

Effectiveness of an 8-Week Low-FODMAP Diet in Improving Gastrointestinal Symptoms and Health-Related Quality of Life in Adults with Irritable Bowel Syndrome: A Randomized Controlled Trial

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Abstract: Background: Irritable bowel syndrome (IBS) is one of the most prevalent disorders of gut–brain interaction and is characterized by recurrent abdominal pain associated with altered bowel habits. Because dietary triggers frequently exacerbate IBS symptoms, dietary modification has become an important component of clinical management. Restriction of fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs) has emerged as an evidence-based therapeutic strategy; however, further randomized controlled studies are needed to evaluate its effectiveness in different populations.

Objective: To evaluate the effectiveness of an 8-week Low-FODMAP dietary intervention on gastrointestinal symptoms and patient-reported outcomes in adults with IBS.

Methods: A single-blind randomized controlled trial was conducted between March and May 2025. Sixty adults diagnosed with IBS according to the Rome IV criteria were randomly allocated to either a Low-FODMAP diet group (n = 30) or a standard dietary advice group (n = 30). Participants in the intervention group received individualized dietary counselling and followed a structured Low-FODMAP diet for eight weeks, whereas the control group continued their habitual diet with general healthy eating advice. Gastrointestinal symptoms were assessed at baseline and after the intervention using a validated symptom questionnaire. Within-group comparisons were performed using paired t-tests, and statistical significance was established at $p < 0.05$.

Results : Participants assigned to the Low-FODMAP diet demonstrated significant improvement in 14 of the 17 assessed symptom domains following the intervention. Marked improvements were observed in abdominal discomfort, bloating, bowel habits, excessive gas, stool consistency, and overall symptom burden. Paired t-test values ranged from 2.504 to 8.226 ($p < 0.05$). In contrast, participants receiving standard dietary advice showed minimal changes, with statistically significant improvement observed in only two symptom domains. Crosstab analyses further demonstrated significant reductions in bowel urgency, harder stools, and excessive gas in the intervention group, whereas no significant improvements were observed in the control group.

Conclusions: An eight-week Low-FODMAP dietary intervention significantly improved gastrointestinal symptoms and patient-reported outcomes among adults with IBS. These findings support the integration of structured Low-FODMAP dietary counselling into routine clinical management of IBS. Larger multicentre studies with longer follow-up are warranted to determine long-term effectiveness and sustainability.

Keywords: Irritable bowel syndrome; Low-FODMAP diet; Diet therapy; Functional gastrointestinal disorders; Rome IV criteria; Randomized controlled trial; Gastrointestinal symptoms; Quality of life.

INTRODUCTION

One of the most prevalent diseases of gut-brain interaction (DGBIs) is irritable bowel syndrome (IBS), which is characterised by changed bowel habits and recurring abdominal discomfort without any obvious biochemical or anatomical abnormalities. Recurrent stomach discomfort that occurs at least once per week for the last three months together with changes in stool frequency, stool shape, or defecation is required for a diagnosis of irritable bowel syndrome according to the Rome IV diagnostic criteria. Depending on the diagnostic criteria and population analysed, there is substantial regional variation in the prevalence of irritable bowel syndrome (IBS), which is believed to vary from 5% to 10% globally. Impairment of quality of life, decreased job productivity, higher healthcare use, and large socioeconomic expenses are all connected with irritable bowel syndrome (IBS), which places a heavy load on healthcare systems.

Irritable bowel syndrome (IBS) has a complicated and multifaceted pathogenesis that includes dysregulation of the gut-brain axis, immunological activation, changes in intestinal permeability, dysbiosis of gut microbes, and disruptions in gastrointestinal motility. There is known to be a two-way connection between the CNS and the GI tract, which means that psychological issues like worry, sadness, and chronic stress may amplify the intensity of symptoms. Therefore, in order to enhance patient outcomes, modern treatment techniques place a greater emphasis on interdisciplinary approaches that include nutritional, psychological, and pharmaceutical therapies.

One of the most powerful environmental variables that may be changed to alleviate irritable bowel syndrome symptoms is one's food. Between seventy and eighty percent of patients say that certain meals cause or worsen gastrointestinal symptoms such as gas, bloating, flatulence, distention of the abdomen, and changes in bowel habits. Because of these findings, dietary treatments are being considered more and more as a first-line therapy option before starting long-term pharmaceutical treatment.

Researchers at Monash University came up with the Low-FODMAP diet, which stands as one of the most researched dietary methods for irritable bowel syndrome. Foods containing short-chain carbs that are resistant to small intestine absorption are known as FODMAPs. They cause an increase in intestinal water content due to their osmotic action, and in sensitive people, they might worsen symptoms by leading to luminal distension and excess gas produced by fast fermentation by the colonic bacteria. Intestinal fermentation and intraluminal gas generation are reduced when FODMAPs are restricted from the diet, which alleviates bloating, abdominal discomfort, and bowel dysfunction.

The therapeutic effectiveness of the Low-FODMAP diet in lowering the severity of irritable bowel syndrome symptoms and enhancing health-related quality of life has been proven in several randomised controlled studies and systematic reviews within the last decade. According to meta-analyses, systematic Low-FODMAP dietary intervention improves symptoms in around two-thirds of individuals. An evidence-based therapy option for suitably chosen people with IBS is a dietitian-guided Low-FODMAP diet, according to numerous worldwide clinical recommendations. These guidelines include those from the American College of Gastroenterology and the British Society of Gastroenterology.

There are still some significant gaps in our understanding, even if the amount of information is increasing. The majority of research has focused on Western people, whose eating patterns vary greatly from South Asian ones. Many Indian foods, such as wheat-based goods, pulses, onions, garlic, and certain fruits, contain fermentable carbs in different levels, which might affect how well people stick to their diets and how well they respond to treatments. Additionally, standardised outcome measures have been used in just a small number of randomised controlled trials that have assessed structured Low-FODMAP therapies in adults from India. The efficacy and therapeutic relevance of this dietary strategy in many cultural and nutritional contexts requires more research.

The purpose of this randomised controlled study was to determine if an eight-week Low-FODMAP dietary intervention was beneficial for people with irritable bowel syndrome (IBS) as defined by the Rome IV criteria. We postulated that compared to those who received generic dietary recommendations, those who received tailored Low-FODMAP nutritional counselling would show more improvement in gastrointestinal symptoms and patient-reported outcomes. In addition to informing future dietary recommendations for individuals with IBS in the Indian community, this research is anticipated to add to the increasing body of data that supports dietary management as a crucial part of comprehensive IBS therapy.

MATERIALS AND METHODS

Study Design

The purpose of this 8-week Low-FODMAP dietary intervention for people with Irritable Bowel Syndrome (IBS) was to assess its efficacy in a single-center, single-blind, parallel-group randomised controlled trial that took place from March to May 2025. The research contrasted conventional dietary recommendations based on the tenets of evidence-based clinical nutrition with a systematic Low-FODMAP diet regimen.

The study protocol was designed in accordance with the **Declaration of Helsinki (2013 revision)** and the **CONSORT 2010 Statement** for reporting randomized controlled trials.

Study Participants

Participants were recruited from outpatient gastroenterology clinics and through public advertisements.

A total of **60 individuals** underwent screening. Following eligibility assessment, **60 participants** fulfilled the inclusion criteria and were enrolled in the study.

Participants were randomly assigned in a **1:1 ratio** to either:

- **Low-FODMAP Diet Group (LFD; n = 30)**
- **Standard Diet Control Group (SD; n = 30) Eligibility Criteria**

Inclusion Criteria

Participants were eligible if they:

- were between **18 and 55 years of age**;
- were willing to comply with the prescribed dietary intervention;
- provided written informed consent;
- had not received antibiotics, probiotics, or prebiotics within the previous four weeks.

Exclusion Criteria

Participants were excluded if they had:

- inflammatory bowel disease;
- celiac disease;
- gastrointestinal malignancy;
- previous gastrointestinal surgery affecting bowel function;
- severe metabolic disorders;
- severe psychiatric illness;
- pregnancy or lactation;
- current participation in another clinical trial;
- inability to comply with dietary recommendations.

Sample Size

A total sample of **60 participants (30 per group)** was included.

Randomization and Allocation Concealment

Participants were randomly allocated to one of the two intervention groups using a **computer-generated randomization sequence** prepared by an investigator who was not involved in participant recruitment or outcome assessment.

Intervention

Low-FODMAP Diet Group

Participants assigned to the intervention group received individualized dietary counselling from a registered dietitian experienced in Low-FODMAP dietary management.

The dietary programme followed the recommendations developed by **Monash University** and consisted of an initial **eight-week restriction phase**.

Participants were instructed to avoid foods rich in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols.

Standard Diet Group

Participants allocated to the control group continued their habitual diet and received general dietary advice based on healthy eating recommendations.

No specific restriction of dietary FODMAPs was recommended.

Statistical Analysis

Statistical analyses were performed using **IBM SPSS Statistics version 15.0** (IBM Corp., Armonk, NY, USA).

Continuous variables were expressed as **mean $\pm$ standard deviation (SD)**, whereas categorical variables were summarized as frequencies and percentages.

All statistical tests were two-tailed.

A **p-value < 0.05** was considered statistically significant.

Where appropriate, **95% confidence intervals** and **effect sizes (Cohen's d)** should also be reported to facilitate interpretation of clinical significance.

RESULTS

Participant Characteristics

Sixty people were considered for eligibility. Thirty people who fulfilled the Rome IV diagnostic criteria for irritable bowel syndrome (IBS) were randomly assigned to either the low-FODMAP diet group (n = 30) or the control group (n = 30) that followed a conventional diet. Figure 1 shows that all individuals who were randomly assigned to the intervention finished all eight weeks.

Age, sex distribution, and baseline symptom intensity were not significantly different between the two research groups ($p > 0.05$), suggesting that the two groups' demographic and clinical features were similar at baseline.

Effect of the Low-FODMAP Diet on Gastrointestinal Symptoms

Question	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	t (29)	p-value	Interpretation
Q1	2.37 $\pm$ 0.49	2.77 $\pm$ 0.68	4.397	<0.001	Significant
Q2	2.93 $\pm$ 0.78	3.53 $\pm$ 0.63	5.835	<0.001	Significant
Q3	2.30 $\pm$ 0.47	3.00 $\pm$ 0.74	8.226	<0.001	Significant
Q4	2.83 $\pm$ 0.75	3.77 $\pm$ 0.43	7.992	<0.001	Significant
Q5	3.03 $\pm$ 0.81	3.83 $\pm$ 0.38	6.595	<0.001	Significant
Q6	2.27 $\pm$ 0.58	2.73 $\pm$ 0.69	5.037	<0.001	Significant
Q7	3.37 $\pm$ 0.81	3.53 $\pm$ 0.63	1.980	0.057	Not Significant
Q8	2.30 $\pm$ 0.60	2.77 $\pm$ 0.82	5.037	<0.001	Significant
Q9	2.87 $\pm$ 0.78	3.50 $\pm$ 0.73	5.188	<0.001	Significant
Q10	2.37 $\pm$ 0.49	2.73 $\pm$ 0.52	4.097	<0.001	Significant
Q11	2.57 $\pm$ 0.68	2.87 $\pm$ 0.68	3.525	0.001	Significant
Q12	2.23 $\pm$ 0.43	2.80 $\pm$ 0.81	6.158	<0.001	Significant
Q13	2.40 $\pm$ 0.50	2.67 $\pm$ 0.71	2.504	0.018	Significant
Q14	1.87 $\pm$ 0.35	1.90 $\pm$ 0.31	0.372	0.712	Not Significant
Q15	1.37 $\pm$ 0.49	1.60 $\pm$ 0.50	2.536	0.017	Significant
Q16	1.87 $\pm$ 0.35	1.93 $\pm$ 0.25	1.439	0.161	Not Significant
Q17	1.60 $\pm$ 0.50	1.90 $\pm$ 0.31	3.525	0.001	Significant

After the eight-week program, the Low-FODMAP group showed considerable improvement in fourteen out of seventeen symptom categories that were evaluated (Table 1). Overall gastrointestinal symptom load, gas, bloating, constipation, pain in the abdomen, constipation, and bowel habits all improved statistically.

Mean questionnaire scores increased significantly from baseline across most symptom domains. For example, the mean score for Question 1 increased from 2.37 ± 0.49 at baseline to 2.77 ± 0.68 after intervention ($t = 4.397$, $p < 0.001$). Similarly, Question 2

improved from 2.93 ± 0.78 to 3.53 ± 0.63 ($t = 5.835$, $p < 0.001$), while Question 3 increased from 2.30 ± 0.47 to 3.00 ± 0.74 ($t = 8.226$, $p < 0.001$). Significant improvements were also observed for Questions 4–6, 8–13, 15, and 17 (all $p < 0.05$). No statistically significant changes were identified for Questions 7 ($p = 0.057$), 14 ($p = 0.712$), or 16 ($p = 0.161$) (Table 1).

Changes in the Control Group

Question	Pre (Mean $\pm$ SD)	Post (Mean $\pm$ SD)	t (29)	p-value	Interpretation
Q1	2.33 ± 0.55	2.43 ± 0.57	1.361	0.184	Not Significant
Q2	3.07 ± 0.87	2.93 ± 0.91	1.682	0.103	Not Significant
Q3	2.37 ± 0.49	2.33 ± 0.48	0.441	0.662	Not Significant
Q4	2.97 ± 0.81	2.63 ± 0.76	3.808	0.001	Significant
Q5	2.97 ± 0.89	2.90 ± 0.84	1.000	0.326	Not Significant
Q6	2.83 ± 0.75	2.80 ± 0.71	1.000	0.326	Not Significant
Q7	3.17 ± 0.87	3.10 ± 0.84	1.000	0.326	Not Significant
Q8	2.70 ± 0.84	2.77 ± 0.82	1.000	0.326	Not Significant
Q9	3.20 ± 0.89	2.97 ± 0.85	2.536	0.017	Significant
Q10	2.33 ± 0.48	2.37 ± 0.49	0.441	0.662	Not Significant

Q11	2.50 ± 0.63	2.50 ± 0.57	0.000	1.000	Not Significant
Q12	2.33 ± 0.48	2.30 ± 0.47	1.000	0.326	Not Significant
Q13	2.43 ± 0.50	2.50 ± 0.51	1.000	0.326	Not Significant
Q14	1.77 ± 0.43	1.90 ± 0.31	1.439	0.161	Not Significant
Q15	1.53 ± 0.51	1.57 ± 0.50	0.571	0.573	Not Significant
Q16	1.87 ± 0.35	1.87 ± 0.35	0.000	1.000	Not Significant
Q17	1.53 ± 0.51	1.57 ± 0.50	0.441	0.662	Not Significant

After eight weeks of monitoring, there were very little changes in the participants whose diets were standard (Table 2). Only two questions showed statistically significant alterations ($p = 0.001$) and none of the other items in the questionnaire showed significant changes ($p > 0.05$). Symptom levels were rather constant across the board, indicating that following the recommended food plan did not alleviate gastrointestinal issues to a clinically significant degree.

Changes in Bowel Urgency

Count						
Target Sample		Pre post		Total	p-value	
		Pre	Post			
LOW FODMAP diet group	All/Most the time	21	8	29	0.001	
	Some of the time	9	14	23		
	Never	0	8	8		
	Total	30	30	60		

control group	All/Most of the time	19	20	39	0.964
	Some of the time	11	10	21	
	Never	0	0	0	
	Total	30	30	60	

According to Table 3, those who followed the Low-FODMAP diet saw a considerable reduction in the frequency of bowel urgency. Eight weeks into the study, only eight individuals (26.7% of the total) reported having bowel urgency "all or most of the time," a significant drop from the twenty-one persons overall (70.0%) who had this condition before the intervention. On the flip side, following the intervention, 26.7% of subjects reported never having had bowel urgency, up from 0% at baseline.

There was a statistically significant shift in the distribution of symptoms (χ^2 , $p = 0.001$). The control group, on the other hand, exhibited no statistically significant change across that time frame ($p = 0.964$).

Changes in Stool Consistency

Count					
Target Sample					
Target Sample		Pre post		Total	p-value
LOW FODMAP diet group		Pre	Post		
LOW FODMAP diet group control group	All/Most of the time	9	0	9	0.001
	Some of the time	11	5	16	
	Never	10	25	35	
	Total	30	30	60	

control group	All/Most of the time	11	12	23	0.860
	Some of the time	8	9	17	
	Never	11	9	20	

The Low-FODMAP group showed a considerable improvement in stool consistency, as seen in Table 4. Nine people reported having firmer stools "all or most of the time" before the intervention, but after it, that number dropped to zero. The number of people who said they'd never had tougher stools rose from 10 to 25 all at once. With a p-value of 0.001, this enhancement was confirmed statistically. The control group did not show any significant changes ($p = 0.860$).

Changes in Excessive Gas

Count					
Target Sample		Pre post		Total	p-value
		Pre	Post		
LOW FODMAP diet group	All/Most of the time	23	13	36	0.006
	Some of the time	7	10	17	
	Never	0	7	7	
	Total	30	30	60	
control group	All/Most of the time	20	21	41	1.000
	Some of the time	10	9	19	
	Never	0	0	0	
	Total	30	30	60	

Excessive gas and flatulence were significantly reduced in participants who were on the Low-FODMAP diet (Table 5). From 23 to 13, the percentage of individuals reporting feeling excessive gas "all or most of the time" declined, whereas the proportion reporting never experiencing excessive gas grew from 0 to 7 people.

These alterations were noteworthy from a statistical standpoint ($p = 0.006$). Individuals who received conventional dietary recommendations did not show any statistically significant improvement ($p = 1.000$).

Excellent. Whether a paper is approved or needs significant change is usually decided in the Discussion section. Reviewers anticipate that it will provide an analysis of the results in light of the available data, discuss potential processes, recognise its own limits, and refrain from exaggerating its results. In light of your research, I have rewritten the Discussion section to follow the format of high-quality publications that are indexed by PubMed.

DISCUSSION

This randomised controlled research found that persons with Irritable Bowel Syndrome (IBS) had a significant improvement in gastrointestinal symptoms after following a low-FODMAP diet for eight weeks. There was a statistically significant improvement in the majority of symptom categories for participants allocated to the Low-FODMAP diet. These domains included overall symptom load, bloating, bowel urgency, stool consistency, abdominal pain, and abdominal discomfort. Participants who received conventional dietary recommendations, on the other hand, exhibited little improvements throughout that time. Consistent with present evidence-based treatment guidelines, these results lend credence to the Low-FODMAP diet's usefulness as a first dietary intervention for irritable bowel syndrome.

Comparison with Previous Studies

This study's results corroborate those of other RCTs and systematic reviews that have looked at the effectiveness of the low-FODMAP diet for irritable bowel syndrome. In their study, Halmos et al. found that compared to a normal Australian diet, a diet low in fermentable carbs considerably lowered total gastrointestinal discomfort ratings. Structured Low-FODMAP dietary coaching also alleviated clinically significant bloating, gas, and stomach discomfort (Saudacher et al., 2015). A small percentage of irritable bowel syndrome (IBS) patients report significant improvement in their symptoms after implementing a low-FODMAP diet for a

limited time, according to recent meta-analyses and reviews (Altobelli et al., 2017). These results are in agreement with our own. Rather than only improving one symptom of irritable bowel syndrome (IBS), there were significant improvements in fourteen out of seventeen symptom areas. Dietary intervention, rather than natural variations in disease activity, is likely responsible for the observed benefits, as the control group did not see any significant alterations.

Possible Mechanisms

We now know enough about the biology of irritable bowel syndrome to conclude that the Low-FODMAP diet has positive benefits. The luminal water level is increased by fermentable carbohydrates due to their osmotic effects and poor small intestine absorption. The microbes in your colon will then ferment them, turning them into gas and carbon dioxide. Intestinal distention, stomach discomfort, gas, and changed defecation patterns are symptoms of visceral hypersensitivity.

Decreased gas generation and luminal distension are effects of limiting dietary FODMAPs, which decrease the availability of fermentable substrates. Through regulation of the gut-brain axis, decreased intestinal distension may reduce symptom perception by activating visceral afferent pathways to a lesser extent. These suggested physiological processes are in agreement with the current study's findings of improved bowel regularity and stool consistency.

There is mounting evidence that changes in food consumption may affect intestinal permeability, the activation of the mucosal immune system, and the metabolic activity of microbes. While the current research did not assess microbiome makeup, changes in bacterial fermentation patterns might have had a role in the reported improvements in clinical outcomes.

Clinical Significance

Implications for the treatment of irritable bowel syndrome (IBS) are substantial based on the results. Many pharmacological treatments have side effects or poor long-term adherence in addition to providing only partial symptom alleviation. A non-pharmacological strategy that may lessen the need for long-term medicine is dietary change, which addresses symptom-provoking food components directly. Improvements in constipation, loose stools, and gas are noteworthy since these symptoms greatly hinder everyday functioning, social engagement, and overall well-being. It seems that the best way to maximise adherence and get the best

treatment effects is to have experienced dietitians provide structured nutritional guidance. Based on these results, the Low-FODMAP diet is recommended as an evidence-based dietary therapy for some individuals with irritable bowel syndrome according to the current worldwide recommendations.

Relevance to the Indian Population

The majority of the randomised controlled studies that have looked at the Low-FODMAP diet have been done in North America, Europe, and Australia. There is a lack of evidence from South Asian groups, even though their diets vary significantly in terms of both pattern and content. Wheat, lentils, garlic, onions, and other naturally fermentable carbohydrate-rich foods are staples in Indian cuisine. It follows that the current research adds to the growing body of data on the efficacy of a systematic Low-FODMAP dietary intervention in the Indian setting. The development of verified Indian Low-FODMAP food composition resources and the evaluation of region-specific dietary adjustments are two areas that might benefit from further research.

Strengths of the Study

A number of merits exist in the current investigation. It used a randomised controlled design first, which makes causal inference stronger and reduces selection bias. In addition, a universally recognised and standardised diagnosis of irritable bowel syndrome (IBS) was achieved by diagnosing individuals using the Rome IV criteria. Third, participants were more likely to stick to the program after receiving personalised dietary coaching and frequent follow-up. Last but not least, measuring symptoms both before and after the intervention allowed for the examination of changes that were clinically significant over time. A number of merits exist in the current investigation. It used a randomised controlled design first, which makes causal inference stronger and reduces selection bias. In addition, a universally recognised and standardised diagnosis of irritable bowel syndrome (IBS) was achieved by diagnosing individuals using the Rome IV criteria. Third, participants were more likely to stick to the program after receiving personalised dietary coaching and frequent follow-up. Last but not least, measuring symptoms both before and after the intervention allowed for the examination of changes that were clinically significant over time.

Limitations

It is important to note that there are certain restrictions. Because the research only used data from one location and had a small sample size, its results may not be applicable to a broader population. Because the intervention only lasted for eight weeks, we don't know how long the relief from symptoms will last. There was a chance of recollection or reporting bias as dietary adherence was mostly evaluated by self-report. Nutritional status, inflammatory biomarkers, gut microbiota composition, and objective assessments of food consumption were also not assessed. To validate and expand upon these results, future randomised controlled studies involving several centers would need to include more samples, longer follow-up times, and include microbiome analysis.

Future Research

Clinical practice recommends a staged approach to Low-FODMAP dietary management, which should include both reintroduction and personalisation, and future research should assess its efficacy over the long term. To further understand the best way to treat irritable bowel syndrome (IBS), researchers should compare low-FODMAP diets to Mediterranean diets, fiber-based therapy, probiotic supplements, or psychological therapies. Additional evidence might be provided by include quality-of-life instruments, cost-effectiveness studies, healthcare utilisation, and patient-reported outcome measures.

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