal resection	5 (11)	10 (22)
Low anterior resection	42 (89)	34 (74)
Sigmoid colectomy	0 (0)	2 (4)
LAR syndrome (LARS) burden[1]		
Minor LARS	6 (15)	6 (16)
Major LARS	35 (85)	31 (84)
Not applicable, ostomy	6	9
Zubrod performance status		
0	37 (80)	31 (69)
1	8 (17)	14 (31)
2	1 (2)	0 (0)
Missing	1	1
Current medications		
Antibiotics	0 (0)	2 (4)
Antidiarrheal medications	15 (32)	13 (28)
Medications for constipation	11 (23)	10 (22)
Probiotics	11 (23)	7 (15)
Used meditation, mindfulness therapy, acupuncture or other alternative therapies for bowel issues in past 5 months		
Yes	5 (11)	4 (9)

Characteristic	Intervention N=47 n (%)	Attention Control N=46 n (%)
No	42 (89)	42 (91)

[1] LAR = Lower Anterior Resection. Valid for anastomosis patients only. Score range 0–42: No LARS (0–20), Minor LARS (21–29), Major LARS (30–42).

Table 3.

MSK-BFI [1] Total Bowel Function Instrument Score

	Intervention		Attention Control		
	N	Mean (95% CI)	N	Mean (95% CI)	p-value [2]
Baseline	47	28.6 (26.9, 30.3)	46	28.4 (26.5, 30.3)	
Week 18	46	30.8 (29.2, 32.4)	44	29.5 (27.3, 31.7)	0.31
Week 26	44	30.3 (28.6, 32.1)	43	29.8 (28.0, 31.8)	0.84

CI, confidence interval

[1] MSK-BFI = Memorial-Sloan Kettering Bowel Function Instrument. Score range 18–90. Higher scores indicate better bowel function.

[2] p-value from comparison of intervention vs control in a linear regression model of outcome as a function of randomization assignment, baseline value of the outcome measure, sex and ostomy status.

Table 4.

Exploratory Outcomes

	Intervention		Attention Control		
	N	Mean (95% CI)	N	Mean (95% CI)	p-value *[1]*
Total BFI					
Baseline	47	28.6 (26.9, 30.3)	46	28.4 (26.5, 30.3)	
Week 18	46	30.8 (29.2, 32.4)	44	29.5 (27.3, 31.7)	
Week 26	44	30.3 (28.6, 32.1)	43	29.8 (28.0, 31.8)	0.37
BFI Dietary					
Baseline	47	13.9 (13.0, 14.8)	46	13.3 (12.3, 14.3)	
Week 18	46	14.7 (13.8, 15.6)	44	13.8 (12.7, 15.0)	
Week 26	44	14.4 (13.4, 15.3)	43	14.1 (13.0, 15.1)	0.62
BFI Urgency					
Baseline	47	14.7 (13.6, 15.9)	46	15.0 (13.9, 16.3)	
Week 18	46	16.1 (15.1, 17.2)	44	15.7 (14.4, 17.0)	
Week 26	44	15.9 (14.8, 17.1)	43	15.7 (14.5, 16.9)	0.07
BFI Frequency (anastomosis only)					
Baseline	41	18.6 (17.5, 19.8)	37	19.3 (18.4, 20.3)	
Week 18	40	20.8 (19.4, 22.2)	36	20.2 (19.0, 21.4)	
Week 26	38	20.9 (19.4, 22.3)	36	20.0 (18.7, 21.3)	0.03
LARS Score (anastomosis only)					
Baseline	41	35.9 (34.3, 37.4)	37	35.4 (33.7, 37.2)	
Week 18	37	29.7 (26.3, 33.0)	36	32.8 (30.4, 35.3)	
Week 26	36	28.7 (25.5, 31.9)	35	32.9 (30.6, 35.2)	0.01
Quality of Life					
Baseline	47	6.4 (5.9, 6.9)	46	6.4 (6.0, 6.8)	
Week 18	44	6.9 (6.4, 7.4)	44	6.8 (6.3, 7.2)	
Week 26	42	7.2 (6.8, 7.7)	44	6.7 (6.3, 7.1)	0.09
Dietary Quality (HEI)					
Baseline	46	48.6 (44.4, 52.8)	46	49.2 (44.6, 53.9)	
Week 18	43	52.6 (48.4, 56.9)	43	51.4 (47.3, 55.5)	
Week 26	41	55.1 (50.8, 59.5)	38	52.0 (46.8, 57.2)	0.50
Motivation					
Baseline	47	32.2 (29.7, 34.7)	46	34.2 (31.7, 36.8)	
Week 18	44	30.5 (27.9, 33.1)	44	31.8 (29.3, 34.4)	
Week 26	42	30.9 (28.1, 33.7)	44	31.4 (29.3, 33.5)	0.76
Self-Efficacy					
Baseline	47	43 (41, 46)	46	44 (42, 46)	
Week 18	44	47 (45, 49)	44	46 (44, 48)	

	Intervention		Attention Control		
	N	**Mean (95% CI)**	**N**	**Mean (95% CI)**	**p-value** [1]
Week 26	42	49 (47, 51)	44	48 (46, 50)	0.19
Positive Affect					
Baseline	47	18.1 (17.1, 19.1)	46	18.0 (16.9, 19.2)	
Week 18	44	18.2 (17.1, 19.3)	44	18.3 (17.1, 19.4)	
Week 26	42	19.1 (18.1, 20.1)	44	18.6 (17.7, 19.5)	0.76
Negative Affect					
Baseline	47	9.9 (8.6, 11.3)	46	10.2 (8.9, 11.6)	
Week 18	44	8.7 (7.6, 9.8)	44	9.2 (8.1, 10.2)	
Week 26	42	8.2 (7.1, 9.3)	44	9.3 (8.1, 10.4)	0.28

CI, confidence interval; BFI, Bowel Function Instrument; LARS, Lower Anterior Resection Syndrome

[1] p-values from comparison of intervention vs control in a repeated measures linear regression model of outcome as a function of randomization assignment, baseline value of the outcome measure, visit week (categorical), sex and ostomy status.

Table 5.

Trial adherence, retention, and acceptability

	Intervention		Attention Control		
	N	**%**	**N**	**%**	**p-value** *[1]*
Adherence	46	97.9%	44	95.7%	0.98
Retention					
Week 18	46	97.9%	45	97.8%	0.99
Week 26	46	97.9%	45	97.8%	0.99
	N	**Mean (95% CI)**	**N**	**Mean (95% CI)**	**p-value** *[2]*
Acceptability					
Week 18	43	4.7 (4.4, 4.9)	44	4.1 (3.9, 4.3)	< 0.001
Week 26	42	4.7 (4.5, 4.8)	44	4.1 (3.9, 4.3)	< 0.001

CI, confidence interval

[1] p-value from comparison of intervention vs control in adherence and retention from chi square tests.

[2] p-value from comparison of intervention vs control in acceptability from a t-test.