	Rivaroxaban vs. Dabigatran	ARR	NNH	Apixaban vs. Dabigatran	ARR	NNH	Apixaban vs. Rivaroxaban	ARR	NNH
Stroke or Systemic Embolism	1.40 vs. 1.39	0.02 (-0.21,0.25)	5000	1.39 vs. 1.52	-0.13 (-0.57,0.30)	769	1.41 vs. 1.31	0.10 (-0.37,0.57)	1000
Major Bleeding	3.77 vs. 2.58	1.20*** (0.67,1.72)	83	2.06 vs. 3.25	-1.20** (-1.99,-0.41)	83	2.01 vs. 4.55	-2.54*** (-3.47,-1.61)	39
GI Bleeding	2.74 vs. 2.02	0.72*** (0.27,1.17)	139	1.38 vs. 2.73	-1.35*** (-2.03,-0.67)	74	1.34 vs. 3.54	-2.20*** (-3.00,-1.40)	45

*p<0.05, **p<0.01, ***p<0.001 *p<0.05, **p<0.01, ***p<0.001

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A Low FODMAP Diet Improves Quality of Life, Reduces Activity Impairment, and Improves Sleep Quality in Patients With Irritable Bowel Syndrome and Diarrhea: Results From a U.S. Randomized, Controlled Trial

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Background: In addition to characteristic GI symptoms, irritable bowel syndrome (IBS) patients have incraesed psychological comorbidity and sleep disturbance as well as reduced health-related quality of life (HRQOL), and work productivity relative to the general population. We assessed the impact of a low FODMAP diet versus a control diet on HRQOL, psychological distress, work productivity, and sleep quality measures in patients with IBS and diarrhea (IBS-D). ***Methods:*** We conducted a prospective, single center, single-blind randomized controlled trial of adult patients with IBS-D (Rome III). After completing a 2-week screening period, eligible patients (mean daily abdominal pain score ≥4 & Bristol stool scale score of ≥5) were randomized to 4-weeks of a low FODMAP diet (LFD) or a control diet based upon modified NICE guidelines. Foods containing FODMAPs were not specifically excluded from the control diet. Both dietary interventions were administered by experienced research dietitians. HRQOL (IBS-QOL), psychosocial distress (Hospital Anxiety and Depression Scale (HADS)), work productivity (Workplace Activity Impairment (WPAI)), and an assessment of sleep quality were conducted before and after the dietary intervention. Fatigue and sleep quality were assessed daily over the study period. ***Results:*** Of the 171 subjects consented for enrollment, 92 (65 women (71%), median age 42.6 years (range = 19 -75 years), 68 Caucasian (74%)) were eligible for randomization based upon the baseline assessment. Eighty-three patients completed the study period (45 LFD, 38 control). Demographics, baseline symptom severity, and baseline HRQOL measures were similar between groups. Baseline energy, nutrient, and FODMAP intake were similar between groups. At 4 weeks, the proportion of patients with a >10-point improvement in IBS-QOL score was significantly greater in the LFD group compared to the control group (58% v 24%, p=0.0032). Similarly, the mean total IBS-QOL score at 4 weeks was higher in the LFD v control (p=.0228). Significant improvements were observed in several IBS-QOL domains (**Table 1**). There was a trend towards improvement in anxiety for the LFD vs. the control diet which did not reach statistical significance (7.73 v 9.26, p=0.0679). For WPAI, only activity impairment significantly improved (LFD 29.29 v control 41.90, p=0.0398). There was no difference between the two groups for fatigue but sleep quality improved in the LFD compared to the control diet (6.33 v 7.46, p=0.0336). ***Conclusion:*** In this US randomized, controlled study of IBS-D patients, a low FODMAP diet improved HRQOL, activity impairment, and sleep quality when compared to a control diet. This is one of the first methodologically rigorous clinical trials to show that diet-based therapy can not only improve symptoms but also HRQOL in patients with IBS-D.

Table. IBS QOL means after dietary intervention.

	Low FODMAP Diet	Control IBS Diet	P value
Total IBS-QOL	68.87	59.04	0.0228
Dysphoria	73.05	62.58	0.0449
Interference with Activity	49.54	37.98	0.0058
Body Image	70	54.22	0.0040
Health Worry	72.92	73.42	0.9054
Food Avoidance	32.71	35.14	0.6432
Social Reaction	72.50	65.88	0.1813
Sexual	80.63	67.23	0.0430
Relationship	79.17	68.47	0.0250

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Prevalence and Predictors of Irritable Bowel Syndrome in the United States

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Background: Irritable bowel syndrome (IBS) is a common functional gastrointestinal (GI) disorder characterized by abdominal pain and altered bowel habits. Previous research found that 7-20% of the US population has IBS, although these studies were often limited by a lack of representative, large-scale sampling. Using data from the "National GI Survey" - a population-based audit of GI symptoms in over 71,000 Americans - we aimed to determine the prevalence and predictors of IBS, and to evaluate the distribution of concomitant GI symptoms in IBS. **Methods:** To evaluate the burden of GI illness in the US, we conducted the National GI Survey in October 2015 using *My Gi Health*, a mobile app that employs a previously validated computer algorithm called AEGIS (Automated Evaluation of GI Symptoms) to systematically collect patient GI symptoms. We partnered with Cint®, a survey research firm, to recruit a representative sample of Americans to complete AEGIS. AEGIS guided participants through NIH GI Patient Reported Outcome Measurement Information System (PROMIS®) surveys along with questions about comorbidities and demographics. Our primary outcome was prevalence of IBS, measured in two ways: (1) Rome III criteria; and (2) self-reported physician diagnosis of IBS. We also compared presence and severity of concomitant GI symptoms between individuals with and without Rome positive IBS. We paired each person with IBS with up to 20 age- and sex-matched controls without IBS. We used multivariable regression to adjust for confounding. **Results:** Of the 71,813 individuals who completed AEGIS, 1411 (2.0%) met Rome III IBS criteria, and an additional 2211 (3.1%) self-reported a physician diagnosis of IBS despite not meeting Rome criteria. Females, non-Hispanic whites, and those who were younger, married, and had comorbidities were more likely to have Rome positive IBS (**Table 1**). Education level, employment status, and household income did not predict IBS. Individuals with Rome positive IBS, when compared to age- and sex-matched controls (n=22,558), were more likely to report concomitant bowel incontinence, heartburn/reflux, bloating, and nausea (**Table 2**). Among symptomatic individuals, those with Rome positive IBS had more severe heartburn/reflux and bloating, as they had significantly higher PROMIS scores vs. those without IBS (adjusted p<.001); there was no difference in PROMIS scores between groups for incontinence and nausea. **Conclusions:** In this population-based survey of community-dwelling Americans, we found that Rome III positive IBS was considerably less prevalent (2%) compared to prior estimates; even when including self-reported IBS, we still only found a 5% overall prevalence in this large cohort. However, among those with Rome positive IBS, there was a much higher burden and severity of concomitant GI symptoms vs. those without IBS.

Table 1. Predictors of having Rome III positive IBS

Variable	Rome III positive IBS (n=1411)	Odds ratio [95% confidence interval] [a]
Age	-	0.993 [0.989-0.997]
Gender:	-	-
Female	2.5%	reference
Male	1.2%	0.57 [0.50-0.65]
Race/ethnicity:	-	-
Non-Hispanic whites	2.4%	reference
Non-Hispanic blacks	0.8%	0.36 [0.27-0.49]
Latinos	1.2%	0.56 [0.46-0.69]
Asians	0.4%	0.20 [0.11-0.34]
Other	1.7%	0.77 [0.57-1.05]
Education level:	-	-
No high school degree	1.8%	reference
High school graduate	1.8%	0.82 [0.61-1.12]
Some college	2.4%	1.08 [0.81-1.46]
College graduate	1.8%	0.88 [0.65-1.19]
Graduate degree	1.5%	0.76 [0.54-1.08]
Marital status:	-	-
Single	1.3%	reference
Divorced or widowed	2.6%	1.40 [1.15-1.71]
Married	2.2%	1.30 [1.12-1.51]
Employment status:	-	-
Unemployed	2.4%	reference
Employed	1.7%	0.90 [0.80-1.01]
Total household income:	-	-
$0 to 20,000	1.8%	reference
$20,001 to 50,000	2.3%	1.20 [1.02-1.41]
$50,001 to 100,000	2.1%	1.14 [0.96-1.36]
$100,001 to 200,000	1.7%	0.99 [0.78-1.26]
≥$200,001	1.2%	0.81 [0.46-1.44]
Prefer not to say	1.0%	0.66 [0.49-0.90]
Num. of comorbidities:	-	-
0	1.3%	reference
1	3.4%	2.44 [2.16-2.76]
2	5.0%	3.47 [2.93-4.11]
≥3	11.9%	8.34 [6.18-11.3]

(a) The logistic regression model included all variables listed in the table above.

Table 2. Prevalence of concomitant GI symptoms among those with Rome III positive IBS

GI Symptom [a]	Individuals without Rome III positive IBS (n=22,558)	Individuals with Rome III positive IBS (n=1411)	Odds ratio [95% CI] [b]
Bowel incontinence	4.3%	13.4%	2.66 [2.24-3.17]
Heartburn/reflux	33.4%	55.2%	1.86 [1.66-2.08]
Bloating	24.6%	62.8%	4.53 [4.03-5.09]
Nausea	11.3%	30.0%	2.64 [2.32-3.01]

(a) Experienced within the past 7 days. (b) The logistic regression model adjusted for age, sex, race/ethnicity, education level, marital status, employment status, household income, and number of medical comorbidities. The reference group was non-Rome III positive IBS individuals.

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Increased Detection of Celiac Disease and Avoidance of Gluten Without a Diagnosis in the United States

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Background: The incidence of celiac disease (CD) is rising globally and most patients remain undiagnosed. Recent awareness of gluten-related disorders has spread in the popular media increasing the use of a gluten-free diet. We have monitored the prevalence rates of diagnosed CD, undiagnosed CD, and people without celiac disease avoiding gluten (PWAG) in the