At What Point in the Elimination Phase of the Low FODMAP Diet is the Level of Symptom Improvement Highest in Patients with Irritable Bowel Syndrome?

Thesis

Presented in Partial Fulfillment of the Requirements for the Degree Master of Science in the Graduate School of The Ohio State University

By

Kelly Michelle Corfman, B.S.
Graduate Program in Allied Medical Professions

The Ohio State University

2017

Thesis Committee:

Dr. Marcia Nahikian-Nelms, Advisor

Dr. Kristen Roberts

Dr. Jill Clutter
Copyright by

Kelly Michelle Corfman, B.S.

2017
Abstract

Background: Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder that affects patients worldwide. A diet low in fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs) has shown to improve symptoms of a majority of patients with IBS. Current literature is insufficient to provide guidelines for how long patients should follow the elimination phase of the diet.

Methods: Patients attended a low FODMAP diet education class and were followed for six weeks. Every two weeks, patients completed the validated IBS-Symptom Severity Scale questionnaire. Patients also completed checklists of all high FODMAP foods consumed daily, to measure adherence.

Results: Five patients participated in this study. By week two, all 5 patients had composite symptom scores classified at least one severity level lower than baseline. By week six, 1 patient’s symptoms had returned to baseline severity classification, indicating an 80% response rate overall. Patients were non-adherent to the diet on 24/210 total patient days (11.4%). Adherence was directly related to symptom severity.

Conclusion: Some patients may benefit from a shortened elimination phase of the low FODMAP diet, while some may require the full six weeks for best effect. Adherence to the diet ensures likelihood of symptom improvement.
Acknowledgements

Thank you to my advisor, Dr. Marcia Nahikian-Nelms, for your encouragement and constant effort to make this project the best it could be. Thank you to my committee, Dr. Kristen Roberts and Dr. Jill Clutter, for your time and dedication. Thank you to my co-investigator, Khawlah Al-Muhanna, for working tirelessly with me. Finally, thank you to the physicians at OSU’s Division of Gastroenterology, Hepatology, and Nutrition, for recommending patients to us for this study.
Vita

November 13, 1992....................................................Born--Cincinnati, Ohio

May 2011..............................................................William Mason High School

May 2015.................................................................B.S. Human Ecology, The Ohio State University

2015-2017.............................................................Combined MS/DI Program in Medical Dietetics, The Ohio State University

Field of Study

Major Field: Allied Medical Professions
# Table of Contents

Abstract ....................................................................................................................... ii
Acknowledgements ....................................................................................................... iii
Vita ................................................................................................................................. iv
List of Tables ................................................................................................................ vi
List of Figures ............................................................................................................ vii
Chapter 1: Introduction ................................................................................................. 1
Chapter 2: Literature Review ....................................................................................... 6
Chapter 3: Methodology ............................................................................................... 30
Chapter 4: Results and Discussion .............................................................................. 37
Chapter 5: At What Point in the Elimination Phase of the Low FODMAP Diet is the
          Level of Symptom Improvement Highest in Patients with Irritable Bowel Syndrome? ........................................................................................................... 68
References for Thesis ................................................................................................... 76
Appendix A: Instruments .............................................................................................. 82
List of Tables

Table 1. Demographic Information.................................................................37
Table 2. Comparison of Excluded Foods to Low FODMAP Diet..........................39
Table 3. Oral Treatments Utilized by Patients..................................................40
Table 4. Symptom Severity Classification over Time.......................................55
Table 5. Days of Non-Adherence and High FODMAP Foods Eaten...................58
Table 6. Bowel Habits over Time..................................................................61
<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Patient A’s IBS over Time</td>
<td>42</td>
</tr>
<tr>
<td>4.2</td>
<td>Patient A’s Composite Score over Time</td>
<td>43</td>
</tr>
<tr>
<td>4.3</td>
<td>Patient B’s IBS over Time</td>
<td>45</td>
</tr>
<tr>
<td>4.4</td>
<td>Patient B’s Composite Score over Time</td>
<td>46</td>
</tr>
<tr>
<td>4.5</td>
<td>Patient C’s IBS over Time</td>
<td>47</td>
</tr>
<tr>
<td>4.6</td>
<td>Patient C’s Composite Score over Time</td>
<td>48</td>
</tr>
<tr>
<td>4.7</td>
<td>Patient D’s IBS over Time</td>
<td>50</td>
</tr>
<tr>
<td>4.8</td>
<td>Patient D’s Composite Score over Time</td>
<td>51</td>
</tr>
<tr>
<td>4.9</td>
<td>Patient E’s IBS over Time</td>
<td>52</td>
</tr>
<tr>
<td>4.10</td>
<td>Patient E’s Composite Score over Time</td>
<td>53</td>
</tr>
<tr>
<td>5.1</td>
<td>Patient B’s Composite Symptom Score over Time</td>
<td>72</td>
</tr>
<tr>
<td>5.2</td>
<td>All Participants’ Composite Scores over Time</td>
<td>74</td>
</tr>
<tr>
<td>A.1</td>
<td>IBS-Symptom Severity Score/Bristol Stool Form Scale Page 1</td>
<td>82</td>
</tr>
<tr>
<td>A.2</td>
<td>IBS-Symptom Severity Score/Bristol Stool Form Scale Page 2</td>
<td>83</td>
</tr>
<tr>
<td>A.3</td>
<td>Demographics and Health Questionnaire Page 1</td>
<td>84</td>
</tr>
<tr>
<td>A.4</td>
<td>Demographics and Health Questionnaire Page 2</td>
<td>85</td>
</tr>
<tr>
<td>A.5</td>
<td>Demographics and Health Questionnaire Page 3</td>
<td>86</td>
</tr>
<tr>
<td>A.6</td>
<td>High FODMAP Checklist</td>
<td>87</td>
</tr>
<tr>
<td>A.7</td>
<td>Class Evaluation Page 1</td>
<td>88</td>
</tr>
</tbody>
</table>
At What Point in the Elimination Phase of the Low FODMAP Diet is the Level of Symptom Improvement Highest in Patients with Irritable Bowel Syndrome?

Chapter 1

Background of the Problem

Irritable bowel syndrome (IBS) is one of the most common functional gastrointestinal disorders and affects patients globally. There are numerous therapies currently being utilized in attempt to reduce symptoms of the disorder, but few are backed by sufficient evidence. The low fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAP) diet has recently gained the support of several research studies as a proposed nutritional therapy for IBS. However, due to varying methods of determining symptom improvement, and different lengths of time spent following the diet, there are no standard protocols for initiation of this diet. In particular, there is no standard recommendation for, nor sufficient evidence to determine, the length of the elimination period for the dietary intervention. Following the diet restrictions long-term may result in a reduced variety of foods consumed and possible nutritional consequences. This pilot study evaluated symptom improvement over time in patients with IBS to determine how long patients should follow the elimination phase of the low FODMAP diet in order to maximize reduction of symptoms and minimize potential consequences.
Statement of the Problem

Irritable bowel syndrome is a common functional gastrointestinal disorder. A diet restricting fermentable oligosaccharides, disaccharides, monosaccharides, and polyols, known as the low FODMAP diet, has recently gained support as an effective treatment for many who suffer from IBS. It is generally accepted that patients should restrict all high FODMAP foods for a designated period of time before gradually reintroducing foods to determine individual tolerance. However, the length of time that patients follow this elimination phase of the diet varies across studies. Therefore, current literature does not provide for a consistent length of time that patients with IBS should eliminate high FODMAP foods from their diets to experience the greatest symptom improvement.

Purpose of the Study

The purpose of this study was to compare the level of symptom improvement over time in participants following the low FODMAP diet. Participants eliminated high FODMAP foods from their diets for six weeks, and were instructed in how to gradually reintroduce these foods to their diets. Symptoms were measured prior to beginning the diet, and every two weeks while completing the elimination phase. This helped researchers determine whether there is an ideal length of time to follow the elimination phase of the low FODMAP diet in order to guide recommendations in clinical practice.

Definition of Terms

Conceptual definitions for this study include:

1) Fermentable- Capable of undergoing fermentation.¹

2) Oligosaccharide- A carbohydrate that consists of a relatively small number of monosaccharides.¹
3) Disaccharide- A general term for simple carbohydrates formed by the union of two monosaccharide molecules.¹

4) Monosaccharide- A simple sugar; a carbohydrate that cannot be broken down to simpler substances by hydrolysis. Subgroups include the aldoses and the ketoses.¹

5) Polyol- Polyhydroxy alcohol; a sugar that contains many -OH (-ol) groups, such as the sugar alcohols and inositols.¹

6) Prebiotic- A non-digestible, selectively fermented food ingredient (oligofructose, inulin, lactulose, galactooligosaccharides) that changes the composition and/or activity in the gastrointestinal microflora, conferring health benefits on the host.¹

Operational definitions for this study include:

1) Elimination phase- The period of time in which participants following the low FODMAP diet completely restrict all foods considered to be high in FODMAPs from their diets.

2) Reintroduction phase- The period of time in which participants follow the steps to reintroduce one type of FODMAP per week into the diet per current reintroduction protocol. Patients will choose one FODMAP group per week (ex: lactose) to reintroduce in their diet. They will consume one food that is not high in any other type of FODMAP (ex: for lactose, it might be milk) on 3 separate days in one week, increasing the amount consumed, unless they experience gastrointestinal symptoms. This will help participants to determine their individual levels of tolerance to specific FODMAPs, to help them follow the most varied diet possible without inducing symptoms.²
3) High FODMAP food- Any food that contains a high amount of one or more FODMAPs, as established by Monash University.

4) Low FODMAP food- Any food that contains low amounts of FODMAPs as established by Monash University.

**Research Questions**

The research questions of this study included:

1) At what point in the elimination phase of the low FODMAP diet is the level of symptom improvement highest in patients with irritable bowel syndrome?

2) How do levels of symptom improvement compare after two, four, and six weeks of following the elimination phase of the low FODMAP diet?

3) What is the average length of time that patients report highest level of symptom improvement?

**Theoretical Framework**

The Adult Learning Theory will help guide the class development that will provide nutrition education on the low FODMAP diet for participants in this study. Two key elements of Adult Learning Theory that are particularly relevant to nutrition education include andragogy and self-directed learning.

Andragogy is used to describe how adults, rather than children, learn. Much of the understanding of andragogy is a result of Malcom Knowles’ work. Knowles proposed five assumptions by which adults learn. The fourth of these assumptions suggests that adults learn based on problems they encounter. The adults that participated in this study engaged in this type of learning. They had a problem in their lives that they wanted to fix, namely, symptoms of irritable bowel syndrome that affect quality of life. Therefore, they
attended a nutrition education class to learn how to use their diet to attenuate their symptoms. Knowles’ fifth assumption proposes that adults are internally motivated. This also relates to this study, as there was no incentive offered to participants who volunteered. They were internally motivated in hopes of experiencing symptom improvement.

Self-directed learning suggests that adults will advance and assess their own learning. This relates to Knowles’ assumption that adults are internally motivated, as the study participants were responsible for attending the diet education classes to learn how to control their symptoms. Self-directed learning has as part of its basis the construct known as behaviorism, in which behaviors are followed by positive or negative events, known as “reinforcement.” Adults then learn to associate those behaviors with those events, and will adjust their behavior appropriately. When adults performed the specific desired behavior (reducing dietary FODMAPs), they would have, ideally, experienced reinforcement (the absence of troubling GI symptoms), and would adopt this nutrition intervention.
Chapter 2

Literature Review

Introduction

Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder (FGID) associated with abdominal pain and discomfort, as well as altered bowel habits. Despite its global prevalence, common treatments for IBS are not supported by a great deal of literature. As the disorder is also associated with substantial economic burden, the development of an evidence-based treatment would be of significant use within the global community. Recently, increasing evidence has supported the use of a diet low in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs) to treat IBS symptoms.

This literature review explores the characteristics, etiology, and pathophysiology of IBS, diagnostic criteria, medical and nutritional treatments, the proposed mechanisms by which certain short-chain carbohydrates may contribute to symptoms of IBS, and the current research related to the low FODMAP nutrition intervention.

Definition of Irritable Bowel Syndrome

Irritable bowel syndrome (IBS) is a functional gastrointestinal (GI) disorder, meaning that those with the disorder have chronic or periodic GI symptoms, but lack any consistent biomarker to indicate the presence of the disorder, making the symptoms of a functional nature, rather than structural or biochemical.
Epidemiology

Estimating the prevalence of irritable bowel syndrome is a challenging task for several reasons. Although validated diagnostic criteria have been developed, not all clinicians use them in practice, and misdiagnoses may be more frequent due to lack of standardized use. Many patients with gastrointestinal symptoms do not seek medical care, so estimated prevalence may represent only a fraction of the true number of people suffering from IBS. Use of prescribed medications to treat IBS is infrequent, so prescription adherence cannot be used to attain an estimate. Likewise, mortality is not a useful source for statistics as IBS is not considered a cause of death. There have been several epidemiological studies conducted, however, and the estimate is that between 10-25% of the global population suffers from IBS, with an average estimate of 11%. This estimate does vary by area of the world, as South America has the highest occurrence of the disorder, and South Asia the lowest. IBS is more common in females than in males, and there appears to be a familial link.

Signs and Symptoms

The most common symptoms of IBS include abdominal pain or discomfort and a change in bowel habits. Patients may also experience bloating, relief of pain or discomfort with defecation, straining with defecation, fecal urgency, the sensation of incomplete bowel movements after defecation, and increased gas. Patients may be subtyped based on the nature of their bowel habits, with those having diarrhea subtyped as IBS-D, those having constipation subtyped as IBS-C, and those with episodes of alternating diarrhea and constipation subtyped as IBS-M. Some patients may be considered IBS-U (for unsubtyped) if they do not experience diarrhea or constipation.
However, bowel patterns may fluctuate, and patients may not remain the same subtype over the entire course of their lives with the disorder.⁶

IBS symptoms are similar to symptoms experienced by patients with other gastrointestinal diseases and disorders.⁷ Patients with IBS typically do not experience specific symptoms associated with diseases of a structural nature, such as GI bleeding and weight loss, so these symptoms can therefore be used to distinguish the functional disorder IBS from other GI disorders related to structural or biochemical irregularities.⁶

**Etiology and Pathophysiology**

IBS is considered a FGID, because there is no single structural abnormality or biomarker that can explain symptoms.⁶ However, there are varying theories regarding the etiology of IBS. One of the potential contributing factors may be gastroenteritis. Up to 25% of IBS cases may be described as post-infectious,⁶ caused by different organisms like *Salmonella*, *Campylobacter*, or *Trichinella spiralis*.¹⁰ However, post-infectious IBS may spontaneously resolve in half of patients within 8 years of diagnosis.¹² Other suggested reasons for developing IBS include genetics, small intestinal bacterial overgrowth (SIBO), or immune response to food sensitivity or food allergy.¹⁰ Additionally, patients with IBS are likely to be diagnosed with other chronic diseases and disorders, such as fibromyalgia or gastroesophageal reflux disease, suggesting that these conditions may have a similar pathogenesis.¹²

Recently, Hungin¹³ et al proposed a three-hypothesis explanatory model to assist primary care practitioners in describing the disorder to patients after diagnosis. The three components provide insight into the etiology and pathophysiology of IBS and include the following: 1) changes in regulation of gastrointestinal function; 2) changes in
communication between the brain and the gastrointestinal tract; and 3) psychological
problems.\textsuperscript{13}

The first element of the explanatory model, changes in regulation of
gastrointestinal function, may be a result of changes in gut inflammation or bacterial
content, dietary factors, or abnormalities in neurotransmitter signaling, between healthy
people and those with IBS.\textsuperscript{13} Serotonin plays a major role in gut motility.\textsuperscript{10} Serotonin is
thought to be a possible explanation of the differences between IBS-C and IBS-D; those
who have too much serotonin available, whether it is due to increased serotonin secretion
or excessive reuptake by transporters, would have increased gut motor activity, and likely
develop IBS-D, whereas those with inadequate serotonin would have reduced gut motor
activity, contributing to symptoms of IBS-C. This decreased motor activity could also
lead to intestinal bacterial overgrowth, and result in increased gas production, bloating
and discomfort.\textsuperscript{13}

The second part of the explanatory model suggests that patients with IBS have an
underlying miscommunication between the brain and the gut. This can manifest as either
visceral hypersensitivity, when the GI tract increases signaling, or as central
dysregulation. Individuals with visceral hypersensitivity experience greater symptomatic
responses to bodily functions than those without hypersensitivity. Visceral
hypersensitivity is a useful concept for explaining symptoms like pain and discomfort,
but cannot be used to explain the changes in bowel habits that patients with IBS
experience, so it alone is an incomplete understanding of IBS pathophysiology.\textsuperscript{13}

Patients may also experience abnormal activity of the central nervous system, also
known as central dysregulation. Whereas in the case of visceral hypersensitivity the
gastrointestinal tract amplifies signals sent to the brain, in central dysregulation, the brain receives normal signals from the gut and amplifies them. Brain scans have shown that patients with IBS have greater responses to gut pain stimuli than do people without IBS. Not all people with IBS will have central dysregulation, but this can be a useful explanation for some patients.13

Finally, the explanatory model describes psychological distress as a component of IBS. Within the context of IBS, there are three main behaviors that can be attributed to psychological problems: somatization, hypervigilance, and catastrophizing. Depression, anxiety, and other conditions associated with psychological distress can induce the process of somatization—interpreting normal sensations within the body as disease symptoms. These same psychological conditions may also make people more likely to be aware of these sensations which others may not notice due to the tendency for hypervigilance that is common within these populations. Finally, these patients may be more likely to catastrophize, assuming that the symptoms they have are not only disease symptoms, but the symptoms of a serious condition.13

All three of these components will not likely apply to every individual with IBS. However, the combination of the three hypotheses can help care providers explain IBS to patients more effectively. This in turn can help patients cope with the disorder and encourage them to work with their providers to best improve their symptoms.13

**Diagnostic Criteria**

A challenge in the diagnosis of irritable bowel syndrome is the lack of a universal biomarker or other form of anatomical abnormality, leading to its classification as a functional disorder.13 Historically, the disease was diagnosed by the exclusion of other
diseases, which could involve invasive procedures to rule out other causes for symptoms. Some clinicians continue to support a diagnosis-by-exclusion approach to the disorder. Common diseases causing similar symptoms that doctors may choose to rule out before diagnosing a patient with IBS include inflammatory bowel disease (IBD), celiac disease, bile acid malabsorption (which can mimic symptoms of IBS-D), and colon cancer (which can mimic symptoms of IBS-C). The standard diagnosis utilizes the Rome III criteria to define IBS. Patients who fall under this definition experience frequent abdominal pain or discomfort three or more days each month, for three months prior to diagnosis, with symptoms having begun at least six months prior to diagnosis. Along with pain or discomfort, patients also experience at least two of the following: the relief of abdominal pain or discomfort after a bowel movement; symptoms associated with a change in frequency of bowel movements; and symptoms associated with a change in stool consistency or form.

After diagnosis, patients may be subtyped by completing the Bristol Stool Form Scale, which assists patients in describing their usual bowel habits. Subtyping patients may guide clinicians in treating the patients’ symptoms, but it is not uncommon for patients to experience changes in subtype over time.

**Medical Management**

Development of therapies to treat IBS has involved varying health professionals. Unfortunately, despite the prevalence of the disorder, there is insufficient evidence to support most current treatments. The development of promising treatments is also hindered by the variations in the disorder between individuals.
Some therapies do seem to be more effective for specific subtypes of IBS. The American Gastroenterological Association (AGA) suggests the use of Linaclotide, Lubiprostone, and laxatives to help treat symptoms of IBS-C. Linaclotide is a prosecretory agent. Through a series of pathways, Linaclotide stimulates the secretion of chloride and bicarbonate into the intestines, which also stimulates the flow of sodium and water into the intestines, improving symptoms of constipation. Linaclotide has been shown to improve stool frequency and abdominal pain. Lubiprostone, another prosecretory agent, activates a chloride channel on the epithelium of the intestines, increasing flow of chloride and water into the intestines and improving intestinal transit. Although Lubiprostone comes with the risk for adverse effects, it has been shown to improve general IBS symptoms. The AGA recommends laxative use for patients with IBS-C due to the evidence of improvement in bowel movement frequency in general, rather than within a specific IBS population.

Rifaximin, Alosetron, and Loperamide are AGA-recommended treatments for IBS-D. Rifaximin is an antibiotic. Although it is not yet approved by the FDA specifically for treatment of IBS-D, this drug does reduce symptoms of IBS-D when taken in a one-time, two-week dosing period. Alosetron is a serotonin antagonist that can improve diarrhea. Alosetron is approved by the FDA for use in women only and has been shown to improve IBS symptoms, especially abdominal pain. Alosetron is associated with adverse effects including ischemic colitis and severe constipation. Loperamide is an antidiarrheal medication. Antidiarrheal medications reduce stool volume and reduce the speed of intestinal transit by inhibiting peristalsis. The AGA
suggests Loperamide for patients with IBS-D due to the strong evidence that the drug reduces stool frequency, although not in an IBS population alone.\textsuperscript{15}

Some treatments are recommended regardless of IBS subtype. The AGA also recommends tricyclic antidepressants,\textsuperscript{15} which prevent the reuptake of serotonin,\textsuperscript{16} for treatment of IBS. Antispasmodics are utilized due to the long-held notion that IBS symptoms such as pain are aggravated by intestinal spasms\textsuperscript{4} and are also recommended by the AGA.\textsuperscript{15} Other oral treatments that may benefit patients with IBS are peppermint oil and probiotics,\textsuperscript{4} although these are not part of the standard for care presented by the American Gastroenterological Association.

Unfortunately, even though these treatments seem to improve symptoms, they are imperfect treatments. It is difficult to recommend specific strains of probiotics, as evidence for different options is insufficient. Antispasmodics only provide short-term relief, and are associated with risks for adverse events. Antidepressants also have significant side effects that may limit patient adherence to a regimen.\textsuperscript{4} Likewise, many of the recommended and commonly used treatments do not improve all IBS symptoms that patients may experience. Laxatives can improve stool frequency for those with IBS-C, but other symptoms are not well-controlled by laxatives. Peppermint oil is effective at improving abdominal pain, but not altered bowel habits. Loperamide improves diarrhea but does not impact other GI symptoms.\textsuperscript{10} Patients with IBS relying on oral treatments to improve their symptoms have often reported using a combination of oral treatments to improve their symptoms.\textsuperscript{15}

Besides pharmacological interventions, some psychological treatments have been shown to be effective at reducing symptoms. Therapies such as cognitive behavioral
therapy, multi-component psychological therapy, dynamic psychotherapy, and hypnotherapy carry a recommendation from the American College of Gastroenterology.\textsuperscript{4} Exercise may also be an effective therapy for IBS, as exercise has been associated with an improvement in IBS symptoms. Exercise also increases intestinal transit time in the general population, and may therefore be especially effective for those patients with IBS-C.\textsuperscript{12}

**Nutrition Therapy**

The American College of Gastroenterology suggests that specialized diets may improve IBS symptoms for some patients, but as is the case for many medical treatments previously mentioned, the recommendation is not strong.\textsuperscript{4} Still, around two thirds of people with IBS believe that certain foods trigger their IBS symptoms,\textsuperscript{14} and many adjust their diets accordingly.\textsuperscript{4}

Nutritional recommendations for treating IBS vary between countries. The American College of Gastroenterology recommends the use of fiber, particularly the soluble fiber psyllium, for the relief of IBS symptoms.\textsuperscript{4} Fiber tends to be more effective in improving symptoms of those patients with IBS-C.\textsuperscript{12} Exclusion diets have been used to treat IBS, in which patients eliminate all foods from their diets that may be causing their GI symptoms, and then add each food back to their diets one at a time. Foods that do not induce symptoms are then assumed not to be trigger foods. However, the use of exclusion diets is not well supported in the literature.\textsuperscript{10}

The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) guidelines for IBS begin with general healthy recommendations, such as eating regularly throughout the day and not eating too quickly. The NICE guidelines also
suggest limiting high fat foods, carbonated beverages, sugar-free products, and any foods with sorbitol. Patients are instructed to consume no more than 3 servings of fruit per day, to avoid resistant starches, and to consume sufficient fluids through non-caffeinated beverages. For those who have diarrhea, the NICE guidelines recommend limiting insoluble fiber, but those with constipation should increase their intake.17

The NICE guidelines also focus on the manner in which foods and beverages are consumed. Patients are instructed to eat meals and snacks, so that they are never too hungry and never too full. The advice recommends peaceful, quiet mealtimes, and that patients chew their food sufficiently.18

While guidelines vary, one specialized diet in particular has received attention in multiple countries. This diet reduces the intake of certain carbohydrates that are poorly absorbed and fermented by bacteria in the GI tract, and has been termed the low FODMAP diet.14

The Low FODMAP Diet

The low FODMAP diet is a diet low in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols. This diet was originally created by Peter Gibson and his team of researchers at Monash University in Australia19 in the early 2000s, but the evidence supporting the diet has been limited until the last several years.20 The diet reduces specific dietary components: fructose, a monosaccharide; lactose, a disaccharide; the oligosaccharides known as fructans and galactans; and polyols.8

Fructose

Fructose, a six-carbon ketose1 is found naturally in apples, pears, and honey, as well as in the sweetener high fructose corn syrup.20 Fructose is absorbed in the
gastrointestinal tract by two facultative transporters: GLUT 5 and GLUT 2. GLUT 5 transports only fructose, but GLUT 2 also transports galactose and glucose. When fructose is consumed with glucose, the absorption of fructose is improved. However, even with two transporters, the absorption of fructose varies by individual and by the dose of fructose consumed. Fructose that is not absorbed by the transporters in the small intestine continues into the large intestine, where it is fermented by bacteria. Early studies in FODMAP restriction focused on fructose. Due to increased consumption of fruit juices and foods containing high-fructose corn syrup, the intake of fructose in the United States has increased. These increased levels of fructose that are easily consumed in the US food system have been shown in one study to cause GI symptoms in more than half of study participants who did not have IBS.

**Lactose**

Lactose occurs naturally in milk from cows, sheep, and goats, as well as any products made from the milk, such as cheese, yogurt, and ice cream. Lactose is made up of a glucose molecule and a galactose molecule, and is hydrolyzed by the enzyme lactase, which allows for cellular absorption. However, many people do not produce sufficient lactase, and so unabsorbed lactose continues to the large intestine for fermentation by bacteria. Similar to fructose, many early FODMAP studies focused on lactose restriction.

**Fructans**

Fructans are found naturally in wheat, onions, and garlic. Structurally, fructans are formed by one glucose molecule bonded to a chain of fructose molecules. Humans lack the digestive enzymes that break down the β-(2-1) fructosyl-fructose linkages, so the
majority of fructans consumed in the diet proceed to the large intestine for fermentation. Fructans are considered to be prebiotic, which means that their fermentation stimulates the growth or activity of beneficial bacteria in the gastrointestinal tract.\(^8\)

**Galactans**

Galactans are found naturally in legumes such as beans and lentils.\(^20\) They are also found in some grains and nuts.\(^8\) Galactans are formed by one fructose molecule bonded to a chain of galactose molecules.\(^20\) Humans do not produce the enzyme \(\alpha\)-galactosidase, which is necessary for digestion of galactans, so the majority of galactans consumed in the diet are fermented in the large intestine. Galactans, like fructans, are considered to be prebiotic.\(^8\)

**Polyols**

Polyols (such as sorbitol and mannitol) are sugar alcohols.\(^8\) Naturally occurring food sources of polyols include cherries, plums, and avocados. Polyols can also be found in sugar-free chewing gums.\(^20\) The rate of their passive absorption in the small intestine varies between individuals, often based on the size of the particular molecule.\(^8\) Polyol intake in the United States is likely increasing, due to the greater demand for “sugar-free” food alternatives.\(^21\)

**Mechanisms of Symptom Induction by FODMAPs**

FODMAPs are poorly absorbed in the small intestine.\(^5\) This has been described individually in previous sections of this literature review. Symptoms of fermentation are seen both in individuals with IBS and healthy individuals, but the level of symptom induction is different. A common measure of carbohydrate malabsorption is the hydrogen breath test. When carbohydrates pass into the large intestine, bacterial fermentation
produces hydrogen. This hydrogen is absorbed into the bloodstream, and is released by the lungs in exhalation. By measuring the amount of hydrogen that is exhaled, it is possible to estimate an individual’s ability to absorb the particular carbohydrate used in the test. For some individuals, the large intestinal bacteria produce mostly methane rather than hydrogen, so measuring the amount of methane that is exhaled is also helpful in assessing malabsorption.\textsuperscript{22} Zhu et al compared breath hydrogen production in healthy controls and participants with IBS. Breath hydrogen production showed no significant differences between the groups, indicating that lactose malabsorption rates are similar in people with and without IBS.\textsuperscript{23} Madsen and her colleagues investigated the effects of a fructose-sorbitol mixture in healthy subjects alone. In comparison to breath hydrogen and methane production following glucose consumption (as a control), all eleven healthy subjects experienced a rise in gas production after the consumption of the fructose-sorbitol mixture, indicating that all subjects malabsorbed the mixture.\textsuperscript{24} The malabsorption of FODMAPs due to normal gastrointestinal mechanisms is a universal human trait.

The symptomatic response to malabsorption of FODMAPs, however, is not a universal human trait. Ong et al compared gas production and symptom induction in healthy volunteers and participants with IBS on high and low FODMAP diets. Despite the fact that both groups had significantly increased breath hydrogen production during the high FODMAP diet, symptom induction was not the same. The only GI symptom that increased during the high FODMAP diet for the healthy volunteers was passage of gas, while for the participants with IBS, all measured GI symptoms significantly increased during the high FODMAP diet.\textsuperscript{25} In Yao and colleagues’ study of the effects of sorbitol
and mannitol in patients with IBS and healthy controls, only those with IBS experienced GI symptoms after consumption of the polyols. This was despite the findings that sorbitol malabsorption was similar between the two groups, and mannitol malabsorption was actually less frequent in patients with IBS. In fact, the researchers in this study found no correlation between markers of malabsorption (breath hydrogen production) and gastrointestinal symptoms. This lack of correlation between malabsorption and gastrointestinal symptoms was also found in Wilder-Smith and associates’ study comparing lactose and fructose malabsorption (based on hydrogen or methane breath test) and lactose and fructose intolerance (based on symptomatic response). In these subjects with varying functional gastrointestinal disorders, malabsorption and intolerance were not directly related. Some patients even experienced symptoms without signs of malabsorption. It is therefore relevant to describe the mechanisms by which FODMAP consumption can lead to gastrointestinal symptoms specifically in those suffering from IBS.

The small chemical size of FODMAPs allows them to impact the movement of water within the GI tract. This is also demonstrated in research involving subjects without IBS. Murray and her colleagues compared the effects of fructose, inulin (a fructan), and glucose (as a control) in healthy volunteers, and found that fructose increased the water content of the small intestine significantly compared to glucose. However, when glucose and fructose were consumed together in a 1:1 ratio, the small bowel water content was lower than that for fructose alone. This finding was not statistically significant, but does align with the knowledge that glucose improves absorption of fructose in the small intestine, leaving less free fructose in the gut to act as
a FODMAP. While the particular fructan in this study was not found to increase small bowel water content, Marciani and her associates observed that small bowel water content increased after consumption of a meal containing wheat bran (a food containing fructans) to a greater extent than after consumption of an identical meal without the wheat bran. A separate arm of this study observed that a test meal containing the polyol mannitol also significantly increased small bowel water content, while a test meal containing glucose did not.

Barrett et al observed the effects of FODMAP restriction in the effluent of twelve patients with ileostomies. This study showed that a reduced FODMAP content in the diet was correlated with decreased volume of water in the effluent, suggesting that the FODMAPs in the diet had drawn water into the gut. The effluent when participants were on a low FODMAP diet weighed significantly less than when they were on the high FODMAP diet, and when on the low FODMAP diet, participants perceived their effluent to be of a thicker consistency.

In Yoon and colleagues’ clinical trial, patients receiving a low FODMAP enteral formula experienced a greater improvement in diarrhea than those on a formula containing moderate or high amounts of FODMAPs. This suggests that the intestinal water content in those patients on a low FODMAP formula was reduced.

FODMAPs are consumed by large intestinal bacteria that produce gases within the gastrointestinal tract. FODMAPs are considered fermentable because they pass through the small intestine without being completely absorbed, and therefore are available for fermentation in the large intestine. The short-chain carbohydrates known to be FODMAPs are not the only carbohydrates that reach the large intestine for
fermentation. Some polysaccharides, such as psyllium and resistant starch, are also fermentable. However, these carbohydrates have longer chain lengths, which cause them to be fermented more slowly than the short-chain carbohydrates. In fact, polysaccharides with fewer than 10 molecules in the chain are fermented about twice as quickly as longer polysaccharides. This slower fermentation produces less gas. When Ong et al compared gas production and symptom induction in healthy volunteers and participants with IBS on low and high FODMAP diets, breath hydrogen production was significantly greater for both groups after the high FODMAP diet than for the low FODMAP diet, demonstrating that the rapid fermentation of these short-chain carbohydrates produces more gas.

The gastrointestinal responses to FODMAP consumption are normal and universal. It is not the consumption of the FODMAPs that induces gastrointestinal symptoms, but rather the exaggerated neurological response to luminal distention, or the enlarged space within the gastrointestinal tract caused by increased gas production from fermentation. As mentioned before, this is known as visceral hypersensitivity, and is likely responsible for the pain, discomfort, and bloating felt when patients with IBS consume FODMAPs. This visceral hypersensitivity may also induce motility changes within the gut, leading to altered stool patterns. Because of this hyper-response to the luminal distention, a diet that reduces consumption of the foods that trigger distention (e.g. FODMAPs) has been studied in an attempt to determine its usefulness in reducing symptoms of IBS.
Instruction in the Low FODMAP Diet

Instruction in the low FODMAP diet varies across studies and clinicians. Some trials do not ask all participants to restrict fructose and lactose consumption, but only restrict these carbohydrates in the diets of those who have had a positive breath test. However, as has been demonstrated previously, markers of fructose and lactose malabsorption and symptoms of intolerance are not always linked, so it may be beneficial for all subjects on the low FODMAP diet to reduce all FODMAPs, at least initially. Likewise, the level of FODMAP consumption considered “low” and “high” varies across studies.

A one-on-one session with a registered dietitian is an effective method of teaching the low FODMAP diet to patients, as individual sessions allow the dietitian to adjust the instruction to fit with the patient’s current diet, emphasizing the low FODMAP foods that person already consumes. Most trials have involved patients educated on the diet through these one-on-one sessions, but education in class settings has been successful as well. Ringström and her colleagues demonstrated that group education is more effective in the IBS population when compared to the provision of written information alone. Participants receiving group education reported greater increases in knowledge than those receiving a guidebook on strategies for reducing symptoms. The participants in the group were also statistically more satisfied with their knowledge than those who received only the guidebook. These differences were seen directly after the intervention and at a follow-up several months later. GI symptoms were also trending lower for those in the group education than those with a guidebook at the end of the intervention, and those reduced symptom scores reached significance at the follow-up.
While the group education in the previously mentioned study was not FODMAP-specific, FODMAP education has been evaluated in the group setting. Whigham and colleagues compared the results of group education to one-on-one education in FODMAP reduction, in terms of symptom improvement, and stool frequency and consistency. FODMAP reduction improved symptoms, stool frequency, and stool consistency, regardless of method of education, and there were no significant differences between those receiving group education and those with one-on-one education, demonstrating that group education in the low FODMAP diet is effective.\textsuperscript{35}

Varying strategies have been used to fully educate participants on the diet. One successful strategy used in Shepherd and associates’ study observing the effects of fructose and fructans intake was to provide participants with “alternative” choices for many of the foods that contained fructose and fructans. The participants who understood alternative choices were better able to adhere to the diet.\textsuperscript{36}

**Adherence**

Greater adherence to the low FODMAP diet recommendations improves patients’ responses to the diet. Shepherd et al found that, when comparing reduction of fructose and fructans alone, 74% of patients experienced symptom improvement. However, when only analyzing the data from participants in the study who were considered “adherent” to the diet, the percentage of participants experiencing symptom improvement significantly jumped to 85%.\textsuperscript{36} Likewise, Croagh et al found that for patients with ileostomies on a low FODMAP diet, consumption of foods containing FODMAPs led to aggravated symptoms, demonstrating that the lack of adherence in consuming those foods induced the symptoms.\textsuperscript{37}
However, one benefit of the diet is that complete adherence to the diet may not be necessary to see some symptom improvement. De Roest and colleagues found in their prospective study of the low FODMAP diet that there was a positive association between dietary adherence and symptom improvement, meaning that the more strictly participants adhered to the diet, the greater improvement in symptoms they saw. However, those who did not adhere completely did demonstrate some symptom improvement. Only 12.2% of the participants claimed to adhere to the diet with no exceptions, and yet 72.1% of participants were satisfied with their symptom improvement. This indicates that the low FODMAP diet, though most effective when followed diligently, can still benefit patients who are unable to completely adhere to the diet, for whatever reason.

Varying factors can impact the likelihood of patients being adherent to the low FODMAP diet. Some patients might find the diet too bland to consume regularly. Some might also find it too complicated to follow, or too expensive to find alternatives for the high FODMAP foods they must avoid. Gearry et al found that low FODMAP cookbooks assisted participants in the diet and improved adherence. Participants with higher levels of education and those who worked less than 35 hours per week were also more likely to be adherent, indicating that having sufficient ability to understand the diet, and sufficient time to follow the diet, respectively, may improve adherence. Though diet adherence may be challenging, it is possible for patients to follow it successfully, and a long-term follow-up of a low FODMAP study found that many who continue to reduce dietary FODMAPs ended up following an adjusted form of the diet, consuming certain FODMAPs that had been reintroduced to tolerance by each individual.
Efficacy

Shepherd and her colleagues demonstrated the efficacy of the low FODMAP diet by completing a placebo-controlled re-challenge trial. Participants in this trial had been previously educated in the low FODMAP diet and had already demonstrated improvement in GI symptoms. Researchers then provided participants with test drinks containing low, medium, or high amounts of fructose, fructans, a combination of fructose and fructans, or glucose as a placebo. Participants had to state whether their symptoms were adequately controlled with each drink. As the amounts of FODMAPs in the drinks increased, the number of participants without adequate control of their symptoms increased, suggesting that the FODMAPs were responsible for symptom induction. This important trial was crucial to establishing FODMAP reduction as the key to symptom improvement in the low FODMAP diet, rather than other confounding factors.

The efficacy of the low FODMAP diet in trials has varied based on several factors. One factor is the definition of symptom improvement that each study uses. For example, Böhn et al. considered patients to be “responders” to the diet if their score on the IBS-Symptom Severity Score questionnaire was reduced by at least 50 points. By this standard, only 50% of the patients following the low FODMAP diet were considered to have responded to the diet, which was not statistically greater than those following typical advice for IBS. Halmos and her colleagues considered symptom improvement to be a 10 mm change in the visual analog scale, and in this study, 70% of the patients had significantly improved symptoms. Researchers might also use the patients’ subjective satisfaction with symptom improvement rather than a more objective measure.
Another factor impacting efficacy is the level of FODMAP consumption considered “low” and “high” by individual research teams. Some researchers have developed diets for their studies containing levels of FODMAPs that are representative of normal intakes to be considered the “high” FODMAP diets. Chumpitazi et al found that children on a low FODMAP diet had less frequent abdominal pain than those on what was termed the typical American childhood diet.\(^{42}\) A similar diet, termed the typical Australian diet, was developed for another study, and participants with IBS had greater symptom reduction on a low FODMAP diet compared to the typical Australian diet. The benefit of using such “typical” diets is to demonstrate a more realistic idea of the efficacy of the diet. High amounts of FODMAPs can induce gastrointestinal symptoms in people without IBS, as has been demonstrated, so comparing a low FODMAP diet to a very high FODMAP diet could exaggerate the efficacy of the low FODMAP diet. Portraying the low FODMAP diet against typical intakes shows truer differences in symptom change.\(^{11}\)

Overall, the low FODMAP diet seems to produce symptom improvement in anywhere from 50% to 86% of patients.\(^{11,17,18,38,43,44}\) It is possible to become completely asymptomatic on the diet as well. In a long-term follow-up of patients on a low FODMAP diet, 37% of patients with IBS were symptom-free after following the diet.\(^{39}\) The diet has been shown to be as effective\(^{18}\) or more effective\(^{17}\) at reducing IBS symptoms than standard dietary advice.

The low FODMAP diet is effective not just in the IBS population. When Fernández-Bañares and colleagues placed patients with functional abdominal bloating with evidence of carbohydrate malabsorption on diets that restricted those malabsorbed carbohydrates for one month, 81% of individuals experienced improvement in symptoms.
Nearly 67% of those patients had continued improvement after one year on the diet.\textsuperscript{45} Multiple studies have also demonstrated the low FODMAP diet’s effectiveness in reducing functional gastrointestinal symptoms in patients with inflammatory bowel disease (IBD). In two separate studies of IBD patients following the low FODMAP diet long-term, 42%\textsuperscript{39} and 50%\textsuperscript{40} of patients experienced symptom improvement.

**Elimination Time for FODMAPs**

Some recommendations for health professionals educating patients on the low FODMAP diet suggest that patients should completely eliminate FODMAPs for 6-8 weeks to allow for the greatest level of symptom resolution. After this period of restriction, patients can then gradually reintroduce FODMAP-containing foods to determine their individual levels of tolerance to each type of FODMAP.\textsuperscript{5} Other recommendations shorten the suggested elimination phase to 4-6 weeks, and suggest that the reason for even this length of time of complete FODMAP restriction is to allow for patients to fully understand the diet, rather than to see greater symptom improvement over more time.\textsuperscript{33} In general, it is thought that patients should follow the elimination phase for several weeks. However, recent evidence has shown that there are risks of adverse effects when following the diet for a long period of time.

In Böhn and her colleagues’ study comparing the effectiveness of a low FODMAP diet to standard dietary advice, those patients on the low FODMAP diet significantly reduced their caloric intake, indicating that this diet may not be nutritionally adequate for long-term use.\textsuperscript{18}

Studies have also shown that a low FODMAP diet can negatively impact the gut microbiota. Staudacher et al determined that a low FODMAP diet decreased the
abundance of the beneficial bacteria species known as Bifidobacteria. A later study conducted by Halmos and her colleagues did not find that Bifidobacteria specifically were reduced on a low FODMAP diet compared to the participants’ baseline diets, but they did determine that overall bacterial content of the gut was decreased. They also found that greater intake of FODMAPs was associated with higher Bifidobacteria content than at baseline. Based on the potential negative effects of following the low FODMAP diet long-term, it is important to determine the shortest length of time necessary to remain on the restrictive version of the diet to receive the greatest symptomatic benefit.

Because level of improvement is determined by many factors, such as definition of symptom improvement, and how much improvement must take place to be considered satisfactory, study comparison is difficult, and it is therefore difficult to determine an appropriate length of time for patients to remain on the elimination phase of the diet before reintroducing FODMAP-containing foods. Children placed on a low FODMAP diet experienced less frequent abdominal pain in the 48 hours they were on the diet as compared to a typical American childhood diet, indicating that this diet can improve symptoms quickly. However, in Pedersen and colleagues’ study of adult patients on a low FODMAP diet who monitored their symptoms weekly by questionnaire, the highest level of symptom improvement occurred during the final week of the study, which was week six. So, while the diet may work quickly for some, it may not reach its fullest effect immediately. In fact, when a subset of patients answered questions about their symptoms in Staudacher and colleagues’ study comparing the diet to NICE guidelines, patients experienced symptom resolution in between 2 to 8 weeks. The average length of time was approximately 3.5 weeks. When Halmos and her colleagues compared
symptom severity between subjects on a low FODMAP diet and those on a typical Australian diet, the greatest variance in symptom severity was seen after only seven days on the two diets, suggesting that the greatest symptom improvement can be reached in as little as one week. As demonstrated, there is little agreement on how long this diet should be followed restrictively to reach optimal symptom improvement.

**Conclusion**

Although the low FODMAP diet is a relatively new area of study, current literature supports this intervention as an effective method of reducing symptoms of irritable bowel syndrome. Reduction of specific fermentable carbohydrates targets the major mechanisms by which diet can aggravate IBS symptoms, providing relief in the majority of IBS patients who follow the low FODMAP diet. Yet like many treatments, it possesses its own shortcomings. Due to the possibility of negative effects after prolonged elimination of all high FODMAP foods, further research should be aimed at illuminating the shortest length of time necessary to achieve the highest level of symptom improvement.
Chapter 3
Methodology

Sample

Researchers recruited a total of 70 people diagnosed with, or suspected to have an underlying medical concern of, irritable bowel syndrome (IBS) for participation. Inclusion criteria included: age of at least 18 years; a diagnosis, or suspected underlying medical concern, of IBS; a doctor’s referral for nutrition consultation; and ability to read and understand English. Participants were excluded from the study if they were unable to provide voluntary informed consent for the study or if they were pregnant. Twenty people signed up to participate in the study, and 8 participants attended the class and were accepted into the study. This study was approved by the Institutional Review Board at the Ohio State University on November 2, 2016, under the study number 2016H0320.

Recruitment

A total of 70 participants were recruited for this study. Participants were recruited by phone call from the list of patients referred to the Division of Gastroenterology, Hepatology, and Nutrition (GHN) at the Ohio State University for nutrition consultation due to a diagnosis, or suspected underlying issue, of IBS, as well as by the placement of a flyer detailing the study in the outpatient GHN clinics, and email notification of the study to all physicians in the GHN practice. Participants were offered their choice of one of two
diet education classes to attend, with the goal of 20 participants in each class. A total of 8 participants attended the low FODMAP diet education class and were accepted into the study.

Study Design

This study was a prospective descriptive study using a sample of convenience.

Prior to Study Visit

Before participating in one of the two low FODMAP diet classes, participants received a packet of documents including a health questionnaire, a three-day diet record, and an IBS-Symptom Severity Score questionnaire. Instructions for completing these documents were included. Participants who were recruited by phone received this packet in the mail, and those who were recruited through the flier in the nurse practitioner’s office received the packet in the office when they agreed to take part in the study.

Study Visit

On the day of the class to which each participant chose to attend, inclusion and exclusion criteria were reviewed with each individual participant. At this time, informed consent to participate in the study was obtained. After providing consent, participants attended the low FODMAP nutrition education class. Participants completed an evaluation of the class after the class. Participants were provided an additional three-day diet record, three additional IBS-Symptom Severity Score questionnaires, and daily checklists of high FODMAP foods. Instructions for completion of each form were provided, as well as stamped envelopes for return of the documents.
After Study Visit

Participants completed the three-day diet record during the second week of following the low FODMAP diet. Participants also completed an IBS-Symptom Severity Score questionnaire during the second, fourth, and sixth weeks of following the low FODMAP diet.

Intervention

Recruited participants chose to attend one of two classes in the low FODMAP diet. The class content was based on the research literature and consisted of a lecture and participant interaction for diet and menu planning during the session. All patients were instructed to follow the elimination phase of the low FODMAP diet for six weeks prior to beginning the reintroduction phase. The length of time to follow the elimination phase of the low FODMAP diet has not been standardized and is variable among current research. This intervention is one part of a larger study of the low FODMAP diet in patients with irritable bowel syndrome. Researchers also investigated the diet quality of the elimination phase of the diet; however, details on this data will not be outlined in this thesis.

Instrumentation

Demographics and Health Questionnaire

A demographics and health questionnaire was designed for this study to gather demographic information and baseline health characteristics. This form is seen in Figures A.1, A.2, and A.3 in the Appendix. The health questions focused on participants’
diagnosis with IBS and any treatments, medical or nutritional, they may have used previously or were currently using to treat their symptoms.

**IBS-SSS**

This study utilized the Irritable Bowel Syndrome-Symptom Severity Score (IBS-SSS) tool, a validated questionnaire developed by Francis and colleagues to standardize the severity descriptions of IBS among clinical practitioners. The IBS-SSS is the most common method of assessing symptom severity within the IBS population, in research and in practice. The questionnaire consists of five questions about symptoms that patients rate on a scale from 0-100. These questions include: severity of pain, severity of current abdominal pain, severity of abdominal distention, dissatisfaction with bowel habits, and how much their IBS symptoms interfere with their lives. This questionnaire assisted researchers in determining symptom severity for individual participants prior to, during, and after intervention. By comparing symptom scores at different time intervals, researchers evaluated whether the length of the intervention affects the level of symptom improvement.

**Bristol Stool Form Scale Form**

The validated Bristol Stool Form Scale is frequently used in gastroenterology practice to assess frequency and consistency of stools. The form consists of seven pictures and descriptions of stool consistency, instructing patients to identify which picture and description most closely resembles their current stool consistency. Pictures 1 and 2 are considered IBS-C, and pictures 6 and 7 are considered IBS-D. For this study, pictures 3-5 were considered IBS-U. Although stool frequency was also measured, this was not considered in the subtyping of patients, as stool consistency is the better indicator
of nature of altered bowel habits.\textsuperscript{50} This tool was attached to the IBS-SSS forms for participants to complete and gave researchers an understanding of IBS subtype breakdown of the participants. The IBS-SSS and Bristol Stool Form Scale can be seen in Figures A.4 and A.5 in the Appendix.

**Three-Day Diet Record**

This tool is a measure of dietary intake over three days. Use of three-day diet records is common in dietary analysis.\textsuperscript{51,52} Participants completed a diet record before participating in the study, and then completed a second record after following the elimination phase of the diet for two weeks. Diet records were used to determine nutritional quality and sufficiency of the low FODMAP diet. The information gathered from the diet records was analyzed for a separate arm of this study and will not be outlined in this thesis.

**High FODMAP Foods Checklist**

A daily checklist of all high FODMAP foods that patients are instructed to avoid was provided to participants. This form can be seen in Figure A.6 in the Appendix. If participants consumed any of these high FODMAP foods, they were instructed to mark this on their daily checklist. They did not need to use the checklist on days that they did not consume these foods, in an attempt to minimize participant burden. On each day where patients consumed a high FODMAP food and marked this on a high FODMAP checklist, they were considered non-adherent for that day. These checklists helped researchers compare symptom levels to adherence. Reduction of symptoms is related to level of adherence,\textsuperscript{38} and symptom levels of participants who did not adhere to the diet
had the potential to confound the results of the data. Measuring adherence with this checklist helped minimize confounding factors.

**Class Evaluation**

This form, designed for this particular study, assessed participant satisfaction with the low FODMAP diet classes. This form can be seen in Figures A.7 and A.8 in the Appendix.

**Definition of Symptom Improvement**

Symptoms of IBS were measured using the IBS-SSS tool. This tool utilizes five questions of symptoms, in which patients rank their level of symptom on a scale of 0-100. The total severity score is taken by adding the symptom levels for each question. Patients with a score of 75-175 are considered to have mild IBS, those with a score of 175-300 are considered to have moderate IBS, and those with a score greater than 300 are considered to have severe IBS. The highest symptom severity score is 500. Those patients with scores below 75 are considered to be in remission.48

As the varying definitions of symptom improvement have impeded the true determination of efficacy of the low FODMAP diet, this study utilized this measurement tool to define symptom improvement. As symptom severity classification is described in the validation study of the IBS-SSS as a way to standardize severity descriptions across practitioners,48 these severity classifications were utilized to determine response to the low FODMAP diet. Symptom improvement for this study was defined as reduction of symptoms as measured by improvement in classification of symptom severity of IBS.
Data Analysis

T-tests were used to compare the continuous measures taken from the health questionnaire. Chi-square analysis was used to assess the differences in categorical measures between participants and non-participants. All results were presented as point estimates with corresponding 95% confidence intervals. Significance was defined as a two-sided p-value of less than 0.05.

Risk to Participants

There was a potential risk of loss of privacy due to review of patient medical records. This was the only anticipated risk involved in this study.

Confidentiality Concerns

Participation in this study was voluntary, and participants were able to withdraw from the study at any time. Participants were still able to attend the low FODMAP diet classes if they decided not to be included in the study. Upon agreeing to participate in this study, patients were assigned a unique study ID number. These study ID numbers and the MRNs that correspond to the IDs were collected into one electronic file, encrypted, and maintained on the OSU network drive, which is password-protected. The hard copies of study documents were secured in a locked office that is only accessible to the PI in the Division of Medical Dietetics (Atwell Hall, room number 306). Any additional information that was provided with participants’ agreement was filed electronically and similarly protected. All data collected will be stored for at least three years.
Chapter 4
Results and Discussion

Results

Demographics and Health Questionnaire

General and Diagnosis Information

Of the patients recruited (n=70), eight individuals attended the low FODMAP diet class held on January 11th, 2017, were consented and accepted into the study. Five of these 8 patients returned data to the investigators throughout the study for a participation rate of 62.5%. Descriptive information for these participants is shown in Table 1.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=8)</th>
<th>Non-Participants (n=3)</th>
<th>Participants (n=5)</th>
<th>P-Values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years (range))</strong></td>
<td>56 (23-74)</td>
<td>63.33 (56-74)</td>
<td>52.0 (23-67)</td>
<td>0.383</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (n, (%))</td>
<td>5 (62.5%)</td>
<td>2 (67%)</td>
<td>3 (60%)</td>
<td></td>
</tr>
<tr>
<td>Male (n, (%))</td>
<td>3 (37.5%)</td>
<td>1 (33%)</td>
<td>2 (40%)</td>
<td></td>
</tr>
<tr>
<td><strong>Body Mass Index (mean, (range))</strong></td>
<td>34.3 (22.8-54.7)</td>
<td>33.47 (26-39.1)</td>
<td>34.78 (22.8-54.7)</td>
<td>0.882</td>
</tr>
<tr>
<td><strong>Years Since Diagnosis (mean, (range))</strong></td>
<td>8.25 (1-20)</td>
<td>13.44 (1-20)</td>
<td>7.21 (1.5-17)</td>
<td>0.693</td>
</tr>
</tbody>
</table>

Table 1. Demographic Information.

Five (62.5%) of these patients were female, and 3 were male. Of the 5 patients who returned data, 3 (60%) were female, and 2 (40%) were male. The mean (range) age
of all patients was 56 (23-74) years, while for those who returned data, the mean (range) age was 52 (23-67). The mean (range) BMI of all 8 patients was 34.3 (22.8-54.7), and for the 5 who returned data, the mean (range) BMI was 34.8 (22.8-54.7). The mean (range) length of time since diagnosis with irritable bowel syndrome was 8.25 (1-20) years for all patients, and 7.21 (1.5-17) years for those patients who returned data. One participant had previously met with a Registered Dietitian for nutrition therapy for IBS, and was instructed in a form of a non-specific elimination diet.

**Lifestyle Factors**

Patients were asked several questions about lifestyle factors that may influence IBS symptoms in the demographics and health questionnaire. Two patients were following a special diet for controlling their IBS symptoms: one was following a low-sugar, low-fat diet, and one was following a diet in line with the NICE guidelines. Five patients, including the two patients following the special diets, were already excluding or limiting consumption of some foods in attempt to control IBS symptoms. Examples of foods that patients reported they had previously excluded or were excluding include: white bread, raisin bran, shredded wheat, nuts, dairy products, potato chips, cookies, desserts, bacon, ice cream, pasta, diet cola, “greasy” foods, and fruits. Table 2 compares these excluded foods to foods that are excluded on the low FODMAP diet.

Five patients were regularly involved in some form of physical activity. All 8 patients denied ever smoking. Two patients denied any alcohol consumption, and 4 patients reported moderate alcohol consumption, as defined by less than 7 drinks per week (1 per day) for women and 14 drinks per week (2 per day) for men. Two patients did not answer the question regarding alcohol consumption.
Medication and Therapy Use

Patients also answered questions about medications, oral supplements, and alternative therapy use in the demographics and health questionnaire. This information is displayed in Table 3.

<table>
<thead>
<tr>
<th>Foods Patients Reported Excluding (n patients excluding)</th>
<th>Are these Foods Excluded on the Low FODMAP Diet?</th>
<th>FODMAP Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>White Bread (1)</td>
<td>Yes-Wheat</td>
<td>Fructans/Galactans</td>
</tr>
<tr>
<td>Raisin Bran (1)</td>
<td>Yes-Bran</td>
<td>Fructans/Galactans</td>
</tr>
<tr>
<td>Shredded Wheat (1)</td>
<td>Yes-Wheat</td>
<td>Fructans/Galactans</td>
</tr>
<tr>
<td>Nuts (1)</td>
<td>Some-Cashews/pistachios</td>
<td>Fructans/Galactans</td>
</tr>
<tr>
<td>Dairy (2)</td>
<td>Some</td>
<td>Lactose</td>
</tr>
<tr>
<td>Potato Chips (1)</td>
<td>No</td>
<td>Fructans/Galactans, Fructose, Polyols</td>
</tr>
<tr>
<td>Cookies (1)</td>
<td>Some-High fructose corn syrup</td>
<td>Fructose</td>
</tr>
<tr>
<td>Desserts (1)</td>
<td>Some-High fructose corn syrup</td>
<td>Fructose</td>
</tr>
<tr>
<td>Bacon (1)</td>
<td>No</td>
<td>Lactose</td>
</tr>
<tr>
<td>Ice Cream (1)</td>
<td>Some</td>
<td>Lactose</td>
</tr>
<tr>
<td>Pasta (1)</td>
<td>Yes-Wheat</td>
<td>Fructans/Galactans</td>
</tr>
<tr>
<td>Diet Cola (1)</td>
<td>Some-Sugar-free sweeteners</td>
<td>Polyols</td>
</tr>
<tr>
<td>&quot;Greasy&quot; Foods (1)</td>
<td>No</td>
<td>Fructans/Galactans, Fructose, Polyols</td>
</tr>
<tr>
<td>Fruits (1)</td>
<td>Some</td>
<td>Fructans/Galactans, Fructose, Polyols</td>
</tr>
</tbody>
</table>

Table 2. Comparison of Excluded Foods to Low FODMAP Diet.

Four patients reported use of prescription medications to treat their IBS symptoms: 3 of these patients reported use of anti-spasmodic or anti-cholinergic agents such as dicyclomine, and 1 reported use of a prescription acid-reducing agent. Five participants reported use of various non-prescription medications to treat their IBS symptoms: 1 reported use of laxatives, 2 reported use of stool softeners, 2 reported use of
anti-diarrheal agents, 2 reported use of gas relief medication, and 1 reported use of non-prescription anti-spasmodic agents.

Six patients were using some sort of supplement: 5 patients took vitamin or mineral supplements, 1 took a fiber supplement, and 1 took probiotics.

<table>
<thead>
<tr>
<th>Type of Treatment</th>
<th># of Patients Using Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rx Anti-Spasmodics/Anti-Cholinergics</td>
<td>3</td>
</tr>
<tr>
<td>Rx Acid-Reduction</td>
<td>1</td>
</tr>
<tr>
<td>Non-Rx Laxatives</td>
<td>1</td>
</tr>
<tr>
<td>Non-Rx Stool Softeners</td>
<td>2</td>
</tr>
<tr>
<td>Non-Rx Anti-Diarrheal Agents</td>
<td>2</td>
</tr>
<tr>
<td>Non-Rx Gas Relief</td>
<td>2</td>
</tr>
<tr>
<td>Non-Rx Anti-Spasmodics</td>
<td>1</td>
</tr>
<tr>
<td>Vitamin/Mineral Supplements</td>
<td>5</td>
</tr>
<tr>
<td>Fiber Supplement</td>
<td>1</td>
</tr>
<tr>
<td>Probiotic</td>
<td>1</td>
</tr>
<tr>
<td>Herbal Supplements</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 3. Oral Treatments Utilized by Patients

Three patients reported consumption of herbal supplements to treat their IBS symptoms: 1 consumed ginger, 1 consumed turmeric, and 1 consumed green tea. No patients reported partaking in non-dietary alternative therapies, such as cognitive behavioral therapy or yoga, to improve their IBS symptoms.

There were no significant differences in age, BMI, or years since diagnosis with IBS between those patients who returned data (participants) and those who did not return data (non-participants). For all other data from the questionnaire, the sample sizes were too small to produce legitimate statistical results.
FODMAP Class Evaluation

Seven patients who attended the class filled out the class evaluation. Six of them felt that the length of the class was just right, and 1 believed it was too short. Five felt that the content presented was just right, while 2 believed it was too complex. Six felt that the balance between lecture and group discussion was just right, while 1 believed there was too much patient involvement in the session. Six stated that they were able to talk about everything they wanted in the session. Six believed that the session provided them with sufficient information to manage their symptoms. One patient stated that they preferred the dietary advice given through a group session, 5 stated that they would have preferred a one-on-one session, and 1 stated that they had no preference.

Patient Case Reports

Patient A

Patient A was a 63 year-old female. The course of her symptoms is portrayed in Figures 4.1 and 4.2. She completed the initial symptom data, and returned data for weeks two, four, and six of the study. On the initial IBS-SSS, Patient A’s composite score was 335/500, indicating severe IBS symptoms. Patient A rated the severity of her current pain as 63/100, the severity of her current abdominal pain as 63/100, the severity of her abdominal distention as 75/100, her dissatisfaction with her bowel movements as 67/100, and the degree of interference of her IBS symptoms with her life as 67/100. Per her Bristol Stool Form Scale, she was classified as IBS-U.

During week two of the study, Patient A’s IBS-SSS composite score was 67/500, indicating IBS symptoms at a control or remission level. Patient A rated the severity of her current pain as 12.5/100, the severity of her current abdominal pain as 12.5/100, the
severity of her abdominal distention as 25/100, her dissatisfaction with her bowel movements as 17/100, and the degree of interference of her IBS symptoms with her life as 0/100. Per her Bristol Stool Form Scale, she was classified as IBS-U. She completed a high FODMAP checklist, indicating lack of adherence, on 1 day during this two-week period.

![Patient A IBS-SSS Questions](image)

Figure 4.1. Patient A’s IBS over Time

During week four of the study, Patient A’s IBS-SSS composite score was 50/500, indicating IBS symptoms at a control or remission level. Patient A rated the severity of her current pain as 12.5/100, the severity of her current abdominal pain as 12.5/100, the severity of her abdominal distention as 25/100, her dissatisfaction with her bowel habits as 0/100, and the degree of interference of her IBS symptoms with her life as 0/100. Per
her Bristol Stool Form Scale, she was classified as IBS-U. She completed high FODMAP checklists, indicating lack of adherence, on 2 days during this two-week period.

During week 6 of the study, Patient A’s IBS-SSS composite score was 191/500, indicating moderate IBS symptoms. Patient A rated the severity of her current pain as 37.5/100, the severity of her current abdominal pain as 37.5/100, the severity of her abdominal distention as 50/100, her dissatisfaction with her bowel habits as 33/100, and the degree of interference of her IBS symptoms with her life as 33/100. Per her Bristol Stool Form Scale, she was classified as IBS-U. She completed high FODMAP checklists, indicating lack of adherence, on 3 days during this two-week period.

Figure 4.2. Patient A’s Composite Score over Time
Overall, Patient A saw a decrease of 144 points on her composite IBS-SSS score. She dropped from severe symptoms initially to symptoms at a control or remission level during weeks two and four, and increased to moderate symptoms during week six.

**Patient B**

Patient B was a 67 year-old male. The course of his symptoms is portrayed in Figures 4.3 and 4.4. He provided the initial symptom data, and returned data during weeks two, four, and six of the study. On the initial IBS-SSS, Patient B’s composite score was 367/500, indicating severe IBS symptoms. Patient B rated the severity of his current pain as 100/100, the severity of his current abdominal pain as 50/100, the severity of his abdominal distention as 50/100, his dissatisfaction with his bowel habits as 67/100, and the degree of interference of his IBS symptoms with his life as 100/100. Per his Bristol Stool Form Scale, he was classified as IBS-D.

During week two of the study, Patient B’s IBS-SSS composite score was 204.5/500, indicating moderate IBS symptoms. Patient B rated the severity of his current pain as 25/100, the severity of his current abdominal pain as 25/100, the severity of his abdominal distention as 37.5/100, his dissatisfaction with his bowel habits as 50/100, and the interference of his IBS symptoms with his life as 67/100. Per his Bristol Stool Form Scale, he was classified as IBS-U. He completed high FODMAP checklists, indicating lack of adherence, on 4 days during this two-week period.

During week four of the study, Patient B’s IBS-SSS composite score was 200/500, indicating moderate IBS symptoms. Patient B rated the severity of his current pain as 25/100, the severity of his current abdominal pain as 50/100, the severity of his
abdominal distention as 25/100, his dissatisfaction with his bowel habits as 33/100, and the degree of interference of his IBS symptoms with his life as 67/100.

Figure 4.3. Patient B’s IBS over Time

Per his Bristol Stool Form Scale, he was classified as IBS-C. He completed high FODMAP checklists, indicating lack of adherence, on 3 days during this two-week period.

During week six of the study, Patient B’s IBS-SSS composite score was 91/500, indicating mild IBS symptoms. Patient B rated the severity of his current pain as 0/100, the severity of his current abdominal pain as 0/100, the severity of his abdominal distention as 25/100, his dissatisfaction with his bowel habits as 33/100, and the degree of interference of his IBS symptoms with his life as 33/100. Per his Bristol Stool Form
Scale, he was classified as IBS-C. He completed high FODMAP checklists, indicating lack of adherence, on 2 days during this two-week period.

![Patient B's Composite Score](image)

**Figure 4.4. Patient B’s Composite Score over Time**

Overall, Patient B saw a decrease of 276 points on his composite IBS-SSS score. He dropped from severe symptoms initially, to moderate symptoms during weeks two and four, and finally to mild symptoms during week six.

**Patient C**

Patient C was a 65 year-old female. The course of her symptoms is portrayed in Figures 4.5 and 4.6. She provided initial symptom data, and returned data during weeks two, four, and six of the study. On the initial IBS-SSS, Patient C’s composite score was 209/500, indicating moderate IBS symptoms. Patient C rated the severity of her current pain as 75/100, the severity of her current abdominal pain as 0/100, the severity of her
abdominal distention as 0/100, her dissatisfaction with her bowel habits as 67/100, and the degree of interference of her IBS symptoms with her life as 67/100. Per her Bristol Stool Form Scale, she was classified as IBS-U.

During week two of the study, Patient C’s IBS-SSS composite score was 100/500, indicating mild IBS symptoms. Patient C rated the severity of her current pain as 0/100, the severity of her current abdominal pain as 0/100, the severity of her abdominal distention as 0/100, her dissatisfaction with her bowel habits as 67/100, and the degree of interference of her IBS symptoms with her life as 33/100. Per her Bristol Stool Form Scale, she was classified as IBS-U. She did not complete any high FODMAP checklists during this two-week period, indicating appearance of 100% adherence.

Figure 4.5. Patient C’s IBS over Time
During week four of the study, Patient C’s IBS-SSS composite score was 150/500, indicating mild IBS symptoms. For the individual questions, Patient C rated the severity of her current pain as 25/100, the severity of her current abdominal pain as 0/100, the severity of her abdominal distention as 25/100, her dissatisfaction with her bowel habits as 67/100, and the degree of interference of her IBS symptoms with her life as 33/100. Per her Bristol Stool Form Scale, she was classified as IBS-U. She did not complete any high FODMAP checklists during this two-week period, indicating appearance of 100% adherence.

![Patient C's Composite Score](image)

**Figure 4.6. Patient C’s Composite Score over Time**

During week six of the study, Patient C’s IBS-SSS composite score was 66/500, indicating symptoms at control or remission level. Patient C rated the severity of her current pain as 0/100, the severity of her current abdominal pain as 0/100, the severity of
her abdominal distention as 0/100, her dissatisfaction with her bowel habits as 33/100, and the degree of interference of her IBS symptoms with her life as 33/100. Per her Bristol Stool Form Scale, she was classified as IBS-U. She did not complete any high FODMAP checklists during this two-week period, indicating appearance of 100% adherence.

Overall, Patient C saw a decrease in IBS-SSS composite score of 143 points. She dropped from moderate IBS symptoms initially, to mild symptoms in weeks two and four, and finally to symptoms considered at control or remission level in week six.

**Patient D**

Patient D was a 42 year-old male. The course of his symptoms is portrayed in Figures 4.7 and 4.8. He provided initial symptom data, and returned data during weeks two, four, and six of the study. On the initial IBS-SSS, Patient D’s composite score was 400/500, indicating severe IBS symptoms. Patient D rated the severity of his current pain as 50/100, the severity of his current abdominal pain as 50/100, the severity of his abdominal distention as 100/100, his dissatisfaction with his bowel habits as 100/100, and the degree of interference of his IBS symptoms with his life as 100/100. Per his Bristol Stool Form Scale, he was classified as IBS-D.

During week two of the study, Patient D’s IBS-SSS composite score was 192/500, indicating moderate IBS symptoms. Patient D rated the severity of his pain as 0/100, the severity of his current abdominal pain as 0/100, the severity of his abdominal distention as 25/100, his dissatisfaction with his bowel habits as 100/100, and the degree of interference of his IBS symptoms with his life as 67/100. Per his Bristol Stool Form Scale,
Scale, he was classified as IBS-U. He completed a high FODMAP checklist, indicating lack of adherence, on 1 day during this two-week period.

Figure 4.7. Patient D’s IBS over Time

During week four of the study, Patient D’s IBS-SSS composite score was 267/500, indicating moderate IBS symptoms. Patient D rated the severity of his current pain as 25/100, the severity of his current abdominal pain as 25/100, the severity of his abdominal distention as 50/100, his dissatisfaction with his bowel habits as 100/100, and the degree of interference of his IBS symptoms with his life as 67/100. Per his Bristol Stool Form Scale, he was classified as IBS-D. He did not complete any high FODMAP checklists during this two-week period, indicating the appearance of 100% adherence.

During week six of the study, Patient D’s IBS-SSS composite score was 304.5/100, indicating severe symptoms. Patient D rated the severity of his current pain as
50/100, the severity of his current abdominal pain as 37.5/100, the severity of his abdominal distention as 50/100, his dissatisfaction with his bowel habits as 100/100, and the degree of interference of his IBS symptoms with his life as 67/100. Per his Bristol Stool Form Scale, he was classified as IBS-D. He filled out high FODMAP checklists, indicating lack of adherence, on 3 days during this two-week period.

Overall Patient D saw a decrease in composite score of 95.5 points. He dropped from severe symptoms initially to moderate symptoms during weeks two and four, but increased to severe symptoms again during week six.

![Patient D's Composite Score](image)

**Figure 4.8. Patient D’s Composite Score over Time**

**Patient E**

Patient E was a 23 year-old female. The course of her symptoms is portrayed in figures 4.9 and 4.10. She provided initial symptom data, and returned data
during weeks two, four, and six of the study. On the initial IBS-SSS, Patient E’s composite score was 434/500, indicating severe IBS symptoms. Patient E rated the severity of her current pain as 100/100, the severity of her current abdominal pain as 100/100, the severity of her abdominal distention as 100/100, her dissatisfaction with her bowel habits as 67/100, and the degree of interference of her IBS symptoms with her life as 67/100. Per her Bristol Stool Form Scale, she was classified as IBS-D.

During week two of the study, Patient E’s IBS-SSS composite score was 0/500, indicating symptoms at control or remission level. Per her Bristol Stool Form Scale, she was classified as IBS-U. She completed high FODMAP checklists, indicating lack of adherence, on 6 days during this two-week period.

![Patient E's IBS-SSS Questions](image)

Figure 4.9. Patient E’s IBS over Time

52
During week four of the study, Patient E’s IBS-SSS composite score was 0/500, indicating symptoms at control or remission level. Per her Bristol Stool Form Scale, she was classified as IBS-U. She did not complete any high FODMAP checklists during this two-week period, indicating appearance of 100% adherence.

During week six of the study, Patient E’s IBS-SSS composite score was 0/500, indicating symptoms at control or remission level. Per her Bristol Stool Form Scale, she was classified as IBS-U. She did not complete any high FODMAP checklists during this two-week period, indicating appearance of 100% adherence.

Overall, Patient E saw a decrease of 434 points on her composite IBS-SSS score. She dropped from severe symptoms initially, to symptoms at a control or remission level by week two and maintained symptoms at control or remission level through weeks four and six.

![Patient E's Composite Score](image-url)

**Figure 4.10. Patient E’s Composite Score over Time**
Discussion

The population of consented individuals in this study had some similarities with the global IBS population. Irritable bowel syndrome is more common in females than in males. This was seen in both the total population of consented individuals and in participants who returned data, with females representing 62.5% and 60% of the groups, respectively. Further, 62.5% of consented individuals had already attempted to improve IBS symptoms by limiting or excluding consumption of certain foods. As it is estimated that about two thirds of people with IBS believe their symptoms are triggered by diet, these results align with the literature. However, the population also differed from what is typically found in IBS populations. In a meta-analysis of epidemiological studies, it was found that individuals over the age of 50 are significantly less likely to have IBS. The total population of this study had a mean age of 56. In fact, only two consented individuals were under 50 years of age. While one patient over the age of 50 was diagnosed 20 years prior to the study, and was therefore under 50 at diagnosis, two patients over 50 years of age reported diagnoses within the past two years. Two patients did not report length of time since diagnosis, so the extent of the difference between this study population and the global population in terms of age is not evident.

The majority of patients who completed the class evaluation believed that the class had provided them with sufficient information to manage their IBS symptoms using the low FODMAP diet. This is supported by the literature, as Whigham and colleagues found no significant differences in symptom improvement for patients that had received the low FODMAP diet education in a group setting as compared to those who received it in a one-on-one setting. However, even though these patients believed they received
sufficient information, the majority still stated that they would prefer diet advice given in the one-on-one format. This may be related to the complexity of the diet, as 2 patients did feel that the content of the class was too complex. Clinicians should provide patients with the option of attending a group session or a one-on-one session, explaining to patients that both formats of education are effective, but allowing patients to choose a one-on-one session if they believe that will be most beneficial for them.

A comparison of change in classification of symptom severity based on initial IBS subtype can be seen in Table 4. All five patients who returned data during the course of this study had an improvement in classification of symptom severity by week two of the study, regardless of initial subtype. As this was the investigators’ definition of response to the diet, all five patients can be classified as responders to the diet by week two, indicating that for this study, the low FODMAP diet had a 100% response rate by this time point.

<table>
<thead>
<tr>
<th>IBS-SSS Severity Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IBS Subtype</strong></td>
</tr>
<tr>
<td><strong>Unsubtyped</strong></td>
</tr>
<tr>
<td>Patient A (classification, (score))</td>
</tr>
<tr>
<td>Patient C (classification, (score))</td>
</tr>
<tr>
<td><strong>Diarrhea Predominant</strong></td>
</tr>
<tr>
<td>Patient B (classification, (score))</td>
</tr>
<tr>
<td>Patient D (classification, (score))</td>
</tr>
<tr>
<td>Patient E (classification, (score))</td>
</tr>
</tbody>
</table>

Table 4. Symptom Severity Classification over Time
However, by week six, Patient D’s symptoms had declined to his original classification of symptom severity. Therefore, for this study, the low FODMAP diet had an overall response rate of 80%. Studies have found the response rate to the low FODMAP diet to be typically around 75% of patients, but the response rate has been found to be as high as 86%, so these results align with current literature.

The rapidity in which Patient A and Patient E reached remission level symptoms leads to the question of whether it was beneficial for these two patients to continue the elimination phase for the full six weeks planned. As has been discussed, there are risks for adverse effects of following the low FODMAP diet. Due to the restrictive nature of the diet, and how foods are eliminated across multiple food groups, there is the potential for the low FODMAP diet to be nutritionally inadequate. This may be especially true if patients are unable to reintroduce many foods to their diets after the elimination phase. Staudacher’s review of FODMAP literature determined that, in the short term, patients who follow the low FODMAP diet typically have decreased intake of calories, carbohydrates, and calcium compared to those on habitual or control diets.

Following the low FODMAP diet may also cause adverse effects in the composition of the microbiome. Staudacher found that multiple studies, including two randomized control trials, have demonstrated that patients following the low FODMAP diet had lower levels of the beneficial Bifidobacteria; studies have also shown decreased bacterial abundance, and decreased levels of another beneficial bacteria, Faecalbacterium prausnitzii.

Finally, there is the potential that a prolonged elimination phase may impact health-related quality of life. The diet may be more costly than habitual diets, may be
challenging to follow, or pose additional burdens for patients. Studies measuring quality of life of those following the low FODMAP diet have been inconsistent, showing either improved quality of life or no effect.\textsuperscript{54}

While further, long-term research is necessary to elucidate the effects of the elimination phase of the low FODMAP diet, it is clear that it is in the best interest of patients to minimize the length of this phase of the diet and allow for reintroduction of foods as quickly as possible. Patients are typically instructed to follow the low FODMAP diet for up to 8 weeks to maximize symptom control,\textsuperscript{5} however, this generalized instruction may not be the most appropriate strategy for all patients. Patient A’s symptoms did decrease an additional 17/500 points by week four, but she was within the remission classification level by week two, and Patient E saw her full improvement by week two. While all patients had responded to the diet by week two, Patient A and Patient E especially may have benefitted from ending the elimination phase at that time.

This argument is strengthened when observing patient adherence to the low FODMAP diet. Adherence to the diet, including number of days during each two-week period that participants were non-adherent, and which high FODMAP foods were consumed on the non-adherent days, is shown for each patient based on initial IBS subtype in Table 5. Patient A and Patient D both had symptoms decreased from baseline through week four, but by week six, their symptom severity level spiked upwards, with Patient D’s symptoms reaching severe classification. These spikes coincided with the final two-week time period, where these two patients had their greatest number of non-adherent days.

This trend of declining symptoms with decreased adherence is consistent with the
literature. Shepherd and associates found that when analyzing symptom improvement overall, and only of those who were considered adherent to their study diet (reduction of fructose and fructans), the percentage of participants with significant symptom improvement jumped from 74% to 85%. \(^{36}\)

### Table 5. Days of Non-Adherence and High FODMAP Foods Eaten

<table>
<thead>
<tr>
<th>IBS Subtype</th>
<th>Non-Adherence</th>
<th></th>
<th>Week 4</th>
<th>Week 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td># of Days</td>
<td># of Days Foods Eaten</td>
<td># of Days Foods Eaten</td>
</tr>
<tr>
<td>Unsubtyped</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient A</td>
<td>1</td>
<td>Garlic, soy (salad dressings)</td>
<td>2 Wheat, onion powder, garlic powder</td>
<td>3 Garlic (salad dressing), buttermilk (salad dressing), HFCS (2x), milk, wheat</td>
</tr>
<tr>
<td>Patient C</td>
<td>0</td>
<td>N/A</td>
<td>0 N/A</td>
<td>0 N/A</td>
</tr>
<tr>
<td>Diarrhea Predominant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient B</td>
<td>4</td>
<td>Sorbitol, milk, honey (2x)</td>
<td>3 Soy (3x), onion powder/salt</td>
<td>2 Onion, soy (2x), milk</td>
</tr>
<tr>
<td>Patient D</td>
<td>1</td>
<td>Garlic powder/salt, wheat</td>
<td>0 N/A</td>
<td>3 Garlic, wheat (2x), garlic powder/salt, mushrooms</td>
</tr>
<tr>
<td>Patient E</td>
<td>6</td>
<td>Ice cream, wheat (5x), garlic, garlic powder/salt (3x), yogurt (3x), cottage cheese</td>
<td>0 N/A</td>
<td>0 N/A</td>
</tr>
</tbody>
</table>

De Roest and colleagues found a positive association between adherence and
improvement in symptoms: the greater patient adherence, the greater the reduction in symptoms that patients experienced. This was seen in the increase in symptoms that Patient A and Patient D experienced with more non-adherent days. The importance of adherence was also seen in Patient B’s symptom trend.

Patient B’s symptoms improved by classification of symptom severity by week two, but it took until week six for him to reach his greatest level of symptom improvement, a reduction to mild symptoms.

The number of days in each measured period that he was non-adherent decreased throughout the study, from 4 days in the first two-week period, to 3 days in the second two-week period, and 2 days in the final two-week period. His symptoms coincided well with his adherence, decreasing with each measured time point. It is likely that as Patient B attempted to adhere to the diet, his symptoms improved, encouraging him to adhere more completely each two-week period of measurement.

However, despite the improvement in symptoms that is seen with greater adherence to the low FODMAP diet, the diet is challenging. Only 60% of the participants in De Roest and associates’ study found the low FODMAP diet easy to follow. Maagaard and colleagues found similar challenges in adherence. Of the participants with IBS in their study who stopped following the low FODMAP diet earlier than instructed, 50% blamed this on the challenge of following the diet. It is likely that the longer the patients in the current study were requested to follow the elimination phase of the low FODMAP diet (i.e, six weeks), the more challenging it became for them to fully adhere to the diet, leading to increased non-adherence, and therefore increased symptom severity. If the length of the elimination phase was shortened, patients could begin to
reintroduce foods earlier, and better identify which type of FODMAPs cause their symptoms.

Lack of adherence did not seem to be an issue for Patient E. Patient E was non-adherent on 6 of the first 14 days of the study based on returned high FODMAP checklists, which was the most number of non-adherent days in a two-week period of any participant in the study. Yet, not only did her symptoms decrease despite the lack of adherence, but the magnitude of her symptom improvement was greater than for any other participant (an overall decrease of 434 points as compared to 285, 276, 143, and 95.5 points for Patients A, B, C, and D, respectively).

Overall, out of 210 total patient days on the diet, patients were non-adherent for 24 days (11.4%). The most common foods that patients consumed on non-adherent days were: garlic and onion (whether whole, or in powder or salt form), wheat, milk, and soy. This holds important implications for clinicians hoping to implement instruction of the low FODMAP diet into their practice. These common high FODMAP foods represent an area where more detail into options for replacement would be beneficial for patients. Similarly, the garlic, onion, and soy were frequently consumed as ingredients of salad dressings. Stressing the importance of reading food labels and providing specific alternatives to dressings and condiments that contain high FODMAP ingredients will help ensure the success of patients.

Satisfaction with bowel habits likely also had an impact on overall symptom improvement. Information about bowel habits for each patient based on initial IBS subtype, including frequency of bowel movements and change in IBS subtype, can be seen in Table 6.
Patient C went from having 2-3 bowel movements per day at baseline, to having 1 bowel movement every 4-6 days at week two. Although her subtype did not change, as the subtyping method values the consistency of stool as more important than the frequency of bowel movements, this is indicative of development of constipation. Patient C explained during a reminder phone call that she believed the constipation was due to a medication prescribed to her. One of the investigators counseled her on low FODMAP fiber sources and fluid consumption for constipation.

<table>
<thead>
<tr>
<th>Bowel Habits</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBS Subtype</td>
</tr>
<tr>
<td>Unsubtyped</td>
</tr>
<tr>
<td>Patient A</td>
</tr>
<tr>
<td>Patient C</td>
</tr>
<tr>
<td>Diarrhea Predominant</td>
</tr>
<tr>
<td>Patient B</td>
</tr>
<tr>
<td>Patient D</td>
</tr>
<tr>
<td>Patient E</td>
</tr>
</tbody>
</table>

Table 6. Bowel Habits over Time

Current FODMAP literature does suggest that the low FODMAP diet may take six full weeks to reach greatest effect. Pedersen and colleagues found that the highest level of symptom improvement for their participants was not reached until week six of their study, and recommended the diet be followed for at least this long. While this could explain why Patient C (and even Patient B) did not reach full improvement until week six, it is also possible that Patient C took the full six weeks to reach her highest
level of symptom improvement not because the diet takes six weeks for best effect, but rather because of the interaction between her medication and the diet. This seems especially likely when considering her responses to the individual questions on the IBS-SSS questionnaire. The greatest contributor to her composite IBS-SSS score during week two and week four was her dissatisfaction with her bowel habits, at 67/100 during both of those measuring points. The severity of her pain in question 1 of the IBS-SSS dropped from 75/100 initially, to 0/100 during week two. As abdominal pain is thought to be the most important symptom to consider in patients with IBS, as it is a good predictor of overall health status, her decrease in pain is a good sign that the diet truly improved Patient C’s IBS. As seen in Table 6, Patient C had begun to have 1 bowel movement every day on average during week four and week six, which likely led to her reaching her greatest level of symptom improvement by week six.

While Patient B did not report any medication that would likely make him constipated during the diet, he also experienced constipation during the course of the study, as evidenced by his initial Bristol Stool classification of IBS-D and the change to IBS-C in week four. The mechanisms by which reduction of FODMAPs improves symptoms of IBS demonstrate how constipation could be a consequence of following the low FODMAP diet. Because FODMAPs are osmotically active, they increase the content of water in the intestine, often causing osmotic diarrhea. By restricting FODMAP consumption, less water is drawn into the intestine, causing harder stools. Likewise, many fruits, vegetables, and whole grains are on the list of high FODMAP foods, and these foods are great sources of dietary fiber. An important strategy in improving success on the low FODMAP diet is to identify alternative or replacement food items for the
foods that are excluded.\textsuperscript{36} It has been suggested that constipation may occur in patients following the low FODMAP diet if they struggle to replace their fruits, vegetables, and whole grains with proper alternatives, and thereby reduce their fiber intake.\textsuperscript{17} The replacement strategy was emphasized in the low FODMAP class for this study, but it is possible that Patient B experienced constipation because he did not implement the replacement strategy well enough.

It is also possible that some unknown characteristics about the participants led them to be more or less likely to respond to the diet. Chumpitazi and colleagues compared the microbiomes of children who responded to a low FODMAP diet to children who did not. These investigators found that the microbiomes of children who responded to the low FODMAP diet had higher concentrations of microorganisms with greater capacity for carbohydrate hydrolysis and metabolism. The children with lower concentrations (or the absence of some of the microorganisms) were less likely to respond to the diet. The investigators suggested that identifying patients with similar microbiome compositions may help predict which patients will respond to the low FODMAP diet, and which will not.\textsuperscript{42}

An abstract of a more recent study has shown the importance of the microbiome in determining whether a patient will respond to the low FODMAP diet. Bennet and associates, in a secondary analysis, compared fecal samples of patients taken prior to beginning the low FODMAP diet, and found that patients with more severe dysbiosis of the microbiome were less likely to respond to the low FODMAP diet.\textsuperscript{55} Analysis of the microbiome of patients was beyond the scope of this study, but it is possible that differences in the microbiomes of patients in this study were factors in determining
whether a patient would respond to the diet.

In conclusion, the point in the elimination phase of the low FODMAP diet in which patients experience the highest level of symptom improvement requires further study, but in this study, we documented that symptoms improved by at least one severity level classification within two weeks of following the diet. Two patients reached control or remission level symptoms by the second week of the study, while two patients did not achieve their greatest level of symptom improvement until the sixth week. Many patients may achieve substantial improvement after following the diet for only two weeks, while others may require six weeks to achieve the greatest effect. A prolonged elimination phase may lead to decreased adherence, which may interrupt the progression of symptom improvement, as was demonstrated by the increase in composite symptom scores for two patients with decreased adherence in week six. At this time, there is insufficient evidence to suggest a change in general recommendation as to the length of the elimination phase, but close monitoring of patients may allow for individualization so that, if an early response is demonstrated, the reintroduction phase can be initiated.

**Limitations**

This study was limited by its sample size. Of the original 70 patients recruited, only 20 (29%) agreed to participate in the study. Of this group of 20, only 8 (40%) attended the low FODMAP diet class. Of the 8 who attended the class, full data was only received by 5 (62.5%) patients. This full data represents only 7.1% of the total patients recruited to participate in this study.

This study was also limited by its nature of using patient-reported data, and attrition of 3 patients throughout the study. The study relied on prompt return of
documents on three separate occasions. Despite efforts to minimize patient burden (such as paid postage for return of documents, timely reminder calls and emails to return documents), only 5 patients returned all three sets of documents. Although researchers attempted to measure adherence to the diet using daily high FODMAP checklists, this also relied on patient report. It is impossible to know the true level of adherence of each individual, as researchers did not require strict food records from every day of the study, which would still be limited by patient report. Although diet records are a useful tool for analyzing diet quality and content, they have disadvantages as well. Patients utilizing diet records may be more likely to report meals that align with what is considered appropriate, rather than what they actually ate or would normally eat. In this case, patients may not have reported high FODMAP foods that they consumed, since they were aware of which foods they should have been avoiding during the study. The accuracy of diet records also decreases as the number of days recorded increases. Had the investigators of this study required a daily diet record, these records would not likely have been accurate for the entire six week study.

Similarly, the high FODMAP checklists did not require the report of amounts of high FODMAP foods consumed. Measurement of symptoms compared to varying amounts of high FODMAP foods could have further emphasized the need for adherence to the diet, as it is well-established that FODMAPs have an additive effect on GI symptoms.

Finally, as the data was patient-reported, there was a risk of bias involved in the return of data. It is possible that the patients who returned data did so because they were experiencing some success on the diet, and continued to follow it, while those who did
not return data failed to experience a reduction in symptoms and therefore did not feel compelled to return any data.

**Future Research**

As has been described, future research should seek to expound on current knowledge of the potential negative effects of following the elimination phase of the low FODMAP diet long-term. Determining the appropriate length of time for the elimination phase will continue to become more important as those negative effects are clarified.

Due to the limitations of this study, continued research into the appropriate length of time to follow the elimination phase of the low FODMAP diet is warranted. This was a pilot study, and the current study should be continued with a greater number of participants, to allow for identification of trends among large groups of people.

Further research should also take the form of individualized instruction. Studies allowing participants to discuss their symptom improvements with Registered Dietitians and gastroenterologists on a frequent basis (weekly, for example), and thereby enter the reintroduction phase when their symptoms have reached an acceptable level of improvement, could be of particular benefit. Results of this research could demonstrate whether a generalized recommendation of length of time to follow the elimination phase is appropriate, or whether an individualized approach would be more beneficial.

Researchers should also continue to investigate the differences in individuals with IBS that may make them more or less likely to respond to the low FODMAP diet. If research can demonstrate consistent factors that make certain individuals unlikely to respond to the diet, those individuals can receive more specialized instruction in other
methods of improving symptoms, without attempting a diet that can be challenging to follow and will be unlikely to improve their symptoms.
Chapter 5

At What Point in the Elimination Phase of the Low FODMAP Diet is the Level of Symptom Improvement Highest in Patients with Irritable Bowel Syndrome?

Abstract

Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder. Current literature supports the low fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAP) diet as a nutritional therapy for IBS, but the length of time that patients should restrict all high FODMAP foods from their diets is not well-supported. This study followed 5 patients on the low FODMAP diet for six weeks, collecting data on diet adherence, symptoms, and bowel habits. The course of one patient’s symptoms is detailed further in this case report. Symptom reduction may be possible in as little as two weeks on the diet, and adherence to the diet impacts level of symptom improvement.

Introduction

Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder that affects between 10-20% of the global population, with averaged estimates of about 11%. According to the Rome III diagnostic criteria, to be diagnosed with IBS, a patient must have frequent abdominal pain or discomfort for at least 3 days per month for the past 3 months prior to diagnosis. They must also experience at least two of the following symptoms: improvement of pain or discomfort with defecation, a change in frequency of
stool, or a change in consistency of stool. Other signs and symptoms of IBS include bloating, fecal urgency, straining with defecation, the sensation of incomplete bowel movements, and increased gas production.

Patients may be subtyped based on the nature of their bowel habits, with IBS-D classifying those who are diarrhea-predominant, IBS-C classifying those who are constipation-predominant, and IBS-M classifying those with episodes of alternating diarrhea and constipation. Researchers also classify patients based on severity of their IBS symptoms utilizing the validated IBS-Symptom Severity Score (IBS-SSS) questionnaire. This questionnaire consists of 5 questions that patients use to rate their symptoms on a scale of 0-100, with the highest possible total score of 500. A score of less than 75 indicates that symptoms are at a control or remission level. A score between 75 and 175 indicates mild symptoms. Scores between 175 and 300 indicate moderate symptoms, and scores above 300 indicate severe symptoms.

Etiology & Pathophysiology

There are many proposed mechanisms by which IBS arises. Many cases of IBS are post-infectious, occurring after a case of gastroenteritis. Small intestinal bacterial overgrowth, genetic predisposition, and immune response to food allergy or sensitivity are other suggested causes.

A three-hypothesis explanatory model has been developed to assist practitioners in explaining the etiology and pathophysiology of the disorder to patients. The three hypotheses include: 1) changes in regulation of gastrointestinal (GI) function; 2) changes in signaling between the brain and the peripheral nervous system of the GI tract; and 3) psychological distress.
Nutritional Relevance

About two-thirds of patients with IBS believe that their symptoms are triggered by food.\textsuperscript{14} Many patients will adjust their diets, eliminating any foods they believe induce their symptoms.\textsuperscript{4} Although these exclusion or elimination diets are sometimes utilized in practice, they are not well-supported in the literature.\textsuperscript{10} Recent literature has suggested the impact of fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs) on inducing symptoms of IBS. FODMAPs are short-chain carbohydrates that are poorly absorbed, osmotically active, and rapidly fermented by bacteria in the large intestine, mechanisms by which they might induce altered bowel habits, excess gas production, and abdominal pain or discomfort.\textsuperscript{39}

Description of the Case

Patient B was a 67 year-old male. He was diagnosed with IBS 17 years prior to the study. He had previously met with a Registered Dietitian for nutrition therapy to improve his IBS symptoms, and had been advised in the form of an elimination diet. At the start of the study, Patient B was already excluding potato chips, cookies, desserts, bacon, ice cream, nuts, and pasta from his diet. He reported participating in mild aerobic activity (less than 150 minutes per week), denied ever smoking, and reported moderate alcohol consumption (less than 14 drinks per week). Patient B was prescribed an acid-reducing agent, and also relied on non-prescription anti-diarrheal and anti-spasmodic medications. He supplemented his diet with a multivitamin, probiotics, and turmeric. Patient B’s initial composite IBS-SSS was 367/500, indicating that his symptoms were severe. Per the Bristol Stool Form Scale questionnaire, Patient B was classified as having IBS-D.
**Intervention**

Patient B, along with 7 other patients with IBS, attended a low FODMAP diet education class. The low FODMAP diet, though relatively new, has consistent support in the literature as a method of improving IBS symptoms. Though definitions of symptom improvement, and the length of time patients follow the diet, vary by study, the diet has shown to improve symptoms in anywhere from 50% to 86% of patients.\textsuperscript{11,17,18,38,43,44} Symptom improvement has also been shown to be directly related to how well patients adhere to the diet.\textsuperscript{38} There is the potential risk of adverse effects, including alterations to the microbiome and dietary inadequacy,\textsuperscript{54} by restricting all FODMAPs from the diet, so determining the shortest length of time of the elimination phase necessary to reach greatest level of symptom improvement would be beneficial to patients.

Ringström and colleagues have demonstrated that group education in patients with IBS is more effective than written information alone,\textsuperscript{34} and group education has been shown to be effective in the low FODMAP diet.\textsuperscript{5,9} The class content for this study was based on current literature and consisted of a lecture, plus participant interaction for diet and menu planning, during the session.\textsuperscript{9,17,44} Patients were also provided sufficient time for the instructors to answer all questions.

All patients were instructed to follow the elimination phase of the low FODMAP diet, in which all high FODMAP foods are restricted, for six weeks prior to beginning the reintroduction phase, in which patients add one type of FODMAP into their diet at a time, as tolerated by the individual. Patients were instructed to complete the IBS-SSS every two weeks while on the diet. They were provided a checklist of high FODMAP foods that were to be avoided for every day of the study, to be completed on days when they were
unable to adhere to the diet. The instructors called and emailed patients to remind them to complete their documents, and were available for questions at those times, and by phone or email throughout the study.

**Discussion**

**Outcomes**

The course of Patient B’s composite symptom score over time is demonstrated in Figure 5.1. Patient B’s composite IBS-SSS score dropped from 367/500 at baseline, to 204.5/500 at week two, indicating a reduction to moderate level symptoms. He completed 4 high FODMAP checklists, indicating he was non-adherent on 4 days, during the first two-week period.

Figure 5.1. Patient B’s Composite Symptom Score over Time
At week four, his IBS-SSS composite score dropped to 200/500, still classified as moderate symptoms. He completed 3 high FODMAP checklists, indicating he was non-adherent on 3 days during the second two-week period. At week six, his composite score was reduced to 91/500, indicating a reduction to mild level symptoms. He completed 2 high FODMAP checklists, indicating he was non-adherent on 2 days during the final two-week period.

In this study, the definition of response to the low FODMAP diet was that patients would experience a reduction in symptoms as classified by improvement in classification of severity level. According to this definition, Patient B responded to the diet by week two. However, he did not reach his greatest symptom improvement until week six.

This lag in reaching fullest symptom improvement could have several interpretations. First, it is possible that the diet truly takes six weeks for full effect. Pedersen and colleagues demonstrated this in their study, in which patients following a low FODMAP diet did not reach their greatest level of symptom improvement until the sixth week of the study. Current general recommendations for the diet suggest that patients should follow the elimination phase for 6-8 weeks, so Patient B requiring six weeks to reach greatest symptom improvement is supported by the literature.

Secondly, it is likely that Patient B’s improved adherence over time impacted his improvement in symptoms as well. De Roest and colleagues demonstrated that adherence was directly related to level of symptom improvement. Patient B was non-adherent for 1 fewer day during each two-week period, and his symptoms improved over time.

Finally, Patient B experienced some constipation, which likely prevented his symptoms from resolving quickly. Although he started as IBS-D, by week four he was...
classified as IBS-C. As satisfaction with stool habits is one component of the IBS-SSS, it is likely that his dissatisfaction with being constipated prevented a more rapid decrease in symptoms.

Four of the other 7 patients included in the study returned data. The composite scores over time of all 5 participants are shown in Figure 5.2.

![Composite Scores Over Time](image)

Figure 5.2. All Participants’ Composite Scores over Time

Of those 4 other patients, all had reduced symptoms of at least 1 severity level by week two. By week six, one patient’s symptoms had returned to baseline classification, demonstrating an overall response rate of 80% for the entire study. This is consistent with current literature’s suggestion that 75% of patients will respond to the diet. Two patients had declining adherence over time, which resulted in increased symptom severity,
sustaining the low FODMAP diet for six weeks.

Conclusions and Future Directions

Although some patients may require six weeks on the elimination phase of the diet, some may benefit from a reduction in length of time restricting all high FODMAP foods to improve adherence. Adherence to the low FODMAP diet is important in maximizing symptom improvement.

Future research should continue to explore the relationship between length of time on the low FODMAP diet and symptom improvement. As some patients seem to experience impressive symptom reduction within two weeks, these patients may benefit from a shorter elimination phase, while others may benefit from six weeks or longer. Research determining the differences in patients with IBS that impact diet response would also be beneficial for this patient population. As the diet does not work for about a quarter of patients,\(^5\) those who will be less likely to respond to the diet should not attempt it, but should instead be instructed in alternative methods of symptom reduction.
References


Appendix A: Instruments

IBS Severity Score
Place an X anywhere on the line between 0 and 100 to indicate as accurately as possible the severity of your symptoms.

1. How severe is your pain?
   0  20  40  60  80  100
   No pain  Not very severe  Quite severe  Severe  Very severe

2. If currently in pain, how severe is your abdominal pain?
   0  20  40  60  80  100
   No pain  Not very severe  Quite severe  Severe  Very severe

3. If you currently have abdominal distention, how severe is it?
   0  20  40  60  80  100
   No distention  Not very severe  Quite severe  Severe  Very severe

4. How satisfied are you with your bowel habits?
   0  20  40  60  80  100
   Very happy  Quite happy  Unhappy  Very unhappy

5. How much does your IBS affect or interfere with your life in general?
   0  20  40  60  80  100
   Not at all  Not much  Quite a lot  Completely

6. Currently, how often do you pass a bowel action? (Please check one box)
   Once a week
   Once every 1-4 days
   Once every 2-3 days

Figure A.1. IBS-Symptom Severity Score/Bristol Stool Form Scale Page 1
7. Please check the box that best describes your current stool:

**Bristol Stool Chart**

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Separate hard lumps, like nuts (hard to pass)</td>
</tr>
<tr>
<td>2</td>
<td>Sausage-shaped but lumpy</td>
</tr>
<tr>
<td>3</td>
<td>Like a sausage but with cracks on its surface</td>
</tr>
<tr>
<td>4</td>
<td>Like a sausage or snake, smooth and soft</td>
</tr>
<tr>
<td>5</td>
<td>Soft blobs with clear-cut edges (passed easily)</td>
</tr>
<tr>
<td>6</td>
<td>Fluffy pieces with ragged edges, a mushy stool</td>
</tr>
<tr>
<td>7</td>
<td>Watery, no solid pieces. Entirely Liquid</td>
</tr>
</tbody>
</table>

Figure A.2. IBS-Symptom Severity Score/Bristol Stool Form Scale Page 2
Demographics and Health Questionnaire

The following questionnaire will help us evaluate your health status. Please fill out and mail back to us in the stamped envelope we provided or bring it with you on day of your class session.

If you have any questions, please contact: Marcia Nahkian-Netto, PhD, RDIV 014-292-4738

1. Name: __________________________________________

2. Gender:  M  F  Other

3. Age: ________________

4. Weight ______________

5. Height: ______________

6. When were you diagnosed with IBS?: ________________

7. Have you previously received information about nutrition therapy for your IBS from a health care provider or met with a Registered Dietitian to discuss diet for managing your IBS symptoms? Yes  No

   If yes, please indicate the type of nutrition recommendation made for you:

   ______________________________________________________

8. Do you currently follow a special diet to help with your IBS symptoms? Yes  No

   If yes, please specify or describe the diet:

   ______________________________________________________

9. Do you currently exclude any foods to help with your IBS symptoms? Yes  No

   If yes, please indicate which foods you avoid:

   ______________________________________________________

10. Do you engage in physical activity? Yes  No

    If yes, please indicate:

    Type of exercise (example: walking, running etc.): __________________________

    Length of physical activity period (example: 10 minutes): ______________________

Figure A.3. Demographics and Health Questionnaire Page 1
How often do you engage in such activity per week? (once, twice, etc) ___________________

11. Do you smoke? __________ Yes __________ No __________

12. Do you consume alcohol? __________ Yes __________ No __________

   If yes, how many drinks per week on average? ___________________

15. Are you currently taking any prescription medications for your IBS? __________ Yes __________ No __________

   Check all that apply.
   Anti-cholinergic and antispasmodics:
   _______ hyoscyamine (Levin), _______ dolantin (atropine)
   _______ oxybutynin (Dolantin, Zeantin), _______ oxybutynin (Atrogin)
   _______ chlorpheniramine (Chlorpheniramine, Atrogin)
   _______ diphenhydramine (Benadryl, Atrogin)
   _______ pseudoephedrine (Pseudoephedrine, Atrogin)
   _______ diphenhydramine (Benadryl, Atrogin)
   _______ chlorpheniramine (Chlorpheniramine, Atrogin)
   _______ diphenhydramine (Benadryl, Atrogin)
   _______ pseudoephedrine (Pseudoephedrine, Atrogin)

   Bile acid binders:
   _______ Colestipol (Colestid), _______ cholestyramine (Questran)
   _______ Colestid, _______ colestipol (Colestid), _______ cholestyramine (Questran)

   Antidepressants:
   _______ fluoxetine (Prozac, Sarafem), _______ paroxetine (Paxil)
   _______ fluoxetine (Prozac, Sarafem), _______ paroxetine (Paxil)
   _______ sertraline (Zoloft), _______ citalopram (Celexa)
   _______ escitalopram (Lexapro, Cital)
   _______ fluoxetine (Prozac, Sarafem), _______ paroxetine (Paxil)
   _______ sertraline (Zoloft), _______ citalopram (Celexa)

   Others, please specify ______________________

16. Do you take any of the following non-prescription medications to improve your IBS symptoms?

   If yes, please state the name and how often you take these medications:

<table>
<thead>
<tr>
<th>Type of Medication</th>
<th>Yes or No</th>
<th>Name of Medication</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laxative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stool Softener</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-diarrheal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gas Relief</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain Relief</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-Spasmodic</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. Do you take any of the following supplements? *

   If yes, please state the name and how often you take these supplements:

<table>
<thead>
<tr>
<th>Type of Supplement</th>
<th>Yes or No</th>
<th>Name of Supplement</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin or Mineral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fiber</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probiotics or Prebiotics</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
16. Do you take any herbal supplements/tea/ols or juices to help with your IBS symptoms?

<table>
<thead>
<tr>
<th>Type of Supplement</th>
<th>Yes or No</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ginger</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turmeric</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Senna</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fennel seed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evening primrose oil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peppermint oil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Camphor oil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aloe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

17. Do you use any alternative therapies to improve your IBS symptoms? Yes No

<table>
<thead>
<tr>
<th>Type of Therapy</th>
<th>Yes or No</th>
<th>Frequency per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive behavioral therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Massage therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypnotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acupuncture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure A.5. Demographics and Health Questionnaire Page 3
### High FODMAP Checklist

*If you consume a high FODMAP food from this list, please circle the item.*

- Agave
- Apples
- Apricots
- Artichokes
- Asparagus
- Baked Beans
- Barley
- Blackberries
- Boysenberry
- Carob > 2 tsp
- Cashews
- Cauliflower
- Cherries
- Chickpeas >1/4 c canned
- Cottage Cheese
- Currants
- Custard
- Dates
- Evaporated Milk
- Figs (Fresh or Dried)
- FOS
- Garlic
- Garlic Powder/Salt
- Grapefruit
- High Fructose Corn Syrup (HFCS)
- Honey
- Ice Cream
- Isomalt
- Inulin
- Leeks
- Lentils
- Maltitol
- Mango
- Mannitol
- Milk
- Mushrooms
- Nectarines
- Onion
- Onion Powder/Salt
- Peaches (including White)
- Pears
- Persimmons
- Pistachios
- Plums
- Prunes
- Red Kidney Beans
- Ricotta Cheese
- Rum
- Rye
- Shallot
- Sorbitol
- Soybeans & Soybean Products
- Snow Peas
- Sugar Snap Peas
- Sun-Dried Tomatoes
- Sweet Corn
- Teas (Chamomile, Fennel, Oolong)
- Tomato Paste
- Watermelon
- Wheat
- Xylitol
- Yogurt

---

Figure A.6. High FODMAP Checklist
Evaluation of Low Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols (FODMAP) Diet Class

1. What do you think about the length of today’s session (please circle)?
   - too long
   - just right
   - too short
   Comments

2. What do you think about the content of today’s session (please circle)?
   - too basic
   - just right
   - too complex
   Comments

3. What did you think about the balance of lecturing and group discussion (please circle)?
   - too much lecturing
   - just right
   - too much patient involvement
   Comments

4. Were you able to talk about everything you wanted to in the group session?
   - Yes
   - No
   Comments

Figure A.7. Class Evaluation Page 1
5. Did the group sessions provide you with enough information for you to now manage your symptoms without further advice?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Comments
_______________________________________________________________________

6. Now that you have been to this session, if you were to get dietary advice again what sort of session would you prefer (please circle)?

- Group session
- One-to-one appointment
- Either

Comments:
_______________________________________________________________________

Any other comments?
_______________________________________________________________________

Thank you for completing the evaluation.