Pilot study confirms feasibility, acceptability of bowel symptom intervention studies

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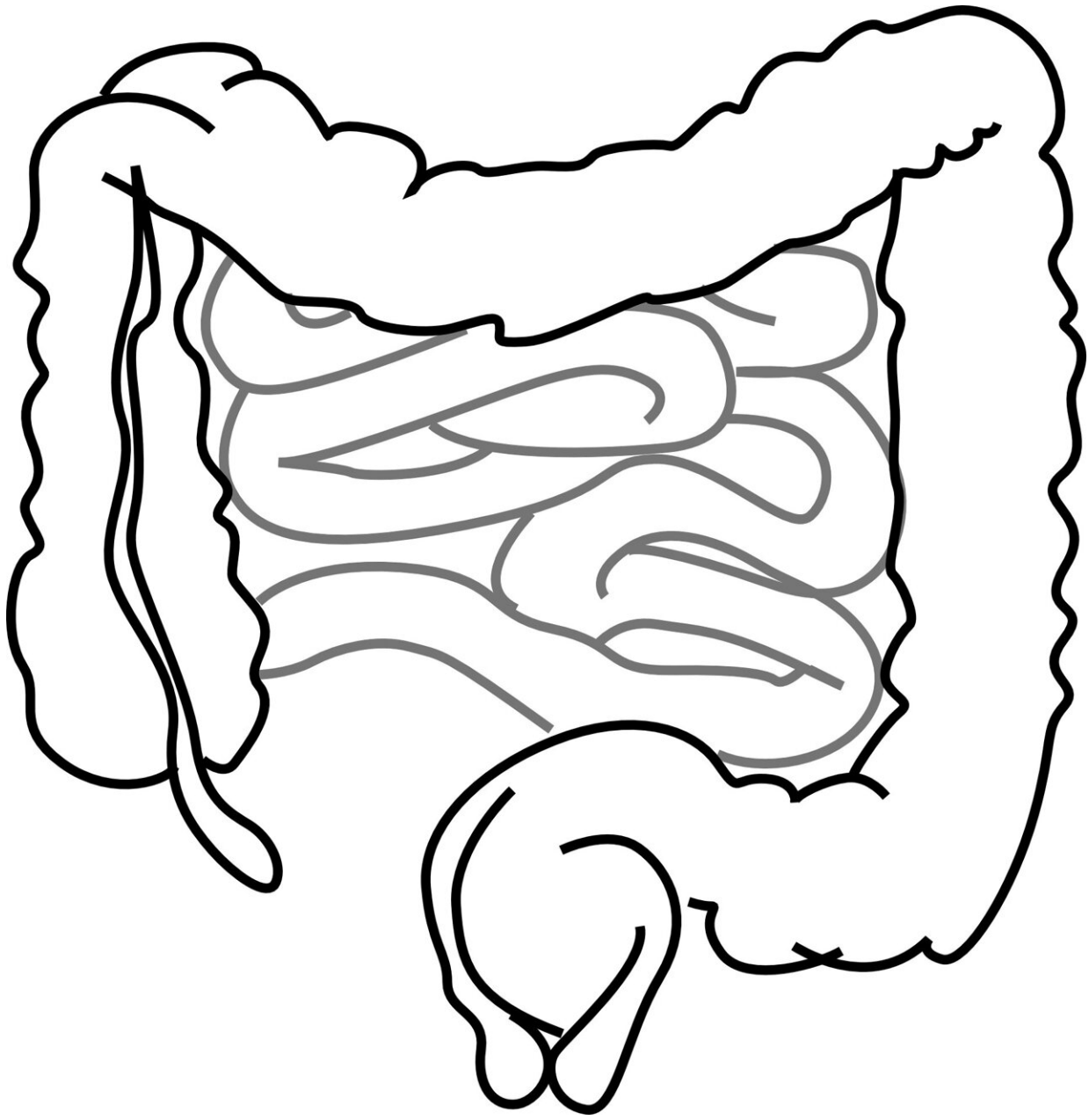

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In a pilot study, a telephone-based dietary intervention designed to improve bowel function was shown to be widely acceptable to participants who had had surgery for rectal cancer. The intervention did not significantly improve overall bowel function in these participants, but it did provide some benefit, and the pilot demonstrated that it is feasible to conduct large studies of such approaches.

Results are being reported in the journal *Cancer* and are expected to help guide the course of future research into approaches to improving bowel function in survivors of colorectal cancers.

The randomized phase 2 study, known as S1820, was led by the SWOG Cancer Research Network, and it was conducted through the NCI Community Oncology Research Program (NCORP).

Principal investigator on the trial was Virginia Sun, Ph.D., MSN, RN, a SWOG investigator who is professor in the Department of Population Sciences and the Department of Surgery at City of Hope, a cancer research and treatment organization.

"Beyond preliminary efficacy, we sought to assess if a single institution like City of Hope and collaborators could leverage national infrastructure such as NCORP to deliver behavioral interventions that patients could accept, thus transforming everyday life choices and improving quality of life," Sun said.

"We succeeded in meeting the acceptability endpoint. The results provide foundational understanding that will help clinicians and

researchers think about how to continue to improve the lives of people who have had rectal cancer surgery. The next step is to secure funding to conduct a definitive phase 3 trial."

Many people who undergo surgery for rectal cancer subsequently experience persistent bowel dysfunction. This can include frequent, erratic bowel movements and difficulty maintaining bowel control, often accompanied by symptoms such as gas, bloating, and alternating diarrhea and constipation.

These symptoms can limit survivors' social activities and have a negative impact on their quality of life overall.

In an attempt to ease their symptoms, survivors often adjust their dietary intake, but they most often do this with minimal guidance from health care providers, in part because there are few evidence-based interventions available to guide oncology care teams working with these survivors.

Sun and her team developed a conceptually driven intervention to help survivors better control their bowel symptoms through dietary management—the Altering Intake, Managing Symptoms for Survivors of Rectal Cancer, or AIMS-RC, intervention. In S1820, this intervention was administered through 10 telephone sessions between survivors and trained health coaches, spread over a four-month period. Among other components, the sessions incorporated the use of a food and symptom diary to help participants see the relationship between the foods they ate and their bowel symptoms.

The calls were conducted by a centralized team of health coaches based at the University of Arizona Cancer Center's Behavioral Measurement and Interventions Shared Resource. Delivering the intervention centrally eased the workload on clinical sites and helped ensure the intervention

was applied consistently from participant to participant.

For the trial's control arm, the team developed a Healthy Living Education attention control condition. Participants on this arm received information on a range of topics related to cancer survivorship and also had 10 telephone sessions with health coaches over four months.

The study included a two- to three-week run-in period designed to evaluate and enhance participant adherence to the study activities and to promote participant engagement. During the run-in, participants completed a three-day food and symptom diary and had an introductory phone call with a study coordinator.

This run-in was essential in helping researchers assess the feasibility of the study by measuring the percentage of consented participants who successfully completed the run-in period and could then be randomized to one of the study arms.

The S1820 study enrolled 117 participants who had undergone surgery for rectal cancer within the previous six to 24 months. Of these, 95 (81%) completed the run-in step, and 93 eligible participants were randomized to either the AIMS-RC intervention or the Healthy Living Education attention control.

The primary efficacy endpoint in S1820 was total bowel function as measured on the Memorial Sloan Kettering Cancer Center Bowel Function Index (BFI), assessed at 18 weeks and 26 weeks after randomization. The researchers did not see a statistically significant difference in this measure between the two arms.

They did, though, observe statistically significant improvements in two exploratory measures—frequency of bowel movement and participants' lower anterior resection syndrome (LARS) score. These two measures

applied only to the 84% of participants whose surgery had included an anastomosis—that is, a reconnection of the healthy sections of their colon after the cancerous portion had been removed (the remaining participants had undergone a colostomy, with their colon connected to an opening created to outside the body).

The researchers found no significant differences between arms in measures of participants' quality of life, dietary quality, motivation, self-efficacy, or positive/negative affect, but they did find that the AIMS-RC group reported significantly higher acceptability of the study.

In addition to confirming the feasibility of such a study and the acceptability of the intervention among participants, S1820 also demonstrated it was possible to rapidly accrue to these trials, enrolling 117 participants in just over two years.

The results are expected to help guide the development of larger trials designed to give more definitive answers about the efficacy of this and other interventions meant to alleviate such symptoms in cancer survivors.

More information: Virginia Sun et al, SWOG S1820: A pilot randomized trial of the Altering Intake, Managing Bowel Symptoms Intervention in Survivors of Rectal Cancer, *Cancer* (2024). DOI: 10.1002/cncr.35264

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