Assessment of the FODMAP Diet Experience and Change in Gastrointestinal Symptoms and Quality of Life in Participants Following a Registered Dietitian-Administered FODMAP Elimination Diet

by

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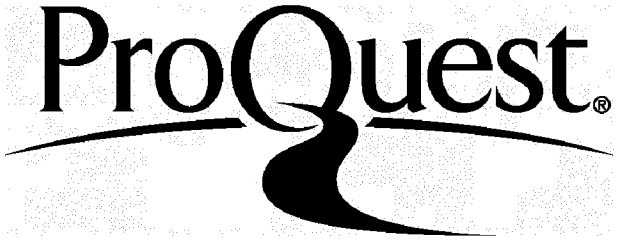
B.S., Saint Louis University, 2015

Submitted to Rush University in partial
fulfillment of the requirements for the
degree of

Master of Science



THESIS APPROVAL FORM

The undersigned have examined the thesis entitled:

Assessment of the FODMAP diet experience and change in gastrointestinal symptoms and quality of life in participants following a registered dietitian-administered FODMAP elimination diet.

Presented by: Melanie Battaglia

A candidate for the degree of Master of Science,

And hereby certify that, in their judgment, it is worthy of acceptance.

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ABSTRACT

Title of Thesis: Assessment of the FODMAP diet experience and change in gastrointestinal symptoms and quality of life in participants following a registered dietitian-administered FODMAP elimination diet.

Melanie Ann Battaglia, Master of Science in Clinical Nutrition, 2017

Thesis Directed by: Heather Rasmussen, PhD, RD, Associate Professor, Clinical Nutrition, Rush University Medical Center

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Signature of Thesis Advisor

Objective: To evaluate change in gastrointestinal (GI) symptoms and quality of life (QOL) before and after implementing the Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols (FODMAP) elimination diet with guidance by a registered dietitian (RD) and to learn about patients' experience with the FODMAP elimination diet for irritable bowel syndrome (IBS).

Methods: The GI symptom rating scale for IBS (GSRS-IBS) and the IBS-QOL were administered before and after the 4-week elimination diet and analyzed using Wilcoxon signed rank test. Qualitative one-on-one phone interviews focusing on the elimination diet experience were completed after a 4-week elimination diet, and content analysis was completed using transcripts.

Results: Participants (n=16) were predominantly female (75%) and White (81%), with an average age of 47 (±14) years. Significant differences (p=0.02) in the total GSRS-IBS median (IQR) score (45.5 (29.9, 55.6) vs 36.7 (24.7, 48.8)) after elimination (range of 13-91 with higher score indicating more symptoms). Total IBS-QOL median (IQR) score

significantly improved after elimination (94.5 (78.8, 110.5) vs. 73.5 (58.0, 100.3)), respectively; (p=0.002), (range of 35-175 with higher score indicating more symptoms) indicating an improved QOL after the elimination diet. Eight of 12 participants discussed receiving physician recommendations before meeting with the RD. After meeting with the RD, 11 of 12 participants reported RD's education materials as helpful, and five of 12 discussed that the most beneficial aspect of the RD was having the RD's support throughout the diet to improve adherence.

Conclusion: Inclusion of the RD during the FODMAP elimination diet improves GI symptoms and QOL through helpful resources and support, reinforcing the role of the RD when a FODMAP elimination diet is recommended.

ACKNOWLEDGEMENT

I cannot express enough thanks to my thesis advisor, Dr. Rasmussen, for all of her help and guidance throughout this entire process. I would also like to thank my committee members, Hannah Roosevelt, for input and assistance throughout the study and Dr. Keim, for guiding me through the qualitative analysis within the current study. I am sincerely appreciative for all I have learned while working with my committee. I would also like to thank the faculty members, Dr. Tangney and Dr. Foley, for sharing their passion for research over the course of the program.

Lastly, I would like to thank my classmates, friends and family for their ongoing support and encouragement which helped with my completion of this project.

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INTRODUCTION

Irritable Bowel Syndrome (IBS) is a functional gastrointestinal disorder characterized and diagnosed according to ROME III criteria. Irritable bowel syndrome often causes recurrent abdominal discomfort and altered bowel habits and is sub-typed into IBS with constipation, IBS with diarrhea, and mixed type. IBS is defined by its symptoms of abdominal pain, bloating, flatus, and dissatisfaction with stool consistency. These symptoms may occur by mechanisms of osmolarity and gas production. First, undigested short chain carbohydrates or sugar alcohols create an osmotic force by pulling water into the gastrointestinal tract creating frequent and loose stools.[1] Second, they rapidly ferment and trigger generation of excess gas in the small and large intestine, then luminal distension occurs.[1] When the gas-producing carbohydrates and sugar alcohols are eliminated from the diet, symptoms may improve. Because it is not known what causes IBS, treatment is based on management of symptoms or with a diet low in fermentable carbohydrates, called the FODMAP elimination diet.[2]

FODMAP is an acronym for the types of poorly digested carbohydrates that cause symptoms: fermentable oligosaccharides, disaccharides, monosaccharides, and polyols. Recently, a low-FODMAP diet has been researched and linked with improved symptoms of IBS.[3, 4] However, it is still unclear whether a dietitian can further improve symptoms with the use of a FODMAP diet protocol. Furthermore, for patients following the diet with the consultation and monitoring of a registered dietitian, there is limited evidence of improved symptoms and quality of life. Determining the experience on the-FODMAP elimination diet may help dietitians gain knowledge on how to assist patients in the future in making the diet more feasible.

Purpose

The purpose of the current study is to determine how to make the FODMAP elimination diet more feasible for patients by analyzing their experience on the diet.

Objectives

The objectives of this study are:

1. Adapt a protocol and education materials for dietitians to use when administering the low-FODMAP diet
2. Assess the experience of those following the low-FODMAP diet using a subjective feasibility questionnaire and qualitative analysis
3. Assess gastrointestinal symptoms before and after the FODMAP elimination diet using the validated GSRS-IBS questionnaire,
4. Evaluate the change in quality of life using the validated IBS-QOL questionnaire before and after the FODMAP elimination diet.

**The introduction, purpose, and objectives of the project changed from the proposal. An updated version is located within the manuscript.

REVIEW OF LITERATURE

Irritable Bowel Syndrome

Irritable Bowel Syndrome (IBS) is a functional gastrointestinal disorder affecting an estimated 11% of people in industrialized countries, characterized by chronic abdominal symptoms and changes in bowel habits without any specific pathological cause.[5] Perhaps because the pathogenesis of the disorder is multifactorial, IBS is one of the most common gastrointestinal (GI) disorders found in gastroenterology clinics.[6] IBS may present as a constellation of waxing and waning GI symptoms including abdominal pain, bloating, altered stool consistency, diarrhea, or constipation. These symptoms may begin at any age; 10-15% of school-aged children has IBS, while in adults onset is most prevalent in those fifty years of age or younger.[5, 7, 8]

Due to the absence of known pathological markers for IBS, symptom-based criteria are used to standardize the diagnosis of IBS. The Rome III diagnostic criteria defines IBS as abdominal pain that occurs at least three times a month for the last three months with two or more of the following criteria: improvement with defecation, onset associated with a change in frequency of stool, or onset associated with a change in form of stool.[2] In addition to the Rome III criteria, IBS is separated into three subtypes differentiating between the types of bowel conditions, such as constipation, diarrhea, and a mix of constipation and diarrhea.

Subtypes of Irritable Bowel Syndrome

Irritable Bowel Syndrome is separated into three subtypes: constipation-based IBS (IBS-C), IBS with diarrhea (IBS-D), or a mix of constipation and diarrhea (IBS-M).

Bowel habits are likely to change, which cause subtypes to change; physicians and patients often identify subtype based on stool form with the Bristol Stool Form Scale. The scale classifies stool into seven types. Type one on the scale is the constipation subtype and is classified as separate hard lumps and type seven is the diarrhea subtype and is classified as stools of watery and liquid form.[2] Physicians treat patients by subtype because the patients have differences in symptoms and quality of life (QOL). IBS-D and IBS-M have lower QOL than IBS-C. Individuals with IBS-D and IBS-M are affected by diarrhea, consequently altering daily activities, social activities, and intake of food.[9] With increased bowel frequency in the IBS-D or IBS-M subtype, patients are less likely to engage in social, leisure and physical activities. Quality of life scores therefore are lower compared with IBS-C. Once physicians gain an understanding of the patient's particular subtype of IBS, management to address the IBS presentation can be tailored to that particular patient.

Quality of Life

Symptoms of IBS impact an individual's daily lifestyle, such as social activities, physical activity, and meal times. The negative effect on lifestyle may be a contributor of lower quality of life in patients with IBS versus healthy individuals. For example, while many people may associate mealtime with joy, comfort, and community; IBS patients' often associate food with anxiety and painful or uncomfortable abdominal symptoms. About two-thirds of IBS patients consider their symptoms to be triggered by food and therefore self-restrict their habitual diet.[10] It is not only at mealtime that quality of life is affected in the IBS patient. Data from the Health Related Quality of Life questionnaire (HRQOL; IBS-36) was created to assess IBS patient quality of life. The

IBS-36 consists of thirty-six questions and can score on a scale 0 – 216, initially and for the purpose of the study at a two-month follow up.[11] The questionnaire demonstrated that IBS patients score lower than non-IBS individuals. In fact, patient IBS-HRQOL scores were about the same as the scores of diabetic patients.[12] Examples of diminished quality of life in IBS patients include avoiding social settings out of anxiety towards being away from the bathroom and avoidance of activities, such as eating out. Considering the large psychosocial component of IBS, it is essential that the impact of IBS on daily life be taken into account in order to optimize patient care.

Irritable Bowel Syndrome Treatment

Depending on the IBS presentation, several treatment options can be recommended by physicians. For instance, to improve stool consistency, loperamide (e.g., Imodium) can be used to decrease colon transit and increase water absorption. However, loperamide can result in constipation if not dosed correctly. Another therapy includes peppermint oil as an antispasmodic to improve abdominal pain, although the side effect of heartburn may occur. Furthermore, antidepressants are commonly used in IBS-D because it has been associated with reduction in loose stools and the feeling of incomplete defecation. Probiotics are another possible treatment option because the probiotics may improve gut barrier function to relieve symptoms of abdominal pain and bloating.[13] Pharmaceuticals continue to evolve to provide therapies for patients with IBS, which offer quick and easier ways to improve symptoms without changing lifestyle factors, such as diet. However, over-the-counter and prescribed medicine can trigger side effects, (e.g., heartburn), are not always approved by the FDA, and often the long-term effects of the treatments are not researched.

Dietary intervention is also recommended for those with IBS, The Academy of Nutrition and Dietetics recommends the following: 5 to 6 small meals/snacks per day, gradually increased fiber intake, water intake of 6 to 8 cups per day, limited intake of spicy and acidic foods, and a low-fat diet of reduced fried food and foods cooked with added fat. The term FODMAP, which will be described in a latter section, is identified as a dietary treatment option for IBS; however, it is not emphasized as a meal plan and handout with details of how to follow the diet are not provided. While there are benefits and barriers to all treatments, new research proposes that dietary management of a low-fermentable carbohydrate diet may improve IBS symptoms, while also helping to identify the specific dietary triggers.

Self-Administered Dietary Intervention for Irritable Bowel Syndrome

Patients often initiate dietary intervention for IBS without guidance from a healthcare professional. This could lead to unnecessary exclusion of foods and impose limitations on key nutrient intake. To better understand what patients with IBS are doing on their own in regards to dietary changes, Hayes et al 2014 surveyed 135 Irish patients with IBS and 111 healthy subjects.[14] Hayes et al explored whether IBS patients consider food as triggers for symptoms. For instance, whether patients alter their diet to avoid symptoms and whether the patients associate certain foods and food groups with the symptoms. Hayes determined that IBS patients often associate food with IBS symptoms, and therefore the patients self-initiate diet change, including self-restriction. Food was reported to contribute to worsened GI symptoms in 90% of the IBS patients and 55% of healthy individuals ($P< 0.001$). IBS patients reported restriction of milk products, wheat products, fruit, and vegetables. IBS patients also reported diet changes based on their own

experiences (92%), based on recommendations from an alternative practitioner (18%), a doctor (17%), or a dietitian (12%). The minimal number of patients that consulted a dietitian (12%) is concerning because self-restricting the diet due to symptoms may put patients with IBS at risk of developing dietary inadequacies in calcium, iron, fiber, and other micronutrients.

Monsbakken et al. examined the prevalence of perceived food intolerance and food restriction in IBS patients in Norway.[15] Patients had a consultation with a dietitian to discuss symptoms in relation to diet, dietary habits, and nutrition status. Out of 84 IBS patients, 59 had symptoms of IBS related to food intake; perceived food intolerance was prevalent (70%) in this population of IBS patients. The mean number of reported symptom-causing food items was 4.8 food items (range 0-19). The food items most frequently reported to trigger symptoms were milk, vegetables, coffee, and chocolate. A total of 62% of the IBS population (51 out of 82 patients) limited or excluded one or more food items from the diet (mean of 2.5 excluded foods on a range 0-14), which could be a potential problem for the patient because it can lead to nutritional risks. The most common excluded items were milk (35%), cabbage (29%), and coffee (26%). It was concluded that 10 patients (12% of the IBS population) had an inadequate diet that consisted of low energy intake with under-nourishment and weight loss, avoidance of food groups, unvaried diet, or risk of vitamin and mineral deficiency. In conclusion, because perceived food intolerance and self-restriction of diet are prevalent in IBS, it is important for IBS individuals to have a knowledge base about foods that may trigger symptoms in patients with IBS. A dietitian can advise how to incorporate specific foods to avoid altered nutritional status in patients with IBS.

Evidence that Fermentable Carbohydrates trigger Symptoms

Fructans are linear or branched fructose polymers found in foods such as asparagus, leeks, garlic, onion, wheat, bananas, and legumes. Intake of fructans has increased in the United States due to the high intake of pasta, pizza, cakes, and bread. [16] Evidence has not established whether the IBS symptoms are induced by non-celiac gluten intolerance in the form of wheat in some individuals or whether fructans are the culprit. A study by Biesiekierski et al. was conducted to determine whether gluten or fructans trigger gastrointestinal symptoms in non-celiac patients. The trial was a randomized, double-blind, placebo-controlled, dietary challenge trial in IBS patients who were not diagnosed with celiac disease. IBS participants followed either a diet with gluten or a gluten free diet over the course of the six-week study. Those in the gluten treatment group (n=19) were given one muffin and two slices of bread containing gluten, totaling 16 g/day of gluten (1 slice of bread contains about 5 g of gluten). The placebo treatment group (n=15) received only gluten free foods. Symptoms were evaluated on a 100-mm visual analog scale (VAS) at the end of each week of the study and the 3 weeks post study treatment. The VAS was measured with 0 representing no symptoms and assessed bloating, abdominal pain, satisfaction with stool consistency, nausea and tiredness. The 68% (n=13/19) of subjects in the gluten group reported that within the first week symptoms were not adequately controlled, significantly more so than those in the placebo group (40%; n=6/15) (p=0.001). The exact VAS scores were not stated for symptom severity of each symptom. However, Biesiekierski reported statistical significance of the symptom severity scores for those consuming the gluten diet compared to those on the gluten-free diet over the entire course of the study. Statistically significant symptoms

include abdominal pain (p=0.016), satisfaction with stool consistency (p=0.024), and tiredness (p=0.001). In conclusion, all participants receiving gluten had worsening of symptoms throughout the trial, whereas the placebo group had less severe symptoms that occurred at a slower level; the rate of change in symptoms was not identified. Additionally the sample size was small, only 19 subjects in the gluten protocol and 15 in the placebo protocol. Thus, gluten is a possible trigger for gut symptoms in IBS patients who do not have celiac disease. Gluten restriction may be a management option for those with IBS and gut symptoms, however further research is needed to identify whether gluten is causing the worsened symptoms or whether fermentation of carbohydrates, such as fructans, in the wheat products are causing symptoms.[17]

Fructose is a naturally occurring 6-carbon monosaccharide found in added sweeteners, high fructose corn syrup, honey, and fruit. Hydrogen breath tests can measure fructose malabsorption, where a positive test after ingestion of fructose implies that bacteria ferment the fructose in the large intestine rather than it being absorbed in the small intestine.[16]

Shepherd et al provided evidence that two of the symptom-causing molecules, fructans and fructose, may play a role in IBS symptoms.[18] The trial was double-blinded, randomized, and placebo-controlled crossover with 25 IBS patients. The patients included tested positive for fructose malabsorption, pre-recruitment had followed the FODMAP elimination diet for at least 3 months, and had improved gastrointestinal symptoms on the FODMAP elimination diet. After a 10-day FODMAP elimination baseline diet, the patients were randomly challenged with 1 of 4 test substances comprised of fructans, fructose, fructose-fructan mix, or glucose (control). The

substances initially were powders and patients were instructed on how to mix them with water. Patients were randomized to their test substance and were instructed to take the test substance with food three times per day. Each test substance was tested at a low dose for three days, immediately followed by a medium dose for three days, immediately followed by a large dose for three days, and then a washout period for an average of 14 days occurred before crossing over to the next randomly assigned test substance. The low dose was either 7 grams of fructan, 14 grams of fructose, a mixture of 7 grams of fructan and 14 grams of fructose, or 7 grams of glucose. The medium daily dose consisted of either 14 grams of fructan, 28 grams of fructose, a mixture of 14 grams of fructan and 28 grams of fructose, or 14 grams of glucose. The high dose was either 19 grams of fructan, 50 grams of fructose, a mixture of 19 grams of fructan and 28 grams of fructose, or 20 grams of glucose. in drink form with a provided FODMAP elimination meal. All subjects started with a low dose given with three meals per day, followed by the medium dose began also given with three meals each day for 3-days and lastly the high dose consumed at three meals for three days. Subjects with intolerable symptoms ended the test phase early. Following the high-treatment dose was a minimum 10-day washout period where subjects followed the FODMAP elimination diet. Based on 100-mm VAS, for overall abdominal symptoms, wind, bloating, abdominal pain, tiredness, and nausea after the maximal treatment dose taken by subjects (specific maximal dose not reported with the following statistics) and compared with glucose (control), symptoms were significantly greater with ingestion of fructose (P=0.001), fructans (P=0.0005), and fructose-fructan mix (P=0.002). Compared with the lowest dose of each test drink, intensity of abdominal symptoms worsened as the dose increased (p=0.01). When intake

of fructose in excess of glucose, fructans, and the mixture of fructose-fructans were compared with the glucose control, overall symptoms, abdominal pain, bloating, and wind were exacerbated. Shepherd's trial provided preliminary evidence that fructose and fructans may trigger IBS symptoms. Therefore, restriction of both of these poorly absorbed short-chain carbohydrates may improve symptoms in IBS patients.

Lactose is also a fermentable carbohydrate found in dairy products such as milk, ice cream, and soft cheeses. Lactose malabsorption, occurring in about 70% of adults, is due to inadequate lactase activity.[19] Without a sufficient amount of lactase, lactose is not digested and absorbed in the small intestine and instead passes into the colon where it is fermented into gas and short-chain fatty acids causing luminal distention and abdominal symptoms. Malabsorption can be assessed with a hydrogen breath test consisting of an oral challenge of 20-50 g of lactose.[19] Thus, lactose is a key component to avoid as part of a FODMAP elimination diet. When Monsbakken et al. studied the prevalence of perceived food intolerances in IBS individuals, he discovered that lactose was the most common perceived food intolerance (41.7%, n=84).[15] Lactose is most commonly malabsorbed compared to other carbohydrates due to genetics of lactase non-persistence.[20] Throughout development, lactase activity declines, yet tolerance to lactose does persist through adulthood in some humans, especially Caucasians with Northern European roots. Lactase persistence is prevalent in 80-95% of adults from Scandinavia, the British Islands, and Germany. Lactase persistence is not as prevalent in Indian adults (20-40%), Mexicans adults (30%), African American adults (30%), and adults in Southeast Asia (<10%). In summary, lactose malabsorption is related to the activity of

the lactase enzyme. When lactase activity declines symptoms of IBS may occur due to the fermentation of undigested lactose in the colon.

Sorbitol and mannitol are polyols that are naturally occurring in certain fruits and vegetables and also used as a sugar substitute for sugar-free foods. A study by Yao et al. tested the food quantity of sorbitol and mannitol in natural foods and examined the patterns of absorption and symptoms in IBS patients and healthy individuals.[21] Sorbitol content was highest per average portion size in prunes (10.8 g/.25 cup), apricots (1.3 g/ 1 fruit), dried pears (2.2 g/ 6 pieces), sugar-free chewing gum (1.7 g/ 2 gum strips, plums (1.6 g/ 1 fruit), apple juice (1.1 g/1 cup), dried apples (.9 g/.5 cup), wasabi (.6 g/1 tsp.), cherries (.3 g/5 cherries), coconut milk (.3 g/1 cup), and dried coconut (.2 g/.5 cup). Mannitol was highest in celery (1.5 g/1 cup), pumpkin (.4 g/1 cup), and pomegranate (.3 g/1 fruit).

In addition to measuring sorbitol content in different foods, Yao et al. conducted a randomized, double-blinded, placebo controlled, crossover study with 21 healthy individuals and 20 IBS patients. In this study, 10 grams of sorbitol, mannitol, or glucose (placebo), were ingested; this dose was reflective of a realistic but high intake of the polyols that was not likely to induce diarrhea in the healthy individuals.. Between sugar challenges, a washout period of 1 to 7 days (length dependent on symptom relief) took place before crossing over to the next challenge. Symptoms were scored on 100-mm visual analogue scales (VAS) before and after each sugar challenge. Malabsorption was defined as a rise in breath hydrogen concentrations greater than 10 ppm compared with baseline in two repeated breath samples. Area-under-the-curve (AUC) against time (ppm) was used to determine the degree of malabsorption; results were categorized as marked

(61-100%), moderate (31-60%), low (6-30%), or no malabsorption (0-5%). The IBS group had significantly worse gastrointestinal symptoms compared with the healthy controls (sorbitol, P=0.02; mannitol, P=0.004) at treatment end. There were no significant differences in symptoms after sorbitol intake compared with mannitol intake in both groups. IBS patients had significantly greater symptoms after sorbitol ($p = 0.05$) and mannitol ($p = 0.02$) compared to glucose (placebo), whereas the healthy controls had no differences in symptoms for both polyols compared with glucose. Additionally, the IBS group had significantly longer transit time for both polyols compared with the healthy controls ($P= 0.03$), with a mean of 105 minutes in IBS compared to a mean of 75 minutes in healthy controls. Breath hydrogen tests were not reflective of the symptoms that occurred in the IBS group. For instance, the breath hydrogen test results showed that significantly more IBS individuals absorbed mannitol compared with the healthy controls (P=0.02). Breath hydrogen tests for sorbitol between the IBS group and healthy controls were not significantly different. Also, breath hydrogen tests for sorbitol and mannitol were not significantly different within the healthy controls. However, the IBS group produced significantly greater breath hydrogen after ingestion of sorbitol than mannitol (P=0.002). In conclusion, abdominal symptoms were induced by sorbitol and mannitol over the duration of the 4-hour breath test in patients with IBS, but not in healthy individuals. Further research is needed to conclude why breath hydrogen results were not related to gastrointestinal symptom scores.

Combined intake of poorly absorbed carbohydrates may contribute to worsened symptoms in comparison to isolated intake. Symptom improvement has shown the greatest results when poorly absorbed short-chain carbohydrates are restricted together

rather than restricted individually. For instance, in a study by Goldstein et al., 94 IBS patients and 145 patients who did not meet the Rome I criteria but had functional complaints (FC) were included in the study to examine change in symptoms after taking a lactose, fructose, and mixture of fructose and sorbitol breath test. The tests took place on 3 separate occasions, over an unidentified number of weeks, and each test consisted of consuming each of the following every 30 minutes for 4 hours: a lactose solution (18 g), a fructose solution (25 g), and a mixture of fructose and sorbitol (25 g and 5 g). A total symptom score on a range of 0 to 15 was taken for each patient after the breath test. More than 70% of patients reported symptoms during the tests. 61% of all patients were positive for lactose and fructose-sorbitol malabsorption. Isolated lactose malabsorption occurred in 16% of IBS patients and 12% of FC patients. Additionally, malabsorption of both lactose and fructose-sorbitol occurred in 27% of IBS and 29% of FC patients and malabsorption of lactose, fructose, and fructose-sorbitol occurred in 34% of IBS and 32% of FC patients, respectively. For the next phase of the trial, patients were asked to restrict the offending sugar from their diet for 1 month and record symptoms, symptom improvement after removing the offending sugar, and compliance to the restricted diet. While only 34% of IBS and 32% of FC patients returned the questionnaire, among the respondents it was found that more than 50% improved after the restricting the offending sugar from their diet (16/30 IBS. 56%; 26/43 FC, 60%) and a reduction in total number of symptoms in both IBS and FC groups ($P<0.001$). Lastly, compliance to the diet was recorded as 70% in the IBS patients and 67% in the FC patients.[22] Goldstein's results conclude that lactose, fructose, and sorbitol trigger symptoms in the IBS and the FC group and malabsorption of multiple sugars combined are more common than isolated

malabsorption, and symptoms improve within one month of restricting the offending sugar from the diet.

The FODMAP Elimination Diet

Fermentable oligosaccharides, disaccharides, monosaccharides and polyols are short-chain poorly absorbed carbohydrates known as FODMAPs. The carbohydrates, such as fructose, fructans, lactose, galactans, and sugar alcohols that are in the FODMAP category, act individually as triggers for symptoms of IBS. The carbohydrates ferment possibly due to incomplete absorbed in the small intestine or because the enzymes required for carbohydrate breakdown are not available. As stated in the previous section, when the fermentable carbohydrates are ingested together, symptoms are exacerbated. Therefore, restriction or eliminating of foods containing FODMAPs from the diet reduces gastrointestinal symptoms, thus the FODMAP elimination diet.

Functional Properties of FODMAPs

FODMAPs trigger symptoms of IBS in response to luminal distention. Luminal distention may occur due to visceral hypersensitivity, excessive gas production due to the microbiota, or motility problems with clearance of fluid/gas.[23] Excessive gas production can occur when poorly absorbed carbohydrates are not absorbed in the small intestine and ferment in the large intestine. Poor absorption may occur due to slow, low-capacity transport mechanisms across the epithelium, reduced activity of brush border hydrolases, lack of hydrolases, or molecules being too large for simple diffusion.[23] After transport into the colon, an osmotic effect occurs, which pulls in fluid. FODMAPs are then fermented by colonic microflora producing hydrogen, carbon dioxide, and short-chain

fatty acids. The speed of fermentation by bacteria differs by the chain length of the carbohydrate; oligosaccharides and sugars are rapidly fermented compared with polysaccharides.[23] If abundant FODMAPs reach the colon, luminal distention occurs due to the osmotic load and rapid gas production. The luminal distention induces symptoms of bloating, abdominal pain, distention, diarrhea and flatulence.[24 25] Irritable bowel syndrome patients often have an underlying bowel response that is exaggerated or abnormal, thus when dietary FODMAPs enter the small or large intestine symptoms are often generated.[23] Thus, reducing the consumption of FODMAPs can improve abdominal symptoms.

The FODMAP Reintroduction Phase

The FODMAP elimination diet is not intended for patients to follow long-term. The purpose of the FODMAP reintroduction phase is to add back foods into the diet to identify the foods that trigger symptoms. After symptom resolution following FODMAP elimination diet, IBS individuals can individually reintroduce each type of FODMAP (lactose, galactans, fructans, fructose, and polyols) into the FODMAP elimination diet. In this phase, each FODMAP food is dosed based on the grams of FODMAP. Individuals are advised to consume a low dose on the first day and a higher dose on the second day. In between each challenge, the patients return to the FODMAP elimination diet as a washout for symptom resolution before challenging the next FODMAP. Even if a FODMAP is tolerated, that FODMAP is to be eliminated for the remainder of this phase. Tolerated FODMAPs can then be reintroduced back into the diet after all FODMAPs have been challenged. The FODMAPs that are not tolerated can be eliminated from the diet and depending on severity of the reaction; instruction to challenge them may be

advised again in the future. [26]While food elimination diets and food challenges are time consuming and require patience, motivation and compliance, elimination diets are necessary for identifying offending foods. No randomized control trials have focused on this phase of the diet; therefore further research is needed to identify a feasible protocol for patients following the reintroduction phase of the diet.

Efficacy of the FODMAP Elimination Diet for Patients with IBS

FODMAPs are highly fermentable, poorly absorbed short-chain carbohydrates that have been linked to symptoms of IBS. Shepherd et al first published the research that established the term FODMAP and connected it to IBS in 2006.[25] IBS symptoms improved in association with reduced dietary intake of fructose and fructans. The study was retrospective and uncontrolled; however, several subsequent studies have been conducted which support Shepherd's original findings that symptoms of IBS are correlated with FODMAP consumption (**Table 1**). Evidence suggests that when FODMAPs are removed from the diet, symptoms improve. The randomized control trials by Ong et al., Saudacher et al., Halmos et al., and Bohn et al. have tested the efficacy of the FODMAP elimination diet in alleviating the symptoms in individuals with IBS.

Ong et al. researched the effects of a FODMAP elimination diet and high-FODMAP diet on gastrointestinal gas production in relation to IBS symptoms (**Table 1**). In a crossover study, IBS (4 IBS-D; 7 IBS-C; 2 IBS-M; 2 unclassified) and healthy patients followed both a FODMAP elimination diet and a high-FODMAP diet (FODMAPs differed by 40 g), each for 2 days [4]. All food was provided, and there was a 7-day washout period in between diets. Food and symptoms were reported daily, and hydrogen breath samples were completed on the second day every hour for 14 hours.

Table 1. Studies Assessing the Effect of a FODMAP Elimination Diet on Gastrointestinal Symptoms in Patients with Irritable Bowel Syndrome

Author, Year	Study Design	Participants	Intervention	Outcome Measures	Results
Ong, 2010	Randomized, single-blind, crossover	•IBS (n=15) •Healthy Controls (n=15)	2-day HFD (50 g/day) 7-day washout period 2-day FED (9 g/day)	Un-validated symptom scoring tool (0-3) and breath H_2 collected hourly over 14 h on day 2 of both interventions	TBH greater on HFD in both groups (p<0.0001). More TBH on both diets in IBS patients (IBS HFD: 242 ppm vs Healthy HFD: 181 ppm) (IBS FED: 62 ppm vs Healthy FED: 43 ppm). Composite IBS score of reported symptoms (bloating, abdominal pain, wind) higher on HFD than FED (P=0.002). Composite healthy symptom score higher on HFD (P= 0.014).
Staudacher, 2012	Randomized, parallel, controlled trial	IBS with diarrhea and bloating (n=41)	4-week Habitual diet (n=22) 4-week FED (gram quantity not defined) (n=19)	•GSRS-IBS (1-4) •Bristol Stool Form Scale •Microbiota	Week 4 GSRS scores significantly lower in incidence (d/wk) in FED group vs habitual diet group: bloating (mean 3.8 vs 5.7; P=0.002), abdominal pain (3.6 vs 4.8; P=0.02), and overall symptoms (0.9 vs 1.6; P=0.001). Week 4 severity scores (0-4) significantly lower in intervention group vs habitual diet group: bloating (mean 0.9 vs 1.4; P=0.002), flatulence (0.8 vs 1.2; P=0.018), and tiredness (0.5 vs 0.9; P=0.015) and overall (1.1 vs 1.7; P=0.002). Greater relief following FED (68%) vs habitual diet (23%). Lower stool frequency in LFD vs habitual diet (10.2 vs 13.5; P=0.008) Greater proportion of stools with normal consistency in FED vs habitual diet (23.6% vs 6.6%; p=0.02)
Halmos, 2013	Randomized, controlled, single-blind, cross-over	• IBS with diarrhea, constipation, mixed and unsubtyped (n=30) •Healthy Controls (n=8)	21-day FED (Mean FODMAP: 3.1 g) 21-day washout 21-day typical Australian diet (Mean FODMAP: 23.7 g)	•Daily GI symptoms rated using a 0-100-mm VAS •Stool collected days 17-21 to assess frequency, weight, water content using KSC (0-10 cm)	No significant changes in healthy controls. KSC score only significant in IBS-D on FED vs typical diet: FED 6.1 vs typical 7.2; P=0.034. Mean VAS for all IBS subtypes at baseline compared to day 14 of each diet listed below, each P<0.001. **Bloating** **Abdominal Pain** **DSC** **Baseline:** 36 35.5 35.1 **FED:** 24.2 22.5 25.9 **Typical** 45.1 43.8 47.8
Bohn, 2015	Randomized, multi-center, parallel, single-blind control trial	IBS (n=67)	4-week TD (Mean FODMAP intake: 13.5 g; n=34) 4-week FED (Mean FODMAP intake: 3.8 g n=33)	IBS severity using IBS-SSS (range 0 – 500)	Significant decrease in IBS-SSS scores from baseline to day 29 of FED and TD; IBS-SSS total score: FED 324 vs 246; P<0.001; TD 302 vs 236; P<0.001; Abdominal pain frequency: FED 57.6 vs 43.6; P=0.008; TD 60.6 vs 37.8; P<0.001; Abdominal distension: FED 68.7 vs 45.8; P<0.001; TD 62.4 vs 50; P=0.003; TD 69.6 vs 58.6; P=0.002; Stool frequency: FED 1.9 vs 1.5; P<0.001.

***FODMAP**: Fermentable Oligosaccharides, Disaccharides, Monosaccharides, and Polyols. **HFD**: High-FODMAP diet. **FED**: FODMAP elimination diet. **IBS**: Irritable Bowel Syndrome. **IBS-SSS**: IBS Symptom Severity Score. **GSRS-IBS**: Gastrointestinal Symptom Rating Scale for Irritable Bowel Syndrome. **GI**: Gastrointestinal. **VAS**: Visual Analogue Scale. **KSC**: King's Stool Chart rating. **TD**: traditional IBS recommended diet based on the NICE guidelines, NICE guidelines are the dietary guidelines for IBS patients in England. **TBH**: total breath hydrogen. **DSC**: dissatisfaction with stool consistency.*

Outcomes included hydrogen breath test results because the rapid fermentation of FODMAPs in the intestinal lumen generates hydrogen gases. Due to the manipulation of FODMAPs, gas production was altered in both groups of patients. The high-FODMAP diet increased hydrogen production significantly in both healthy and IBS patients because the increased FODMAP load increased production of short chain fatty acids. While both groups had increases in breath hydrogen on both diets, the IBS patients produced more hydrogen gas than the healthy controls on the FODMAP elimination diet ($p=0.025$) and high-FODMAP diet ($p=0.039$). Patients also rated their symptoms on a Likert scale where 0 represented no symptoms and 3 represented severe symptoms. IBS on the high-FODMAP diet had significantly worse symptoms compared to when following the FODMAP elimination diet. For instance, on the FODMAP elimination diet subjects reported 0-1 (no symptoms to slight) and on the high-FODMAP subjects reported 2-3 (moderate to severe) for the following symptoms: abdominal pain/discomfort 9/15 patients ($p=0.006$), abdominal bloating 11/15 patients ($p=0.002$), excessive flatus 13/15 patients ($p=0.002$). Healthy participants on the high-FODMAP diet had significantly worse symptoms of excessive flatus 8/15 ($p=0.007$) compared to the FODMAP elimination diet. Although the study followed patients on each diet for only two days, symptoms developed quickly and were noticeable on the first day in the high-FODMAP IBS group, possibly because all food was provided and subjects were blinded. In conclusion, a diet high in FODMAPs contributes to increased hydrogen production in the intestine in healthy individuals and IBS patients. Furthermore, the IBS patients produced a greater amount of hydrogen than the healthy volunteers and experienced exacerbated symptoms on the high-FODMAP diet.

Staudacher et al. conducted a randomized controlled, 4-week trial to examine the effect of a FODMAP elimination diet on gastrointestinal microbiota. The purpose was to determine the effect of the FODMAP elimination diet versus a regular habitual diet on gastrointestinal symptoms, gut microbiota, and production of short chain fatty acids in IBS patients with diarrhea and bloating.[27] At baseline and week four, the patients recorded symptoms using the GSRS-IBS and dietary intake using a 7-day food diary. Luminal bifidobacteria were observed to investigate whether removal of certain carbohydrates reduces gut microbiota and fermentation products. A FODMAP elimination diet may reduce fermentation products potentially decreasing the symptoms of gastrointestinal discomfort experienced by IBS patients; however, this may have a detrimental impact on microbiota. Stool samples from thirty-five patients were analyzed for luminal bifidobacteria. Bifidobacteria significantly decreased in the IBS patients after restricting FODMAPs for four weeks ($P<0.001$). Stool frequency was significantly different in the intervention group than control group ($p=0.008$). The IBS-GSRS reported significantly lower symptoms in the intervention group when compared with the control group ($p=0.005$), with significant decrease in bloating ($p=0.002$) and abdominal pain ($p=0.02$). This trial provided evidence that a FODMAP elimination diet has a potential risk of reducing specific beneficial gut microbiota, perhaps contributing to a reduction in gut health. Evidence also showed that bloating and abdominal pain improved in individuals with IBS when following a FODMAP elimination diet.

Halmos et al. randomly assigned 30 IBS patients and 8 healthy controls to follow either a FODMAP elimination diet or a typical Australian diet (representing usual dietary intake of FODMAPs) for 21 days.[28] All subjects were blinded and food was provided.

Overall gastrointestinal symptoms, abdominal pain, bloating, passage of wind, and dissatisfaction with stool consistency were measured using a 100-mm visual analogue scale (VAS), where 0 indicated no symptoms and 100 indicated the worst symptoms. Baseline information such as gastrointestinal symptoms using a VAS and food diaries were collected the first week. A 21-day washout period occurred after the first phase; patients were then crossed over to follow the other diet for 21 days. IBS patients had a statistically significant lower VAS score in all symptoms when following the FODMAP elimination diet compared to the typical Australian diet. Compared to baseline, the VAS score for IBS patients on the FODMAP elimination diet was reduced by at least 10-mm for each symptom, which was necessary for symptoms to be identified as under control on the FODMAP elimination diet. Healthy controls maintained the same symptoms as baseline on both diets. The stool analysis results showed that the KSC score was higher in the IBS-D group compared with the IBS-C on the typical Australian diet ($P = 0.002$). Additionally, the IBS-D group had higher KSC score ($P <0.001$) and FWC ($P = 0.004$) compared with healthy controls on the typical Australian diet. IBS-D on the FODMAP elimination diet had reduced KSC score ($P=0.034$) and stool frequency ($P=0.018$) compared to the typical Australian diet. Intervention diets were provided and matched for all nutrients to eliminate confounding dietary factors; thus, results provide evidence that FODMAPs specifically affect those with IBS.

The previous studies have established that the FODMAP elimination diet can improve the symptoms of IBS patients; however, a recent study compared the FODMAP elimination diet with traditional IBS dietary advice, known as the NICE guidelines. NICE guidelines are dietary recommendations from the National Institute for Health and Care

Excellence and the British Dietetic Association. NICE guidelines focus on when to eat versus what to eat, limiting high-fat and high-fiber foods, reducing caffeine, reducing sugary beverages and sorbitol, and avoiding gas-producing foods. Bohn et al. examined 67 IBS patients that were randomized to one of the diets for four weeks. [29] Assessment for symptom severity (IBS-SSS), bowel patterns, and nutrient intake (4-day food diary) was administered at baseline and at week-4 follow-up. Compared with baseline, IBS-SSS was significantly reduced by the fourteenth day in the FODMAP elimination group (P=0.002) and at the four-week follow symptom improvement occurred in both groups. Both groups had significantly reduced IBS-SSS at the end of the trial. The FODMAP elimination group and the traditional IBS diet group each had significant decreases in IBS-SSS total score, abdominal pain frequency, abdominal distension, and interference on life in general. The FODMAP elimination group had significant improvement in IBS-SSS for stool frequency and the traditional IBS diet group had significant improvement in dissatisfaction of bowel habit. There were no significant differences between intervention groups. The difference between grams of FODMAPs between the groups were only about 10 grams (3.8 vs. 13.5), therefore the traditional IBS recommended diet was also low in FODMAPs, which may indicate why IBS-SSS was similar between the groups. This trial provided evidence for the need of close monitoring by a dietitian when following a strict diet because the FODMAP elimination group significantly reduced caloric intake (P<0.001), protein (P=0.001), fat (P<0.001), carbohydrates (P<0.001), and fiber intake (P=0.001). This trial was the first FODMAP trial conducted to represent the clinical setting. Both a FODMAP elimination diet and traditional IBS diet improved IBS symptoms.

Summary

Efficacy of the FODMAP elimination diet in treating symptoms of IBS is demonstrated in several research studies, specifically reduction of symptoms of bloating, abdominal pain, and normalization of stool consistency. The investigators of these trials reported strong evidence and conducted well-designed studies; however there are limitations. The trial by Bohn et al. was the only study representative of clinical practice. The trials are not necessarily representative of a US population because the studies were conducted in other countries. Inconsistent amounts of FODMAPs were tested between the diets. Additionally, a dietitian was not actively working with the patients following the FODMAP elimination intervention. Patients who restrict their diet without guidance from a dietitian risk developing nutrition inadequacies. A dietitian can advise how to incorporate specific foods to avoid altered nutritional status in patients with IBS. Research has not compared the change in patient symptoms when the FODMAP elimination diet is administered and monitored by a dietitian followed by the reintroduction phase of the FODMAP diet.

Aside from the limitations, the FODMAP elimination diet offers an alternative therapy for IBS symptom treatment. Further research is needed in which a dietitian monitors patients' diet quality, change in gastrointestinal symptoms, and quality of life in both the FODMAP elimination diet and FODMAP reintroduction diet. Therefore, the purpose of the current study is to examine the change in diet quality, self-reported gastrointestinal symptoms, quality of life and assess feasibility of each diet phase in IBS individuals educated by a registered dietitian with structured monitoring in clinical practice.

METHODS

Overview of Study

The purpose of this study was to assess the FODMAP elimination diet experience of patients with IBS. The objectives of this study were to 1) learn about the patients' experience with the FODMAP elimination diet for IBS 2) develop a specific protocol for administering the FODMAP elimination and reintroduction diet and specific educational and assessment tools for use, and 3) evaluate the change in gastrointestinal symptoms and quality of life with the monitoring and education by a registered dietitian. These objectives were accomplished through enrolling patients with IBS or functional gastrointestinal disorders recommended to follow the FODMAP elimination diet by a physician. This study was a pre-test post-test study design with no comparison group conducted at Rush University Medical Center.

Sample Description

A convenience sample of participants from Rush University Medical Center gastroenterologists' clinic in Chicago, Illinois was included in this study. All patients were 18 years or older, were referred to follow an RD-led FODMAP elimination diet by a gastroenterologist, and signed consent and HIPAA forms. Patients were excluded if diagnosed with symptomatic celiac disease, symptomatic inflammatory bowel disease, or other contraindicated condition as determined by the dietitian. The Rush University Medical Center IRB approved the study (**Appendix A**).

Study Protocol

After consenting, participants completed questionnaires and received diet education prior to beginning the 4-week FODMAP elimination diet (Figure 1). At baseline, participants completed an Irritable Bowel Syndrome- Quality of Life Questionnaire (IBS-QOL), Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome (GSRS-IBS), and a subjective feasibility questionnaire (**Appendix B**). Patient received counseling in clinic from a dietitian at baseline visit with study developed handouts, and follow-up by phone every two weeks to assess compliance and problem solve dietary issues. Prior to the FODMAP reintroduction phase, patients completed the IBS-QOL, GSRS-IBS, subjective feasibility questionnaire and over the phone questionnaire using open-ended questions to discuss the FODMAP elimination diet experience. FODMAP reintroduction diet counseling was provided by phone after four weeks of low-FODMAP elimination diet. After the reintroduction diet patients completed the subjective feasibility questionnaire, IBS-QOL, and GSRS-IBS (reintroduction results not reported).

Development of Education Materials

Education materials and a study protocol for the FODMAP elimination diet were developed using current FODMAP resources and information in the literature. Resources included the MONASH University Low-FODMAP diet app and booklet and the book by Lee Martin *Re-challenging and Reintroducing FODMAPS a self-help guide to the entire reintroduction phase of the low-FODMAP diet*©.[30] Creation of grocery lists were developed after assessing nutrition labels of products low-FODMAP products found in US grocery stores. The varieties of education materials created, such as meal plans, are

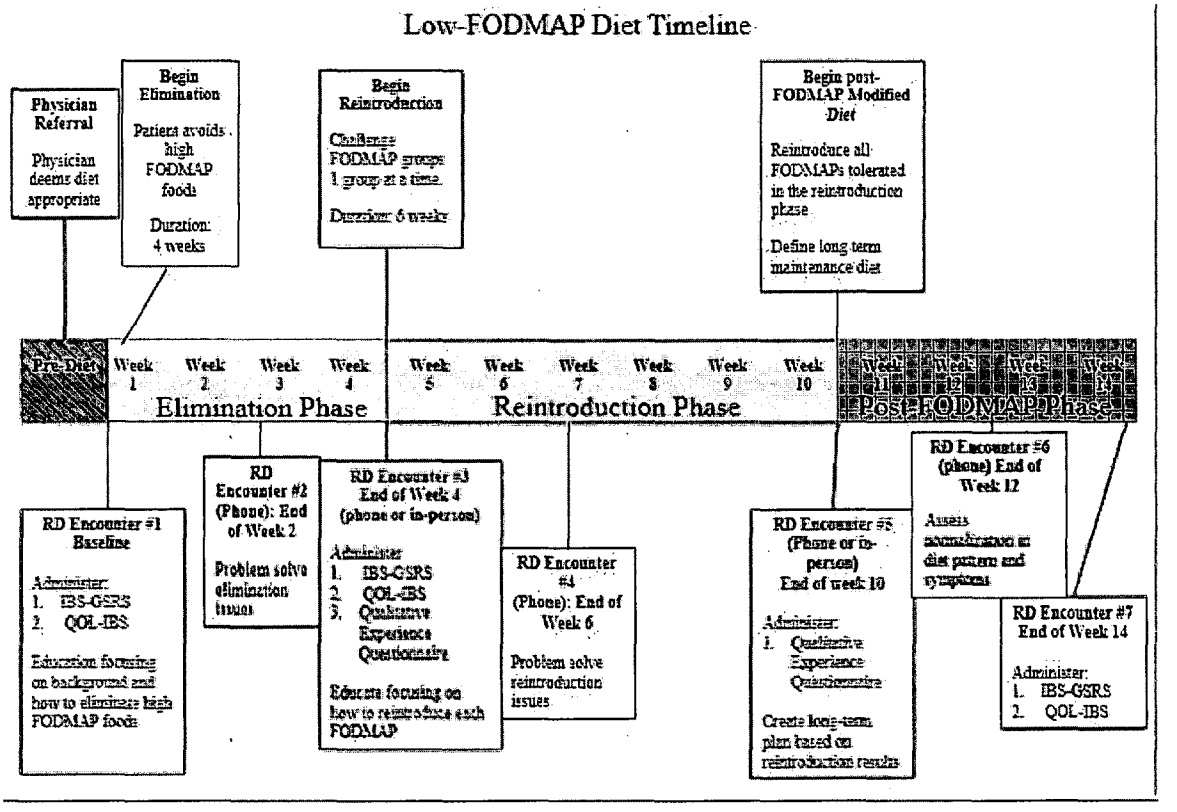

Figure 1. FODMAP Diet Timeline. The entire FODMAP diet (elimination phase, reintroduction phase, and post-FODMAP diet modification) took about 14 weeks to complete. Before each phase began, the patient met with the Registered Dietitian (RD). At RD encounter 1, 3, and 5 patients were asked to fill out specific questionnaires as detailed above; IBS-GSRS: Irritable Bowel Syndrome- Gastrointestinal Symptom Rating Scale; QOL-IBS: Quality of Life-Irritable Bowel Syndrome Questionnaire

based on feedback of patients not in the study who have recently completed the low-FODMAP diet at RUMC. Education materials to be provided to participants will include a FODMAP elimination grocery list, which will identify specific foods and brands, a list with each of the foods allowed on the elimination diet, a high-FODMAP food list, a one-week elimination diet meal plan and elimination diet recipes. The registered dietitian (HR) will also be involved in helping create the education materials and protocols.

Questionnaires

Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome (GSRS-IBS)

The GSRS-IBS (**Appendix B)** is a validated tool used to examine symptom frequency and severity over the last week. The questionnaire has thirteen questions, five subscales, and is rated on a 7-point Likert scale.[31] The subscales include pain syndrome (questions 1 and 2), bloating syndrome (questions 3, 4, and 13), constipation syndrome (questions 5 and 8), diarrhea syndrome (questions 6, 7, 9, and 10), and satiety (questions 11 and 12). To score the GSRS-IBS, each question was added to create the total score. The total score can have a minimum of 13 being the least amount of symptoms and 91 as the most symptoms[31] The subscales were scored by adding the total score for each of the specific subscale questions. Higher scores mean increased symptom severity and frequency over the past week.

Irritable Bowel Syndrome-Quality of Life (IBS-QOL)

The IBS-QOL (**Appendix B)** is a validated tool used to assess quality of life in patients with IBS.[32] The questionnaire has 34 questions, eight subscales and is scored on a five-point Likert scale. Subscales include dysphoria (questions 1, 6, 7, 9, 10, 13, 16, and 30), interference with activity (questions 3, 18, 19, 22, 27, 29, and 31), body

image (question 5, 21, 25, and 26), health worry (questions 4, 15, and 32), food avoidance (questions 11, 23, and 28), social reaction (questions 2, 14, 17, and 34), sexual (questions 12 and 20), and relationship (questions 8, 24, and 33). The questionnaire total score was calculated by adding the score for each question, thus a minimum of 34 and maximum of 170 for the total score).

Subjective Questionnaire

The subjective questionnaire is not validated and was used as a tool to assess the helpfulness of the designed protocol, provided resources, and RD after completion of the elimination phase. Using a five-point Likert scale, the following factors were evaluated: symptom improvement, whether the patient felt they could have followed the diet without the help from an RD, if the written information was easy to understand, if they were able to identify the foods that trigger symptoms, and if they needed more assistance from an RD.

Qualitative Experience Questionnaire

The questions from the Qualitative Experience Questionnaire (**Appendix C**), containing a series of open-ended probing questions about the participants' experiences on the FODMAP elimination diet, was completed via recorded phone call. Open-ended questions focused on the challenges faced by those following the diet, the experience of following the elimination diet when working with a dietitian, and additional strategies or information which would increase success of following the diet were asked.

Statistical Analysis

Measures of central tendency (means $\pm$ SD) were used to describe the continuous demographic variables, including BMI, age, and length of IBS diagnosis. Frequency

distributions were used to describe categorical demographic information, including gender, IBS subtype, test group (control or intervention), previous consult with dietitian (yes/no), and prior attempts of following the low-FODMAP diet (yes/no). Data were examined for normality; if data were not normally distributed, nonparametric statistics were used. Significance was set at $p<0.05$.

Objective 1: To assess the participant's experience of the elimination diet using a developed qualitative experience questionnaire.

The questions from the FODMAP Elimination Diet Experience questioning guide (**Appendix C**), containing a series of open-ended probing questions about the participants' experiences on the FODMAP elimination diet was completed via recorded phone call. Open-ended questions focusing on the challenges faced by those following the diet, the experience of following the elimination diet when working with a dietitian, and additional strategies or information which would increase success of following the diet were asked. Interviews were transcribed verbatim and analyzed by three experts using content analysis methods.

An initial set of recurring themes were generated using content analysis from the qualitative interviews were identified as code words.[40] Code word definitions were created to provide the meaning of text segments found in the transcripts **(Appendix D)**. New themes that occurred in the transcripts were either given a new code word or subcategorized with an existing code. These categorical variables were organized to correspond with each question for the questioning guide. The questioning guide objectives included, determining the challenges faced by participants, the participant's experience when working with a RD, and strategies or information RDs can provide from the viewpoint of the participant when following the FODMAP elimination diet.

Transcripts were coded by three researchers reached agreement as to attachment of code words to specific text segments. A frequency distribution was used to assess the common themes for each of the questionnaire objectives (**Appendix E**).

Objective 2: To adapt a protocol and education materials for registered dietitians to use when administering the FODMAP elimination diet and reintroduction phase.

The elimination diet protocol was adapted based on the literature of peer-reviewed articles and clinical experience. The reintroduction phase protocol was developed based on published books and clinical experience. Specific outcomes included a final protocol and the following education material: FODMAP elimination diet allowed food list, high-FODMAP foods grouped by FODMAP category, FODMAP elimination recipes, 1-week FODMAP elimination meal plan, and FODMAP elimination grocery list identifying specific brand names.

Objective 3: To assess gastrointestinal symptoms before and after following the FODMAP elimination diet using the validated IBS-GSRS questionnaire.

The gastrointestinal symptom scores before and after following the FODMAP elimination diet was assessed using the Wilcoxon sign-rank test.

Objective 4: To evaluate the change in quality of life using the validated IBS-QOL questionnaire before and after following the FODMAP elimination diet.

The quality of life scores before and after following the FODMAP elimination diet was expressed as median (IQR) assessed using the Wilcoxon signed-rank test.

MANUSCRIPT

This chapter includes a manuscript to be submitted for publication to the Journal of Gastroenterology and Hepatology, which follows the Vancouver formatting and styling guide. The title of the research manuscript is "Assessment of the FODMAP Diet Experience and Change in Gastrointestinal Symptoms and Quality of Life in Patients following a Registered Dietitian-Administered FODMAP Elimination Diet." The purpose of this study was to learn about patients' experience with the FODMAP elimination diet for irritable bowel syndrome and to evaluate change in gastrointestinal symptoms and quality of life immediately before and after implementing the FODMAP elimination diet with guidance from a registered dietitian. Supplemental tables and figures not found in the manuscript can be found in the Appendix.

Abstract

Title: Assessment of the FODMAP elimination diet experience and change in gastrointestinal symptoms and quality of life in participants following a registered dietitian-administered FODMAP elimination diet.

Objective: To evaluate change in gastrointestinal (GI) symptoms and quality of life (QOL) before and after implementing the Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols (FODMAP) elimination diet with guidance by a registered dietitian (RD) and to learn about patients' experience with the FODMAP elimination diet for irritable bowel syndrome (IBS).

Methods: The GI symptom rating scale for IBS (GSRS-IBS) and the IBS-QOL were administered before and after the 4-week elimination diet and analyzed using Wilcoxon signed rank test. Qualitative one-on-one phone interviews focusing on the elimination diet experience were completed after a 4-week elimination diet, verbatim transcripts were created and content analysis was completed.

Results: Participants (n=16) were predominantly female (75%) and white (81%), with an average age of 47 (±14) years. The total GSRS-IBS median (IQR) score significantly improved (p=0.02) (45.5 (29.9, 55.6) vs 36.7 (24.7, 48.8)) after elimination (range of 13-91 with higher score indicating more symptoms). Total IBS-QOL median (IQR) score significantly improved after elimination (94.5 (78.8, 110.5) vs. 73.5 (58.0, 100.3)), respectively; (p=0.002), (range of 35-175 with higher score indicating more symptoms) indicating an improved QOL after the elimination diet. The qualitative analysis revealed 8 of 12 participants discussed receiving physician recommendations before meeting with the RD. After meeting with the RD, 11 of 12 participants reported RD's education

materials as helpful, and 5 of 12 discussed that the most beneficial aspect of the RD was having the RD's support throughout the elimination diet to improve adherence.

Conclusion: Inclusion of the RD during the FODMAP elimination diet improves GI symptoms and QOL through helpful resources and support, reinforcing the role of the RD when a FODMAP elimination diet is recommended.

Introduction

Irritable Bowel Syndrome (IBS) is a functional gastrointestinal disorder characterized and diagnosed according to ROME III criteria. Irritable bowel syndrome often causes recurrent abdominal discomfort and altered bowel habits and is sub-typed into IBS with constipation, IBS with diarrhea, and mixed type IBS. Irritable bowel syndrome is defined by its symptoms of abdominal pain, bloating, flatus, and dissatisfaction with stool consistency. Although there are multiple hypotheses for the etiology of IBS symptoms, the actual cause is poorly understood. One potential cause for IBS-related symptoms is shift in osmolarity and gas production secondary to dietary intake. Small particles of undigested short-chain carbohydrates or sugar alcohols can create an osmotic force by pulling water into the gastrointestinal (GI) tract, resulting in frequent and loose stools.[1] Short-chain carbohydrates or sugar alcohols can also be rapidly fermented, triggering generation of excess gas in the small and large intestine with luminal distension.[1] When these gas-producing carbohydrates and sugar alcohols are minimized in the diet, symptoms may improve. For symptom relief, a recent emphasis is placed on a diet low in fermentable carbohydrates, called the FODMAP elimination diet.[2]

A FODMAP elimination diet eliminates poorly digested carbohydrates that may cause symptoms; these carbohydrates consist of fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAP). A diet low in FODMAPs has been linked with improved symptoms in patients with IBS in a controlled research settings.[4, 18, 28] Diet administration with dietary counseling resulted in reduced IBS symptoms.[27, 29, 33, 34]

Preliminary research suggests the diet should be followed under the supervision of an experienced dietitian, [28, 29, 33, 35] though these studies have not been conducted with

adults in the United States. Little has been done to assess the patient experience while following the FODMAP elimination diet clinically. It is still unclear whether a dietitian can further improve symptoms with the use of a low-FODMAP diet protocol. Furthermore, there is limited evidence on how specifically consultation with a dietitian using a diet protocol in the clinical setting may impact symptoms and quality of life. The low-FODMAP diet is considered restrictive and compliance is difficult; therefore, determining the patients' experience on the low-FODMAP diet may assist dietitians and referring practitioners on how to increase the feasibility of following the diet. Therefore, the purpose of this study was to determine change in gastrointestinal symptoms and quality of life scores, as well as overall patient experience while following the low-FODMAP diet with a dietitian.

Methods

Participants

A convenience sample of patients from Rush University Medical Center gastroenterologists' clinic in Chicago, Illinois was included in this study. Participants were 18 years or older, were referred by a gastroenterologist to follow an RD-led FODMAP elimination diet (low-FODMAP diet), and signed a consent and HIPAA form (**Appendix A**). Patients were excluded if diagnosed with symptomatic celiac disease, symptomatic inflammatory bowel disease, or other contraindicated condition as determined by the RD. The Rush University Medical Center IRB approved the study in July 2016.

Study Protocol

At baseline, participants completed an Irritable Bowel Syndrome-Quality of Life Questionnaire (IBS-QOL), Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome (GSRS-IBS), and a subjective feasibility questionnaire, all found in **Appendix B**. Participants then received counseling in clinic from the RD with study-developed handouts and followed-up by phone at two weeks to assess compliance and problem-solve dietary issues. At the end of the four week elimination phase, participants again completed the IBS-QOL, GSRS-IBS and subjective feasibility questionnaire. In addition, an over the phone questioning guide using open-ended questions to discuss the FODMAP elimination diet experience was conducted found in **Appendix C**. FODMAP reintroduction diet counseling was provided by phone after four weeks of a FODMAP elimination diet. After the reintroduction diet, patients completed the subjective feasibility questionnaire, IBS-QOL, and GSRS-IBS (reintroduction results not reported).

Questionnaires

Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome (GSRS-IBS)

The GSRS-IBS is a validated tool used to examine symptom frequency and severity over the past week. The questionnaire has thirteen questions, five subscales, and is rated on a seven-point Likert scale.[31] The subscales include pain syndrome (questions 1 and 2), bloating syndrome (questions 3, 4, and 13), constipation syndrome (questions 5 and 8), diarrhea syndrome (questions 6, 7, 9, and 10), and satiety (questions 11 and 12). The response to each question was added to create the total score.[31] The subscales were scored by adding the scores for each of the specific subscale questions. Higher scores are associated with increased symptom severity and frequency over the past week with a possible range of 13 to 91.

Irritable Bowel Syndrome-Quality of Life (IBS-QOL)

The IBS-QOL is a validated tool used to assess quality of life in patients with IBS.[32] The questionnaire has 34 questions and eight subscales scored on a five-point Likert scale. Subscales include dysphoria (questions 1, 6, 7, 9, 10, 13, 16, and 30), interference with activity (questions 3, 18, 19, 22, 27, 29, and 31), body image (question 5, 21, 25, and 26), health worry (questions 4, 15, and 32), food avoidance (questions 11, 23, and 28), social reaction (questions 2, 14, 17, and 34), sexual (questions 12 and 20), and relationship (questions 8, 24, and 33). The questionnaire total and subcomponent scores were calculated by adding the score for each question, with a minimum of 34 and maximum of 175 for the total score. Higher scores are associated with worse quality of life over the past month.

Subjective Questionnaire

A subjective questionnaire (**Appendix B**) was used as a tool to assess the helpfulness of the protocol, resources, and RD after completion of the elimination phase. Using a five-point Likert scale, the following factors were evaluated: symptom improvement, if the patient felt they could have followed the diet without the help from an RD, if the written information was easy to understand, if they were able to identify the foods that trigger symptoms, and if they needed more assistance from an RD.

Qualitative Experience Questionnaire

The questions from the Qualitative Experience Questionnaire (**Appendix C**), containing a series of open-ended questions about the participants' experiences on the FODMAP elimination diet, was completed via recorded phone call. Open-ended questions focusing on the challenges faced by those following the diet, the FODMAP elimination diet experience with a dietitian, and additional strategies or information which would increase success of following the diet were asked. Qualitative content analysis was used to examine the data collected from this open-ended questionnaire Interviews were transcribed and analyzed by three experts using content analysis methods.

Statistical Analysis

The gastrointestinal symptoms scores using the GSRS-IBS and quality of life scores using the IBS-QOL were analyzed using the Wilcoxon signed-rank test. Scores were reported using median (IQR). The difference in IBS-QOL and GSRS-IBS scores between IBS subtypes and gender within time point was assessed using Wilcoxon signed-rank test. The change in IBS-QOL and GSRS-IBS scores between IBS subtypes and gender were assessed using Mann Whitney-U test. Correlation between change in IBS-

QOL and GSRS-IBS was analyzed using Spearman's rank correlation. Frequency distribution was used to evaluate change in the subjective questionnaire (**Table 5**). SPSS software (Version 22, Chicago, IL) was used for data analysis. Significance was set at $p<0.05$.

In brief, an initial set of text segments from the verbatim transcripts were identified using code words.[40] Code word definitions were created to identify text segments (**Appendix D**). New themes that occurred in the transcripts were either given a new code word or subcategorized with an existing code word. These categorical variables were organized to correspond with each objective for the qualitative experience questionnaire. The objectives included determining the challenges faced by participants, the participant's experience when working with a RD, and strategies or information RDs can provide from the viewpoint of the participant when following the FODMAP elimination diet. The proportion of participants who discussed that theme was generated and the common themes were identified.

Results

Twenty-one patients were referred by a gastroenterologist, then met with the RD and verbally agreed to participate, 16 consented and signed a HIPAA form, and three participants did not complete the FODMAP elimination diet. Of the participants who completed the elimination diet, one participant did not complete the qualitative interview (**Figure 2**). The participants (n=16) had an average (mean ± SD) age of 47±14.2 years and a BMI in the normal range (24.1 ± 2.9 kg/m^2). The participants were predominately white (81%) and female (75%) with an IBS-diarrhea (IBS-D) subtype (56.3%). Demographic and clinical characteristics of those enrolled are in **Table 2**.

Gastrointestinal Symptoms

A decrease in the total GSRS-IBS score (p=0.02) and the subcomponent score for bloating (p=0.03) indicated improvement in these symptoms (**Table 3**). Subcomponent scores of pain, constipation, diarrhea and satiety were not statistically significant. The total GSRS-IBS score at baseline and post-elimination diet between IBS subtype (**Appendix E**) and between genders (**Appendix F)** were not statistically significant. The change in scores, calculated by taking the difference from pre to post FODMAP elimination diet, between IBS subtype and gender were not significantly different. Individual participants were plotted to compare change in overall GSRS-IBS score (**Appendix G**).

Quality of Life

Significantly improved quality of life occurred as reflected by the total QOL score (p=0.002), dysphoria (p=0.002), body image (p=0.01), health worry (p=0.02), and social reaction (p=0.03) following the FODMAP elimination diet. Health worry and food avoidance were the highest subcomponent scores at baseline, indicating areas of low quality of life (**Table 4**); while health worry scores decreased indicating an improvement, food avoidance did not change.

At baseline, body image scores were significantly higher for females compared to males (14.0 vs 6.5, respectively; p=0.03), indicating females had worse perceptions of body image compared to males at baseline; however, there was no difference in body image between genders at the end of the elimination diet. (**Appendix H**). Moreover, significantly improved quality of life in females occurred in the total score (p=0.02) and the following subcomponents: dysphoria (p=0.01), body image (p=0.04), social reaction (p=0.04), and sexual (p=0.04) (**Appendix I**). No significant improvements occurred in

males. The difference in change between males and females for total and subcomponent scores was not statistically significant.

Between those with IBS-C and IBS-D, health worry was significantly different at baseline (9.0 vs 6.0, respectively; p=0.03) (**Appendix J**). Significantly improved QOL scores occurred after the elimination phase in those with IBS-D, including the total score (p=0.02), dysphoria (p=0.02), and interference with activity (p=0.03), body image (p=0.04) and sexual (p=0.04) (**Appendix K**). Those with IBS-C significantly improved in total score (p=0.04), dysphoria (p=0.04), and relationship (p=0.05) (**Appendix K**). The changes in the IBS-QOL total and subcomponent scores were not statistically significant between IBS-C and IBS-D.

Change in IBS-QOL total score was plotted for each individual participant (**Appendix L**). Overall, total quality of life score decreased about 20 points for the entire sample, indicating a trend in overall quality of life improvement. A significant positive correlation existed between the change in QOL and GI symptoms (p=0.04; rho=0.569) (**Figure 3**), indicating as GI symptoms improved, quality of life also improved when following the FODMAP elimination diet.

Subjective Questionnaire

Usefulness of the education, resources provided, and RD was assessed using the subjective questionnaire before and after the RD FODMAP elimination diet (**Table 5**). Before following the diet, none of the participants reported that they could follow the FODMAP elimination diet without RD (**Appendix M**). After completion of the FODMAP elimination diet, majority of participants (85%) agreed that the resources were helpful and that they needed more assistance from the RD (62%). Fewer participants

agreed that they can identify food triggers after working with the RD (40% vs 31% after before and after the diet, respectively).

FODMAP Elimination Diet Experience

The major themes that emerged included before the RD intervention physicians recommended the FODMAP elimination diet and did not provide support to those following the elimination diet on their own. In addition, participants found the RD as most beneficial in providing support throughout the elimination diet and increased nutrition knowledge about foods containing FODMAPs and how they are digested. Lastly, the diet was difficult to follow due to lack of time and when eating outside the home.

The physicians recommended the participants follow the FODMAP elimination diet, however did not provide support or thorough education. Most participants (n=8) reported their physician recommended the FODMAP elimination diet and only provided an educational handout (**Table 6**). Participants stated the physician handout consisted of a list of few foods allowed on the diet and did not specify directions for following the diet. Before beginning the FODMAP elimination diet with the RD, most had found education materials or resources from the Internet or electronic applications to help them follow the diet. Few participants reported strictly following the diet on their own (prior to meeting with the RD) after the physician recommendation (n=3). These participants who strictly followed the elimination diet reported the physician nutrition handout was not helpful and that they had no support. Then when describing the educational handouts from the RD, the participants made statements that the handouts (meal plan, grocery list, and recipes) were helpful. One participant noted that they still use the grocery list when shopping.

The participants identified the RD as most beneficial in terms of support. The RD was also reported as being beneficial in providing education on general healthy nutrition and the importance of staying in-tune with food intake and symptoms. They also reported that the RD was beneficial because the provided resources were helpful. Participants stated the support of the RD was most beneficial (n=5). Half of the participants who reported having no support before the RD intervention identified the support of the RD as most beneficial (n=2). Participants noted that the support experienced from the RD included the biweekly phone calls and emails, which provided guidance or "coaching," holding the participants accountable to stay on track with the diet, and the ability to ask questions about the diet.

The participants expressed learning from the RD about FODMAPs, healthy suggestions and recommendations, and symptom information. Many participants who reported learning about FODMAPs from the RD (n=7) learned about foods containing FODMAPs, importance of reading nutrition labels to identify FODMAPs, and awareness of why FODMAPs are poorly digested in terms they could understand. After learning more about FODMAP foods, one participant discussed how they were able to apply this info through adapting recipes. Another participant noted a better understanding of the FODMAP elimination diet after learning how FODMAPs are digested, as well as understanding why too much of one FODMAP can lead to symptoms. A few participants stated that they learned how to associate symptoms with dietary intake.

Participants discussed the challenges faced while following the elimination diet. Several described following the FODMAP elimination diet as very time consuming (n=4). Several participants stated time was most difficult because of the time needed to prepare food, grocery shop, and basic meal planning was more difficult. Of the

participants who identified time as most difficult, several of the same participants identified grocery shopping and label reading as most difficult (n=3). Participants (n=2) stated the excessive time included cooking two separate meals (one for their family and one for themselves), while working a full-time job.

Participants considered eating outside the home as most difficult (n=3) due to not having control over the food, seeing others eat foods not allowed on the diet, making special orders or requests when eating outside the home, and having limited options of food available. The participants who reported eating outside of the home was difficult (n=3), when asked for suggestions to make the diet easier, most of these participants reported the need for a resource with tips for eating outside of the home and a list of restaurants with FODMAP friendly meals (n=2). Additionally, they recommended creating a smartphone app to identify FODMAP friendly restaurants. Others suggested creating additional recipes and meal plans for restricted diets, such as vegetarians.

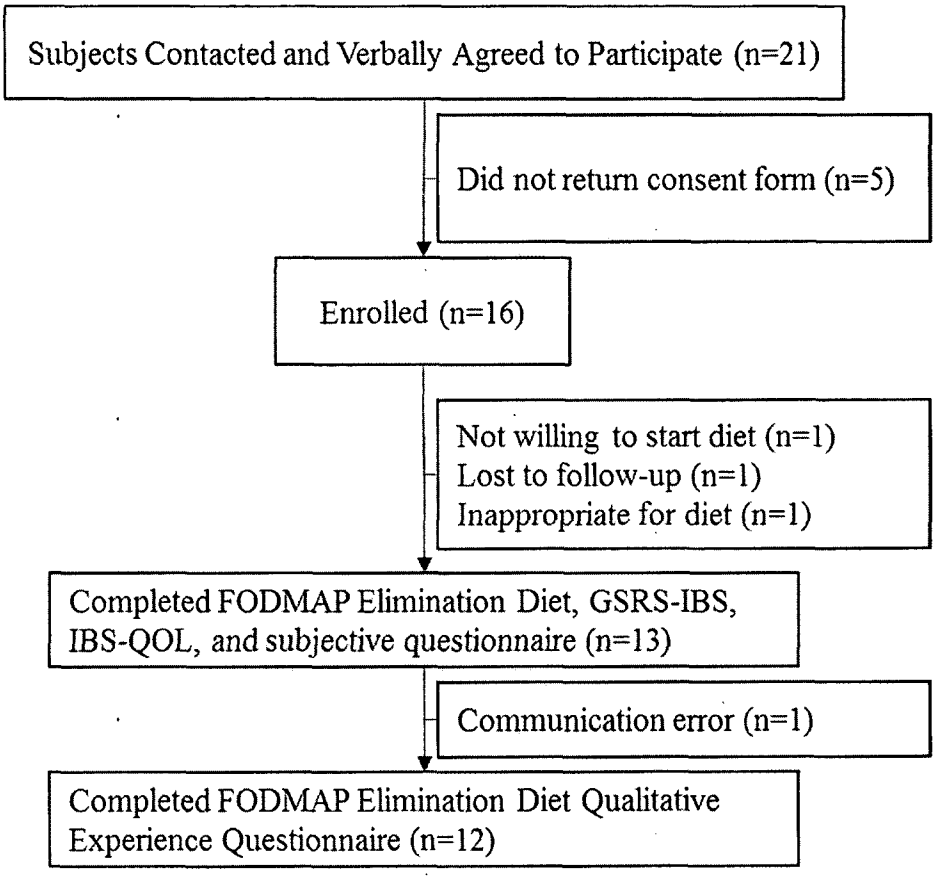

Figure 1. Participant Enrollment and Retention. Figure indicating number of participants enrolled in the study, reasons for lost to follow-up, and the sample that completed the study. All participants that completed the elimination diet also completed study end points, including Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome questionnaire (GSRS-IBS), Irritable Bowel Syndrome-Quality of Life questionnaire (IBS-QOL), and subjective questionnaire, and all phone call follow-ups with the registered dietitian. One participant did not complete the qualitative experience questionnaire.

Table 2. Baseline characteristics of enrolled participants with irritable bowel syndrome (IBS) (n=16)

	Means ±SD
Age, years	47.0±14.2
BMI, kg/m^2	24.1±2.9
	n (%)
Race	
White	13 (81.3)
African American/Black	1 (6.3)
Unknown/Not Reported	2 (12.5)
Gender	
Female	12 (75.0)
IBS Subtype[1]	
IBS-C	6 (37.5)
IBS-D	9 (56.3)
IBS-M	1 (6.3)

[1]IBS-C, IBS with Constipation; IBS-D, IBS with Diarrhea; IBS-M, IBS mixed

Table 3. Gastrointestinal symptom scores in participants with IBS before and after following the FODMAP[1] elimination diet using the GSRS-IBS (n=13)

	Median (IQR)		
	Before FODMAP Elimination	After FODMAP Elimination	P Value[2]
Total Score	45.5 (29.9, 55.6)	36.7 (24.7, 48.4)	**0.02**
Bloating	12.0 (10.0, 14.0)	11.0 (7.5, 12.8)	**0.03**
Pain	8.0 (5.0, 10.0)	5.5 (3.3, 8.8)	0.24
Constipation	5.0 (2.5, 9.0)	4.0 (2.0, 6.5)	0.06
Diarrhea	10.0 (8.0, 17.0)	7.5 (6.0, 16.5)	0.31
Satiety	5.0 (2.0, 9.5)	3.5 (2.0, 8.8)	0.40

GSRS-IBS = Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome; Higher scores indicate higher symptom severity and lower scores indicate lower symptom severity in the past week. Total GSRS-IBS score: minimum 13, maximum 91; Bloating score: minimum 3, maximum 21; Pain score: minimum 2, maximum 14; Constipation score: minimum 2, maximum 14; Diarrhea score: minimum 4, maximum 28; Satiety score: minimum 2, maximum 14.

[1]FODMAP = Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols.

[2]Wilcoxon Signed-Rank Test for comparison of medians. Significance set at $p<0.05$.

Table 4.Change in quality of life[1] in participants with IBS following the FODMAP[2] elimination diet (n=13)

	Median (IQR)		
	Before FODMAP elimination	After FODMAP elimination	P Value[3]
Total Score	94.5 (78.8, 110.5)	73.5 (58.0, 100.3)	**0.002**
Dysphoria	22.0 (20.5, 28.0)	17.0 (13.3, 22.5)	**0.002**
Interference with Activity	14.0 (11.0, 22.0)	12.5 (8.5, 21.0)	0.07
Body Image	9.0 (7.5, 13.5)	7.5 (6.0, 13.3)	**0.01**
Health Worry	9.0 (6.0, 9.5)	6.0 (5.0, 9.0)	**0.02**
Food Avoidance	11.0 (9.5, 14.0)	11.5 (9.3, 13.8)	0.53
Social Reaction	11.0 (8.5, 12.5)	8.5 (4.8, 12.8)	**0.03**
Sexual	3.0 (2.5, 7.0)	2.5 (2.0, 5.8)	0.14
Relationship	6.0 (4.0, 8.0)	4.0 (3.0, 8.5)	0.35

[1]IBS-QOL = Irritable Bowel Syndrome-Quality of Life Questionnaire; Higher scores indicate a poor quality of life and lower scores indicate a good quality of life. Total quality of life score: minimum 34, maximum 170; Dysphoria score: minimum 8, maximum 40; Interference with activity score: minimum 7, maximum 35; Body image score: minimum 4, maximum 20; Health worry score: minimum 3, maximum 15; Food avoidance score: minimum 3, maximum 15; Social reaction score: minimum 4, maximum 20; Sexual score: minimum 2, maximum 10; Relationship score: minimum 3, maximum 15.

[2]FODMAP = Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols.

[3] Wilcoxon Signed-Rank Test for comparison of medians. Significance set at $p<0.05$.

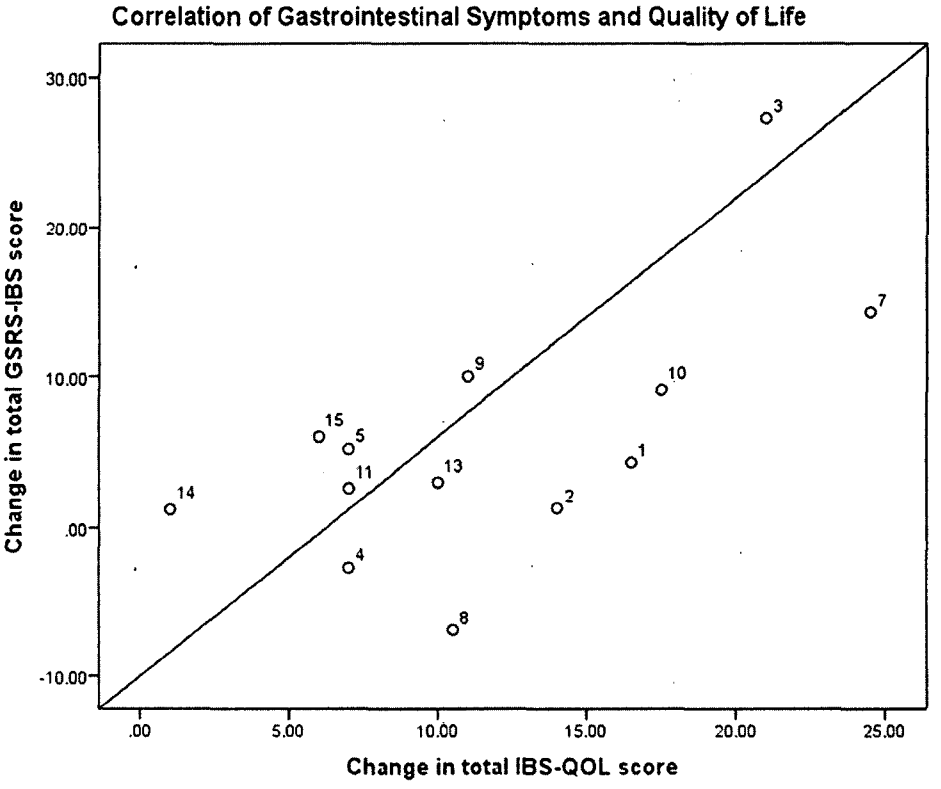

Figure 2. Correlation between the change in GSRS-IBS and IBS-QOL scores following the FODMAP elimination diet (p=0.04; rho=0.57)

Table 5. Responses to the subjective questionnaire before and after following the FODMAP elimination diet (n=13)

	n (%) Before RD	n (%) After RD
Overall I am satisfied in the change in my symptoms		
Disagree	4 (30.8)	3 (23.1)
Agree	1 (7.7)	5 (38.5)
Not Applicable	8 (61.5)	5 (38.5)
I could have followed this diet without help from a dietitian		
Disagree	8 (61.5)	6 (46.2)
Agree	0 (0.0)	5 (38.5)
Not Applicable	5 (38.5)	2 (13.3)
I found the resources helpful in following a low-FODMAP diet		
Disagree	3 (20.0)	1 (7.7)
Agree	8 (53.3)	11 (84.6)
Not Applicable	2 (13.3)	1 (7.7)
I can identify the foods that trigger my symptoms		
Disagree	2 (13.3)	3 (23.1)
Agree	6 (40.0)	4 (30.8)
Not Applicable	5 (33.3)	6 (46.2)
I need more assistance from a dietitian		
Disagree	1 (6.7)	3 (23.1)
Agree	11 (73.3)	8 (61.5)
Not Applicable	1 (6.7)	2 (15.4)

Table 6. Code words used in coding transcripts of interviews about the FODMAP diet experience from participants following the FODMAP elimination diet with quotations and number of times code was identified in transcripts (n=12)

Code Word	Subcategory	Quote [Participant ID]	n (%)
Prior to RD intervention			
	Physician Recommended FODMAP Diet and Educational Materials	"The doctor, my gastroenterologist put me on that diet and then when I asked him, how do I get off? He said well start reintroducing one food category at a time. He gave me a list of what was high and low-FODMAP and I followed that." [ID10]	8 (66.7)
	Education materials or resources used before RD	"Basically googled it and you know I have a master's degree and I've worked in hospitals for a long time so I know how to search out for a reliable resource on the internet and kind of looked at some different websites. I think there's like a mayo clinic one that talks about it a little bit, as well as that blog." [ID 3]	6 (50.0)
	Restricted Diet	"I don't do things that are heavily seasoned like you know with a lot of spices you know hot sauce I don't do like garlic I don't do pepper that sort of stuff. You know I stick to salt and pepper, things that are obviously looking at ingredients and making sure they don't contain high fructose corn syrup stuff like that. I try to keep it as simple as possible that way you know it also helps me then if I do encounter something that you know gets cross-contaminated or something like that that I can really pinpoint like hey what happened." [ID 14]	6 (50.0)
	Not Following FODMAP diet	"A lot of eating out. So I used to eat out a ton. Most of my day is meetings and lunches and dinners, stuff like that. So a lot of my schedule is always eating out and not healthy food or good for my issues. A lot of hamburgers, hotdogs, pizza, or tacos. A lot of fried foods like chicken fried not grilled, stuff along those lines." [ID 2]	6 (50.0)

	Electronic Applications	"I was just sort of using my own tools, which included a low-FODMAP app, which was the Monash© app and using that as the guide for following the low-FODMAP diet. As far as like green light for what are totally fine to eat; yellow light, you know you eat a little bit, and red light, not at all. That was really helpful for shopping." [ID 7]	5 (41.7)
	No Support	"I met with a specialist sometime last year and they suggested that I start this diet. But it really wasn't closely monitored." [ID 1]	4 (33.3)
	FODMAP Elimination	"For months before I had been on the elimination diet for six weeks and I didn't know how to start reintroducing the food groups" [ID 10]	3 (25.0)
	Physician Nutrition Information not Helpful	"Anyone following this would have needed a lot more information." [ID 7]	3 (25.0)
Concepts Learned from RD			
	FODMAP Food Information	"I am more conscious of not consuming like excess dairy products. She does a phenomenal job of explaining you know many things, food and how they digest." Or "I felt more comfortable looking at any recipe or say, oh I want to make tacos this week and like just seasoning it without the things that you know are not allowed." [ID 8]	7 (58.3)
	Healthy Recommendations	"Just focusing on eating healthier and better. I'm a big sandwich person. So she definitely helped point out some ideas and give some ideas on ways to eat a little bit better compared to how I was." [ID 2]	6 (50.0)
	Symptom Information	"Listening to what my body needs. If I'm feeling low-energy finding food, you know eat what makes me feel better and just really being kind of in-tuned with symptoms. That's been really helpful for me." [ID 14]	3 (25.0)
Helpful Resources from RD			
	FODMAP Study Handouts from RD	"The papers that I think the research is that you developed were really helpful because it is a list of like here are the things you can eat. Here	11 (91.7)

		are some really good recipe ideas. Here's some paperwork to remind you how to do it. Here are some other resources. So if we're not available if you're in the grocery store you have this. The lists that you gave me were super helpful because online there's a lot of conflicting lists of what you can and can't eat on FODMAP. So it was really helpful to have the one from you guys because it was just a stronger guide I think." [ID 3]	
	Electronic Applications	"When I met with the RD and she pointed me to the Monash© app, that was when a light went off, like wow there are a lot of foods I can eat on here that I didn't know about before. The MySymptoms© app is also a great tool in terms of documenting things and to get data back to you." [ID 5]	7 (58.3)
Most Beneficial of RD Intervention			
	Support	"I think having the biweekly check-ins is helpful because it keeps me accountable. So maybe I'm not being as focused on the diet as I should because I have so many other things going on in my life. But knowing I've got to talk to the RD. Ok last time I said I was going to download that app, I better download that app. Or I said I was going to do something, I better do it because I am being held accountable by somebody other than myself." [ID 4]	5(41.7)
Elimination Difficult			
	Limited variety	"There are so many vegetables that I can't have. I just want more variety in my diet. I get tired of eating the same vegetables." [ID 10]	8 (66.7)
	Grocery Shopping and Label Reading	"Adjusting the shopping and the cooking habits to accommodate the diet. That was the learning curve I had to go through." [ID 5]	5 (41.7)
	Alone or Isolated	"Where I work, they provide lunches to us once a week, which is really great. A lot of times it's stuff I have to avoid. But I think I don't know that it's a difficulty in practice as it's more of like a mental thing. Like	3 (25.0)

		everyone else is getting to eat stuff and I don't get to eat it and I'm sitting you know with my chicken." [ID 14]	
Most Difficult Elimination			
	Time	"It is the preparation and time management with this diet that's the hardest thing" [ID 7]	4 (33.3)
	Eating Outside of the Home	"For someone who revolves around you know a job where he eats out almost every day or twice a day, it is hard. It's really hard because there's not a lot of options out there, at restaurants or different places. I would say that Is the biggest thing or the hardest thing. That's especially true when you have no control over it." [ID 2]	3 (25.0)
Reasons for Non-Compliance			
	Eating Outside of Home	"It's easier to swing through the drive through on the way to work than to be thoughtful about getting out that lactose-free milk and getting out the expresso machine. So that has definitely caused me to stop the diet" [ID 4]	5 (41.7)
	Limited Variety	"I had maybe like a quarter to half a slice of regular bread, like white bread it wasn't gluten free. And because I was just in a situation where there was really no other option I needed to eat" [ID 7]	3 (25.0)
	Accidently Eating FODMAP	"I think I accidently ate something once and I wasn't supposed to. Yeah I accidentally ate the red level" (Red level signifying high FODMAP from Monash©) [ID 9]	3 (25.0)
	Temptation	"Sometimes on really stressful days when I just kind of wanted to sneak something fast and quick it's difficult because not all of the ingredients are you know, okay for me to eat, like even simple things like chocolate. Sometimes cravings are hard to not cave into" [ID 1]	2 (16.7)
Actions Taken after RD			
	Made Changes to Diet	"I've been trying not to eat out anymore. I've been trying to cut that out completely. If I do eat out I just have a salad wherever we go." [ID 2]	11 (91.7)

	Symptoms Status	"I have had some relief of my symptoms not as much relief as I would like to have, but I've got a lot of other things like stress and anxiety that I'm sure is contributing to less relief than I probably could have. But I think that is obviously a big positive that is the whole point of doing it to feel better." [ID 3]	7 (58.3)
	Cooking at Home	"I was able to actually adapt recipes that I already knew of or search specifically for recipes that I could easily leave out onions." [ID 3]	5 (41.7)
	Helpful Resources Found on Own	"The internet it was extremely helpful for educating. Just Google, so low-FODMAP suggestive meals." [ID 8]	4 (33.3)
Needed Resources			
	Additional Meal Plans and Recipes	"Oh gosh you know more from a vegetarian perspective It might be a little more direction on meal planning for a vegetarian. Like it would be a little bit easier if there were maybe some more examples of vegetarian friendly." [ID 9]	5 (41.7)
	FODMAP Diet Tips Handout	"Maybe a tip sheet of here are the things you can do when you go out to eat, here are the things you should talk to your family about, just tips like that are helpful. Things I've learned just through you know all the things I've been doing." [ID 14]	4 (33.3)

Discussion

In the present study, participants with IBS reported significantly improved gastrointestinal symptoms and quality of life after the elimination diet, which is in accordance with previous studies.[27, 28, 29, 33,35,36] Moreover, the patient experience on the FODMAP elimination diet while working with the RD was explored, which has not been completed in earlier studies. Patients revealed difficulties experienced on the FODMAP elimination diet, as well as the lessons learned and suggestions made to increase diet adherence.

The FODMAP elimination diet reduced overall GI symptoms and bloating in participants with IBS, which is supported by previous randomized controlled trials.[4, 27, 28,29] However, although the previous studies were randomized controlled trials, only Ong et al[4] used a validated tool to measure GI symptoms. Previous researchers have found a limited effect of the FODMAP elimination diet on constipation,[4, 28] which was also found in the current study.

Overall gastrointestinal symptoms, as reported on the GSRS-IBS improved; however, these symptoms did not improve in two participants (participant 4 and 8). Qualitative reports of these two participants were similar. For instance, both participants reported that the FODMAP elimination diet was not difficult. It is unclear if the diet was not difficult because they were not correctly following the diet, thus contributing to worsened GI symptoms. In addition, these participants reported that they experienced symptom improvement while following the diet; however the GSRS-IBS indicated no improvement. The GSRS-IBS only captures the last week, thus it is possible that the participants did have symptom improvement that was not captured by the GSRS-IBS.

Lastly, these participants identified stress as a possible component for their symptoms, thus the symptoms may have worsened as reported by the GSRS-IBS due to stress rather than diet.

There are a limited number of studies assessing change in quality of life following the elimination diet. Quality of life scores improved in the present study, and these findings are supported by previous studies that included the IBS-QOL.[35, 37, 38] For instance, in a randomized controlled study, Pedersen et al. compared the FODMAP elimination diet to a normal Danish/Western diet over six-weeks and reported a significant improvement in median IBS-QOL total score (81 vs. 67, respectively) in all patients following the FODMAP elimination diet ($n=123$; $p<0.01$). Mazzawi et al. had a similar sample size to the present study ($n=17$) and found that three, 45-minute sessions of dietary guidance over three months significantly improved total mean IBS-QOL score ($p<0.01$).

Statements relating to social reaction (a subcomponent of the IBS-QOL) were extracted from the qualitative analysis. Before the RD intervention, a theme of feeling alone, and lacking support and dietary guidance existed. Participants also reported that the FODMAP elimination diet was most difficult because it had an effect on social life, as they often were not able to eat the same food as their coworkers, friends, and family. Although negative statements about social reaction during the elimination diet were made in the qualitative analysis, social reaction per the IBS-QOL did not get worse. Scores did not worsen perhaps because the IBS-QOL questions are more related to GI symptoms and bowel habit, whereas the FODMAP Elimination Diet Experience questionnaire discussed diet. Moreover, social reaction may have improved because of the concepts

learned by the RD and the support provided throughout the RD intervention. For example, concepts learned from the RD included not worrying about asking questions when eating out because having less symptoms is important. Additionally, participants reported that the RD intervention provided positive support. Therefore, inclusion of the RD may have contributed to the overall improvement in quality of life.

The FODMAP elimination subjective questionnaire in the current study assessed the helpfulness of the RD and resources through the changes in responses after the RD intervention. Fewer participants agreed that they could identify food triggers after working with the RD (40% before agreed vs 31% after agreed); this is likely because the next phase of the low-FODMAP diet, the reintroduction phase, is designed to determine food triggers. Additionally, the majority of participants reported needing more assistance from an RD as participants were not yet educated on how to reintroduce FODMAPs back into the diet. The responses to the subjective questionnaire relating to helpfulness of resources are in accordance with the qualitative results as participants reported that the resources the RD provided were helpful.

The FODMAP diet experience via the qualitative analysis was not compared to the literature because this concept has not yet been researched outside of the current study. A recent survey reported that 79% of doctors provide lifestyle or dietary advice to patients with IBS.[39] Prior to meeting with the RD, most participants in the current study were recommended by physicians to follow the FODMAP elimination diet. Subsequently, most participants reported using the internet to self-educate about the FODMAP diet, and in a few of the participant's cases, they attempted the diet alone before meeting with the RD. These participants reported limited support from the

physician aside from receiving a short handout about foods to include and avoid while on the elimination. Due to lack of physician time and resources, perhaps a more in-depth educational handout created by the RD can be provided by the physician in an effort to prevent self-educating that could lend itself to improper management of the FODMAP elimination diet. In addition, creation of a protocol in clinic to reduce the time between physician and RD visits may be warranted.

The qualitative data indicated that RD guidance throughout the FODMAP elimination diet resulted in patient reports of feeling supported and having a better understanding of how to associate symptoms with dietary intake. Participants indicated that the RD resources were helpful and increased general nutrition knowledge. Indeed, participants reported the RD was most beneficial because of the provided support throughout the elimination phase of the diet. The one-on-one guidance, coaching, and accessibility to the RD to ask questions through email or during biweekly phone calls held them accountable. Providing support for patients following a FODMAP elimination diet requires substantial time and knowledge; thus, it is not realistic for a physician to provide the support needed, and thus incorporation of an RD into patient care is needed. It is important to note that several participants reported continuing to have symptoms through the end of the elimination diet and often blamed stress as the trigger; however, the symptoms were less severe per GSRS-IBS than at baseline. The RD informed these participants that symptoms may not be completely eliminated by the FODMAP diet. Without the support of the RD, participants may have interpreted these symptoms differently and stopped following the diet.

In addition to RD support, some participants also reported feeling supported within the home through family assistance in meal preparation. Additionally, the support of coworkers and friends when eating outside of the home helped participants adhere to the diet. Thus the RD should be aware that more support is needed outside of the RD interaction. Thus, the RD can work with the patient to recognize who will help them at home and away from home to increase adherence.

Even though participants reported the RD helpful throughout the elimination diet, participants stated that the diet was still difficult to follow. Items that made the diet difficult included grocery shopping and label reading because of the time needed to identify FODMAP foods on the ingredient label, feeling alone or isolated when watching friends or family eat items not allowed on the diet, eating outside of the home, and having limited variety of food options. These challenges relate to the suggestions the participants provided to make the diet more feasible. For example, participants identified the need for a restaurant list or tips for making eating outside of the home easier. With this information, the RD can be prepared to advise patients on questions to ask when eating out or tips for choosing appropriate menu selections. Several participants reported limited variety as they already had other food restrictions or allergies, such as being vegetarian. These participants recommended creation of more vegetarian meal plans and recipes. Participants found specific FODMAP friendly food products and suggested recommending these products to future patients to provide convenient options and potentially save time cooking or grocery shopping.

There were several limitations to this study. One limitation was the use of convenience sampling, which may have led to over or under-representation of certain

groups of people. Therefore, the results cannot be generalized to other populations. The current study was not able use a control group with no FODMAP diet education because subjecting patients to lack of instruction regarding the diet would not be ethical in a clinical setting. Two interventionists took part in the study to provide individualized dietary advice to patients. This may result in differences in patients' interpretation of the diet and items learned while working with the RD. Additionally, almost half of the participants had food allergies (n=6), thus were already on a restricted diet when beginning the FODMAP elimination diet. It is possible that those with food allergies have a different experience with the diet because they are already accustomed to being restricted. To better assist participants, 24-hour diet recall were performed by the RD; however, adherence was not measured after collecting the diet recalls. Also, the IBS-QOL and GSRS-IBS are self-reported questionnaires, with the IBS-QOL based on the last month and the GSRS-IBS based on the last week, which may not be representative of the symptoms and quality of life over the entire four weeks.

There are several strengths to this study. Over 80% of the enrolled participants completed the FODMAP elimination diet, indicating a low dropout rate. Examining the experience on the FODMAP elimination diet, a component that was unique to this study, allowed for improved understanding of the specific areas of the diet that remain challenging and items learned from working with an RD. Transcripts used in qualitative analysis were coded by three researchers until an agreed list of codes were created, providing an accurate analysis to best describe the participant experience.

Implications and Recommendations

Based on the results of this study, the FODMAP elimination diet may be appropriate to reduce symptoms and improve quality of life in patients with IBS. An RD can be beneficial throughout the FODMAP elimination diet by providing support, educating about FODMAP food and digestion, and providing resources. The qualitative analysis revealed that the RD support helps patients adhere to the diet and the identified gaps in resources. Therefore, RDs need to create additional resources (vegetarian meal plans, tips for eating outside the home, and recipes) and assure that the patient is in contact with the RD multiple times to encourage adherence. One study by Whigham et al. found that dietitian-led group sessions were as effective as one-on-one sessions in improving symptoms and quality of life and more cost effective.[5] Perhaps initiating a group education session on a regular basis in clinics would be more feasible as a dietitian is often busy in the clinical setting. The entire low-FODMAP diet should be assessed prior to making further recommendations.

CONCLUSION

In summary, the participants following the FODMAP elimination diet experienced an improvement in both GI symptoms and quality of life. Understanding the challenges faced by the participants over the course of the elimination diet may provide important insight to help RDs best provide evidence-based interventions focusing on these common challenges. Evidence that RDs provide crucial support during the FODMAP elimination diet may increase collaboration between RDs and gastroenterologists. Further studies are needed to assess the FODMAP diet experience with a RD.

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APPENDICES

Appendix A: Low-FODMAP Diet Timeline

ORA: 15032606-IRB01 Date IRB Approved: 8/5/2015

RUSH

ORA #

Rush University Medical Center

AUTHORIZATION TO SHARE PERSONAL INFORMATION IN RESEARCH

Name of the Research Study: Comparison of symptom resolution, quality of life, and diet quality of individuals following Registered Dietitian administered low-FODMAP diet versus standard clinic treatment.

Name of Principal Investigator: Hannah Roosevelt, MS, RD, CNSD

The word "you" means both the person who takes part in the research, and the person who gives permission to be in the research. The word "we" refers to Rush University Medical Center, its employees and affiliates, including the study doctor and his/her research staff. You will be asked to sign this form along with the attached research consent form.

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect, use and possibly share information that identifies you. Some of this identifiable information may come directly from you and some may come from results of questionnaires or interviews. We will only collect information that is needed for the research. This information is described in the attached consent form.

If you sign this form, we will collect your identifiable information until the end of the research. We may keep the information forever, in case we need to look at it again for this research study.

Your information may also be useful for other studies. We can only use your information again if a special committee in the hospital gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your identifiable information private.

If you sign this form, you are giving us permission to collect, use, and share your identifiable information.

You do not have to sign this form. If you decide to NOT sign this form, you cannot be in the research study. We cannot do the research if we cannot collect, use and share your identifiable information.

If you change your mind later and do not want us to collect, use and or share your identifiable information, you need to send a letter to the researcher listed above. The letter needs to say that you have changed your mind and do not want the researcher to collect, use and share your identifiable information. If we cannot collect, use and share your identifiable information, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

If you sign this form, we may continue to share the identifiable information collected for this study with the people listed in the Confidentiality section, without any time limit, unless you withdraw your authorization. This authorization does not expire.

CONFIDENTIALITY

We may share your information with people who help with the research. Some of these people may be other researchers outside of the hospital or are in charge of the research, pay for, or work with us on the research. Some of these people make sure we do the research properly. Some of these people may share your information with someone else. If they do, the same laws that Rush must obey may not protect your health information. For this study, we will share information with:
Your information will not be shared.

If your information is transferred outside of the United States, different privacy laws may apply. Additionally, if one of the companies or institutions listed above merges with, or is purchased by, another company or institution, this authorization to use and disclose protected health information in the research will extend to the successor company or institution.

Any questions? Please ask the researcher or his/her staff. Their phone numbers appear in the attached consent form. You can also call 1-800-876-0772 at Rush with general questions about your rights and the research use of your health information. The researcher will give you a signed copy of this form.

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

The health information about _____ can be collected and used by the researchers and staff for the research study described in this form and the attached consent form.

Signature: _____ Date:

Print name: _____ Legal authority:

ORA: 15032606-IRB01 Date IRB Approved: 6/29/2016 Expiration Date: 6/29/2017 Amendment Date: 7/25/2016

Investigator: *Hannah Roosevelt, MS, RD*

Contact Information: *Triangle Office Building Suite 425 1700 W Van Buren St, Chicago Il 60612*

Title of Study: *Comparison of symptom resolution, quality of life, and diet quality of individuals following low FODMAP diet after education by a Registered Dietitian versus standard clinic treatment.*

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you have been identified by your physician, nurse practitioner, or physician assistant as appropriate to try a special diet (low FODMAP [fructo-, oligo-, di-, mono- and polyol]) to help manage your gastrointestinal issues including Irritable Bowel Syndrome.

What is the purpose of this study?

The purpose of this study is to see if there is an improvement in dietary compliance (doing what you have been asked to do), quality of life, and gastrointestinal symptoms when patients are seen by a registered dietitian.

How many study subjects are expected to take part in the study?

Approximately 72 subjects will be included in this study.

What will you be asked to do?

If you agree to be in the study, you will be a part of a group that receives a diet intervention by a registered dietitian (RD). Seeing a RD is part of routine medical care. You will be asked to complete at least one visit to Rush University Medical Center (RUMC), as well as participate in at seven phone calls to discuss your diet; you can choose to do these six encounters in person or by phone with the registered dietitian, whatever is most convenient for you. You will be asked to

complete two surveys (the Gastrointestinal Symptom Rating Scale for Irritable Bowel Symptoms and Irritable Bowel Quality of life tool) at three time points (before starting the diet, one month following the initial appointment, and one month after food reintroduction at the end of the study). You will also be asked to complete a feasibility questionnaire at four time points (before starting the diet, one month following the initial appointment, right after food reintroduction, and one month after food reintroduction at the end of the study) You will also be expected to complete a food and symptom log (diary) for one week before starting the diet and throughout the study as standard clinical practice. You will also be asked to complete a questionnaire about your normal dietary pattern before and after the diet intervention.

You will schedule an appointment with the RD when you start the study. At your visit, you will complete the questionnaires stated above. At the end of intervention month, you will complete the same questionnaires as was done at the baseline visit to determine changes in symptoms and diet. These questionnaires will be completed online as your visit may be over the phone. You will then complete the same questionnaires after the reintroduction of foods, once you have a consistent diet that helps your symptoms. Payment for the initial visit where you will receive diet education will be you or your insurance's responsibility. However, the subsequent follow-up visits will be free to you for your participation in the study.

How long will you be in the study?

Study subjects can expect to be in the study for about 14 weeks depending on to the exact length of the reintroduction phase. The length of this phase will depend on how you react to reintroducing foods, but should be about 14 weeks long.

You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, your disease becomes worse, you are unable to follow the diet as directed, or the study is canceled.

What are the possible risks of the study?

No risks are expected to result from participation in this study. For some subjects, some stress may result from a not being allowed certain foods when following the diet.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study.

What other options are there?

Instead of participating in this study, you may choose to receive education from the RD regarding the low-FODMAP diet without participating in the study.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. All identifying information from surveys and diet recalls will be removed and data stored in a locked drawer in a locked room

If you withdraw from this study, the data already collected from may not be removed from the study records. The study team may ask you whether they can continue to collect follow-up data

on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings.

In order to conduct the study, the study RD, Hannah Roosevelt, will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as cost of an initial visit with an RD for education regarding low-FODMAP diet will be charged to you or your insurance company. If the appointment is not paid for by your insurance, then the expected cost to see the dietitian is about $80. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study.

- Six subsequent encounters (2-week phone call during elimination, 1-month follow up, 2 weeks into reintroduction, end of reintroduction, 2-week follow-up after reintroduction, and 1 month follow-up after food reintroduction) with the RD will be free of charge to all participants.
- You will be asked to purchase the Monash University FODMAP app from iTunes or Google play for approximately $7.99, but purchase is not required to be in this study. This app will be used to guide your diet elimination by helping you understand foods you can eat on your diet.

Will you be compensated or paid?

No compensation will be offered to study subjects.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this

study.

Whom do you call if you have questions or problems?
Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Hannah Roosevelt, 312-942-2860. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR:
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily.

Signature of Witness/Translator	Date of Signature

Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

ORA: 15032606-IRB01 Date IRB Approved: 6/29/2016 Expiration Date: 6/29/2017 Amendment Date: 7/25/2016

Signature of the Principal Investigator Date of Signature

Check here if Principal Investigator obtained consent and a separate signature is not required.

Appendix B: Questionnaires

Subjective Questionnaire

Please answer the following questions regarding your experience on the FODMAP diet for the current phase you are in (pre-diet, elimination, reintroduction, or post-FODMAP phase). Put a check or "X" in the appropriate box. If the question is not applicable to the phase you are in, mark "Not Applicable."

	Strongly disagree	Disagree	Agree	Strongly agree	Not Applicable (N/A)
1. Overall I am satisfied with the change in my symptoms					
2. I could have followed this diet without help from a dietitian					
3. I found the resources helpful in following a low FODMAP diet.					
4. I can identify the foods that trigger my symptoms					
5. I need more assistance from a dietitian					

Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome (GSRS-IBS)

Developed by I.K. Wiklund, S. Fullerton, C.J. Hawkey, R. H. JOnes, G.F. Longstreth, E.A. Mayer, R.A. Peacock, I.K. Wilson & J. Naesdal

	1. No Discomfort at all	2. Minor Discomfort	3. Mild Discomfort	4. Moderate Discomfort	5. Moderately Severe Discomfort	6. Severe Discomfort	7. Very Severe Discomfort
1)Have you been bothered by abdominal pain during the past week?							
2)Have you been bothered by pain or discomfort in your abdomen, relieved by a bowel action during the past week?							
3)Have you been bothered by a feeling of bloating during the past week?							
4)Have you been bothered by passing gas during the past week?							
5)Have you been bothered by constipation (problems emptying the bowel) during the past week?							
6)Have you been bothered by diarrhea (frequent bowel movements) during the past week?							
7)Have you been bothered by loose bowel movements over the past week?							

	1. No Discomfort at all	2. Minor Discomfort	3. Mild Discomfort	4. Moderate Discomfort	5. Moderately Severe Discomfort	6. Severe Discomfort	7. Very Severe Discomfort
8)Have you been bothered by hard stools during the past week?							
9)Have you been bothered by an urgent need to have a bowel movement (need to go to the toilet urgently to empty the bowel) during the past week?							
10)Have you been bothered by a feeling that your bowel was not completely emptied after having a bowel movement during the past week?							
11)Have you been bothered by feeling full shortly after you have started a meal during the past week?							
12)Have you been bothered by feeling full even long after you have stopped eating during the past week?							
13)Have you been bothered by visible swelling of your abdomen during the past week?							

The IBS-QOL Questionnaire
About how you feel

Please think about your life over the past month (last 30 days), and look at the statements below. Each statement has five different responses. For each statement, please circle the response that best describes your feelings.

Q1. I feel helpless because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q2. I am embarrassed by the smell caused by my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q3. I am bothered by how much time I spend on the toilet.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q4. I feel vulnerable to other illnesses because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q5. I feel fat/bloated because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q6. I feel like I'm losing control of my life because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q7. I feel my life is less enjoyable because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q8. I feel uncomfortable when I talk about my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q9. I feel depressed about my bowel problems.

(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q10. I feel isolated from others because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q11. I have to watch the amount of food I eat because of my bowel problems.
(Please circle one
number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q12. Because of my bowel problems, sexual activity is difficult for me.
(Please circle one number)
(If not applicable, please circle "NOT AT ALL")
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q13. I feel angry that I have bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q14. I feel like I irritate others because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q15. I worry that my bowel problems will get worse.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q16. I feel irritable because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q17. I worry that people think I exaggerate my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q18. I feel I get less done because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q19. I have to avoid stressful situations because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q20. My bowel problems reduce my sexual desire.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q21. My bowel problems limit what I can wear.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q22. I have to avoid strenuous activity because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q23. I have to watch the kind of food I eat because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q24. Because of my bowel problems, I have difficulty being around people I do not know well.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q25. I feel sluggish because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q26. I feel unclean because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT

5 EXTREMELY

Q27. Long trips are difficult for me because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q28. I feel frustrated that I cannot eat when I want because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q29. It is important to be near a toilet because of my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Q30. My life revolves around my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q31. I worry about losing control of my bowels.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q32. I fear that I won't be able to have a bowel movement.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q33. My bowel problems are affecting my closest relationships.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 A GREAT DEAL

Q34. I feel that no one understands my bowel problems.
(Please circle one number)
1 NOT AT ALL
2 SLIGHTLY
3 MODERATELY
4 QUITE A BIT
5 EXTREMELY

Appendix C: Experience on the FODMAP Elimination Diet Questioning Guide

- Determine the challenges faced by patients following the FODMAP elimination diet.
- Assess the patient's experience following the FODMAP elimination diet when working with a registered dietitian.
- Determine strategies or information dietitians can provide from the viewpoint of the patient.

Open-ended questions

1. Since meeting with the dietitian, describe how you are currently eating to minimize your gastrointestinal symptoms.
2. How is this different than what you were doing before?
    1. Before following the elimination diet, how did you learn to eat that way?
    2. What other people have helped you eat that way?
3. Describe any situations since starting the elimination diet with the RD where you stopped following the diet.
4. Describe the positive things you learned while working with the dietitian to follow the FODMAP elimination diet.
    1. What is the most beneficial take-away that you learned from the dietitian?
5. What remains difficult about following the FODMAP elimination diet?
    1. Of all the things you've mentioned, what is the biggest challenge you've experienced when following the FODMAP elimination diet?
6. Describe any suggestions that you have for the dietitian to make the FODMAP elimination diet easier for you to follow.
    1. What resources were most helpful?
    2. What other resources that you are aware of might also be helpful?

Appendix D. Code words used in coding transcripts of interviews about the FODMAP diet experience from participants following the FODMAP elimination diet (n=12)		
Code Word	**Subcategory**	**Definition**
Prior to RD Intervention		Something the participant was doing before meeting with the RD
	Physician Recommended FODMAP Diet and Educational Materials	Statements of physician recommendations to follow FODMAP elimination diet and of education materials provided by physician
	Education Materials or Resources Used	Description of educational materials used before seeing the RD
	Restricted Diet	Statements about restricting diet before meeting with the RD
	Not Following FODMAP Diet	Statements of not following the FODMAP diet before meeting with RD
	Electronic Applications	Identifies electronic applications used before meeting with the RD
	No Support	Statements about no support when following the FODMAP elimination diet before meeting with the RD
	FODMAP Elimination	Statements of dietary habits they were doing while following the FODMAP elimination diet before meeting with the RD
	Physician Nutrition Information not Helpful	Statements of physician's FODMAP diet education material as not helpful
Concepts Learned from RD		Statement that something was learned from the RD
	FODMAP Food Information	Statements of learning about specific foods containing FODMAPs and how they are digested
	Healthy Recommendations	Statements about receiving recommendations related to healthy eating from the RD
	Symptom Information	Statements about learning from the RD how to interpret their symptoms

Helpful Resources from RD		Statements of resources that were helpful when on the FODMAP elimination diet
	FODMAP Study Handouts from RD	Statements that education handouts (meal plan, recipes, allowed food list, grocery list) provided prior to starting the FODMAP elimination diet were helpful resources
	Electronic Applications	Statements that an electronic application(s) was a helpful resource when following the FODMAP elimination diet
Most Beneficial of RD Intervention		Most beneficial experience about working with the RD
	Support	Statements that the support of the RD was most beneficial
Elimination Difficult		Statements about what was difficult when following the FODMAP elimination diet
	Limited Variety	Statements that the FODMAP elimination diet lacks variety
	Grocery Shopping and Label Reading	Statements that grocery shopping and label reading was difficult
	Alone or Isolated	Statements that they felt alone or isolated on the FODMAP elimination diet
Most Difficult Elimination of FODMAP Elimination		Statement that something was the most difficult during the elimination diet
	Time	Statements that following the FODMAP elimination diet took excessive time
	Eating Outside of the Home	Statements that eating outside of the home was most difficult
Reasons for Non-Compliance		Statements of not following the FODMAP elimination diet after meeting with the RD
	Eating Outside of the Home	Statements of not following the FODMAP elimination diet due to eating outside of the home
	Limited Variety	Statements of not following the FODMAP elimination diet due to limited variety

	Accidently Eating FODMAP	Statements of accidently eating a food containing FODMAPs
	Temptation	Statement of feeling tempted to eat something not on the FODMAP elimination diet or not following the diet due to temptation
Actions Taken after RD		Statements of actions taken after meeting with the RD
	Made Changes to Diet	Statements of removing or adding foods into diet on the FODMAP elimination diet
	Symptom Status	Statements about GI symptoms after completing FODMAP elimination diet
	Cooking at Home	Statements of increase in cooking at home after working with the RD
	Helpful Resources Found on Own	Statements of tools used to help with the FODMAP elimination diet
Needed Resources		Suggestions about additional resources for RD to use
	Additional Meal Plans and Recipes	Suggests providing additional meal plans and recipes
	FODMAP Diet Tips Handout	Suggests providing a handout with tips for completing FODMAP Elimination Diet (restaurant suggestions, diagram of FODMAP digestion, specific food products)

Appendix E. Difference in gastrointestinal symptoms between participants with IBS-C[1] (n=5) and IBS-D[1] (n=6) before and after following the FODMAP[2] elimination diet

	Before FODMAP Elimination Median (IQR)			After FODMAP Elimination Median (IQR)		
	IBS-C	IBS-D	P Value[3]	IBS-C	IBS-D	P Value[3]
Total Score	47.0 (25.2, 61.1)	45.5(32.5, 54.0)	0.94	37.0 (26.5, 46.9)	37.1 (17.4, 54.9)	0.87
Bloating	14.0 (9.5, 17.0)	11.0 (9.0, 13.0)	0.37	11.0 (8.5, 12.5)	10.5 (6.0, 14.0)	0.74
Pain	8.0 (3.0, 10.0)	8.0 (7.0, 10.0)	0.93	6.0 (4.5, 8.5)	5.5 (2.0, 9.0)	0.81
Constipation	7.0 (4.5, 12.0)	5.0 (2.0, 7.0)	0.19	5.0 (5.0, 9.0)	2.0 (2.0, 4.5)	0.11
Diarrhea	9.0 (6.0, 11.0)	16.0 (9.0, 19.0)	0.07	7.0 (5.5, 9.0)	15.0 (5.8, 19.5)	0.14
Satiety	8.0 (2.0, 11.0)	4.0 (2.0, 8.0)	0.50	5.0 (2.0, 10.0)	2.5 (2.0, 9.3)	0.93

GSRS-IBS = Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome; Higher scores indicate higher symptom severity and lower scores indicate lower symptom severity in the past week. Total GSRS-IBS score: minimum 13, maximum 91; Bloating score: minimum 3, maximum 21; Pain score: minimum 2, maximum 14; Constipation score: minimum 2, maximum 14; Diarrhea score: minimum 4, maximum 28; Satiety score: minimum 2, maximum 14.

[1]IBS= Irritable Bowel Syndrome; IBS-C, IBS with Constipation. IBS-D, IBS with Diarrhea

[2]FODMAP = Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols.

[3]Mann Whitney-U Test for comparison of medians. Significance set at $p<0.05$.

Appendix F. Difference in gastrointestinal symptoms between male (n=4) and female (n=9) following the FODMAP[2] elimination diet

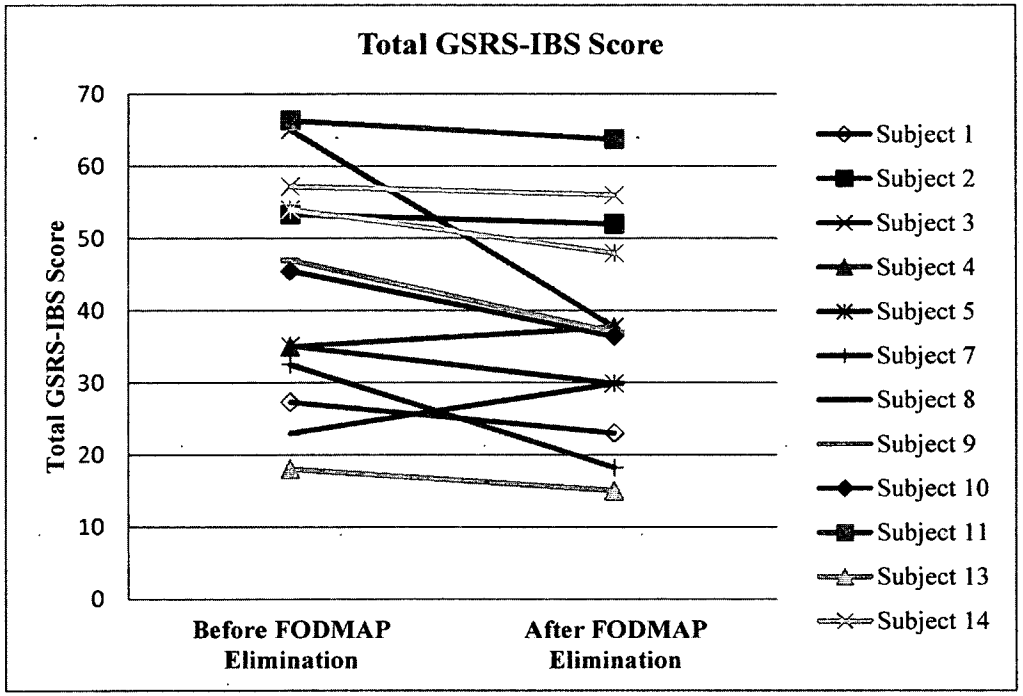
	Before FODMAP Elimination Median (IQR)			After FODMAP Elimination Median (IQR)		
	Male	Female	P Value[3]	Male	Female	P Value[3]
Total Score	29.0 (19.3, 48.8)	47.0 (33.8, 61.1)	0.12	29.9 (18.7, 46.5)	37.4 (26.4, 51.4)	0.31
Bloating	9.5 (5.0, 13.3)	13.0 (11.0, 16.5)	0.12	11.5 (5.0, 12.0)	11.0 (7.5, 13.8)	0.73
Pain	4.0 (2.0, 9.0)	8.0 (7.0, 10.0)	0.12	4.5 (2.5, 8.0)	6.0 (3.5, 8.8)	0.44
Constipation	4.0 (2.0, 9.0)	7.0 (3.0, 11.0)	0.24	2.5 (2.0, 6.0)	5.0 (2.0, 8.0)	0.48
Diarrhea	8.5 (6.3, 16.0)	11.0 (9.0, 17.5)	0.35	6.5 (6.0, 15.3)	9.0 (5.5, 17.3)	0.55
Satiety	3.5 (2.0, 7.3)	6.0 (2.0, 11.0)	0.38	3.0 (2.0, 8.5)	4.0 (2.0, 8.8)	0.73

GSRS-IBS = Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome; Higher scores indicate higher symptom severity and lower scores indicate lower symptom severity in the past week. Total GSRS-IBS score: minimum 13, maximum 91; Bloating score: minimum 3, maximum 21; Pain score: minimum 2, maximum 14; Constipation score: minimum 2, maximum 14; Diarrhea score: minimum 4, maximum 28; Satiety score: minimum 2, maximum 14.

[1]IBS= Irritable Bowel Syndrome; IBS-C, IBS with Constipation. IBS-D, IBS with Diarrhea

[2]FODMAP = Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols.

[3]Mann Whitney-U Test for comparison of medians. Significance set at $p<0.05$.



Appendix G. Individual scores for total Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome (GSRS-IBS) score before and after following the FODMAP elimination diet (n=13).

Appendix H. Difference in quality of life between male (n=4) and female (n=10) participants following the FODMAP[1] elimination diet

	Before FODMAP Elimination Median (IQR)			After FODMAP Elimination Median (IQR)		
	Male	Female	P Value[2]	Male	Female	P Value[2]
Total Score	94.5 (55.4, 111.1)	94.5 (78.8, 110.5)	0.76	84.0 (45.3, 100.6)	73.5 (58.0, 99.4)	0.93
Dysphoria	24.5 (12.0, 28.0)	22.0 (20.5, 28.0)	0.88	19.5 (10.5, 23.3)	16.0 (13.3, 22.0)	0.73
Interference with Activity	17.0 (9.0, 27.3)	14.0 (11.0, 21.0)	0.58	15.5 (7.8, 21.8)	12.5 (8.5, 20.0)	1.00
Body Image	6.5 (5.3, 8.3)	13.0 (8.5, 15.0)	**0.03**	6.0 (5.3, 7.5)	10.0 (6.3, 14.8)	0.06
Health Worry	6.0 (5.3, 8.3)	9.0 (7.0, 10.5)	0.12	5.5 (3.5, 8.3)	6.5 (5.0, 9.0)	0.38
Food Avoidance	13.0 (9.3, 13.8)	10.0 (9.5, 14.5)	0.94	10.5 (4.5, 13.5)	11.5 (10.3, 13.8)	0.44
Social Reaction	11.0 (5.5, 13.5)	11.0 (8.5, 12.5)	0.88	10.5 (5.3, 14.3)	7.5 (4.8, 12.3)	0.61
Sexual	3.5 (2.3, 8.5)	3.0 (2.5, 7.0)	1.00	3.5 (2.0, 8.8)	2.5 (2.0, 5.8)	0.79
Relationship	5.0 (3.3, 7.5)	7.0 (4.0, 8.0)	0.43	6.0 (3.0, 9.0)	4.0 (3.3, 6.8)	1.00

IBS-QOL = Irritable Bowel Syndrome-Quality of Life Questionnaire; Higher scores indicate a poor quality of life and lower scores indicate a good quality of life. Total quality of life score: minimum 34, maximum 170; Dysphoria score: minimum 8, maximum 40; Interference with activity score: minimum 7, maximum 35; Body image score: minimum 4, maximum 20; Health worry score : minimum 3, maximum 15; Food avoidance score: minimum 3, maximum 15; Social reaction score: minimum 4, maximum 20; Sexual score: minimum 2, maximum 10; Relationship score: minimum 3, maximum 15.

[1]FODMAP = Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols.

[2]Mann-Whitney-U Test for comparison of median score. Significance set at $p<0.05$.

Appendix I. Change in quality of life within male and female participants following the FODMAP[1] elimination diet (n=13)

	Male (n=4) Median (IQR)[2]			Female (n=9) Median (IQR)[2]		
	Before FODMAP Elimination	After FODMAP Elimination	P Value[3]	Before FODMAP Elimination	After FODMAP Elimination	P Value[3]
Total Score	94.5 (55.4, 111.1)	84.0 (45.3,	0.07	98.0 (79.6, 115.5)	77.0 (60.0, 113.0)	**0.02**
Dysphoria	24.5 (12.0, 28.0)	100.6)	0.07	24.5 (20.8, 29.5)	16.0 (13.5, 24.0)	**0.01**
Interference with Activity	17.0 (9.0, 27.3)	19.5 (10.5, 23.3)	0.11	17.0 (11.0, 22.0)	13.0 (9.0, 22.5)	0.26
Body Image	6.5 (5.3, 8.3)	15.5 (7.8, 21.8)	0.29	13.0 (8.8, 16.5)	11.0 (6.5, 15.5)	**0.04**
Health Worry	6.0 (5.3, 8.3)	6.0 (5.3, 7.5)	0.18	9.0 (7.5, 11.0)	7.0 (5.0, 10.5)	0.07
Food Avoidance	13.0 (9.3, 13.8)	5.5 (3.5, 8.3)	0.19	10.5 (9.8, 15.0)	12.0 (10.5, 14.0)	0.83
Social Reaction	11.0 (5.5, 13.5)	10.5 (4.5, 13.5)	1.00	11.5 (9.3, 14.3)	8.0 (5.5, 15.0)	**0.04**
Sexual	3.5 (2.3, 8.5)	10.5 (5.3, 14.3)	1.00	4.5 (2.8, 8.5)	3.0 (2.0, 7.0)	**0.04**
Relationship	5.0 (3.3, 7.5)	3.5 (2.0, 8.8) 6.0 (3.0, 9.0)	0.41	7.5 (4.0, 8.8)	4.0 (3.5, 9.0)	0.39

IBS-QOL = Irritable Bowel Syndrome-Quality of Life Questionnaire; Higher scores indicate a poor quality of life and lower scores indicate a good quality of life. Total quality of life score: minimum 34, maximum 170; Dysphoria score: minimum 8, maximum 40; Interference with activity score: minimum 7, maximum 35; Body image score: minimum 4, maximum 20; Health worry score: minimum 3, maximum 15; Food avoidance score: minimum 3, maximum 15; Social reaction score: minimum 4, maximum 20; Sexual score: minimum 2, maximum 10; Relationship score: minimum 3, maximum 15.
[1]FODMAP = Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols.
[2]Wilcoxon singed rank test for comparison of median score. Significance set at $p<0.05$.

Appendix J. Difference in quality of life between participants with IBS-C[1] (n=5) and IBS-D[1] (n=6) following the FODMAP[2] elimination diet

	Before FODMAP Elimination Median (IQR)			After FODMAP Elimination Median (IQR)		
	IBS-C[1]	IBS-D[1]	P Value[3]	IBS-C[1]	IBS-D[1]	P Value[3]
Total Score	80.5 (78.8, 119.0)	94.5 (59.5, 109.0)	0.74	70.0 (60.0, 113.0)	73.5 (48.6, 95.4)	0.75
Dysphoria	21.0 (20.5, 29.0)	22.0 (14.0, 28.0)	0.87	18.0 (12.5, 24.0)	16.0 (11.8, 19.5)	0.81
Interference with Activity	11.0 (9.5, 17.0)	20.0 (11.0, 22.0)	0.29	10.0 (8.0, 22.5)	12.5 (9.3, 18.0)	0.81
Body Image	13.0 (7.5, 16.0)	9.0 (8.0, 13.0)	0.37	11.0 (7.5, 15.0)	6.5 (6.0, 9.8)	0.10
Health Worry	9.0 (9.0, 13.0)	6.0 (5.0, 9.0)	**0.03**	9.0 (5.5, 11.5)	5.5(4.5, 7.5)	0.24
Food	14.0 (10.5, 14.5)	10.0 (9.0, 13.0)	0.10	11.0 (10.0, 13.5)	11.5 (7.5, 14.0)	0.94
Avoidance	10.0 (7.0, 15.5)	12.0 (7.0, 13.0)	0.57	9.0 (5.5, 13.5)	7.5 (4.0, 13.5)	0.87
Social Reaction	3.0 (2.0, 6.5)	4.0 (3.0, 6.0)	0.36	2.0 (2.0, 6.5)	2.5(2.0, 5.3)	0.86
Sexual	5.0 (3.5, 9.5)	6.0 (4.0, 8.0)	0.87	4.0 (3.0, 8.5)	4.0 (3.0, 7.5)	0.80

IBS-QOL = Irritable Bowel Syndrome-Quality of Life Questionnaire; Higher scores indicate a poor quality of life and lower scores indicate a good quality of life. Total quality of life score: minimum 34, maximum 170; Dysphoria score: minimum 8, maximum 40; Interference with activity score: minimum 7, maximum 35; Body image score: minimum 4, maximum 20; Health worry score : minimum 3, maximum 15; Food avoidance score: minimum 3, maximum 15; Social reaction score: minimum 4, maximum 20; Sexual score: minimum 2, maximum 10; Relationship score: minimum 3, maximum 15.

[1]IBS= Irritable Bowel Syndrome; IBS-C, IBS with Constipation. IBS-D, IBS with Diarrhea

[2]FODMAP = Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols.

[3]Mann-Whitney-U Test for comparison of median score. Significance set at $p<0.05$.

Appendix K. Change in quality of life within participants with IBS-C[1] (n=5) and IBS-D[1] (n=6) following the FODMAP[2] elimination diet

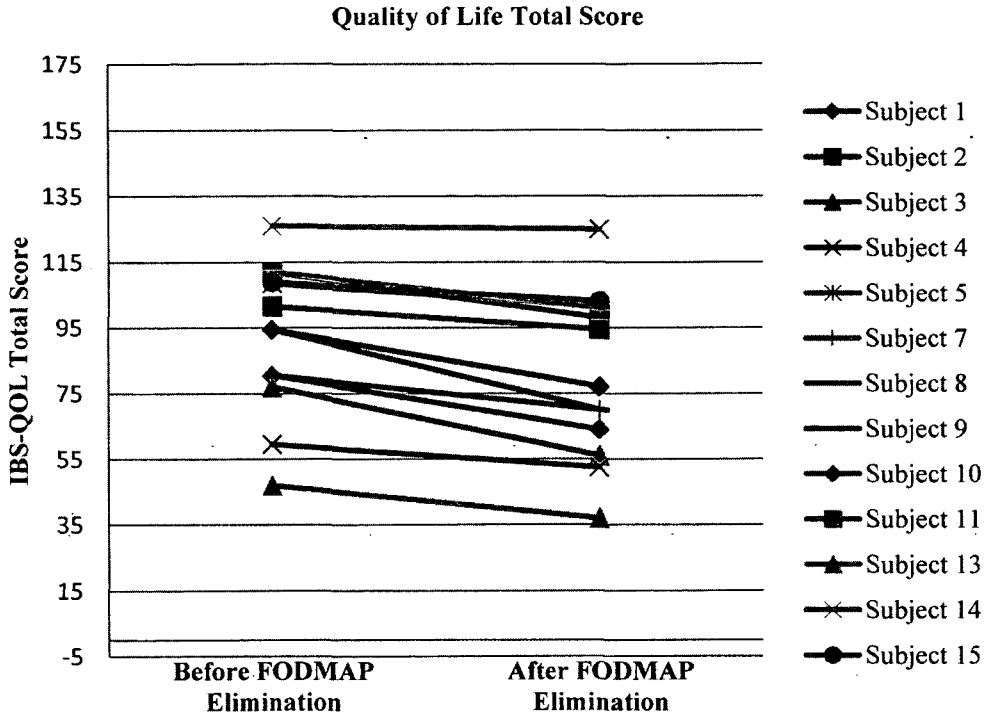
	IBS-C (n=5) Median (IQR)			IBS-D (n=6) Median (IQR)		
	Before FODMAP Elimination	After FODMAP Elimination	P value[3]	Before FODMAP Elimination	After FODMAP Elimination	P Value[3]
Total Score	80.5 (78.8, 119.0)	70.0 (60.0, 113.0)	**0.04**	98.0 (68.3, 111.3)	77.0 (52.5, 98.0)	**0.02**
Dysphoria	21.0 (20.5, 29.0)	18.0 (12.5, 24.0)	**0.04**	24.5 (15.8, 28.8)	16.0 (13.0, 21.0)	**0.02**
Interference with Activity	11.0 (9.5, 17.0)	10.0 (8.0, 22.5)	0.72	20.0 (11.8, 27.3)	13.0 (10.0, 21.0)	**0.03**
Body Image	13.0 (7.5, 16.0)	11.0 (7.5, 15.0)	0.16	10.5 (8.0, 15.3)	7.0 (6.0, 15.0)	**0.04**
Health Worry	9.0 (9.0, 13.0)	9.0 (5.5, 11.5)	0.11	7.0 (5.3, 9.8)	6.0 (5.0, 9.0)	0.20
Food Avoidance	14.0 (10.5, 14.5)	11.0 (10.0, 13.5)	0.68	10.0 (9.0, 14.5)	13.0 (9.0, 14.0)	0.83
Social Reaction	10.0 (7.0, 15.5)	9.0 (5.5, 13.5)	0.11	12.0 (8.0, 13.8)	8.0 (4.0, 15.0)	0.22
Sexual	3.0 (2.0, 6.5)	2.0 (2.0, 6.5)	0.79	5.0 (3.0, 7.5)	3.0 (2.0, 6.0)	**0.04**
Relationship	5.0 (3.5, 9.5)	4.0 (3.0, 8.5)	**0.05**	7.0 (4.0, 8.0)	4.0 (3.0, 9.0)	0.49

IBS-QOL = Irritable Bowel Syndrome-Quality of Life Questionnaire; Higher scores indicate a poor quality of life and lower scores indicate a good quality of life. Total quality of life score: minimum 34, maximum 170; Dysphoria score: minimum 8, maximum 40; Interference with activity score: minimum 7, maximum 35; Body image score: minimum 4, maximum 20; Health worry score : minimum 3, maximum 15; Food avoidance score: minimum 3, maximum 15; Social reaction score: minimum 4, maximum 20; Sexual score: minimum 2, maximum 10; Relationship score: minimum 3, maximum 15.

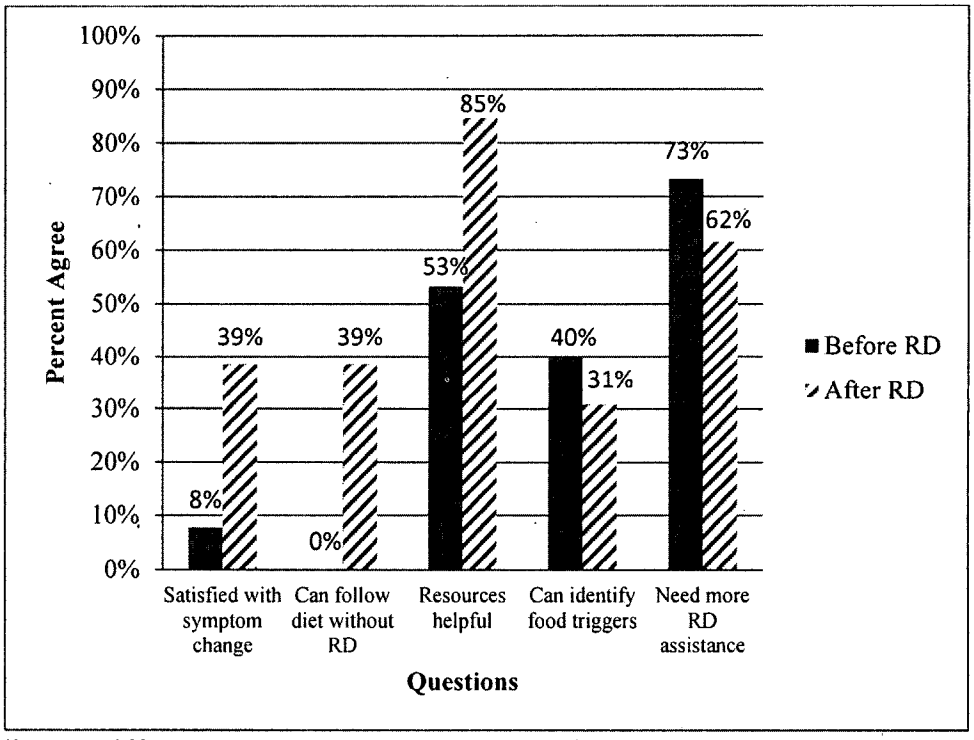
[1]IBS= Irritable Bowel Syndrome; IBS-C, IBS with Constipation. IBS-D, IBS with Diarrhea

[2]FODMAP = Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols.

[3]Wilcoxon Signed-Rank Test for comparison of median score. Significance set at $p<0.05$.



Appendix L. Individual scores for total IBS-QOL score before and after following the FODMAP elimination diet (n=13). IBS-QOL = Irritable Bowel Syndrome-Quality of Life Questionnaire; Higher scores indicate a poor quality of life and lower scores indicate a good quality of life.



Appendix M. Difference in agreement before and after RD intervention (n=13) as assessed by the FODMAP Elimination Diet Subjective Questionnaire.

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