



## Effects of a perioperative geriatric intervention for older adults with Cancer: A randomized clinical trial



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### ARTICLE INFO

#### Article history:

Received 31 July 2021

Received in revised form 27 November 2021

Accepted 3 January 2022

Available online 21 January 2022

#### Keywords:

Geriatric oncology

Surgical oncology

Health care delivery

Perioperative care

Randomized controlled trial

Cancer

### ABSTRACT

**Background:** Older adults with gastrointestinal cancers undergoing surgery often experience poor outcomes, such as prolonged postoperative hospital length of stay (LOS), intensive care unit (ICU) use, hospital readmissions, and complications. Involvement of geriatricians in the care of older adults with cancer can improve outcomes. We conducted a randomized trial of a perioperative geriatric intervention (PERI-OP) in older patients with gastrointestinal cancer undergoing surgery.

**Methods:** From 9/2016–4/2019, we randomly assigned patients age  $\geq 65$  with gastrointestinal cancer planning to undergo surgical resection to receive PERI-OP or usual care. Patients assigned to PERI-OP met with a geriatrician preoperatively in the outpatient setting and postoperatively as an inpatient consultant. The primary outcome was postoperative hospital LOS. Secondary outcomes included postoperative ICU use, 90-day hospital readmission rates, and complication rates. We conducted intention-to-treat (ITT) and per-protocol (PP) analyses.

**Results:** ITT analyses included 137/160 patients who underwent surgery (usual care = 68/78, intervention = 69/82). PP analyses included the 68 usual care patients and the 30/69 intervention patients who received the preoperative and postoperative intervention components. ITT analyses demonstrated no significant differences between intervention and usual care in postoperative hospital LOS (7.23 vs 8.21 days,  $P = 0.374$ ), ICU use (23.2% vs 32.4%,  $P = 0.257$ ), 90-day hospital readmission rates (21.7% vs 25.0%,  $P = 0.690$ ), or complication rates (17.4% vs 20.6%,  $P = 0.668$ ). In PP analyses, intervention patients had shorter postoperative hospital LOS (5.90 vs 8.21 days,  $P = 0.024$ ), but differences in ICU use (13.3% vs 32.4%,  $P = 0.081$ ), 90-day hospital readmission rates (16.7% vs 25.0%,  $P = 0.439$ ), and complication rates (6.7% vs 20.6%,  $P = 0.137$ ) remained non-significant. **Conclusions:** In this randomized trial, PERI-OP did not have a significant impact on postoperative hospital LOS, ICU use, hospital readmissions, or complications. However, the subgroup who received PERI-OP as planned experienced encouraging results. Future studies of PERI-OP should include efforts, such as telehealth, to ensure the intervention is delivered as planned.

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### 1. Introduction

Cancer is a disease of aging, with the majority of new cancer diagnoses and deaths occurring in adults age 65 and older [1,2]. Importantly,

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although surgical resection generally represents the only curative approach for most cancers, older patients are less likely to receive surgery, and those who do undergo resection experience worse postoperative outcomes compared with younger patients [3–10]. Gastrointestinal cancers, including pancreatic, colorectal, esophageal, and gastric cancers, are among the most prevalent cancer diagnoses in older adults, and the surgeries for these cancers represent some of the most challenging procedures with the greatest risk of adverse postoperative outcomes in the geriatric oncology population [10–14]. These unfavorable results are likely related to not only the inherent risk of these invasive procedures but also older patients' complex geriatric issues, such as comorbid conditions, polypharmacy, malnutrition, inadequate social support, and impaired mental and physical function [2–7,11]. Thus, older adults with gastrointestinal cancer would benefit from perioperative interventions targeting their unique geriatric needs.

Guidelines from prominent international organizations emphasize the need to integrate geriatric evaluation and management perioperatively for older adults with cancer undergoing surgery [15–18]. Despite these guidelines, interventions targeting the comprehensive geriatric needs of older patients with cancer have not been routinely incorporated into their perioperative care [19,20]. Importantly, evidence suggests that older adults can have favorable surgical outcomes [5,14,21,22], but clinicians must vigilantly evaluate and manage these patients' geriatric issues both pre- and post-operatively, which rarely occurs in routine care [15–17,23]. Geriatricians are uniquely poised to improve surgical outcomes in geriatric oncology by addressing older patients' complex needs (e.g., comorbidity, functional impairment, and social support) and targeting modifiable factors (e.g., polypharmacy, malnutrition, and symptom burden) [23–26]. Evidence from the orthopedic surgery literature has demonstrated that integrating geriatricians into the perioperative care of older adults leads to shorter hospital length of stay (LOS), fewer surgical complications, and lower readmission rates [27–34]. However, efforts to effectively incorporate geriatricians into the perioperative care of older patients with cancer are lacking and further research evaluating the impact of perioperative geriatric interventions is critically needed.

In the current study, we sought to assess the effects of a perioperative geriatric intervention called “Perioperative Intervention for Older Patients (PERI-OP)” on postoperative outcomes in older adults with gastrointestinal cancer undergoing surgery. We hypothesized that patients assigned to PERI-OP would experience shorter postoperative hospital LOS (primary outcome) and lower rates of intensive care unit (ICU) admissions, hospital readmissions, and surgical complications compared with those assigned to usual care.

## 2. Materials and methods

### 2.1. Study design and procedures

From 9/13/2016–4/30/2019, we enrolled patients at Massachusetts General Hospital (MGH) in a nonblinded, randomized trial of a perioperative geriatric intervention (PERI-OP) versus usual care (ClinicalTrials.gov identifier NCT02810652). Trained study staff identified and recruited consecutive patients throughout the study period by monitoring the oncology and surgery clinic schedules for patients planning to receive surgical resection at MGH. Following written informed consent, study staff asked patients to complete baseline study measures. After patients completed baseline study measures, the Office of Data Quality randomly assigned patients in a 1:1 fashion to receive PERI-OP or usual care via permuted blocks with random block sizes of two and four, stratified by cancer type (e.g., pancreas, esophageal, gastric, rectal, colon, hepatobiliary). The Dana-Farber/Harvard Cancer Center Institutional Review Board approved the study protocol.

### 2.2. Participants

Eligible patients included those age  $\geq 65$ ; diagnosed with pancreatic, gastric/esophageal, colon/rectal, or hepatobiliary cancer; planning to

receive surgical resection at MGH (curative or palliative resections); and able to read and respond to questions in English. We excluded patients who were already receiving geriatrician services and those with significant psychiatric or other comorbid condition, which the treating clinician believed would prohibit informed consent or participation in the study.

### 2.3. Perioperative intervention for older patients (PERI-OP)

We developed PERI-OP based on a conceptual model for delivering geriatric oncology care, with a focus on the distinct perioperative needs of older adults with cancer [20,35,36]. Patients assigned to PERI-OP received referral to a geriatrician preoperatively as a single outpatient visit and postoperatively the geriatrician served as an inpatient consultant (Fig. 1). We provided the geriatricians with templated notes for documenting study visits in the electronic health record (EHR), which included topics focused on geriatric domains. Specifically, we instructed the geriatricians to assess and address patients' comorbid conditions, complex medication regimens, nutritional needs, physical and mental function, social support, symptom management, and delirium risk-reduction strategies. After the visit, the geriatricians communicated (either in-person or via phone/email) their findings with the surgical/oncology teams. Following surgery, the geriatricians provided inpatient consultative care and communicated their findings and recommendations with the inpatient team. The geriatricians' postoperative care focused on addressing comorbid conditions and complications,

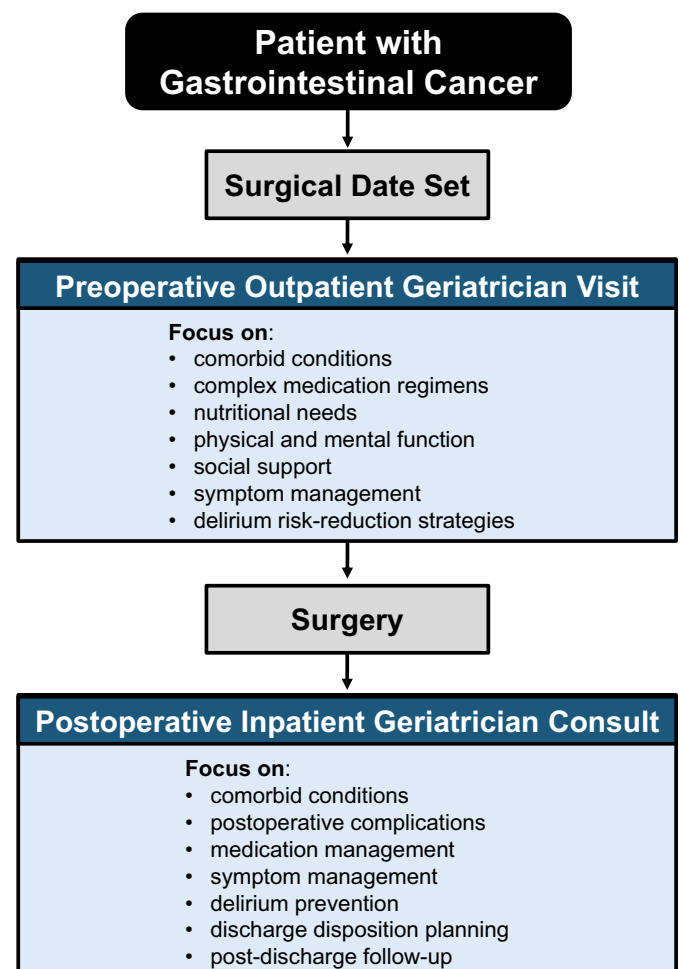


Fig. 1. Perioperative geriatric intervention (PERI-OP).

managing medications, treating symptoms, preventing delirium, and planning appropriate discharge and follow-up.

#### 2.4. Usual care

Participants receiving usual care could meet with a geriatrician upon request. However, no patients receiving usual care ultimately chose to meet with a geriatrician. All patients, regardless of group assignment, continued to receive routine perioperative care throughout the study period.

#### 2.5. Study measures

##### 2.5.1. Sociodemographic and clinical characteristics

Participants completed baseline study measures prior to randomization. To describe participant characteristics, we asked patients to self-report their sex, race, ethnicity, relationship status, employment, education, annual income, and comorbid conditions. We obtained information about participants' age, surgery, and cancer from the EHR.

##### 2.5.2. Postoperative outcome measures

Nonblinded study staff obtained data from the EHR regarding patients' postoperative hospital LOS (primary outcome), ICU admissions, hospital readmissions, and surgical complications. For postoperative LOS, we determined the number of days of patients' hospital admission for surgery. For ICU admissions and hospital readmissions, we tracked rates of admission to the ICU (during hospital admission for surgery) and hospital readmissions (90-days postoperatively). For surgical complications, a trained study physician used the Clavien-Dindo classification to assess postoperative complications [37,38]. The Clavien-Dindo classification categorizes surgical complications from grade I to V, with higher grades indicating more severe complications, and prior work has classified grades of III and above as major complications [37].

#### 2.6. Statistical analysis

The primary outcome was postoperative hospital LOS. We chose this as our primary outcome, as postoperative length of stay is meaningful to patients, clinicians, and health systems as a key measure of patients' postoperative recovery [39–42]. Based on prior work of perioperative geriatric interventions, we estimated that with 160 patients, our current study would have 80% power to detect a 2-day difference in postoperative hospital LOS between study groups (with  $P < 0.05$ ) [19,28]. To examine differences in postoperative LOS, we used independent-samples *t*-tests. For all outcomes, we conducted intention-to-treat and unplanned (exploratory) per-protocol analyses. To compare differences in the rates of postoperative ICU admissions, readmissions, and major complications, we used Fisher exact tests. We did not employ imputation or multiple testing correction, as these were secondary/exploratory outcomes.

### 3. Results

#### 3.1. Participant characteristics

We enrolled and randomized 160 patients (72.4% of patients approached, Fig. 2). Table 1 displays baseline characteristics. Patients had a median age of 72.0 years (range: 65.0–92.0), and the majority were white (91.3%), male (59.4%), married (71.9%), and retired (66.9%). The most common cancer type was pancreatic (54.4%), followed by gastric/esophageal (20.0%), colon/rectal (17.5%), and hepatobiliary (8.1%). At baseline, the majority of patients (53.1%) reported at least one comorbid condition.

#### 3.2. PERI-OP intervention delivery

The intention-to-treat analyses included 137/160 (85.6%) patients who underwent surgery (usual care = 68/78, PERI-OP = 69/82). The per-protocol analyses included all 68 usual care patients and the 30/69 (43.5%) intervention patients who received the planned pre- and post-operative components of PERI-OP. Patients who did not receive PERI-OP per-protocol all missed the preoperative outpatient geriatrician visit (patients who did not attend the preoperative visit were still able to receive the postoperative care). Most of the geriatrician visits included assessment(s) of patients' physical function (95.7%), cognition (92.6%), social support (90.4%), medication regimen (88.3%), advance care planning (88.3%), nutritional needs (87.2%), psychological history (86.2%), and frailty (85.1%). Recommendations from the geriatricians commonly focused on physical function (91.5%), cognition and delirium risk-reduction strategies (89.4%), comorbid conditions (84.0%), symptom management (81.9%), and nutritional needs (36.2%). We found no significant differences in age, sex, and race for the PERI-OP patients who did and did not receive the intervention per-protocol, but patients who received the intervention per-protocol were significantly more likely to be college graduates and had lower rates of heart failure (Supplemental Table 1).

#### 3.3. Postoperative outcomes

Overall, the mean postoperative hospital LOS was  $7.72 \pm 6.37$  days, with 38.0% of patients staying  $\geq 7$  days. Over one-fourth (27.7%) had a postoperative ICU admission, 23.4% were readmitted within 90 days, and 19.0% experienced a major postoperative complication.

In the intention-to-treat analyses, we found no significant differences between intervention and usual care patients for the primary outcome of postoperative hospital LOS (7.23 vs 8.21 days,  $P = 0.374$ ) (Table 2). Additionally, we found no significant differences in the rates of postoperative ICU admissions (23.2% vs 32.4%,  $P = 0.257$ ), 90-day readmissions (21.7% vs 25.0%,  $P = 0.690$ ), or major complications (17.4% vs 20.6%,  $P = 0.668$ ).

In the per-protocol analyses, intervention patients had shorter postoperative hospital LOS (5.90 vs 8.21 days,  $P = 0.024$ ) (Table 2). Study groups did not differ significantly in the rates of postoperative ICU admissions (13.3% vs 32.4%,  $P = 0.081$ ), 90-day readmissions (16.7% vs 25.0%,  $P = 0.439$ ), or major complications (6.7% vs 20.6%,  $P = 0.137$ ).

### 4. Discussion

In this randomized trial of older adults with gastrointestinal cancer undergoing surgery, PERI-OP did not have a significant impact on patients' postoperative hospital LOS, ICU admissions, hospital readmissions, or major complications. However, the subgroup of patients who received the intervention as planned experienced encouraging results related to their postoperative hospital LOS. Notably, over half of patients assigned to PERI-OP missed the planned preoperative outpatient visit, likely due to the burden of an added clinic visit. Thus, our findings highlight the need for future studies of PERI-OP to include efforts, such as telehealth, that help to ensure the intervention is delivered as planned.

We found that PERI-OP did not achieve significant effects on our primary outcome in the intention-to-treat analyses, potentially related to implementation challenges. Specifically, the lack of an intervention effect may have resulted from the fact that many patients could not attend the preoperative geriatrician visit, as the added trip to clinic created a barrier to participation. We worked to schedule study visits at convenient times for patients, but with the profound illness severity of our study population, extra clinic visits can represent a considerable barrier to participation [43,44]. Implementation challenges often decrease the impact of the results seen in multicomponent intervention studies, with common issues including difficulties related to the added burden of study visits, the complexities of study procedures, and inadequate

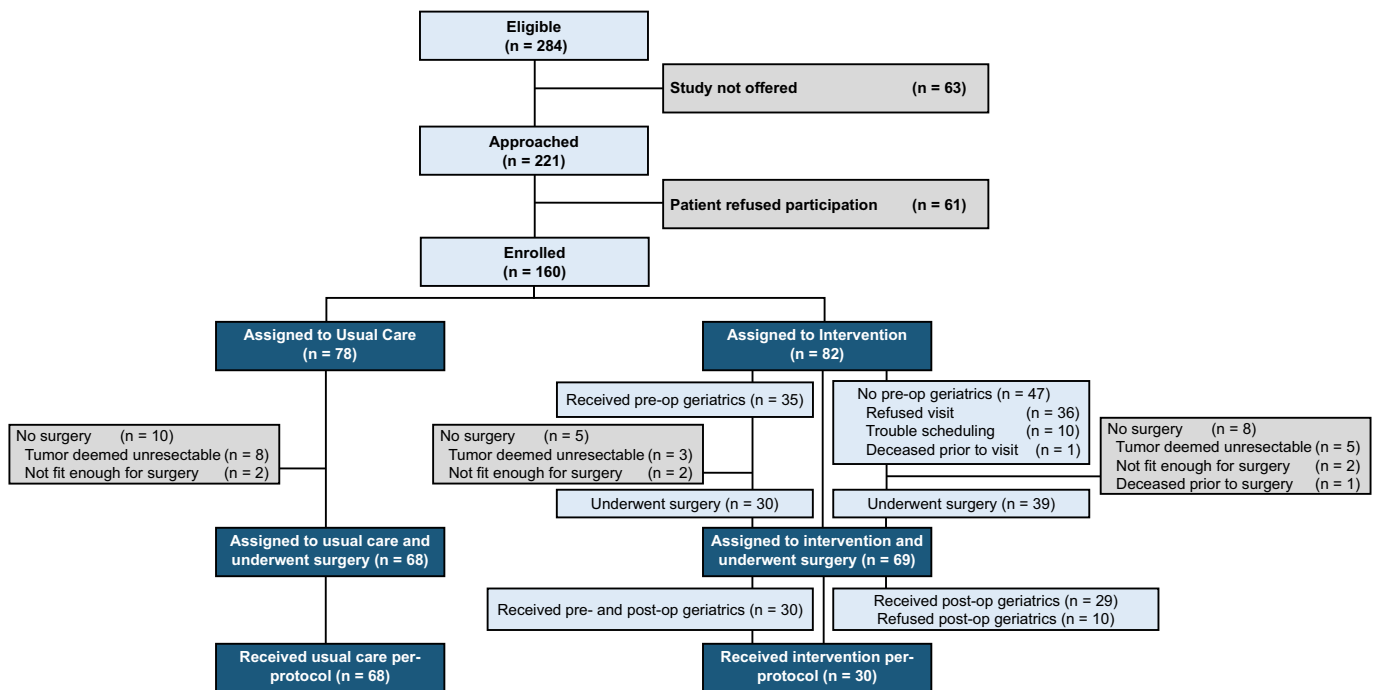


Fig. 2. CONSORT diagram.

recruitment and retention of study patients [26,45–48]. In future studies of PERI-OP, we will modify the intervention to remove participation barriers and ensure patients can feasibly receive the intervention, such as offering the option of telehealth video visits with geriatric clinicians to help avoid the undue burden of added trips to clinic [49,50].

Despite the implementation challenges encountered, we found encouraging results for PERI-OP in the per-protocol analyses. Notably, in the per-protocol analyses, intervention patients had significantly shorter postoperative hospital LOS, with non-significantly lower rates of postoperative ICU use, 90-day readmissions, and major complications. These findings align with evidence from the orthopedic surgery literature demonstrating that perioperative geriatric interventions can enhance these and other surgical outcomes [27–34]. Mechanisms underlying the impact of perioperative geriatric interventions on postoperative LOS include the ability to target modifiable factors (e.g., comorbid conditions, complex medication regimens, and symptom burden, as reflected by the assessments/recommendations from the geriatrician visits in our current work), while also striving to decrease the rates of postoperative ICU admissions and major complications [51,52]. Recent work has shown benefits from perioperative geriatric comanagement, which was associated with lower postoperative mortality, with a potential mechanism for this finding related to higher rates of physical/occupational therapy, speech/swallow rehabilitation, and nutrition services [23]. Growing literature supports the use of prehabilitation to enhance surgical outcomes, highlighting the importance of efforts to address physical and functional outcomes perioperatively [53,54]. Moreover, although we evaluated postoperative LOS, ICU use, hospital readmissions, and complications, novel patient-centered outcomes, such as time spent at home following surgery, will be important to consider in future efforts [14]. Ultimately, our results support the need for additional studies to investigate the ability for PERI-OP to enhance perioperative care delivery and outcomes for the geriatric oncology population, the largest and most rapidly growing group of patients with cancer [1,2,55].

Importantly, our work highlights the need for interventions targeting the perioperative care of older adults with cancer. Patients receiving usual care in our study experienced prolonged postoperative

hospital LOS, with nearly one-third requiring an ICU admission, one-fourth experiencing a hospital readmission, and one-fifth developing a major postoperative complication, which aligns with prior research [23,45,48,53]. Consistent with previous work, over half of patients had at least one comorbid condition, which increases the risk for poor surgical outcomes, particularly for the complex gastrointestinal procedures included in the current study [4,6,8,9]. Collectively, our findings underscore the tremendous need for efforts, such as PERI-OP, to enhance perioperative care for older adults with cancer, particularly those undergoing surgery for gastrointestinal cancer, as these surgeries are the most common and complex in the geriatric oncology population [10–13].

Several limitations merit discussion. First, we conducted the trial at an academic center with limited sociodemographic diversity, thereby limiting the generalizability of our results. Notably, most patients receiving their surgery/oncology care at our institution are readmitted within our healthcare system, and we tracked all hospitalizations within our system, but we may be underestimating healthcare utilization for those hospitalized outside our healthcare system. Second, we lack data regarding some factors that could influence the impact of PERI-OP, such as patients' social supports, cognition, and health literacy [20,56,57]. Future studies should investigate whether these, and other important factors, such as cancer type and use of additional support services (e.g., nutrition, physical/occupational therapy), influence the effects of PERI-OP on patient outcomes [23]. We also lack information about postoperative delirium, polypharmacy, or inappropriate medication use, which are important geriatric outcomes to consider in future iterations of this work [45,58,59]. Third, the patients included in the per-protocol analyses represent a unique group of individuals who were able to receive all PERI-OP components, and thus these patients may differ from the overall study population, as highlighted by the higher rates of education and lower rates of some comorbid conditions among those who received the intervention per-protocol. The study was also not specifically powered for secondary outcomes and subgroup analyses, which could limit the ability to determine statistically significant differences. Fourth, patients in our study had several types of gastrointestinal cancer and underwent different surgeries with varying

**Table 1**  
Patient characteristics.

Characteristics	Usual Care (n = 78)		Intervention (N = 82)	
	N	%	N	%
Age - median (range)	72.0 (65 to 92)		70.0 (65 to 92)	
Sex				
Female	28	35.9	37	45.1
Male	50	64.1	45	54.9
Race				
White	75	96.2	71	86.6
Asian	1	1.3	5	6.1
Black	1	1.3	1	1.2
American Indian or Alaska Native	1	1.3	2	2.4
Other	0	0.0	3	3.7
Hispanic Ethnicity	2	2.6	2	2.4
Relationship Status				
Married	57	73.1	58	70.7
Living with partner	3	3.8	6	7.3
Widowed	9	11.5	9	11.0
Divorced	5	6.4	4	4.9
Separated	1	1.3	0	0.0
Never married	3	3.8	5	6.1
Employment Status				
Working	11	14.1	20	24.4
Retired	54	69.2	53	64.6
Disability	7	9.0	6	7.3
Unemployed	1	1.3	2	2.4
Other	5	6.4	1	1.2
Education Status				
Less than college graduate	31	39.7	33	40.2
College graduate and beyond	47	60.3	49	59.8
Annual Income				
Under \$60,000	30	38.5	31	37.8
\$60,000 and above	38	48.7	41	50.0
Declined to answer	10	12.8	10	12.2
Cancer Type				
Pancreas	41	52.6	46	56.1
Gastroesophageal	16	20.5	16	19.5
Colorectal	14	17.9	14	17.1
Hepatobiliary	7	9.0	6	7.3
Underwent Surgery	68	87.2	69	84.1
Comorbid Conditions				
Heart attack	3	3.8	10	12.2
Heart failure	4	5.1	6	7.3
Stroke	10	12.8	7	8.5
Chronic lung disease	11	14.1	11	13.4
Diabetes	21	26.9	28	34.1
Kidney problem	7	9.0	15	18.3

degrees of complexity, and future investigations are needed to determine how best to personalize PERI-OP according to patients' distinct perioperative needs. Additionally, we did not collect information about patients', caregivers', and clinicians' perceptions of PERI-OP, and future efforts to integrate geriatricians into the perioperative care of older patients should consider these key stakeholder viewpoints to enhance implementation. Lastly, although we collected information about assessments/recommendations from the geriatrician visits, we lack data about how these recommendations formally resulted in changes to patients' care.

In this study, we sought to determine the impact of PERI-OP on postoperative outcomes in older patients with gastrointestinal cancer undergoing surgery. Although we did not find a significant difference between PERI-OP and usual care on our primary outcome in the intention-to-treat analyses, we found significantly shorter postoperative hospital LOS in the subgroup who received the intervention as planned. Importantly, we also found promising results for PERI-OP to help decrease postoperative ICU use and reduce major complications. Additionally, our data highlight the critical importance of efforts to address the perioperative needs of older adults with cancer undergoing surgical resection. Collectively, these results support the need for a larger effectiveness-implementation trial to determine the effects of

**Table 2**  
Intervention Effects on Clinical Outcomes.

Clinical Outcomes	Mean or Rate	Difference between Groups (95% CI)	P
<b>Intention-to-Treat Analyses</b>			
Postoperative hospital length of stay	Mean Days		
Usual Care	8.21		
Intervention	7.23	0.97 (−1.19 to 3.13)	0.374
Postoperative ICU admission	Rate		
Usual Care	32.4%		
Intervention	23.2%	9.2% (−5.8% to 23.6%)	0.257
Readmission within 90-days	Rate		
Usual Care	25.0%		
Intervention	21.7%	3.3% (−10.9% to 17.3%)	0.690
Major postoperative complications	Rate		
Usual Care	20.6%		
Intervention	17.4%	3.2% (−10.0% to 16.4%)	0.668
<b>Per-Protocol Analyses</b>			
Postoperative hospital length of stay	Mean Days		
Usual Care	8.21		
Intervention	5.90	2.31 (0.31 to 4.30)	0.024
Postoperative ICU admission	Rate		
Usual Care	32.4%		
Intervention	13.3%	19.0% (0.0% to 33.3%)	0.081
Readmission within 90-days	Rate		
Usual Care	25.0%		
Intervention	16.7%	8.3% (−10.7% to 23.1%)	0.439
Major postoperative complications	Rate		
Usual Care	20.6%		
Intervention	6.7%	13.9% (−2.7% to 26.0%)	0.137

PERI-OP on postoperative outcomes in the geriatric oncology population, while also ensuring patients can receive all intervention components.

**Funding sources**

NCI K24 CA181253 (Temel), NCCN Foundation Young Investigator Award (Nipp). This work was funded by the NCCN Foundation®. Any opinions, findings, and conclusions expressed in this material are those of the author(s) and do not necessarily reflect those of National Comprehensive Cancer Network® (NCCN®) or the NCCN Foundation.

**Author contributions**

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data. All were involved in drafting the article or revising it critically for important intellectual content. All provided final approval of the manuscript and agree to be accountable for all aspects of the work.

**Declaration of Competing Interest**

Dr. Knight reports stock ownership in Illumina, Assembly Biosciences, and Thermo Fisher Scientific. No other authors have conflicts of interest to disclose.

**Appendix A. Supplementary data**

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jgo.2022.01.001>.

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