# A diet and lifestyle-factor intervention program to improve nutritional status, symptoms, and quality of life in patients with inflammatory bowel disease

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# **Abstract**

**Background:** This study sought to evaluate the impact of an evidence-based diet and lifestyle-factor intervention program on nutrition status, symptoms and quality of life of patients with IBD.

**Methods:** In this retrospective observational study, de-identified medical records from patients with a self-reported diagnosis of IBD were analyzed. All patients included in the study completed an intervention program consisting of 12 to 24 one-on-one counseling sessions with an IBD-focused registered dietitian in a group-practice setting. Measures collected at baseline and at the conclusion of the program were SIBDQ, MUST, patient-reported symptoms, bowel movement frequency and consistency, measures of stress, fatigue, sleep quality as well as risk of eating and feeding disorders (NIAS-9, EAT-26).

**Results:** 67 patients met the inclusion criteria for the study. Patients with MUST scores >0 at baseline had significantly decreased MUST scores at the end of the program (p=0.004). IBD-related quality of life scores were significantly higher (mean improvement of 18.6 points) at the end of the program compared to baseline (p<0.001). 67 out of 67 patients (100%) reported fewer symptoms at the end of the program with the most improvements related to cramping (97.1%), nausea (94.4%), and fatigue (93.8%). 96.4% of patients experiencing >3 bowel movements per day (BMPD) at baseline decreased their BMPD by the end of the program with 75% experiencing  $\leq$  3 BMPD. Patients also significantly improved their sleep quality (p<0.001), fatigue level (p<0.001), and stress levels (p<0.001).

**Conclusions:** This study demonstrates the potential of a nutrition and lifestyle-factor intervention program to improve IBD patient outcomes. Further study is needed to validate these outcomes alongside a comparable control population and in other patient populations such as those associated with a health plan or employer.

## Introduction

There is increased awareness among patients and providers that diet and nutrition are integral to the management of inflammatory bowel disease (IBD). While evidence of varying quality has identified potentially harmful or beneficial dietary components to the pathogenesis of IBD and symptoms experienced by patients, there remain gaps in knowledge among healthcare providers related to nutrition in IBD. To overcome these gaps, consensus guidelines have recently been developed for nutritional assessment and dietary management of patients with IBD (1-2). In addition to diet, there is evidence that lifestyle factors such as sleep quality (3-4), stress (5), and exercise may significantly impact natural history and clinical outcomes in patients with IBD (6).

Many patients implement dietary changes based on various sources of information or in response to the onset of IBD-related symptoms (7-8). It's recommended that patients partner with a registered dietitian (9) with specialized interest in IBD (10) to establish and implement an individualized medical nutrition therapy intervention based on the patient's medical history and comorbidities, ensure adequate nutrient intake, adjust for anatomic changes due to surgical intervention or other disease complications, and incorporate the patient's unique preferences, tolerances, and disordered eating patterns into the patient's care plan (11). However, less than half of all providers (46%) in a recent study felt that they had access to adequate resources to help initiate and guide discussions related to nutrition with their IBD patients (12). Other barriers including lack of access to dietitians with IBD-specific counseling experience, lack of provider training and understanding of the tests and therapies recommended by nutrition care pathways, and lack of coverage by health insurance have been reported when implementing nutrition care pathways for IBD patients in routine clinical practice (13).

To overcome some of these challenges, we have designed an evidence-based diet and lifestyle intervention program delivered using telehealth for patients with IBD that utilizes consensus guidelines and behavioral science methodologies to help patients make sustainable diet and lifestyle changes to improve nutritional status, symptoms, and quality of life. In this study, we sought to assess the impact of this program on patient outcomes in a real-world, routine care setting.

## Methods

#### Study Design and Patient Population

This study is a retrospective observational study of electronic medical record data from patients with a self-reported diagnosis of inflammatory bowel disease who participated in a 12 to 24 week medical nutrition therapy and lifestyle-factor intervention program at a single group practice. Patients with a self-reported diagnosis of Crohn's disease, ulcerative colitis, or other type of inflammatory bowel disease (IBD) and who completed their 12 to 24 week program before August 1st 2022 were included in the study. The primary outcome measures of the study were change in Malnutrition Universal Screening Tool (MUST) score (14), change in patient-reported symptom frequency, and change in Short Inflammatory Bowel Disease Questionnaire (SIBDQ) score (15) from baseline. Secondary outcome measures were change in bowel movements per day, change in stool consistency, change in Pittsburgh Sleep Quality Index (PSQI) score (16), change in Multidimensional Fatigue Inventory (MFI) score (17), change in Perceived Stress Scale (PSS) score (18), change in Nine Item Avoidant/Restrictive Food Intake Disorder Screen (NIAS-9) score (19), and change in Eating Attitudes Test (EAT-26) (20) score from baseline. A description of each of these measures, including scoring methodology and range of scores, is shown in Table 1. All outcome analyses were paired and measurements at baseline (prior to starting the intervention program) were compared to measurements collected at the end of the 12 to 24 week intervention program.

#### **Data Collection**

Patient data were obtained from the electronic medical record of a single group practice and de-identified in accordance with the Health Insurance Portability and Accountability Act of 1996. The variables extracted from the medical record included demographic information (age, gender), primary self-reported diagnosis, program length (in weeks), MUST score, patient-reported symptoms, average bowel movements per day, stool consistency (as measured using the Bristol Stool Scale (21)), SIBDQ score, PSQI score, MFI score, PSS score, NIAS-9 score, and EAT-26 score.

# Nutrition and Lifestyle-Factor Intervention

All patients whose records were included in this study had completed a 12 to 24 week nutrition and lifestyle-factor intervention program consisting of 12 to 24 one-on-one telehealth counseling sessions with a registered dietitian with experience working with

patients with IBD. Each session was 30-60 minutes in length. For the duration of the program, patients had 24/7 access to text-based messaging directly with their registered dietitian through their patient portal mobile application. Patients were also given access to a curated library of evidence-based content related to IBD to support asynchronous learning throughout the program.

During their initial session, patients were assessed for nutritional status (including food and nutrition-related history, current supplement regimen, and evaluation of nutrition-related labs), lifestyle factors (sleep quality, stress, fatigue, and quality of life), and patient-specific goals for the end of the program. A patient-specific diet and lifestyle intervention was then designed by the registered dietitian and patient. Interventions included providing education, coordinating patient care, and guidance for practical real-world application. During each follow up session, the dietitian and patient worked together to implement the intervention plan and problem-solve to remove barriers and adjust the plan as needed. At the conclusion of the program, the patient was reassessed using the same measures computed at the beginning of the program and the results were shared with the patient.

#### Statistical Analysis

All statistical analyses were paired unless otherwise specified. Differences in outcome measures at baseline and at the end of the program were assessed using Wilcoxon rank-sum tests (non-normally distributed data) or Welch T-test (normally distributed data). All statistical tests were two-sided and a p-value of less than 0.05 was considered statistically significant.

# Results

#### **Study Population**

67 patients met the inclusion criteria for the study. 58 females and 9 males were included. 62 patients completed 12 sessions and 5 patients completed 24 sessions with a registered dietitian. The average age of patients was 33 years with a standard deviation of 10 years. 32 patients had a self-reported primary diagnosis of Crohn's disease and 34 patients had a self-reported primary diagnosis of ulcerative colitis. One patient had a self-reported diagnosis of indeterminate colitis (Table 2).

#### Malnutrition Risk

64 patients had Malnutrition Universal Screening Tool (MUST) scores computed at baseline. 43 patients had MUST scores equal to 0 at baseline indicating low malnutrition risk while 21 patients had MUST scores greater than 0 at baseline indicating medium to high malnutrition risk (Table 2). Of these 21 patients with baseline MUST >0, 11 had MUST scores computed at the end of the program. We were unable to compute MUST scores at the end of the program for 10 out of these 21 patients due to missing patient-reported weight measurements within 60 days prior to their last session. Patients with MUST scores >0 at baseline had significantly decreased MUST scores at the end of the program (p=0.004, n=11) with a mean decrease in scores of 1.5 (SD, 1.0) points. Of the patients with a baseline MUST score >0 (n=11), 36.4% (n=4) had a MUST score equal to zero at the end of the program. Of the patients with a baseline MUST score of >1 (n=8), 87.5% (n=7) had a MUST score ≤1 at the end of the program (Figure 1).

#### Symptom Burden

Patients reported a mean of 5.3 (SD, 2.0) symptoms related to their IBD at baseline. All 67 patients included in the study reported at least one and at most 9 symptoms at the start of the program. The most frequently reported symptoms at baseline were gas (76.1%, n=51), diarrhea (71.6%, n=48), fatigue (71.6%, n=48), and bloating (70.1%, n=47). Patients reported a mean of 0.9 (SD, 1.1) symptoms related to their IBD at the end of the program. All 67 out of 67 patients (100%) reported fewer symptoms at the end of the program compared to baseline. The greatest number of patients reported improvements in cramping (97.1% of patients), nausea (94.4%), and fatigue (93.8%). The fewest number of patients reported improvements in diarrhea (72.9%), blood in stool (78.3%), and gas (78.4%) (Table 3).

# IBD-Related Quality of Life

21 patients completed the Short Inflammatory Bowel Disease Questionnaire (SIBDQ) at baseline and at the end of the program. 20 patients (95.2%) had higher SIBDQ at the end of the program compared to baseline. SIBDQ scores were significantly higher at the end of the program compared to baseline (p<0.001, 95% CI 24.1, 13.0) with a mean increase in score of 18.6 (SD, 12.2) points. The greatest improvements in factors related to quality of life were observed in patients' frequency of feeling angry as a result of their bowel problems (95.2% reported improvement), problems related to feelings of fatigue (85.7%), and troubles related to pain in the abdomen (85.7%). The smallest improvements in factors related to

quality of life were observed in the degree to which maintaining or getting to one's ideal weight was a problem during the past two weeks (57.1%) (Table 4).

#### Frequency and Consistency of Bowel Movements

Of the 67 patients included in this study, 62 reported their average bowel movements per day at baseline and at the end of the program. 3 patients were missing data at baseline or at the end of the program and 2 patients who underwent IBD-related surgery during the program were excluded from this analysis. Across all patients (n=62), there was a significant decrease in the average number of bowel movements per day at the end of the program compared to baseline (p<0.001) with a mean decrease of 1.4 (SD, 2.2) bowel movements per day. In patients with greater than normal bowel movement frequency at baseline (>3 bowel movements per day (22), n=28), 96.4% (n=27) reduced the number of bowel movements reported by the end of the program with 75.0% (n=21) reporting a normal frequency of ≤3 bowel movements per day.

Excluding 2 patients who underwent IBD-related surgery during the program, 46 patients (74.2%) reported the presence of loose-textured, diarrhea-like stool in at least some of their bowel movements at baseline (presence of a type 6 or 7 stool in the past week according to the Bristol Stool Scale). 8 patients (12.9%) reported the presence of firm-textured, constipation-like stool in at least some of their bowel movements at baseline (presence of a type 1 or 2 stool in the past week according to the Bristol Stool Scale). 4 patients (6.5%) who reported presence of type 6 or 7 stool also reported presence of type 1 or 2 stool at baseline. 16 patients (25.8%) reported only type 3-5 stools during the past week at baseline.

Of the 46 patients with type 6 or 7 stool at baseline, 34 (73.9%) reported no presence of type 6 or 7 stool at the end of the program while 12 patients (26.1%) reported at least some persistent type 6 or 7 stools. Of the 8 patients with type 1 or 2 stool at baseline, all 8 (100%) reported no presence of type 1 or 2 stool at the end of the program. Of the 16 patients with only type 3-5 stool at baseline, 1 (6.3%) reported stool of type 6 or 7 at the end of the program and none (0%) reported stool of type 1 or 2.

# Sleep Quality, Stress, and Fatigue Levels

57 patients had Pittsburgh Sleep Quality Index (PSQI) assessment scores completed at baseline and at the end of the program. 47 patients (82.4%) had lower PSQI scores at the end of the program compared to baseline. PSQI scores were significantly lower at the end of the program compared to baseline (p<0.001) with a mean decrease in score of 3.8 (SD,

4.1) points. In patients with an initial PSQI score >5 (n=38), which indicates poor sleep quality, there was a significant reduction in score at the end of the program compared to baseline (p<0.001) with a mean decrease in score of 5.1 (SD, 4.2) points. Of the patients with a baseline PSQI score >5, 71.1% (n=27) reported a PSQI score  $\leq$ 5 at the end of the program.

In Crohn's disease patients with initial PSQI score >8 (n=10), which has been shown to be predictive of surgery or hospitalization risk (4), there was a significant reduction in scores at the end of the program (p=0.01) with a mean decrease in scores of 6.3 (SD, 5.0) points. Of the Crohn's disease patients with a baseline PSQI score >8, 80.0% (n=8) reported a PSQI score  $\leq$ 8 at the end of the program.

58 patients had Multidimensional Fatigue Inventory (MFI) assessment scores completed at baseline and at the end of the program. 51 patients (87.9%) had lower MFI scores at the end of the program compared to baseline. MFI scores were significantly lower at the end of the program compared to baseline (p<0.001) with a mean decrease in score of 18.6 (SD, 15.5) points.

59 patients had Perceived Stress Scale (PSS) scores completed at baseline and at the end of the program. 52 patients (88.1%) had lower PSS scores at the end of the program compared to baseline. PSS scores were significantly lower at the end of the program compared to baseline (p<0.001) with a mean decrease in score of 11.4 (SD, 8.6) points.

# Relationship with Food

45 patients had NIAS-9 assessment scores completed at baseline and at the end of the program. 38 patients (82.6%) had lower NIAS-9 scores at the end of the program compared to baseline. NIAS-9 scores were significantly lower at the end of the program compared to baseline (p<0.001) with a mean decrease in score of 7.5 (SD, 7.8) points. In patients with an initial NIAS-9 score  $\geq$ 24 (n=7), which indicates a positive screen for ARFID, there was a significant reduction in score at the end of the program compared to baseline (p=0.04) with a mean decrease in score of 19.1 (SD,11.8) points. Of the patients with an initial NIAS-9 score  $\geq$ 24, 85.7% (n=6) reported a NIAS-9 score  $\leq$ 24 at the end of the program.

36 patients had EAT-26 assessment scores collected at baseline and at the end of the program. 27 patients (75.0%) had lower EAT-26 scores at the end of the program compared to baseline. EAT-26 scores were significantly lower at the end of the program compared to baseline (p<0.001) with a mean decrease in score of 5.5 (SD, 6.3) points.

## Discussion

In this study we have established evidence that a 12 to 24 week nutrition and lifestyle factor intervention program may decrease malnutrition risk, reduce symptom burden and improve IBD-related quality of life in patients with Crohn's disease and ulcerative colitis. Furthermore, we have shown that patients who complete the program may significantly improve their stool frequency and consistency, improve their sleep quality, reduce levels of fatigue, and reduce levels of stress. We also observed that patients who complete the program may improve their relationship with food as measured by NIAS-9 and EAT-26, though our sample size of patients surpassing scoring thresholds for risk of eating or feeding disorder (>24 NIAS-9 and ≥20 EAT-26) was too small to draw any statistical conclusions.

This study underscores the importance of nutrition and lifestyle-factor support for patients with IBD and demonstrates the potential of a high-touch intervention program to improve outcomes that are important to patients. A key strength of this study was it was performed using real-world data from a group practice and the intervention was delivered as part of routine standard of care and may be well suited for further study in a prospective pragmatic trial or retrospective study using a comparable real-world cohort as a control arm. This study also has a number of important limitations. First, this study was retrospective and observational in nature and does not compare the results to a control population or account for potential confounding factors such as treatment regimen. This study has also not been peer reviewed nor published in any journal. A second limitation of this study is that the study population was treated in a group practice in which patients must pay for clinical services out of pocket rather than procuring services through their insurance provider. The study population may be biased towards patients with a higher than average income or patients with higher levels of intrinsic motivation. Finally, it is important to note that the Perceived Stress Assessment, NIAS-9, and EAT-26 survey instruments have not been validated in patients with inflammatory bowel disease. While these surveys may reveal useful insights about a patient's stress levels or relationship with food, further study is required to validate their use in this population.

Considered together, the findings of this study demonstrate the potential of a nutrition and lifestyle-factor intervention program to improve IBD patient outcomes. Further study is needed to validate these outcomes alongside a comparable control population and in other patient populations such as those associated with a health plan or employer.

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Measure/ Instrument	Description	Threshold(s)	Scoring Range
Malnutrition Universal Screening Tool (MUST)	Screening for malnutrition risk based on BMI, weight loss, and acute disease score.	0 = low risk 1 = medium risk >2 = high risk	Min = 0 Max = 6
Symptom frequency	Count of number of unique N/a symptoms		Min = 0 Max = 12
Short Inflammatory Bowel Disease Questionnaire	10-item questionnaire to assess health-related QOL among IBD patients.	Higher scores are associated with better quality of life	Min = 10 Max = 70
Bowel movements per day	Trailing 7-day average of bowel movements per day	<0.5 = abnormal 0.5-3 = normal >3 = abnormal	N/a
Stool consistency	Measured using the Bristol Stool Scale (7-item ordinal scale). Patients may report multiple stool types at any time point.	Type 1-2: constipation-like stool Type 3-5: normal stool Type 6-7: diarrhea-like stool	Min = 1 Max = 7
Pittsburgh Sleep Quality Index (PSQI)	7-component self-rated questionnaire assessing sleep quality and disturbances over a 1-month time interval.	>5 = poor sleep quality ≤5 = good sleep quality >8 = predictive of surgery or hospitalization risk in Crohn's patients (4)	Min = 0 Max = 21
Multidimensional Fatigue Inventory (MFI)	20-item scale designed to evaluate five dimensions of fatigue: general fatigue, physical fatigue, reduced motivation, reduced activity, and mental fatigue.	Higher score is associated with higher levels of fatigue	Min = 10 Max = 100
Perceived Stress Scale (PSS)	A measure of the degree to which situations in one's life are appraised as stressful.	≤13 = low stress 14-26 = moderate stress ≥27 = high stress	Min = 0 Max = 40
Nine Item Avoidant/Restrictive Food Intake Disorder Screen (NIAS-9)	A nine-item screening questionnaire for avoidant/restrictive food intake disorder (ARFID)	<24 = negative screen for ARFID ≥24 = positive screen for ARFID	Min = 0 Max = 45
Eating Attitudes Test (EAT-26)	A 26-item questionnaire assessing risk of an eating disorder	<20 = less risk ≥20 = more risk	Min = 0 Max = 78

Table 1. Measures and instruments used in the study.

Gender (N)	
Female	58
Male	9
Program Length (weeks)	
12 weeks	62
24 weeks	5
Age (years)	
Mean (SD)	33 (11)
Primary Diagnosis (N)	
Crohn's disease	32
Ulcerative colitis	34
Indeterminate colitis	1
MUST (N, Baseline)	
MUST = 0	43
MUST > 0	21

Table 2. Clinical and demographic information of patients whose records were included in the study.

Symptom	Number of Patients Reporting Symptom at Baseline (N)	Number of Patients Reporting Symptom at End of Program (N)	Percent of Patients No Longer Reporting Symptom (%)	Number of Patients Newly Reporting Symptom (N)
Nausea	18	1	94.4%	1
Vomiting	0	0	_	0
Diarrhea	48	13	72.9%	1
Constipation	19	2	89.5%	0
Blood in Stool	23	5	78.3%	1
Mucus in Stool	6	1	83.3%	1
Bloating	47	5	89.4%	1
Gas	51	11	78.4%	1
Pain in Abdomen or Rectum	33	3	90.9%	0
Cramping	35	1	97.1%	1
Fatigue	48	3	93.8%	0
Joint Pain	24	4	83.3%	1

Table 3. Patient-reported symptoms at baseline and at the end of the program.

Question	Percent of patients reporting improvement	p-value
How often has the feeling of fatigue or being tired and worn out been a problem for you during the past 2 weeks?	85.7%	p<0.001
How often during the last 2 weeks have you delayed or canceled a social engagement because of your bowel problem?	71.4%	p<0.001
As a result of your bowel problems, how much difficulty did you experience doing leisure or sports activities during the past 2 weeks?	76.2%	p=0.002
How often during the past 2 weeks have you been troubled by pain in the abdomen?	85.7%	p<0.001
How often during the past 2 weeks have you felt depressed or discouraged?	71.4%	p<0.001
Overall, in the past 2 weeks, how much of a problem have you had with passing large amounts of gas?	61.9%	p=0.004
Overall, in the past 2 weeks, how much of a problem have you had maintaining or getting to the weight you would like to be?	57.1%	p=0.03
How often during the past 2 weeks have you felt relaxed and free of tension?	76.1%	p<0.001
How much time during the past 2 weeks have you been troubled by a feeling of having to go to the bathroom even though your bowels were empty?	71.4%	p<0.001
How often during the past 2 weeks have you felt angry as a result of your bowel problem?	95.2%	p<0.001

Table 4. Change in IBD-related quality of life survey components from baseline.

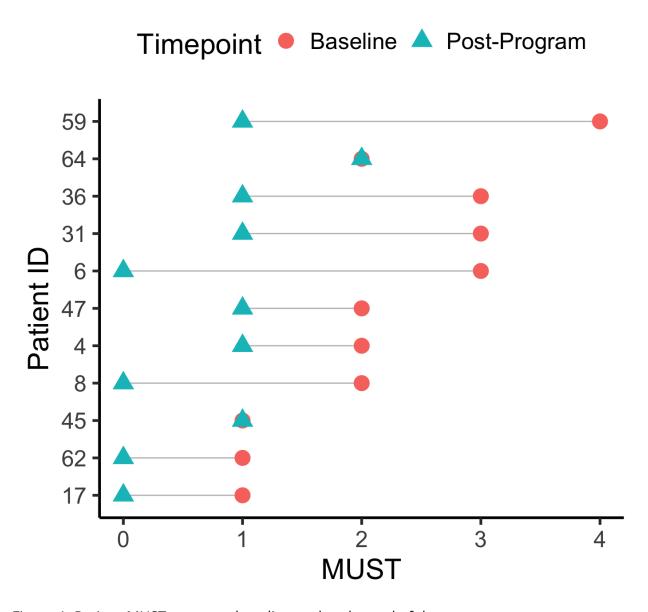


Figure 1. Patient MUST scores at baseline and at the end of the program.