

THE EFFECTIVENESS OF AN INTERNET-BASED LOW FODMAP DIET
EDUCATION PROGRAM TO IMPROVE SYMPTOMS
OF PATIENTS WITH IBS

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DEDICATION

To my dearly loved husband, Jody Adams, and adored children, Clayton and Caroline, who supported me throughout this journey. Your encouragement and love carried me. To my mother, who has blessed me richly with her love and care for my babies during this especially busy season. To both my mom and dad, who always knew I could do it.

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ABSTRACT

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Irritable Bowel Syndrome (IBS) is the most commonly diagnosed gastrointestinal disorder in the United States. The Low FODMAP Diet (LFD) is an effective treatment for IBS symptoms in 50-80% of people. The purpose of this multi-phase study was to determine if an internet-, module-based program (“The FODMAP Fix”) of the elimination phase of the LFD would improve symptoms and quality of life in patients with IBS. Phase 1 included a formal survey as part of the needs assessment to inform the development of the program. Phase 2 was designed as a four-week, randomized, controlled trial to test the effectiveness of the program. After failed recruitment and a high rate of attrition, the trial was modified and Phase 3 was launched. Phase 3 is a non-randomized, trial with pre- and post-intervention assessments including adults 18 to 65 years of age who identify as having IBS. One hundred thirty-five participants were screened, and 52 (39%) were invited to participate in the program. Fifteen participants completed baseline and final assessments. IBS Symptom Severity Scale (IBS-SSS), Quality of Life (IBS-QOL) indices, and a self-efficacy (SE) survey were used to assess outcomes. Due to the high dropout rate, the study was underpowered to detect changes in

the IBS-SSS, IBS-QOL, and SE assessments. While the trial was underpowered to detect differences in the pre- and post-assessments, most participants did experience improvement in symptom severity and reported this internet-based intervention was an effective method to educate on the LFD. When asked if they felt this approach would be at least as effective as a one-on-one visit, 73% responded affirmatively. This same percentage stated they would recommend the program to others suffering from IBS. Future trials are needed to assess the effect of internet-based LFD interventions on IBS symptom management and how to achieve better engagement and completion rates of internet-based, diet interventions.

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CHAPTER I

INTRODUCTION

Irritable Bowel Syndrome (IBS) is a potentially debilitating condition that affects 35 million Americans.¹ It is the most commonly diagnosed gastrointestinal disorder and the seventh most common diagnosis in primary care.^{1,2} IBS affects around 20% of the population in America with most patients being women.³ IBS is a complex condition with an unknown pathophysiology. There is no known cure and currently no reliable biomarker; thus, it is treated through symptom management.² The effectiveness of pharmacologic therapies is highly variable and, as a result, patients often leave traditional medical care for alternative therapies.⁴

The Low FODMAP Diet (LFD) is an established therapy for IBS symptoms and also improves patients' quality of life, as evidenced by multiple randomized controlled trials, systematic reviews, and meta-analyses.⁵⁻⁹ FODMAPs are "Fermentable, Oligosaccharides, Disaccharides, Monosaccharides, and Polyols," which can be difficult for people with IBS to digest.¹⁰ Research into the mechanism of action and evidence of efficacy for the diet increased rapidly over the last decade, and the LFD is increasingly used in clinical settings.¹¹ A current review of the literature showed that the LFD leads to a positive clinical response in IBS symptom relief in 50%–80% of patients.¹¹

The diet begins with a strict elimination phase lasting two to six weeks followed by gradual reintroduction of FODMAPs, then the development of an adapted diet the patient can adhere to long-term.¹² The elimination phase removes a significant number of

foods commonly consumed by Americans, including wheat-based products, onions, garlic, legumes, and numerous other fruits and vegetables (Appendix – The FODMAP Fix, Module 1, Lesson 4). The diet is difficult to implement even for patients with sufficient diet education. Studies that have sought to establish the efficacy of the diet include limited diet instruction with one initial visit with a dietitian and occasionally a follow-up visit for the reintroduction phase.¹³⁻¹⁶ These studies often utilize handouts for supplemental information.^{15,17}

Currently published interventions are limited to education through traditional approaches including in-person, one-on-one,^{13,18} small group counseling,¹⁹ or a combination of individual and small group counseling sessions^{12,20} provided by a Registered Dietitian/Nutritionists (RDN)^{14,17,19,21-23} or a Registered Nurse (RN)^{24,25}. RDNs are the most appropriate choice for LFD education delivery, as they have expert knowledge in food and nutrition in health and disease, and are trained on providing disease-specific dietary management.²⁶ Nevertheless, there are a number of barriers to adequate diet education, including the following:

- only a small number of specialized RDNs trained on the LFD,
- a lack of physician referrals despite recognition of the benefits of specialized RDN-delivered LFD education,²⁷
- poor insurance coverage for IBS-related diet therapy,
- issues of sensitivity surrounding IBS symptoms that may cause patients to be reluctant to meet with a dietitian, and

- the restrictive nature of the elimination portion and very gradual reintroduction phase.

Ideally, patients with IBS need credible, accurate, and affordable diet education that addresses their symptoms.²⁶

The FODMAP Fix, a 100% online, module-based LFD education program was developed by the author to address these issues. The program includes a thorough education on the LFD through an introductory module followed by four modules released every 3-4 days over two weeks. The author is a RDN trained on the LFD by Monash University, a recognized leader in LFD education²⁸. The author developed The FODMAP Fix after completing a needs assessment of the population in May/June 2018 through the “Irritable Bowel Syndrome and Diet Study” survey (Texas Woman’s University IRB #20050). Out of 148 completed surveys, the majority (93%) of respondents was female and ages ranged from 19 to 65 years with an average age of 36 years. This survey provided insight for the educational content of the program and the type of resources provided, including videos on label reading, easy to prepare snacks and meals, tips for dining out, and an e-cookbook with links to low FODMAP recipes that were easy to prepare. Education on the LFD was primarily provided through video, as it can improve health literacy levels that are often compromised in individuals with burdensome medical conditions.^{29,30} Educational programs that incorporate narrative videos can be effective strategies to reduce health disparities and reduce the burden on working memory.^{29,31} Narrative is an effective tool used in multimedia interventions to engage participants and promote behavior change.^{29,30} Also, researchers and scientists may be perceived as

lacking warmth, which can negatively affect trust.³² The credibility of the communicator is affected by both expertise and trust.³² Strategies to gain credibility with the audience include teaching and sharing information.³² The author has personal experience with IBS and related her story through a narrative video describing her experience with the LFD.

After The FODMAP Fix was developed (Phase 1), Phase 2 was designed as a four-week trial to assess the same outcomes as the present study. After four months, limited enrollment, an excessive dropout rate (83%), and almost total noncompliance among the control group necessitated the project be redesigned as a two-week, pre-post study. Revisions were made to the study design, exclusion criteria were revised, assessments were removed, and the program was decreased from a four-week to two-week elimination diet. These changes were made to increase the likelihood of enrollment and in answer to feedback provided from participants in the program feedback survey in Phase 2.

Purpose

The primary aim of this study is to determine if a two-week trial of the elimination phase of the LFD delivered through an internet- and module-based program (“The FODMAP Fix”) developed by a RDN trained on the LFD improves symptoms and quality of life in patients with IBS.

Research Questions

1. Will the two-week elimination phase of The FODMAP Fix program lead to post-intervention changes in the participant’s IBS Symptom Severity Scale (IBS-SSS)?

2. Will any changes in symptoms be enough to affect post-intervention changes to the participant's Quality of Life (IBS-QOL) indices?

Hypothesis

A two-week trial of “The FODMAP Fix” in adult patients with IBS will result in significant improvements in pre/post scores as assessed by the IBS Symptom Severity Scale (IBS-SSS) and Quality of Life (IBS-QOL) instruments with a significance of $P < 0.05$.

Delimitations

The delimitations for this study are as follows:

1. The sample population is limited to adults 18 to 65 years of age, as adults over 65 are more likely to have other conditions that could affect outcomes;³³
2. All communication with participants occurs over the internet to simulate a real-world, 100% online intervention;
3. Only the elimination phase of the FODMAP diet is assessed, as data is sparse on the reintroduction and adapted portions of the LFD;

Limitations

The limitations of this study are as follows:

1. The use of surveys for assessments has limitations and is affected by responder fatigue, motivation, and potentially honesty – particularly given the sensitive nature of some survey questions;
2. The number of assessments during the two-week period may have attributed to dropout;

3. Female menstruation was not accounted for and may have impacted results;
4. While HRQOL was assessed via the IBS-QOL, additional assessments on stress, anxiety, and depression may have provided additional information on non-usage and dropout rates;
5. Validity and reliability of the SE assessment could be in question from the modification of an existing instrument;
6. Lower average baseline IBS-SSS scores (*median* = 210 v. 292-318) scores compared to other studies assessing a LFD intervention;
7. Phase two of this study was developed after a failed attempt to assess a four-week controlled trial, resulting in a two-week trial with pre/post assessments

Assumptions

The assumptions of this study are as follows:

1. The Canvas-based FODMAP Fix program is easily accessible and requires only moderate technology literacy,
2. Participants are able to interpret the validated IBS-SSS and IBS-QOL and answer accordingly without assistance,
3. The \$20 amazon.com gift card is enough for participants who start the two-week study will complete it,
4. Participants want to engage and receive feedback on their diet and symptoms.

Definitions

Below are the definitions of terms utilized in this study:

FODMAP: The acronym stands for Fermentable, Oligosaccharides, Disaccharides, Monosaccharides, and Polyols.³⁴ Certain types of short-chain carbohydrates that are not well absorbed in the gut and may cause gastrointestinal symptoms in people with IBS.

Low FODMAP Diet (LFD): There are three phases to the LFD: elimination, reintroduction, and adapted. This study focuses on the elimination phase, which includes eliminating those foods from the diet that are determined to be above the threshold of tolerance established by Monash University. This threshold varies by FODMAP type and is determined by High Performance Liquid Chromatography (HPLC) analysis.²⁸ Foods are rated with a red (high), yellow (moderate), or green (low) light for FODMAP content in the Monash FODMAP app.

Registered Dietitian Nutritionist (RDN): Experts in food and nutrition who have met certain criteria established by the Commission on Dietetic Registration to earn the RDN credential.³⁵

Gastroenterologist: A physician with specialized training in management of diseases of the gastrointestinal tract and liver.³⁶

Importance of Study

The current research study was designed to assess whether an internet-based LFD education program can result in significant improvement of IBS symptoms. Study findings can be used to enhance delivery of an online LFD education program to improve the symptoms and lives of patients suffering from IBS. Such a program could make a significant impact on public health by providing an affordable, accessible, and credible

option to patients with IBS who do not have access to a specialized RDN trained on the LFD.

CHAPTER II

REVIEW OF THE LITERATURE

IRRITABLE BOWEL SYNDROME (IBS)

Burden of Irritable Bowel Syndrome

IBS is the most commonly diagnosed gastrointestinal disorder in the US, significantly affecting the quality of life and productivity of afflicted individuals.¹ IBS is characterized by abdominal pain related to changes in bowel habits.² Patients with IBS have a higher average incidence for a broad spectrum of diseases, such as other gastrointestinal disorders and symptoms and psychiatric disorders.³ Thus, although clinical diagnostic criteria exist, in clinical practice IBS often becomes a diagnosis of exclusion.⁴

IBS is a chronic, often relapsing disease in which symptoms vary over time.⁵ Symptoms worsen in 2–18% of IBS patients, and remain unchanged in 30–50% of patients, with 12–38% of patients experiencing improvement or disappearance of symptoms in studies with a median follow-up duration of two years.⁵ Predictors of worsening symptoms include prior surgery and higher baseline anxiety and depression scores.⁵

Lovell and Ford⁶ conducted a meta-analysis of studies involving 260,960 subjects and reported global incidence of IBS at 11.2% with a variability between countries of 1.1% to 45%.⁶ IBS is more prevalent in women, those younger than 50 years old, and in

the US and Canada.⁶ IBS accounts for around 20% of outpatient gastroenterology visits,⁷ and it is the seventh most common primary care diagnosis in the US.⁸ An estimated 12% of North Americans have IBS;⁹ however, this figure could underestimate the total prevalence as 76.6% people with IBS are never formally diagnosed.¹⁰ Estimates including this undiagnosed population identify a prevalence as high as 20%.⁷ Several factors prevent patients from seeking healthcare which include severity of illness, life event stress, psychological disorders, particular personality traits including neuroticism, a history of physical or sexual abuse, abnormal illness behavior, and beliefs about the efficacy of conventional IBS treatments.¹¹

Physical and psychological symptoms are independently associated with decreased health-related quality of life (HRQOL) in patients with severe IBS.^{1,12} The degree of impairment to HRQOL in patients with IBS is similar to other chronic disorders, including depression and GERD.¹³ Gastrointestinal (GI) symptom anxiety is associated with both mental and physical component scores as assessed via the Medical Outcomes Study Short Form 36 (SF-36), while perceived stress is a strong predictor of low mental component scores (MCS).¹² When perceived stress, somatic symptom severity, and mindfulness are at optimal levels, HRQOL is similar between patients with IBS and healthy controls.¹² IBS symptom severity, as measured by IBS-SSS, is directly related to HRQOL and its subscales.¹⁴ However, when a patient's illness perception is used in a mediation analysis, the direct relationship only remained for total HRQOL scores and not its subscales.¹⁴ In addition, there is a corresponding improvement to

therapeutic response to pain related to IBS symptoms and HRQOL in patients with moderate to severe IBS.¹³

IBS has such a significant impact on HRQOL that one survey found that patients would be willing to give up 25% of their remaining life (average of 15 years), and 14% would risk a 1/1000 chance of death for a treatment that would remove their symptoms.¹⁵ A study using the SF-36 assessing HRQOL found individuals with IBS fared worse than those without IBS.¹⁶ The authors attributed these findings to poor functional outcomes for those with IBS.¹⁶ In the same study, IBS was associated with a 21% reduction in work productivity, equivalent to working less than four days in a five-day workweek.¹⁶ In another survey, patients with IBS reported their symptoms led to decreased work productivity an average of nine days per month and resulted in an average of two missed days of work per month.⁸ These decreases in productivity cost up to \$20 billion annually in the US, with an estimated annual cost per patient of \$9,933 (in 2012 US dollars).⁸

IBS is a significant expense to the individual patient and healthcare system as a whole as a result of both direct and indirect costs. Direct annual costs of IBS are estimated to be up to \$10 billion; however, this figure doesn't include the cost of prescription or over-the-counter (OTC) drugs.¹⁷ Total annual cost of IBS per patient in the US is estimated to exceed \$15,000.¹⁸ The distribution of healthcare cost for IBS estimate per outpatient costs to be 12.7% to >50% of total costs, inpatient costs to be 6.2% to 40.8%, and pharmacy or drug costs to be 5.9% to 46.6%.¹⁸ In addition to the significant additional costs of medication, the direct cost estimation is likely a gross

underestimation as around 76% of sufferers are never diagnosed, although they may still be treated for their symptoms or seek alternative care.^{10,17}

IBS Defined

IBS is a colorectal disorder that is the most prevalent of the “Functional Gastrointestinal Disorders” (FGIDs),^{19,20} which are defined as “morphologic and physiological abnormalities that often occur in combination including motility disturbance, visceral hypersensitivity, altered mucosal and immune function, altered gut microbiota, and altered central nervous system processing”.²¹ IBS is a heterogeneous and chronic condition, thus many patients diagnosed with IBS experience symptoms ten years or more before formal diagnosis.²² The Rome IV diagnostic criteria, developed by a panel of international experts in the field of FGIDs and frequently used in clinical research, was updated in 2016 along with a gradual reclassification of FGIDs to “Disorders of Brain-Gut Interaction”. The Panel recognized that classifying IBS and other such disorders as “functional” was overly simplistic.^{2,20} The experts also reported a growing body of research that supports the role of an imbalanced microbiota, increased gut permeability, altered immune function, and an important link between neural and hormonal interaction between the gut and brain in the symptoms of IBS and related disorders.

According to Lacy and Patel,² diagnosis of IBS should include the following: “a careful review of the patient’s symptoms, taking a thoughtful history (e.g., diet, medication, medical, surgical, and psychological history), evaluating the patient for the presence of warning signs (e.g., ‘red flags’ of anemia, hematochezia, unintentional weight loss, or a family history of colorectal cancer or inflammatory bowel disease),

performing a guided physical examination, and using the ROME IV criteria.”² The most recent diagnostic criteria, according to ROME IV, include the fulfillment of the following criteria with symptom onset at least six months prior to diagnosis: “Recurrent abdominal pain on average at least one day/week in the last three months, associated with two or more of the following criteria:

1. Related to defecation;
2. Associated with a change in the frequency of stool;
3. Associated with a change in the form (appearance) of stool.”²

The updated criteria included the exclusion of the word “discomfort,” as the previous version read “Recurrent abdominal pain or discomfort...,” because the meaning of the term is imprecise, and it was unclear whether the distinction between pain and discomfort is quantitative or qualitative.²⁰ Also, the previous ROME III criteria designated that symptoms only be present at least three days per month. This criteria was updated based upon results of a symptom survey.²⁰

ROME IV classifies patients into the following subtypes: IBS with predominant constipation (IBS-C), IBS with predominant diarrhea (IBS-D), with mixed bowel habits (IBS-M) or IBS un-subtyped (IBS-U), though subtypes are known to change over time.²³ Subtype classification also changed from ROME III in that the IBS subtype is now based on the patient’s primary bowel habit on days when they are experiencing symptoms, as opposed to average days.²⁴ The Bristol stool form scale is the tool recommended by the ROME committee to classify bowel habits. To increase reliability of subtype

categorization, physicians should collect two weeks of data from patient diaries to validate subtype.²³

Pathogenesis

Until recently, the pathogenesis of IBS was attributed to one or more of the following: abnormalities in gut motility or gut-brain interactions²⁵, visceral hypersensitivity, and/or psychosocial distress.²⁰ However, a recent review noted that the pathophysiology of IBS is even more complex and is likely due to a combination of factors in addition to those previously listed.²⁶ The list of potential contributors now includes activation of the mucosal immune system; viral, bacterial, protozoan, and helminth infections resulting in increased risk; malabsorption, potentially as a result of enteric infections; acute *Campylobacter enteritis* resulting in increased serotonin-containing enteroendocrine cells and T-lymphocytes; antibiotic use; changes in gut microbiota; small intestinal bacterial overgrowth (SIBO); food sensitivities; and genetic polymorphisms affecting serotonin reuptake efficacy which may alter intestinal peristalsis.²⁶ These contributors may result in a weakened epithelium, increasing the likelihood of translocation of gram negative bacteria outside the gut, frequently termed “leaky gut.”²⁷ Low grade systemic inflammation and visceral hypersensitivity may result.^{28,29}

Bidirectional gut-brain interactions are increasingly recognized as playing an important role in the pathogenesis of IBS, as well as other FGIDs that include pain.^{25,28} Under normal conditions, gut-brain interactions regulate appetite and food intake, the gut-associated immune system, and play a role in overall functioning²⁵. However, in the

diseased state, changes in these gut-brain interactions can result in chronic pain and gut dysfunction.²⁵ Pain in IBS is often associated with altered bowel habits that may be a related to changes in gastrointestinal functioning and ensuing visceral hypersensitivity.²⁵

Chronic psychological stress is also known to contribute to IBS symptoms, including a positive correlation to IBS pain severity.^{30,31} In a review of the literature examining the role of stress in IBS, Moloney et al.²⁸ reported stress affects gut motility, mucosal transport, gut barrier function, visceral perception, and changes in gut microbiota. Further, the authors postulated that increased pain and pain signaling mechanisms within the gastrointestinal tract contribute to visceral hypersensitivity through stress-induced changes in the immune, neurochemical, and physical mechanisms that make the gastrointestinal tract more habitable for pathogenic bacteria and less habitable for helpful bacteria in the gut microbiota.²⁸

Gut microbiota affect both gut function and brain morphology and function, leading some to propose that the microbiota-gut-brain axis is central to IBS pathophysiology.³² The microbiota-gut-brain axis includes the central nervous system, neuroendocrine and neuroimmune systems, autonomic nervous system, enteric nervous system, and the gut microbiome.^{33,34} While it is relatively well understood how a network of neural, hormonal (primarily serotonin), and immunological fiber networks influence bidirectional gut-brain function, it is unclear exactly how the microbiota exerts its influence.^{28,35}

Around 10% of patients believing their IBS is the result of a GI infection.³⁶ While a causal relationship cannot be established in most patients, some speculate that

host-microbial interactions occurring early in IBS in vulnerable individuals may permanently alter immune responses and the microbiota.²⁵ This dysbiosis may influence pain perception and chronic low-grade inflammation in some individuals.²⁵ The dysbiosis is evidenced by abnormal methane and breath hydrogen test profiles suggestive of bacterial fermentation as well as 16s-rDNA with PCR-GDDE studies noting changes in the microbiota of IBS patients.³⁷⁻⁴⁰

Several reviews have investigated differences in gut microbiota of patients with and without IBS and found consistently different bacterial profiles.^{35,41} However, some subgroups of IBS patients have similar microbiota profiles and can be differentiated from healthy controls yet these cannot be differentiated by IBS sub-type.⁴² A review of data supporting IBS as a gut-brain-microbiota disorder stated patients with IBS generally have increased levels of *Firmicutes* and a reduced abundance of *Bacteroidetes*.³⁵ The authors speculated these differences may lead to the reduced bacterial diversity seen in the microbiota of IBS patients compared to healthy controls.³⁵ Interventions aimed at altering the intestinal microbiota of IBS patients include the use of prebiotics, probiotics, antibiotics, and fecal transplants, all of which may affect key symptoms including pain and bowel habits.³⁵

IBS Management

First-line treatment of IBS typically focuses on OTC therapies designed to treat symptoms related to constipation and diarrhea.⁹ Given the heterogeneity of IBS, there is no standard algorithm for treatment; therefore, the treatment should be adjusted according to the patient's subtype and severity.^{9,43} This approach has several benefits including cost,

availability, and safety; however, OTC therapy offers little benefit for global IBS symptom treatment as it does not address pain and bloating.⁹

Prescription medications for IBS frequently include side effects and their efficacy is highly variable.^{9,15} As these drugs are often symptom-specific, polypharmacy is common, further complicating treatment.^{15,44} Narcotic medications are often used to treat pain – the predominant symptom reported by patients based on the ROME diagnostic criteria.²⁰ In an international survey of 1,966 patients with IBS, 18.1% reported taking narcotics.¹⁵ However, a consequence of chronic opioid use is Narcotic Bowel Syndrome, which is not uncommon among patients with FGIDs.⁴⁵ Additionally, treating IBS patients is challenging as there is no validated treatment algorithm, patients respond differently to the same treatment, and some patients are nonresponders to treatment approaches.¹⁹ Complementary and alternative therapies are frequently utilized by patients with IBS. A 2009 survey found 37% of patients had used different therapies at some point with the most common treatments being dietary supplements and probiotics, followed by massage therapy, meditation and relaxation, homeopathy, acupuncture, Chinese herbal therapy, and colonic irrigation.¹⁵

Alternative approaches to symptom management are not surprising as approximately two-thirds of patients experience symptoms for a year before consulting a physician, and many go undiagnosed for a decade.^{8,22} In this in-between time, many take advice from friends and family members on symptom treatment.⁸ Also, patients frequently attempt to manage their IBS symptoms through dietary changes prior to consulting with a physician.⁴⁶ Patients with IBS frequently alter their diet, with 84%

practicing food avoidance based on the belief that their symptoms are related to food intolerance.⁴⁷ Twenty-eight percent of patients report symptoms begin within 15 minutes of eating, while 93% report symptoms within three hours.⁴⁸ In a recent US survey of gastroenterologists, 60% reported their patients attributed their IBS symptoms to food.⁴⁶ The survey also found that the majority of gastroenterologists reported recommending diet therapy to “most” of their IBS patients. Over 90% of gastroenterologists believed it to be at least as effective as pharmacological treatment.

Gastroenterologists report that the most common diet therapies attempted by patients prior to their first appointment were trial and error (50%), reduced lactose (33%), gluten-free (24%), and the low FODMAP (Fermentable Oligosaccharides, Disaccharides, Monosaccharides, and Polyols) diet (LFD) (2%).⁴⁶ However, the percentage of these patients who are actually avoiding high FODMAP foods, as a result of trial and error and other diet therapies is not clear. Patient knowledge of the LFD is still limited in the United States.⁴⁹ While patients may not report following an LFD, they may be inadvertently avoiding foods high in FODMAPs as they perceive they are “sensitive” to these foods (e.g., wheat-based foods, dairy, corn, garlic, onion, soy, and foods high in fructose).⁴⁹

In a recent study, the LFD was the most frequently recommended diet therapy by gastroenterologists with 77% either “usually” or “almost always” recommending it.⁴⁶ Eighty-five percent of these practitioners believed the LFD to be a “very effective” or “somewhat effective” treatment.⁴⁶ Food hypersensitivity has been linked to microbial fermentation of poorly absorbed carbohydrates, including FODMAPs.⁵⁰ Fifty to eighty

percent of patients following a LFD report symptom improvement.⁴⁴ Significant improvements in fatigue and quality of life scores have also been reported.^{51,52}

FODMAPs AND THE LOW FODMAP DIET

Definition and Mechanisms of Action

FODMAPs are short-chain carbohydrates that are slowly or poorly absorbed in the small intestine, result in an osmotic effect, and are fermented in the large intestine.⁵³ Excess amounts of certain FODMAPs result in gastrointestinal symptoms even in healthy controls.⁵⁴ In individuals with IBS, even small amounts of these food components can lead to symptom exacerbation.⁵⁴ A detailed explanation of the FODMAP acronym is listed below: ⁵⁵

- **Fermentable:** Foods capable of producing hydrogen, methane, and carbon dioxide gas: kombucha, kefir
- **Oligosaccharides (fructans and galactans):** Fructans: wheat, rye, onions, and garlic; Galactans: beans, legumes
- **Disaccharides (lactose):** Dairy milk, yogurt
- **Monosaccharides (excess fructose):** Honey, apples, high fructose corn syrup
- **And**
- **Polyols:** Sorbitol and mannitol based artificial sweeteners, stone fruits

A diet low in FODMAPs positively affects gastrointestinal and psychological indices in patients with IBS, including improvements in quality of life, anxiety, and depression.^{48,51,52,56-58}

Undigested FODMAPs particles result in an increase in luminal water through an osmotic effect in the large intestine where gas is produced via fermentation by colonic bacteria resulting in distention that leads to pain and bloating in susceptible individuals.⁵⁹⁻⁶¹ FODMAP avoidance may lead to changes in both the colonic microbiome and metabolome.⁶² McIntosh, et al.⁶² found a significant role of dietary FODMAP content in influencing metabolomic profiles when comparing patients on a high versus LFD. Specifically, those consuming a LFD had an eight-fold reduction in histamine (H2), and increases were noted in hydroxybenzoic acid (pHBA) and azelaic acid. Azelaic acid has anti-inflammatory properties and may have been elevated due to increased consumption of oat and sorghum, which are both commonly used in gluten-free flours. pHBA is found often in berries and, at the time of this study, raspberries and blueberries were still considered low in FODMAPs. Increased consumption of these fruits may have increased to offset decreases in other commonly consumed fruits. H2 has three major functions in the GI tract, modulation of GI motility, enhancement of gastric acid production, and alteration of mucosal ion secretion.⁶³ Elevated H2 levels found in the mucosa of IBS patients is associated with mast cell activation and sensitization of enteric and pain-sensing neurons.⁶⁴ The mechanism of action for how FODMAPs affect H2 is unclear.

SCFAs induce colonic distention, which could lead to mast cell degranulation and histamine release.⁶² However, the effect of the LFD on SCFAs is inconsistent.⁶⁵⁻⁶⁷ Histamine is known to play a role in immediate hypersensitivity responses and IBS symptomology.^{62,63,68} H1 antagonists affect the histamine blockade and have been

effective in treating IBS symptoms with histamine-releasing foods considered as triggers of IBS symptoms in some.^{69,70}

LFD and IBS Symptoms

The LFD is being increasingly used in a clinical setting with research into its mechanisms of action and efficacy of the diet growing significantly in recent years.⁴⁴ The diet was first developed by Gibson and Shepherd⁷¹ and includes two phases: elimination and re-challenge. The elimination phase lasts two to six weeks and includes the strict removal a significant number of foods commonly consumed by Americans, making it difficult to implement. There is no single approach to the re-challenge phase and, in fact, three different approaches are discussed in Monash University's training on the LFD for dietitians with the recommendation to choose an approach based on the needs of the patient. Essentially, the re-challenge phase slowly reintroduces FODMAPs into the diet to help patients understand which FODMAP groups might be triggering their symptoms. Patients learn how to increase the amount of the particular FODMAP group consumed and are advised to retest those groups that they are currently sensitive to in the future, as sensitivity can change over time. Patients who follow the elimination phase of the diet often continue on an adapted version of the diet for at least six months.⁵⁸

Most studies have found that the LFD significantly improves IBS symptoms and quality of life,^{48,50,57,72,73} though the response can vary by sub-type.⁷⁴ Patients with IBS-C tend to see less benefit and some have experienced symptom exacerbation, which may be due in part to the reduction in fibers, specifically prebiotic fibers that promote laxation.^{75,76} There is also a known difference in the fecal bacterial profiles of IBS

patients with constipation and diarrhea predominant subtypes.⁷⁷ Studies also vary in methods used to assess symptom response to the LFD with most using IBS-SSS, while others have used the Visual Analog Scale (VAS) or classifying patients as responders or non-responders. Patients have been classified as “responders” based upon either a 50% reduction in IBS-SSS scores⁷⁸ or a 50-point decrease in these scores.^{50,51,75,79}

Therapeutic interventions that yield positive health outcomes are expected to positively impact HRQOL.⁷⁴ Indeed, the LFD has been shown in a number of studies to improve HRQOL;^{48,52,80,81} however, there is limited evidence on the burden of the restrictive nature of the diet.^{82,83} Two studies have noted that participants believed there was a significant food cost associated with the diet^{82,83} and one noted it affected social eating.⁸³ Two studies have noted no effect of the LFD on food-related QOL.^{83,84} A study comparing the LFD with a yoga intervention found that changes in QOL as assessed by the SF-36 had no effect though a within group difference was found to be significant for the Cohen Perceived Stress Scale (CPSS).⁵¹ LFD studies which have assessed HRQOL and the LFD are either uncontrolled, nonrandomized, or implemented dietary changes not exclusive to the LFD. Staudacher⁷⁴ recommends randomized, placebo-controlled trials to confirm the effect of the diet on HRQOL.

LFD v. Standard IBS Recommendations

A 2015 study by Bohn et al.⁵⁰ is frequently cited, which indicates that there is no advantage of the LFD compared to traditional IBS recommendation, which focus on when and how – and less on what – to eat. Specifically, the study by Bohn and colleagues advised patients randomized to the traditional dietary advice to “regularly eat three meals

and three snacks a day, never too much or too little each time, never to be hungry or too full; to eat in peace and quiet and to chew thoroughly; reduce intake of fatty or spicy foods, coffee, alcohol, onions, cabbage, and beans; avoid soft drinks and carbonated beverages, chewing gums, and sweeteners that ends with -ol, and to eat fibers but distribute the intake evenly during the day.” They found that the severity of IBS symptoms was reduced in both groups during the intervention ($p < 0.0001$). At the end of the four-week diet period, there were similar reductions in IBS-SSS scores between the two study groups. However, there was an overlap between the two studied diets with respect to restriction of FODMAP-containing carbohydrates. The traditional IBS dietary group was allowed to maintain lactose restriction, reduced intake of foods with fructans (onions) and galactans (beans), and avoided polyols. In addition, there was a significant decrease in excess fructose intake in the traditional IBS dietary group, which may mean they also decreased some high FODMAP foods.

In another study, Eswaran et al.⁴⁸ assessed the effectiveness of dietitian-led education on LFD compared to standard dietary recommendations (National Institute for Health and Care Excellence – mNICE) in managing IBS symptoms and found 52% of patients on the LFD and 41% of those following mNICE reported adequate relief of their IBS-D symptoms ($p = 0.31$). While the difference between groups was not significant, the LFD resulted in a higher proportion of responders to abdominal pain and bloating compared with the mNICE group. Modest improvements in stool consistency were also noted in those on the LFD. The authors published a second report on the cohort focusing on disease specific QOL, psychological distress, work productivity, and sleep and found

the LFD significantly improved health-related QOL, anxiety, and activity impairment compared to mNICE recommendations.⁴⁸ Staudacher et al.⁸⁵ also evaluated the LFD against mNICE recommendations through a questionnaire administered two to six months after follow-up to dietary counseling. Seventy-six percent of patients in the LFD group reported satisfaction with their symptoms compared to 54% in the mNICE group ($p = 0.038$). Also, significantly more patients in the LFD group reported improvements in bloating (82% LFD versus 49% NICE, $p = 0.002$), abdominal pain (85% LFD versus 61% NICE, $p = 0.023$) and flatulence (87% LFD versus 50% NICE, $p = 0.001$).

LFD v. Typical Diets

Dietary compliance is a significant issue with elimination diets. One double-blind, randomized, controlled trial provided food to patients to improve compliance. Halmos et al.⁷⁵ provided almost all food to 30 patients with IBS and 8 healthy controls and asked them to follow a 21-day LFD or typical Australian diet, followed by a 21+ day washout then alternate diet for 21 days. Patients with IBS had significantly lower overall gastrointestinal symptom scores while on the LFD, compared with the Australian diet and the subjects' habitual diet. Seventy percent of patients with IBS on the LFD experienced symptom improvement, with symptoms being reduced by half.⁷⁵ Changes were not observed in healthy participants.

LFD v. High FODMAP Diet

McIntosh et al.⁶² compared a high versus LFD to account for a potential nocebo effect and found the LFD decreased IBS-SSS scores by 28%, but the high FODMAP diet actually increased scores by 7% compared to baseline. "Responders," defined as those

with a greater than 50-point improvement in IBS-SSS, were more likely in low FODMAP (72%) compared to high FODMAP (21%) groups. Also, patients on the LFD reported a 52% decrease in abdominal pain ($p < 0.01$), but the high FODMAP group reported a ~16% increase in frequency of pain ($p = 0.03$).

Pre- and Post-LFD Results

Numerous studies have found that the LFD significantly improved symptom scores from baseline in IBS patients.^{51,72,78,86,87} Valeur et al.⁸⁸ found that total IBS-SSS scores improved from ~292 to ~149 ($p < 0.0001$), which is an improvement from moderately severe to mild IBS. The IBS-SSS sub-scores of pain severity and frequency, bloating, bowel habit dissatisfaction, and life interference also significantly improved. An analysis by IBS subtype did not find differentiating effects of the LFD on IBS-C, IBS-D, or IBS-M. More recently, Valeur et al.⁷⁸ converted the IBS-SSS scores from the participants (minus two) into two groups, classifying 32 patients classified as “responders” (>50% improvement in IBS-SSS scores) and 29 as “non-responders” to the LFD. The groups were similar in terms of mean IBS-SSS scores and the distribution of IBS-SSS categories (mild, moderate, severe) was similar in both groups. After the LFD intervention, IBS severity improved with mild IBS reported by 13 of the 32 responders and only 1 of 29 non-responders. Both responders and non-responders reported significantly lower IBS-SSS scores compared to baseline.

LFD v. Alternative Therapies

In addition to other diets as a comparison or control group, some studies have investigated the effectiveness of alternative therapies including yoga, gut hypnotherapy,

and probiotics. The effects of gut-directed hypnotherapy were compared to a LFD on GI symptoms and psychological indices as individual interventions and against a combined therapy utilizing both.⁵² Significant reductions in VAS were reported for all three therapies with no difference between groups. These improvements represented ≥ 20 mm improvement on VAS in 72% hypnotherapy, 71% diet, and 72% combined and were maintained six months after treatment 74%, 82%, 54% respectively. Gut hypnotherapy resulted in significant improvements in anxiety and depression through six months. Interestingly, there was not an additive effect of the LFD when combined with the hypnotherapy.

Schumann et al. sought to examine the effect of a yoga-based intervention versus the LFD in patients with IBS.⁵¹ The yoga group received two sessions weekly, while patients in the LFD group received a total of three sessions of nutritional counselling over 12 weeks and were followed for 24 weeks. IBS-SSS scores did not differ between the intervention groups at 12 or 24 weeks. Within-group comparisons showed statistically significant effects for yoga and the LFD at both 12 and 24 weeks. There were no between-group differences for the SF-36, a component of the QOL assessment, except for the physical component summary subscale, which showed a significant improvement in the yoga group. Additional QOL assessments did not reveal between-group differences, but within-group comparison showed significant improvements for both groups. The IBS-QOL assessment showed a significant between-group difference only on at week 12, related to FODMAP group patients' avoidance of some foods ($p = 0.01$).

Due to the known differences in the microbiota of patients with IBS, some have speculated that probiotic supplementation might improve symptoms with study results being mixed.¹⁹ The effect of supplementation with *Lactobacillus GG* (LGG) was compared to the LFD and a Danish/Western diet (ND) on IBS symptoms.⁸⁹ There was a significant reduction in mean IBS-SSS from baseline to week 6 between LFD vs LGG vs ND: 133 ± 122 vs 68 ± 107 , 133 ± 122 vs 34 ± 95 , ($p < 0.01$). Adjusted changes of IBS-SSS for baseline covariates showed statistically significant reduction of IBS-SSS in LFD group compared to ND, but not in LGG compared to ND.

VSL#3 is a combination probiotic supplement and was used in an intervention to compare its effectiveness in treating IBS symptoms to that of the LFD and a sham diet in a recent study on patients with IBS-D.⁵⁸ The effects of these interventions on fecal microbiota were also assessed. Patients were randomly assigned to groups and counselled to follow a sham diet or LFD for 4 weeks, along with a placebo or VSL#3. In four groups: 27 patients received sham diet/placebo, 26 received sham diet/probiotic, 24 received LFD/placebo, and 27 received LFD/probiotic. There was no significant interaction between the interventions in relief of symptoms ($p = 0.52$) or Bifidobacterium species ($p = 0.68$). In the ITT analysis, a higher proportion of patients on the LFD had adequate symptom relief (57%) versus the sham diet group (38%) with a difference that approached significance ($p = 0.051$). In the per-protocol analysis, a significantly higher proportion of patients on the LFD had adequate symptom relief (61%) than in the sham diet group (39%) ($p = 0.043$). The total mean IBS-SSS score was significantly lower for patients on the LFD (173 ± 95) than the sham diet (224 ± 89) ($p = 0.001$), but there was no

difference between those given probiotic (207 ± 98) or placebo (192 ± 93) ($p = 0.721$). There was no difference in QOL scores between groups for total score for SF-36 or IBS-QOL. However, when comparing the LFD group to the sham diet groups, there were higher scores for role limitations due to physical health ($p = 0.03$), energy/fatigue ($p = 0.02$) for SF-36 and higher scores for body image ($p = 0.00$), social reaction ($p = 0.03$) and relationships ($p = 0.04$), indicating better quality of life in these domains.

Long-term Effects of LFD

There is limited long-term data assessing the effectiveness of the LFD, as most studies focus on the short-term elimination phase of the diet. The long-term effectiveness of a LFD was assessed via a survey of 143 adults who were contacted after 6 to 18 months after education by an RDN on the adapted version of the diet where FODMAPs are systematically reintroduced in the diet to liberalize food choice and nutrient intake.⁸³ At follow-up, 82% of patients continued to follow an adapted FODMAP diet. Sixty-one percent of patients reported adequate symptom relief at short-term follow-up (FODMAP restriction phase) and 57% at long-term follow-up (6 to 18 months) ($P = 0.003$). The adapted diet resulted in adequate calcium intake, no long-term reduction in fiber, increased fruit and vegetable intake, with 40% of patients reporting weight loss. The authors speculated this was due to a reduced intake of highly processed and high fat foods. Patients reported that issues with the LFD included cost and difficulty dining out, traveling, and social eating. Peters et al.⁵² found in a study of 74 adults that 82% of study participants maintained a significant improvement in IBS symptoms and QOL at 6 months. Similar results were seen in another study where a LFD was initially started on

one group and continued for three months followed by the reintroduction/re-challenge phase of the LFD, while a second group was a control group for the first three months then followed the LFD for months four to six.⁵⁶ The significant decrease in IBS-SSS scores and increase in IBS-QOL was maintained after FODMAPs were reintroduced to tolerance. Fiber was decreased in the diets of patients during the elimination phase of the LFD; but, after reintroduction, it returned to near their normal level.

Compliance

Compliance is one of the most confounding and critical issues to effective diet therapy as well as assessment of the effectiveness of potential therapies. A review by Osicka et al.⁸⁶ noted the extent to which individuals with FGIDs adhere to restricted diets is related to the reduction in symptoms and increases in QOL. Although this relationship exists, studies assessing adherence report that patients with FGID are not often adherent to restrictive protocols.^{58,83,85,90} While adherence is occasionally assessed in LFD studies, the tools can vary considerably, are often based on a single self-reported question, and are of limited utility as they lack additional measures to validate the response (e.g. food frequency questionnaire, diet records, or 24-hour recalls).

A study by McIntosh et al.⁶² provides the best example of compliance assessment. Participants kept daily food logs over three weeks that were scored on a 14-point scale for FODMAP content by a RDN. The third week was reviewed by a blinded RDN. The scores in the low FODMAP group were significantly lower than those in the high FODMAP group, suggesting good compliance. When compliance scores were correlated with IBS symptom scores, a positive correlation was found between symptom severity

and the level of FODMAP intake. Food records have been used in other studies as pre- and post- intervention assessments for compliance with periods often ranging from four to six days.^{51,91}

One of the more common and simple methods to assess diet compliance is using the scale: “Never related to no adherence, Occasionally to less than 50% of the time, Frequently to more than 50% of the time, and Always as being followed totally.”^{82,85,90,92} Shepherd and Gibson were the first to use this scale and validated the response first by asking participants to self-report compliance in structured telephone interviews then checking diet history for specific high FODMAP foods.⁹² The authors reported that improvement of IBS symptoms was reported by 74% of patients and was closely related to dietary compliance, which was defined as adhering to the diet at least 50% of the time. Mansueto et al. questioned these findings noting that this study was a retrospective analysis of diet adherence and that the findings could have easily been the result of a placebo effect.⁹³

De Roest et al.⁹⁰ found 75% of the participants followed the LFD at least 50% of the time over a ~16-month period. Staudacher et al.,⁸⁵ using the same scale, found 94% were adherent and in a second study⁵⁸ reported that all patients followed the diet at least 50% of the time on at least two of the four weeks. While the majority of patients in these studies were considered compliant by the authors, “compliance” in this sense seems very loose and not well defined. However, as previously mentioned, only one study has provided the majority of food to patients on the LFD, and the results were similar in terms of IBS symptom response.⁷⁵

Studies have investigated potential causes of decreased compliance and found a variety of responses. In a study by de Roest et al., participants reported the taste of the diet, ease of following the diet, and incorporating the diet into everyday life were contributors to adherence.⁹⁰ Gearry et al.⁸² reported barriers to following the LFD were perceived increases in cost to follow the LFD (64% of participants) and bland flavor (47% of participants). In another study, diet cost and social eating were significant issues, although there was no overall effect on food-related QOL.⁹⁴

BARRIERS TO DIET THERAPY

Primary care physicians (PCPs) and gastroenterologists have varying views on diet therapy, including knowledge and willingness to provide and/or refer out diet therapy.^{46,95,96} Barriers to nutrition counseling in primary care, where a significant number of IBS diagnosis are made, include lack of time and compensation followed by a lack of resources and knowledge by the physician.^{8,95} A separate survey confirmed PCPs do not often refer patients for nutrition consultations when insurance is unlikely to cover the service, as is often the case with IBS.⁹⁶

Beyond barriers, a key concern may be the patient expectation that doctors, rather than RDNs, provide dietary counseling.⁹⁵ When physicians do not refer patients out for dietary counseling, it reinforces this belief amongst patients.⁹⁵ A survey of physicians found that only 15% felt “highly” confident to discuss nutrition with a patient, although 89% reported they care for patients who “sometimes” or “usually/always” require nutrition counseling.⁹⁷ Many physicians are neither advising their patients on nutrition nor referring them to RDNs. IBS patients report that referrals to an RDN are infrequent.

In a survey of adult patients with IBS, 55% report that their doctor, nurse practitioner (NP), or physician's assistant (PA) recommended diet changes to help manage their IBS symptoms.⁴⁹ However, only seven percent ($n = 8$) of those were referred to an RDN and, of those referred, only six actually saw an RDN.⁴⁹

A survey of gastroenterologists by Lenhart et al.⁴⁶ found that over half of gastroenterologists recommend some type of diet therapy to most (>75%) of their patients and slightly more than half state they are either “comfortable” (38%) or “very comfortable” (18%) providing diet therapy themselves. Unfortunately, only 21% of gastroenterologists are referring these patients to RDNs. However, the lack of referrals is not because these practitioners question the utility of dietitians, as 78% of gastroenterologists believe that a RDN with an IBS focus would improve the delivery of the diet therapy to patients. When they do refer to RDNs, 51% reported they “usually” or “almost always” provide specific diet recommendations.⁴⁶ Caution should be applied when interpreting the Lenhart et al. survey, as there was no patient group surveyed to validate the results. A survey of patients with inflammatory bowel disease (IBD) and providers who treat IBD found that while 98% of gastroenterologists reported providing dietary advice, only 26% of patients stated they received this advice from their specialist.⁹⁸

Gastroenterologists report that handouts are the most common means (70%) of providing nutritional advice, although providers are cautioned against using this as the sole means of diet education.⁴⁶ Gastroenterologists may view handouts as the best option in light of the perceived barriers to effective diet therapy. They report that barriers

include the complexity of the diet for IBS patients, lack of insurance coverage for IBS diet therapy for RDNs, and the lack of specialized dietitians in the US.^{46,70}

PROGRAM DEVELOPMENT

There are a number of frameworks available to assist in planning health promotion programs. This review will focus on the Stepwise Procedure for Designing Theory-Based Nutrition Education, also known as the Stepwise Procedure described by Contento.⁹⁹ This approach provides a planning framework for nutrition education and incorporates theory into the planning process and is similar to the approach presented by Gilbert, Sawyer, and McNeill (2015).¹⁰⁰ The Stepwise Model incorporates logic with a stepwise procedure designed to apply theory to program development and develop strategies for program implementation.⁹⁹

The Stepwise Model includes six steps that fall into one of three categories: Input Output, and Outcomes⁹⁹. These steps are outlined then described in detail below.

Input:

1. Choose issues/concerns; Choose behaviors: Analyze issues and audiences to state a program behavioral goal
2. Identify determinants/mediators: Identify potential mediators to achieve program behavior goals

Output:

3. Select Theory: Select theory, philosophy and components
4. State Objectives: State objectives for mediators
5. Design Activities: Design theory-based strategies and activities for mediators

Outcomes:

6. Plan Evaluation

Step 1: Stepwise Procedure

After an issue or concern is identified, a needs assessment is one of the first steps to program planning.¹⁰⁰ The assessment can be either informal, through personal interactions and conversations, or formal, where quality of life related to the problem is systematically assessed.¹⁰⁰ Oftentimes this assessment is done through focus groups, surveys, and a review of recent literature.¹⁰⁰ These tactics are beneficial in understanding the problem, its associated behaviors and practices that contribute to the issue of concern, and common themes that need to be addressed in the goals and objectives of the program.^{99,100} Once the needs assessment is completed, the next step is to determine program-specific behavioral or action goals. Nutrition education is known to be more effective when it focuses on specific behaviors or practices, thus the goals should be stated accordingly.⁹⁹

Health Literacy. Health literacy (HL) contributes to an individual's health outcomes and an important behavioral capability that affects an individual's ability to carry out a particular behavior or behavioral goal.^{99,101} The Institute of Medicine report, "Health Literacy: A Prescription to End Confusion," states HL is "the degree to which an individual can obtain, communicate, process, and understand basic health information and services to make appropriate health decisions."¹⁰² The US Department of Health and Human Services recommends that HL improvement be incorporated into the mission, planning, and evaluation of health education program development.¹⁰³ Understanding HL

levels may provide key insights into an individual's potential barriers to self-management of disease and health-promoting behaviors.¹⁰⁴ Donovan-Kicken, et al. tested a model that proposed SE is a mediator of the association between HL and patients' understanding of informed consent documents.¹⁰⁵ They found that lower HL results in lower SE, which predicted patients feeling less well informed and prepared for a medical procedure, as well as being more confused about the procedure and the associated risks. HL does not correlate with intelligence, as individuals may function well at home, school, or in the work environment, but find that reading, listening, and analytical skills don't function well in the healthcare setting.^{100,105} Nutbeam identified an HL model with three distinguishing levels: functional HL, the basic level in which an individual would use basic reading and writing skills; interactive HL, including advanced cognitive and literacy skills that are used with social skills are used in daily activities; and critical HL, more advanced cognitive skills used to critically analyze information and to use this information to affect greater control.¹⁰⁶ He argued that improving HL through increased access to information and the individual's ability to effectively use the information was the key to empowerment.

The "Health Literacy of America's Adults (HLAA): Results From the 2003 National Assessment of Adult Literacy (NAAL)" report assessed three domains related to health or healthcare services: clinical, preventative, and navigation of the health system.¹⁰⁷ Results were reported using one of four literacy levels: "Below Basic," "Basic," "Intermediate," and "Proficient." Most adults (53%) had an "Intermediate" level of HL, meaning that they could perform moderately challenging health literacy activities

and interpret and apply more complex health-related information. Only 12% of adults were at a proficient level, while 22% were at the basic level and 14% were below basic.

Demographics can have a significant impact on HL levels. The HLAA found women scored an average of six points higher and were significantly more likely to fall within the “Intermediate” level and less likely to have a “Below Basic” HL level than men. White and Asian/Pacific Islanders were also more likely to be “Proficient” than Black, Hispanic, American Indian/Alaska Native, and Multiracial adults. Hispanics had the lowest average literacy score and the score is likely worse than reported, due to an exclusion of those with language barriers. Also, similar to findings from the National Center for Education Statistics report from the Program for the International Assessment of Adult Competencies in 2016, older adults (> 65 years of age) had lower average literacy levels.^{107,108} Not surprisingly, higher levels of educational attainment are correlated with increasing levels of general and health literacy.^{107,108}

HL levels affect how and where an individual seeks out health-related information. Those at lower HL levels are less likely to turn to print sources such as the internet, magazines/newspapers, brochures, and books.¹⁰⁷ The higher the HL level, the more likely the individual is to seek health information from the internet.¹⁰⁷ Those at lower HL levels were more likely to obtain their health information from television and radio and less likely to receive it from healthcare providers.¹⁰⁷ The “National Action Plan to Improve Health Literacy” reported that the use of technology is essential to improving HL.¹⁰⁹ The plan stated healthcare practitioners should “Use technology, including social

media, to expand patients' access to the health care team and information" and that researchers should "explore technology-based interventions to improve health literacy."

The summary of "The Surgeon General's Workshop on Improving Health Literacy" proceedings highlighted the importance of factoring in current communication characteristics of the healthcare system and evaluating where improvements can be made, specifically the heavy reliance on print materials.¹¹⁰ Since data from the NAAL survey found individuals with lower HL were less likely to get their health information from print sources,¹⁰⁷ practitioners and researchers need to focus on alternative approaches to communicate health and nutrition information. While it can be argued that internet-based programs may be more beneficial for those at higher HL levels, there is significant potential for those at lower HL levels. The use of multimedia allows complex or confusing information to be presented in a simple format and understood by those with low HL and can improve access to services.¹¹¹ This is particularly true for specialized services with limited well-trained practitioners, such as educating patients on the LFD.

Research has shown that HL levels have a direct impact on health outcomes. Low LH was significantly associated with worse glycemic control in a study of patients with Type 2 Diabetes (T2DM).¹¹² In this study, the role of knowledge and a patient's Stage of Change (SOC) within the TTM had an indirect effect of HL on glycemic control. The authors concluded, "dietary knowledge significantly motivated participants to move into the later stages of behavior change, which in turn improved the outcome of glycemic control." Another study of patients with T2DM found patients with high HL had improved diabetes outcomes, were less likely to have negative emotions and distress

related to diabetes, and were more likely to have a positive outlook of their diabetes and healthy coping skills. However, all patients in this study benefitted from participating in a diabetes self-management education program. Health consumers interested in engaging in internet-based self-management programs should be able to not only find accurate and reliable information, but understand and utilize it as well.^{106,113}

Studies have found that video can be an effective tool to reach those with limited HL.^{114,115} Video does not rely on reading fluency, thus providing an advantage for individuals with low literacy levels.¹¹⁶ Using pictures along with texts and spoken direction, as can be accomplished in a video presentation, has been shown to be beneficial to all patients, but especially those with low HL.¹¹⁷ Video and images can also be an important tool, as they lessen the burden on working memory.¹¹⁶

Including narratives in multimedia interventions is another useful strategy to engage participants and promote behavior change.¹¹⁸ In a trial of narrative versus information videos, the use of narrative videos improves likeability, recall, and decreases counter-arguing. Narrative videos significantly reduced barriers to positive health behaviors (e.g. mammography follow-up) in women with less than a high school education, thus decreasing health disparities, and trended toward significant improvements in women who were lacking in support or were distrusting.¹¹⁴ The public perception of scientists and researchers includes the belief that while highly competent, they lack warmth, an essential for building trust – a critical element of communicator credibility.¹¹⁹ When scientists and researchers teach and publicly share information, it can help to further show their trustworthy intentions.¹¹⁹ Including narratives in teaching has

the potential to increase trust and relatability. Internet-based programs featuring researchers or scientists along with personal narratives or their own or of patients could lead to improved health outcomes.

Step 2: Stepwise Procedure.

Step One involves getting to know your audience from a needs assessment, while Step Two includes understanding them at a deeper level.⁹⁹ In this step, the researcher explores why individuals do what they do and how they can change their behaviors.⁹⁹ In this stage, you explore the social and cultural context, life stage, and family situation of your intended audience before diving into potential mediators of behavior change. The mediators are the primary targets of nutrition education and fall into two main categories: personal psychosocial mediators, including the beliefs, attitudes, feelings, and self-efficacy of the individual, and environment-related factors.⁹⁹ In terms of a LFD intervention, environmental factors to consider includes what type of grocery stores or restaurants do they have access to, is their environment conducive to cooking, and do they have access to (and insurance coverage for) an RDN. Self-efficacy, self-regulation, and strategic planning are some key mediators identified in diet and nutrition-related interventions.^{120,121}

Step 3: Stepwise Procedure

The goal of Step 3 is to determine a theory or model to guide the development of the program, clarify the program philosophy, and decide on the various program components. When selecting a guiding theory, it is important to consider how ready the audience is to take action. Does the program need to first increase awareness of the issue

or concern or motivate the audience to act? The researcher also needs to understand how the program will address both personal and environmental mediators of behavior. This can include self-regulation skills, including planning and monitoring¹²²; the method and location of delivery of the nutrition education and what support is available in those contexts⁹⁹; and details of the individuals' economic environmental factors, including perception of price and accessibility of food¹²³. Finally, it is important to consider what the existing literature divulges about the strength of the evidence of the theory constructs or specific mediators of the targeted behavior. Incorporating key learnings from Step 2 will guide the choice of theory.⁹⁹

Health behavior theory is key to the development of health education programs. Theories serve as a link between the program objectives and methods to provide strategies for the intervention program.¹⁰⁰ Theories provide a better understanding of the targeted health behavior and can explain the dynamics of the behavior, processes of change, and what affects external factors might have on the behavior.¹⁰⁰ When interventions targeting health behaviors include a theory-based approach, the educator can better understand what contributes to or impedes the change in the targeted health behavior.¹⁰⁰ Making a theory explicit when designing a program because it helps to determine which specific program components might or might not be useful. It also aids in choosing appropriate teaching activities and evaluation instruments.⁹⁹

Transtheoretical Model and Self-Efficacy. The Transtheoretical Model (TTM) can be a useful predictor of diet-related self-efficacy.¹²⁴ The TTM, also known as the Stages of Change Model, was developed by Prochaska and DiClemente¹²⁵ and is based

on the notion that change is a process, not an event. It includes a number of constructs including Pros and Cons from the Decisional Balance (DB) and Self-Efficacy (SE), and the Processes of Change (POC) beyond the stages of change, which represent activities or experiences that individuals engage in during behavior change.¹²⁶ The model is useful for understanding the decision-making process in dietary behavioral change.¹²⁷ In this model, a person progresses through a series of five stages toward behavior change: precontemplation, contemplation, preparation, action, and maintenance.¹⁰⁰

Precontemplation is the stage in which an individual is not considering changing a behavior or practice at the present time and generally not for the next six months.¹²⁸ Those who have previously tried and failed at a particular behavior change may also fall into this stage, if they no longer want to pursue the change. Often individuals in this stage are considered uninformed of the potential consequences of not making the behavior change and/or lacking motivation and, thus, not ready for health promotion programs. However, Prochaska, Redding, and Evers¹²⁸ argue that such programs might not be designed to meet the needs of these individuals nor provide the necessary motivation.

In the contemplation stage individuals recognize a need and begin to consider a behavior change within the next six months.¹²⁸ Those in this stage are caught between awareness of both the positive outcomes of the behavior change, as well as the time, energy and resources required to make the change.⁹⁹ This thinking can result in conditions known as “chronic contemplation.”¹²⁹ Programs designed for this stage should focus on motivation instead of action.⁹⁹ The preparation stage includes individuals who plan on making a change within the month and have typically formulated a plan of

action.¹³⁰ People in this stage are motivated and ready for action-oriented strategies to help them achieve their desired behavior change.⁹⁹

Individuals who have engaged in a new behavior within the previous six months are considered to be in the action stage.⁹⁹ These individuals have adopted practices to achieve the desired change, though they may be on a small scale.⁹⁹ However, in the context of research, it is important that these changes are clearly defined and based on established criteria whenever possible.¹²⁸ In the context of an elimination diet, small changes are not the target. On the LFD, ideally, total elimination of high FODMAP foods would be achieved during the elimination phase, though compliance is not clearly defined and has been set by some as following the LFD at least 50% of the time.⁵⁸

The maintenance stage is the period when individuals have maintained a behavior change for at least six months and want to avoid a relapse.⁹⁹ Those in this stage are more confident in their ability to continue their new behavior long-term and are less affected by temptation.¹²⁸ Temptation represents the urge to engage in a less healthful behavior in difficult situations and is strongest in the contemplation and preparation stages.⁹⁹ The elimination phase of the LFD would certainly present many opportunities for temptation given the highly restrictive nature of the diet. A sixth stage, termination, occurs when an individual no longer gives into temptation and experiences full self-efficacy.⁹⁹ However, while it is sometimes considered part of the Stages of Change when addressing addictive behaviors, it is not practical or applicable for most dietary intervention.⁹⁹

Within the Stages of Change, individuals move in and out of stages as they work on behavior change, the behavior change process is not considered linear but rather

cyclical in nature. Ideally, an individual would progress to and remain in the “Maintenance” phase where the behavior change has been adopted as a lifestyle.¹⁰⁰ Because the TTM “meets individuals where they are” in the behavior change process, this model can be appropriately applied to the development of an internet-based LFD education program. Due to the very strict nature of the elimination phase of this diet, most participants are likely to experience a relapse in which they consume a high FODMAP food. The TTM is a fluid model that allows for this movement between stages.

There are 10 processes within the POC that individuals use as they move in and out of the Stages of Change.⁹⁹ The POC is based on the assumption that individuals can apply these 10 processes to a range of behaviors and, while the 10 processes do not always apply to all behaviors¹²⁸, they are found useful in changing those that are diet-related.¹²⁷ The processes are divided into two groups – experiential and behavioral – and, in the context of diet, these groups often increase together as one progresses through the stage.¹³¹ Experiential processes include the following: consciousness raising, dramatic relief or emotional arousal, self-reevaluation, environmental reevaluation, and self-liberation or commitment.^{99,128} Behavioral processes include the following: helping relationships, counterconditioning, managing rewards, stimulus or environmental control, social liberation.^{99,128} These processes include both covert and overt activities used to progress through the Stages of Change.¹²⁸

Prochaska, Redding, and Evers¹²⁸ summarized previous work from Prochaska and DiClemente^{129,132} and concluded that in early stages, individuals rely on cognitive, affective, and evaluative processes and in contemplation and action stages individuals

focus on commitments, conditioning, contingencies, environmental controls, and support as they move into maintenance.^{129,132} Contento describes the processes of change at different stages in relation to diet-related behavior:¹³³

- Precontemplation: Processes are used less frequently than in other stages.
- Contemplation: Individuals are open to strategies capable of raising awareness and consciousness of their behavior, as well as to emotionally arousing experiences. Examples: self-assessments, listening to narratives of individuals describing their disease-related experiences
- Action: Individuals make changes through a self-liberating process and commit to change. Skills used include counterconditioning and environmental or stimulus control. Examples: Removing high FODMAP foods from their home, switching their favorite high FODMAP breakfast cereal for a low FODMAP option
- Maintenance: Here, individuals prevent relapse by using behavioral process, which can be assisted by behavior-specific nutrition education. Examples: Using self-rewards for following the diet, engaging with others who are also working on the target health behavior in Facebook groups or online chats

Two mediators of change are proposed for the TTM: the pros and cons of change or Decisional Balance and self-efficacy. In Decisional Balance, pros represent positive beliefs about the benefits of changing, while cons are the costs of the behavior change.^{99,129} Research into how an individual moves through the Stages of Change find that the cons of changing a behavior were higher than the pros in precontemplation, the

pros increased from precontemplation to contemplation, cons decreased from contemplation to action and cons were higher than pros in action.^{130,134}

Self-efficacy is the confidence an individual has in their ability to engage in a particular behavior that leads to an outcome.¹³⁵ Self-efficacy is an established construct exerting a significant influence on diet and physical activity interventions.⁹⁹ It is an important construct of both the TTM and Social Cognitive Theory,^{100,130} particularly when considering an individual's willingness to follow an elimination diet, such as the LFD. An individual's confidence can be enhanced through mastery experiences, social modeling, verbal persuasion, and the opportunity to practice a behavior in a low-stress environment.¹³⁰ SE has been adopted into the TTM model and is based upon the self-efficacy theory by Bandura.¹³⁶ Self-efficacy, behavior, and DB scales are related to the individuals Stage of Change and may vary significantly between stages.¹³⁷

Dietary behavior studies have found self-efficacy to be lowest in the pre-contemplation stage and increasing with each stage.^{135,137} Self-efficacy was first described to phase-specific in studies on addictive behavior,¹³⁸ but studies show the phase-specific approach also applies to other health behavior models.¹³⁹⁻¹⁴¹ The rationale for phase-specific self-efficacy is based on the observation that different tasks must be mastered and mindsets adopted during the course of behavior change – from motivation to initiate the behavior to maintaining the behavior change.^{99,141} Motivational self-efficacy is key in the first phase and followed by coping self-efficacy and, finally, when setbacks occur, recovery self-efficacy is vital to maintaining change.⁹⁹

Self-efficacy is also situational, varying by the environment of the behavior.¹³⁷ It is the confidence an individual has in their ability to take action and a key factor in diet compliance,¹⁴² an important factor in improving IBS-type symptoms and quality of life in individuals with functional bowel disorders.⁸⁶ The stronger the perceived self-efficacy, the more likely the individual is to begin a new behavior and continue in it until success is achieved.¹⁴³ Efforts to increase individual perception of self-efficacy in diet-based interventions can improve the likelihood of successful behavior change.¹⁴⁴

Self-regulation includes an individual's ability to regulate and control their own behavior and is important to initiating and maintaining health behavior change.⁹⁹ Self-efficacy is a key component to self-regulation.⁹⁹ Developing self-regulatory skills includes conscious control and attention, as well as the ability to cope with emotions.⁹⁹ Contento⁹⁹ noted these skills are key to food and nutrition-related practices because of the effort required, including learning to cook to control ingredients in foods. Following the LFD is easier for those who prepare food at home, as they have the most knowledge of the ingredients in the foods they are consuming. FODMAPs may not be evident in restaurant meals and convenience foods, so preparing food at home is the best choice for staying compliant while following the elimination diet.

Coping self-efficacy describes the optimistic beliefs of an individual to handle barriers and setbacks that may occur in the maintenance phase.¹⁴⁵ In some cases, and very likely in making significant dietary changes in the elimination phase of the LFD, a new behavior may be much more challenging to adhere to than was anticipated.¹³³ Those with higher coping self-efficacy are likely to expend more effort and persist longer than those

with lower levels and, when setbacks do occur, they recover faster and remain committed to their goals.¹⁴⁵ Individuals need to understand that relapsing by eating a high FODMAP food doesn't spell the end of the diet and that they are capable of making adjustments and getting back on track. An individual's inability to manage stressful life conditions, potentially including strict elimination diets, can be debilitating and result in impairment of the immune system, the development of physical disorders, and an acceleration of disease progression.¹⁴⁶ Recovery self-efficacy, an individual's belief that they can get back on track after a setback is particularly important within the context of the TTM, as it is expected that individuals will have setbacks on a strict elimination diet.¹³³

A prediction model was developed for adoption and maintenance of health behaviors based on four longitudinal trials on seat-belt use, dental flossing, dietary behavior, and physical activity.¹⁴¹ The study was undertaken to investigate what proximal factors might affect the gap between intention and behavior. The study found that self-efficacy and strategic planning are immediate predictors of behavior, which is supported by previous work.^{147,148} Another study found that without sufficient self-efficacy, planning might not result in desired behavior changes.¹⁴⁸ Intentions translate into action more often with an action plan, which can facilitate behavior change.¹⁴⁸ Planning mediates behavior change when self-efficacy is higher. Self-efficacy is a key social cognitive variable in the Health Action Process Approach (HAPA) Model, as it has been shown to be the universal predictor of transition between the three stages of the Model: preintention, intention and action stage.¹⁴⁹ Low levels of planning were found to predict relapse into the preintention or intention stages.

There are four key factors known to influence self-efficacy: previous experience, vicarious experience, social persuasion, and emotional arousal.¹⁵⁰ Generally the strongest influencer on the formation of self-efficacy is self-mastery, while the other factors vary in strength and importance.¹⁵⁰ Resilience in self-efficacy is developed through perseverance in the face of obstacles.¹⁴⁶ When individuals face these obstacles, and realize they can succeed, they are more likely to persevere and rebound from setbacks.¹⁴⁶ Providing opportunities for individuals to master a particular task, skill, or display mastery of knowledge is important in building self-efficacy.¹³³ Social modeling can have a significant impact on self-efficacy through the vicarious experience of social models.¹⁴⁶ Nutrition educators can use food demonstrations with clear instructions as a way to model behavior and improve self-efficacy.¹³³ If, however, the individual cannot relate to the one doing the modeling, self-efficacy is not impacted.¹⁴⁶ Social persuasion can be achieved by verbally expressing to an audience or individuals that they have what it takes to master the skill or activity.¹⁴⁶ While persuasion can be very effective in boosting self-efficacy, boosts in self-efficacy that are unrealistic can convince individuals that they lack the skills or knowledge necessary to make the change and, in turn, cause them to give up more quickly.¹⁴⁶ For instance, trying to convince an individual that the LFD would be an easy diet to follow because “I did it with no problem” would certainly set the person up for failure. Emotions are modifiers of self-efficacy with positive moods enhancing self-efficacy and negative or despondent moods diminish self-efficacy.¹⁴⁶ The sources of self-efficacy are guides to understanding an individual’s motivation to perform

a task and are useful for planning programs intent on affecting self-efficacy and ultimately health related-behaviors.¹⁵⁰

Numerous studies of internet-based programs have associated self-efficacy with improved diet and clinical outcomes.^{122,151-153} Warziski et al.¹⁵¹ demonstrated that high self-efficacy enhances an individual's ability to change eating habits and has a positive impact on diet compliance and weight loss. An internet-based nutrition and physical activity program for college students improved students' motivation to change eating behavior, social support, and self-efficacy for dietary change while increasing fruit and vegetable intake.¹⁵² An internet-based program for patients with diabetes that sought to assess self-care (glucose monitoring, diet management or physical activity) and self-efficacy of participants found self-efficacy to be a moderator for diabetes-related self-care.¹⁵³ The study also found that the initial level of self-efficacy was related to the level of improvement in self-care. Those with initially lower self-efficacy experienced the greatest improvements in self-care as a result of the internet-based intervention.

Anderson-Bill, Winett, and Wojcik¹²² examined demographic, behavioral, and psychosocial characteristics of participants in the "Web-based Guide to Health" program. Participants were recruited online; were middle-aged, well-educated, upper middle-class women whose poor health behaviors put them at risk for chronic disease and cancer.¹²² In this study self-efficacy was predictive of healthy levels of physical activity and dietary fat consumption but not of intake of fiber, fruits, and vegetables. The authors concluded that the success of internet-based nutrition and physical activity programs might depend on whether participants are able to improve self-efficacy for behavior change. Also, it was

noted was noted that programs should provide social support, a strong contributor to better nutrition. Goal setting, tracking, and providing feedback on behaviors targeted by the programs were also found to be key to their success.

Internet-based, LFD education programs that ask for individuals to take action soon after the program launches should target those who are ready to change and identified as being in the Preparation or Action stage with an adequate self-efficacy to make the desired behavior change.^{99,154} One study assessing differences in fat consumption and psychosocial factors among 507 adults found that attitude and social support were greatest in those in the preparation or action stage and self-efficacy was lowest in the contemplation and preparation stages.¹²⁴ Another study designed to increase fruit and vegetable consumption confirmed that attitudes were the most positive in the preparation and action phases, and reported fruit and vegetable intake and self-efficacy were more positive in the action and maintenance phases.¹⁵⁵ Assessing the stage of research participants during the recruiting phase could potentially lead decreased dropout rates, improved outcomes. Stratifying results of dietary behavior studies by stage at study entry and conclusion could also help provide insight into the types of participants that might most benefit from the interventions.¹⁵⁶ The further development of stage-based nutrition education is recommended.^{124,155}

Step 4: Stepwise Procedure

Step 4 in designing theory-based nutrition education includes stating measurable objectives for the determined psychosocial and environmental support mediators.⁹⁹ These objectives are specific to the program goals established in Step 1 and are general

statements on how to achieve these goals. Process objectives are those that focus on what happens on the path to the outcome objectives and may include measuring engagement, self-assessments, fidelity, participant satisfaction, etc.¹⁰⁰ Outcome and impact objectives focus on what the nutrition education program hopes to accomplish in terms of knowledge, attitudes, skills, and behaviors.¹⁰⁰ The *Taxonomy of Educational Objectives* characterizes objectives into the three categories of the human experience or domains: cognitive (recall and synthesis of information), affective (change of attitude), and psychomotor (performance of a physical skill).^{99,100,157} Each of these domains includes levels of complexity of learning tasks (cognitive), levels of engagement or integration (affective), or levels of performance and skill (psychomotor) that should be considered in setting objectives to achieve goals.^{99,157,158}

Step 5: Stepwise Procedure

Step 5 of the Stepwise Procedure model includes designing activities and strategies based on the theory selected in order to accomplish program goals and objectives.⁹⁹ Creating an educational plan helps to determine the best sequence for the educational activities of the program.⁹⁹ Educational principles, including reinforcement, repetition, and practice should be included in planning the learning methods.¹⁰⁰ Dynamic engagement of participants in nutrition education programs facilitates learning and is the focus of learner-centered education. Program activities need to move beyond simply providing information, as learning is the “interaction between the learners (program participants) and the activities educators have designed that results in active contemplation about issues, changes in how participants view the world, an examination

of their values, and changes in their expectations, attitudes, and feelings about food and nutrition, and indeed, in their actions.”⁹⁹

Contento⁹⁹ suggests a model for strategy development based upon motivational and action phase mediators. In the motivational phase, the objective is to increase motivation for those considering action then to activate decision making. Strategies proposed for enhancing motivation include enhancing risk perception (e.g. narratives, impactful statistics), self-assessments (e.g. 24-hour recall, FFQ), motivational presentations and activities, affect-based messaging, food tastings or demonstrations, and role models. Strategies proposed for facilitating action include decisional balance worksheets or discussions, evaluating issues, and activities to clarify values. Action phase mediators include those that contribute to initiating action or maintaining action and strategies focus on either facilitating the ability to act, including increasing self-efficacy, or enhancing self-regulation. Proposed strategies for facilitating action include goal setting and creating an action plan, developing knowledge and skills, modeling and guided practice for food-related skills, and analyzing and critically evaluating issues. Proposed strategies for improving healthy routines and personal agency include goal maintenance-focused activities, encouragement of routines, creating personal food policies, teaching how to be a personal advocate, and organizing groups for a common purpose.

In a review of 21 studies using technology-based interventions, the following five components were identified as key to successful interventions: self-monitoring, counselor feedback and communication, social support, use of a structured program, and use of an

individually tailored program.¹⁵⁹ Similarly, when participants in an LFD intervention were questioned as to the most important factors contributing to diet compliance and self-efficacy, they ranked written information highest, followed by dietitian consultation, support of friends and family, cookbooks, and online information.⁹⁰

Internet-based interventions are only effective if they are utilized, thus research into ways to increase usage and exposure is important. Intervention characteristics including peer and counselor support, email/phone contact, and updates of the intervention website enhanced exposure.¹⁶⁰ Internet-based health or nutrition interventions sometimes incorporate social network sites into the program design, though research on the effectiveness of this approach is limited due to small effect sizes, variety of methodologies, low engagement and retention.¹⁶¹ However, 9 of the 10 studies assessed in a review reported improvements in some health-related outcome or health behavior and the authors noted that research in this area is in its infancy.¹⁶¹

Step 6: Stepwise Procedure

Step 6 of the Stepwise Procedure is to plan the program evaluation.⁹⁹ Products of planning the program evaluation include a list of measures and indicators for outcomes and procedures and measures for process evaluation.⁹⁹ A good evaluation can help researchers and program planners determine whether and how interventions affect behavior and environmental mediators and how mediating variables affect the targeted nutrition-related behaviors.⁹⁹ This information sheds light on why the intervention may or may not have worked and provides insight for future program development.⁹⁹

There are three main types of program evaluations: formative or pilot testing, outcome, and process. A formative evaluation or pilot test is used during early stages of program development to develop or improve programs.⁹⁹ This evaluation helps researchers understand if the messages are understood as communicated, objectives are clear, relevant issues are adequately addressed, strategies and activities are engaging and feasible as presented, and that findings from the evaluation will be able to be applied.⁹⁹ Outcome evaluations, also called effect impact evaluations, are conducted at the conclusion of the program and are used to provide information on the effectiveness of the program or intervention.⁹⁹ The evaluation is based on previously determined program goals and objectives.⁹⁹ They involve behavioral-focused outcomes that assess changes to the targeted behaviors⁹⁹ (e.g. diet compliance for the LFD). Outcome evaluations also assess whether mediators of targeted behaviors were affected by the intervention⁹⁹ (e.g. assessing changes in self-efficacy pre-/post-intervention). A LFD intervention would also assess physiological or health outcomes, in particular how symptoms or quality of life were impacted by the intervention (e.g. pre-/post-intervention changes in IBS-SSS and the IBS-QOL). Process evaluations investigate if the program or intervention was delivered to the intended audience and if it was delivered as designed.⁹⁹ They can target both behavioral and environmental factors with the hopes of uncovering what did or did not work and why.⁹⁹ Process evaluations can help assure funders and program participants that the intervention or program delivered is high quality and accurately targets the intended population.¹⁶² Also, the cost-effectiveness of interventions is an

important part of intervention planning and evaluation and can be assessed through the process evaluation.¹⁶²

LFD DELIVERY

RDNs are the most appropriate choice for IBS diet education.^{94,163} Also, it is important to consider the use of specialized dietitians for complex IBS diet therapies, such as the LFD, even though most gastroenterologists are opting to refer to general RDNs – likely due to availability and access.⁴⁶ Currently there is only one academic training program for RDNs on the LFD. The program was released by Monash University in 2017 and can be considered cost prohibitive for many dietitians. Also, the program is best suited for dietitians in Australia where it was developed and only briefly addresses some of the complexities and differences in foods and programs available in the US.

Gibson and Shepherd¹⁶⁴ established that standard therapy for the LFD implementation should include a minimum of two intensive, one-on-one appoints with a dietitian. Adequate patient education on the LFD is necessary as the LFD carries potential nutritional risks; including reduced intake of certain vitamins, calcium, and prebiotics.¹⁶⁵ Multiple one-on-one appoints with an RDN are both costly and time consuming. Whigham, et al.¹⁶³ trialed group versus one-on-one LFD education and found both types of delivery significantly improved symptoms and that there was no difference between the methods of delivery in terms of patient satisfaction with symptom reduction. The cost for group education was less than half of the combined cost of one-on-one education.

In addition, patients and health consumers are increasingly turning to the internet for health information.^{166,167} However, the quality of internet-based information on

gastrointestinal diseases is highly variable.¹⁶⁸ Less than half of gastroenterologists feel educational websites and smart phone applications would enhance their ability to provide diet education to their IBS patients. Lenhart et al.⁴⁶ noted that this is likely the result of a lack of awareness of resources or a physician's assumption that patients respond well to verbal communication combined with handouts.⁴⁶

A survey of patients with IBS found 92.6% had used the internet for medical information.¹⁶⁶ Patients preferred information from their physician (68%) followed by the internet (62%), then brochures (45%). Patients who used the internet were more likely to have a higher level of education, be younger, non-African-American, and have IBS-D subtype. These patients and those in another study have reported dissatisfaction with their IBS education and express that they hope to gain more information in the future.^{166,169}

Internet-based Diet Interventions

There is significant potential to both improve health and nutrition education of patients while decreasing cost to provide education using technology. Kreps and Neuhauser¹⁷⁰ reported there was a “communication revolution brewing in the delivery of health care and the promotion of health fueled by the growth of powerful new health information technologies.” Since that time, technology has improved, and reach has grown significantly as a result of social media and increased access to the internet. The authors concluded that there is significant potential for the development, adoption, and implementation of a broad range of internet-based or e-learning health applications. In order to be both effective and “humane”, these applications should be interactive, adaptable, easy to access and use for diverse audiences, and engaging.^{171,172}

Internet-based interventions are not to be confused with health information websites and can be differentiated based on several factors. For example, they are generally very structured; frequently based on face-to-face interventions; self- or semi-self-guided; tailored to the user; interactive; enhanced by graphics, animations, audio, and possibly video; and structured to allow for follow-up and feedback.¹⁷³ From the provider's perspective, internet-based interventions offer the advantage of a broad reach, cost-effectiveness, and the ability to tailor the intervention to an individual or group's needs and still scale it for public health.^{111,174} Benefits to the participant of internet-based interventions include convenience, easy accessibility considering both time and place, and allows an individual to maintain privacy and anonymity.^{111,174}

In 2010, the American Heart Association (AHA) published a review and scientific statement on interventions promoting physical activity and dietary changes to promote cardiovascular health.¹⁴⁴ The review covered the main types of interventions and key components of effective interventions. Citing a number of studies, the AHA panel reported internet-interventions were identified as a strategy with several potential benefits: "ability to reach many people with a single posting; easy storage of large amounts of information; ease of updating information; ability to provide personalized feedback; cost effectiveness and convenience for users; ability to reach people suffering from isolation or conditions that cause them to feel embarrassed or stigmatized; timeliness of access; user control of the intervention; supplier control of the intervention; and ease of adapting information for specific populations."

Two studies have utilized internet-based applications to assist patients in self-monitoring their IBS symptoms;^{57,89} however, no studies to date have examined the potential effectiveness of an internet-based LFD education program. Aside from the LFD, other internet-based nutrition education programs have proven to be as effective in improving outcomes and self-efficacy to follow a diet or plan as face-to-face programs¹⁷⁵⁻¹⁷⁷ with the potential for significant cost savings.¹⁷⁸ Internet-based programs have shown to result in improvements in specific dietary components including increased fiber and fruit intake and decreased saturated fat as a percent of total energy intake.¹⁷⁹ Clinically meaningful decreases in body weight and blood pressure were the result of an internet-based menu planning program.¹⁸⁰ Additionally, a study of an internet-based, diabetes education program combined with communication with a nurse via video conferencing resulted in significant increases in both knowledge and diet adherence.¹⁸¹

While exclusively internet-based interventions have resulted in positive health outcomes, those benefits appear to be enhanced with a multicomponent approach wherein participants receive tailored feedback.^{182,183} Rothert et al.¹⁸² reported a tailored, internet-based weight loss system resulted in significantly greater weight loss compared to an information-only program. Tate et al.¹⁸³ evaluated the effectiveness of human e-mail counseling, computer-automated feedback counseling, and no counseling in an internet-based weight loss program and found that both the tailored feedback and human email counseling both resulted in significant reductions in weight compared to the control group and that the reductions were similar between groups. Two additional studies

reported a combined approach of an internet-based program and e-counseling resulted in greater weight loss than an internet program alone.^{184,185}

Mixed results are reported when comparing in-person versus internet-based interventions. Krukowski et al.¹⁷⁸ found that weight loss was significantly greater in the in-person group, but there was no difference in Life Years Gained (LYG). A cost effectiveness analysis revealed that when incorporating participant time costs in an economic assessment of a behavioral weight loss intervention, the internet-based delivery could be a more cost-effective approach to obesity treatment.¹⁷⁸ An earlier study by Micco et al.¹⁸⁶ found no difference in weight loss between groups when comparing an internet-based intervention to the same intervention combined with in-person support. The ManUp study provided information on nutrition and physical activity to middle-aged men with the intent to examine the difference in delivery modes.¹⁸⁷ The study found both the print and internet-based education improved dietary behavior and physical activity in participants with no significant differences between groups.

Effective e-learning and internet-based programs must be based around the principles of nutrition-related program development and effective e-learning education including health behavior theory. Murray proposed the following characteristics of internet-based interventions that can improve adherence: “a strong theoretical foundation, perceived personal relevance to the user, perceived effectiveness, tailoring, persuasive technologies, credibility, social networking, and regular “push factors” including human support and/or periodic prompts.”¹¹¹ When assessing e-learning effectiveness, Brown and Charlier¹⁸⁸ suggested that comparing the effectiveness of e-learning to classroom or

face-to-face education offers little theoretical or practical value due to the potential of e-learning to increase access to resources that might not be available in the absence of technology. Instead, the central questions should be “how can we increase use of e-learning resources?” and “how can we design e-learning to maximize learning?”¹⁸⁸

Research into organizational and academic e-learning has found that e-learning initiatives can be as effective as face-to-face training and that when differences in effectiveness are found, the cause is often the motivation of the learner, self-efficacy of the participant, perceived usefulness of the instruction, or instructional characteristics.¹⁸⁹⁻¹⁹² When examining factors associated with successful e-learning programs, self-efficacy and perceived usefulness specifically impact course performance, satisfaction, and instrumentality – the likelihood that knowledge, skills, and abilities gained would lead to outcomes.¹⁹⁰ In addition, course interaction was tied to performance and satisfaction; and social presence was linked to satisfaction and instrumentality.

Salas, DeRouin, and Littrell developed a list of distance learning guidelines,¹⁹³ which was restated in the 2013 review by Brown & Charlier¹⁸⁸ who noted that e-learning was currently the most common form of distance learning.¹⁸⁸ The following is a condensed summary of the guidelines adapted for health-related e-learning:

- Only provide e-learning when it can meet the learner’s needs;
- Consider human cognitive processes when designing distance learning programs;
- Enhance the learning experience by including both graphics and text in the presentation of the topic; include learning games; keep learners engaged;
- Offer a blended approach;

- Allow for interaction between the practitioner and learner;
- Target e-learning to those that are proficient in the type of technology utilized or provide training;
- Allow learners control over certain aspects of the program, but consider maintaining control over pacing, sequencing, and providing optional content;
- Guide learners through the e-learning program to help them understand core elements of the program and help them move through it more easily;
- Make the program user-friendly by dividing it into small, manageable sections and limiting webpage content to 200 words.¹⁸⁸

Murray¹¹¹ identified three challenging areas in developing and evaluating internet-based programs: equity, effectiveness, and implementation. The equity of internet-based health interventions is debatable to a point. While access is still limited and encumbered by literacy and numeracy, the global trend is toward an increased use of technology. Studies assessing the effectiveness of internet-based interventions, particularly those that include social media and those that involve dietary behavior change, are still limited and many report small effect sizes.^{111,174} Murray¹¹¹ recommends considering cognitive (understanding, intention, and self-efficacy), behavioral (where positive changes made in behaviors of interest), and emotional (factors affecting quality of life) outcomes when assessing program effectiveness. The review covers the benefits of applying a theoretical framework to the development of internet-based interventions noting that these interventions are more likely to be effective than those without a theoretical foundation. Also, Murray iterates the importance of identifying key constructs

of the theory and determining how the intervention will act on those constructs and how the constructs will be evaluated.

CONCLUSION

IBS is a chronic disease affecting millions of Americans. The symptoms can significantly affect quality of life and be very costly to patients, their employers, and society. Many patients are dissatisfied with their current medical treatment and seek alternative therapies to manage their symptoms. A significant number of IBS patients associate their symptoms with particular foods and have attempted to manage their symptoms through diet.

The LFD has been studied in a number of clinical trials and found to be effective in improving both IBS-related symptoms and quality of life in patients. The LFD includes a strict elimination phase, followed by a systematic reintroduction of high FODMAP foods then an adapted phase for long-term symptom management. RDNs are the most qualified healthcare practitioner to educate patients on the LFD; however, there are a number of barriers to RDN-led, LFD education. There are a limited number of RDNs that are specially trained, and physicians seldom refer IBS patients to RDNs for counseling.

Internet-based diet and health education programs are growing in popularity, as more patients are engaging in chronic disease self-management. While the research into the development, evaluation, and implementation of internet-based diet education programs are still in its early stages, key concepts have been identified that could increase effectiveness of these programs. Research suggests the most effective nutrition and health education programs are built on a foundation of health behavior theory. TTM and, in

particular its self-efficacy construct, provide a theoretical framework to develop and assess these programs with evidence linking increased self-efficacy and SOC with improved outcomes. From a public health perspective, internet-based programs provide a number of benefits including increased reach, cost-effectiveness, accessibility, flexibility, and the potential to improve HL. There is a significant number of people affected by IBS and its effect on their quality of life, the number of barriers to traditional diet therapy, and opportunities associated with internet-based programs, well-designed, internet-based LFD education programs could lead to great improvements in public health and healthcare cost savings.

CHAPTER III

METHODOLOGY

Three phases of this study are described below. Phase One includes the needs assessment, overview of the program development, and an informal pilot test of The FODMAP Fix program. Phase Two describes the study in its original design: a four-week, randomized, controlled trial, as well as a description of why the study failed. Phase Three details the study in its present form: a two-week trial with repeated measures, as well as the follow-up surveys developed and deployed to assess the high dropout rate of the present study.

PHASE ONE: NEEDS ASSESSMENT AND PROGRAM DEVELOPMENT

The central issue for this dissertation research – the need for affordable, accessible, credible LFD education for those with IBS – was identified through course study, informal conversations, and personal experience. Upon issue identification and following the Stepwise Procedure, a needs assessment (“Irritable Bowel Syndrome and Diet Survey”) was conducted as part of the first step in the development of The FODMAP Fix program. The assessment included a review of the existing literature focusing on both the LFD and the use of technology in health programs. Informal interviews were also conducted with members of the Teaching and Learning with Technology staff at Texas Woman’s University to determine the best platform to house

the online program, recommended length of videos, style of videos, content layout, and advice on videography and editing. Next, a formal online survey was developed and launched in May 2018 via PsychData, which served as both part of the needs assessment and a recruiting tool for future studies. The survey was developed at a 6th grade literacy level.

The needs assessment sought to gather the following:

- What information physicians were providing to participants regarding diet for IBS symptoms;
- If participants were being referred to RDNs and, if so, what advice they were receiving from them;
- What was the participant's level of satisfaction with their current IBS treatment;
- How did IBS affect their HRQOL;
- How knowledgeable were participants on the LFD;
- What educational and environmental factors might affect their food choice and ability to change their behavior; and,
- Where participants were in the Stages of Change model.

Population and Sample

The study population was men and women 18 to 65 years who identified as having IBS, as people over 65 are more likely to have additional conditions that might affect outcomes.¹ The sample consisted of a convenience sample of student, faculty, and staff Texas Woman's University. Participants were recruited via bulk email through

TWU and a flyer was advertised via the researcher's social media accounts. A link to the PsychData survey was included on the flyer and in emails.

Self-reported demographic, medical, and personal decision-making data around diet were collected from each participant. Participants were also asked if they would like to be contacted for participation in any future IBS and diet-related research studies. Those who indicated they were at least at the contemplation level of the Transtheoretical Model were invited to provide their email address in order to be contacted for information on this IBS and LFD research study.

Protection of Human Subjects

The study proposal was submitted to the Institutional Review Board of Texas Woman's University, Denton Campus. Informed consent was obtained prior to the start of the survey. The survey was anonymous and participants were not required to disclose their identities. Email addresses were collected through a separate survey, thus identifying information was not connected with the survey. Contact information for the principle investigator (PI) and research advisor were included on the survey for participants, who had the option to email their queries to either researchers before, during, or after participating in the survey.

Risks to the survey included the loss of confidentiality and time. Confidentiality was in place throughout the survey, but had the potential for loss in the case of interaction between participants and researchers via email. Participants were informed of this potential loss. Participants were not required to disclose their identities. The researcher did not discuss contents of this interaction/emails with anyone. The loss of time is a

factor as participants as the estimated maximum time of 20 minutes could be required to complete the online survey. The survey was designed to take a minimal amount of time. Survey settings were such that if left incomplete, it would reset and participant will not be able to resume where they left off.

Electronic data were stored in PsychData and were password protected. Only aggregate data were reported. Data collected are maintained in locked file cabinets in a locked file in the office of the researcher's advisor and will be destroyed via a shredder at the end of five years. The electronic data in the computers were deleted and emptied from the recycle bin.

Data Collection and Analysis

After receiving feedback from the doctoral committee on the survey tool and Institutional Review Board (IRB) approval, recruitment began as described above. Potential participants who followed the link to the PsychData survey were provided additional information about the study in written form and provided informed consent through answering a survey question stating their willingness to participate in the research survey. Participants were then screened by asking if they had IBS and if they were between the ages of 18 to 65. Birth year was also collected later in the survey to confirm eligibility. Eligible participants were directed to the survey (see Appendix). Data were analyzed in Excel version 15.37.

Needs Assessment Survey Results

Results of the survey provided important information used to develop The FODMAP Fix program (see Appendix). Data from the survey focusing on the role of diet

in the treatment of IBS were evaluated.² There were 148 surveys completed and 12 partial responses submitted. Most (93%) of respondents were female. Ages ranged from 19 to 65 years with an average age of 36 years. Respondents were predominantly Caucasian (73%) with 8% being black or African American, 9% Hispanic, and 10% other. IBS-subtypes were fairly evenly distributed with 37% identifying as diarrhea-predominant, 28% constipation-predominant, and 35% with both constipation and diarrhea. Seventy-one percent reported they were diagnosed by a physician, nurse practitioner (NP), or physician's assistant (PA), 4% were diagnosed by another healthcare practitioner, and 25% were self-diagnosed.

Most respondents (57%) reported they believe their IBS symptoms were related to what they ate with another 33% unsure if diet and symptoms were correlated. Ninety-two percent of respondents attempted to manage their IBS with dietary changes and 81% reported currently avoid foods due to perceived sensitivities, which was very similar to previously published findings from Bohn et al.³ that found 84% of IBS patients avoided at least one food item surveyed. Commonly avoided foods reported in the needs assessment survey included wheat, dairy, soy, foods high in fructose, onions, garlic, and corn, which are all foods high in FODMAPs. However, most did not report following the LFD. In Bohn et al.,³ 70% of patients reported avoiding food items with incompletely absorbed carbohydrates, including dairy products (49%), beans/lentils (36%), apple (28%), flour (24%), and plum (23%).

While 55% reported that their doctor prescribed a specific diet or changes to their current diet to help manage their IBS, less than 7% of those patients who saw a physician,

NP, or PA were referred to a RDN for their IBS symptoms. The few that did see an RDN reported the most common diet advice included avoidance of FODMAPs, caffeine, alcohol, gas producing foods (beans, cabbage, onions), and to eat smaller, more frequent meals. Twenty-nine percent reported the diet advice “really helped my symptoms” and 71% said it “helped a little.” Diet changes had their greatest impact on gas, stomach pain, and bloating with moderate effect on diarrhea and variable effect on constipation with some reporting the changes actually made constipation worse. This is not surprising given that many foods containing FODMAPs are important sources of fiber and prebiotics that can improve constipation in some. The survey found that 89% of people knew little to nothing about the LFD; however, 34% had attempted to follow the diet. Most who attempted to follow the diet stopped because either they believed it to be too difficult or it had little effect on their symptoms. Given the general lack of knowledge, this is likely due in part to a lack of adequate diet education.

The survey sought to understand where patients with IBS typically ate. Dining out at “sit down restaurants” is fairly infrequent with 81% of respondents dining out every 5 to 7 days or less. Most (67%) ate at fast food establishments less than once a week, but 19% still ate it every 2 to 4 days. Thus, the program would need to include a module on dining out and downloadable resources on low FODMAP restaurant options at fast food eateries, tips for ordering at sit down restaurants, and small printable cards to present to chefs and/or wait staff that covered key foods and ingredients that were particularly high in FODMAPs that needed to be avoided. Slightly over half (51%) prepared meals daily in their home with another 27% cooking at home at least every few days. While most

respondents were the primary grocery shopper, 28% were not. Survey results revealed that it would be important to discuss reading food labels, as 95% of respondents sometimes or always read food labels while 27% still found them somewhat or very confusing. One third of respondents were also not the primary cook in their home. In the video instruction, participants in The FODMAP Fix program would need to be instructed to share particular videos and downloads with the person who was the cook or grocery shopper in their home to help the participant follow the LFD.

Program Development

In addition to the needs assessment, Step One of the Stepwise Procedure includes identifying action or behavior goals for the program.⁴ Through the needs assessment, it was clear that a LFD education program would need to be accessible, affordable, credible, and relatable in order to affect behavior changes. Based on literature indicating the significant impact health literacy has on an individual's health outcomes and their ability to achieve a behavioral goal^{4,5}, it was evident that the program would need to incorporate tactics to address HL.

Goal: Develop an internet-based, LFD education program for individuals 18 to 65 years of age with IBS that results in a measurable increase in knowledge of the LFD, a significant decrease in IBS symptom severity, and a significant improvement in IBS-related quality of life.

Tasks in Step Two of the Stepwise Procedure include identifying a list of personal psychosocial and environmental support mediators for the goal.⁴ A number of mediators were identified through the survey², literature review, conversations, and personal

experience. Perceived benefits is a known motivational mediator.⁴ As most (57%) respondents believed their IBS symptoms were related to what they ate, had previously attempted to manage their symptoms via diet (91%), as they were completing an IBS and diet survey, it was assumed they perceived a benefit to changing their diet to improve their IBS symptoms.² Self-regulation is another motivational mediator, which, again, based on the number of participants who had already made dietary changes to self-manage symptoms pointed to their desire to self-regulate. Perceived SE was also noted in literature on IBS and the LFD as a potential mediator. Both perceived benefit and self-regulation were assessed through LFD compliance. A participant's stage of motivational readiness from the Stages of Change model as was noted a behavioral mediator for this program.⁴ Because the program would not launch for at least six months, a screening in the needs assessment was used to identify those who were at least in the contemplation stage. Individuals in this stage plan to take action within six months and, thus, were identified as potential participants in the trial to test the program's effectiveness. Participant's limited knowledge of the LFD was considered as the survey found very limited LFD knowledge.² A pre-/post-intervention FODMAP knowledge quiz was used to assess the potential mediator.

Environmental mediators were also noted in the needs assessment survey.² Many participants were not the primary cook or grocery shopper, affecting the control they have over food available in their home and, thus, may be environmental mediators. While most participants reported they read food labels, over a quarter still considered them somewhat or very confusing, making instruction on label reading potentially important for fostering

behavior change. Also, FODMAPs in foods are often only uncovered by reading food labels. The potential effects of the participant not being the primary cook or grocery shopper and confusion over label reading affected program planning, video and content selection, but was not assessed.

Step 3 of the Stepwise Procedure involved selecting the guiding theory or model for the program. The TTM was used as a guiding theory to establish the readiness of the participant to be enrolled in the program. Questions based on the Stages of Change (see surveys in Appendix) were asked in both the needs assessment and screening survey for the trials. Participants who were identified as being at least at the Contemplation stage in the needs assessment survey were invited to participate in the screening survey for the Phase 2 trial. In order to be enrolled in the trial, individuals had to be at least in the Preparation stage. SE was the guiding construct of the TTM on which program planning and specific activities focused. SE is known as a potentially important mediator of behavior change in both the motivational and action phases in theory-based intervention design.⁴

In Step 4, both the program and educational/support objectives directed at the mediators of behavior for the intervention are stated.⁴

Program objectives:

1. Compared to baseline pre-assessment, 70% of participants will experience a statistically significant improvement in the IBS symptoms as measured by the IBS-SSS on Day 15.

2. Compared to baseline pre-assessment, 70% of participants will experience a statistically significant improvement in the IBS-related QOL as measured by the IBS-QOL on Day 15.

Educational/Support Objectives

1. 90% of participants will complete baseline assessments prior to Monday of Week 1.
2. 90% of program participants will accept the invitation for The FODMAP Fix within the Canvas Learning Management System by Tuesday of Week 1.
3. 80% of participants will complete all online post-assessments to evaluate changes in their level of SE, knowledge of LFD via quiz, IBS-SSS scale, IBS-QOL, compliance, and global symptom question by Day 15.
4. 80% of participants will be able to recall and apply their knowledge of the LFD by scoring at least 90% on the LFD quiz post-assessment by the end of Week 1.
5. Compared to baseline pre-assessment, 90% of participants will demonstrate at least an 80% increase in SE in their ability to consistently follow the LFD using an adapted SE survey⁶ post-intervention measure.
6. 90% of participants will report being compliant with the LFD (defined as following the LFD $\geq 50\%$ of the time⁷) during the two-week intervention.

Step 5 includes designing or selecting activities and strategies to address the mediators of behavior that are appropriate for the program and audience. Details regarding the activity, mediator, and strategy are addressed in table form in the Appendix.

The FODMAP Fix program plan is also included in the Appendix, as is an outline of the video plan for each of the four elimination phase modules.

Step 6, the final step in the model, focused on the program evaluation. The first evaluation of The FODMAP Fix program was a small, informal pilot study in which the researcher shared the course with two RDNs, a health educator, three women with IBS with varying degrees of education, and one male who did not have IBS but was willing to provide feedback on the program. Constructive feedback was provided, particularly in regards to issues with video editing. The general program feedback was very positive. The health educator remarked that she believed the narrative video was very impactful. One dietitian asked when it would be available publicly, because she would like to share it with her patients interested in the LFD. The evaluation of program and process objectives are reported within the Results section, Phase 3 of The FODMAP Fix trial.

The FODMAP Fix Program

A research dietitian trained by Monash University on the LFD developed The FODMAP Fix program. The program was based on principles of the diet with a brief introduction to the mechanisms of action through which FODMAPs affect the gut of people with IBS. Participants were encouraged to use the Monash FODMAP Diet App to evaluate FODMAP content in foods. A key benefit of the app is that it is updated as new foods are tested and, sometimes, foods that were originally tested are retested with improved methods. The app uses a traffic light system for an easy way to help participants follow the diet. Green light foods are low in FODMAPs and can be eaten in more than one serving, yellow light foods contain moderate amounts of FODMAPs and

should be used in moderation and red-light foods should be avoided. In the FODMAP Fix, participants were advised to consume only green-light foods during the two-week elimination portion of the diet. However, participants were advised to pay close attention to serving sizes, as some red-light foods can be eaten in small amounts even in the elimination phase of the diet.

The elimination phase of the program included an introductory module followed by four other instructional modules with videos and downloadable resources. Outlines of the program and of the videos are found in the Appendix. The introductory module was designed to establish program expectations and motivate those who might still be in the contemplation stage to move into the preparation stage by making a commitment to change. The module stated potential benefits of the LFD, which are more fully expressed in Module 1.

Module 1 provided diet education that would be standard for a one-on-one visit with an RDN consult on the LFD. The module included teaching on commonly eaten foods in the US that are known to be high in FODMAPs and presented acceptable low FODMAP substitutions. It also included a short quiz and case study to help participants think through how a combination of FODMAPs could affect a meal and to check for understanding to enhance SE. The information provided on IBS and mechanisms of action of the LFD, encouragement and role modeling in the narrative, and self-assessments were designed to encourage action as participants are asked to begin the LFD during this module.

Since internet-based diet education programs tend to be more effective with increased customization,^{8,9} the program incorporated interactive components. Participants were invited in Module 1 to participate in a moderated Facebook group. This was an optional feature and participants were warned about the loss of anonymity that would result from joining the group. Moderating the Facebook group allowed the researcher to preview any posts from participants before they were published. The group was designed to create an opportunity for participants to share recipes, tips, and pose questions to the group or researcher. Also, participants were encouraged to submit a food and symptom diary via email that included a 24-hour dietary recall after any significant IBS symptoms during the two-week elimination phase. These diaries were followed-up within 24 hours with customized feedback to the participant by the researcher.

The second module included more in-depth information on what foods and ingredients to be aware of when dining out or grocery shopping. The aim of this module was to help participants navigate menus and food labels by addressing key words and specific additives, spices, and ingredients that might indicate a product is high in FODMAPs. Unfortunately, the Monash app is limited by a significant lack of processed foods commonly consumed in the US. This module helps participants learn how to evaluate foods themselves in order to at least be able to make an educated guess as to whether a food might be high in FODMAPs. This module includes practical guidance needed to follow the diet in most situations to encourage skill building as they learn to incorporate the LFD into their life.

The third module addressed how to recover, as much as possible, from an overindulgence or accidental ingestion of high FODMAP foods. Given the restrictive nature of this elimination diet, it is important that participants understand that all is not lost when too many FODMAPs are consumed. The module included a discussion on balancing not just meals, but also the entire day with lower FODMAPs when a business or family event makes eating a meal low in FODMAPs near impossible. If symptoms occurred due to an accidental ingestion, participants were also encouraged to eat only green light/low FODMAP foods for the remainder of the day to keep symptoms from worsening. The aim of this module was to keep participants in the action stage by reinforcing knowledge and through promoting recovery SE if they had fallen away from the diet.

Module 4 attempted to increase the variety of foods consumed by participants through presenting new menu options and recipes. The goal was to help increase the variety of nutrients in the diet, as well as to encourage compliance by suggesting new options to avoid food boredom. Module 4 was designed to make participants aware of their food choices and provide support to making good LFD choices to help maintain the action stage of the TTM.

PHASE TWO: ORIGINAL, FOUR-WEEK, RANDOMIZED CONTROLLED TRIAL

Purpose and Hypothesis

The primary aim of this study was to determine if a four-week trial of the elimination phase of the LFD delivered through an internet- and module-based program

(“The FODMAP Fix”) developed by a RDN trained on the LFD would improve symptoms and quality of life in patients with IBS. IBS-SSS, IBS-QOL indices, a SE efficacy survey, and a global symptom question will be used to assess outcomes. Changes in these indicators were to be compared against a control group who would be completing the same assessments to determine if the online delivery method was effective in improving IBS symptoms.

Hypothesis: A four-week trial of “The FODMAP Fix” in adult patients with IBS will result in significant improvements in IBS Symptom Severity Scale (IBS-SSS), Quality of Life (IBS-QOL), and SE indices and a global symptom question by assessing pre/post scores and when compared to the control group’s changes.

Population and Sample

Participants in this randomized, controlled trial included adults, 18 to 65 years of age, as people over 65 are more likely to have additional conditions that might affect outcomes.¹ Participants self-reported whether they have received a diagnosis of IBS from a medical doctor, nurse practitioner, physician’s assistant, or were diagnosed by another healthcare provider and then asked to indicate the provider type. ROME IV diagnostic criteria were evaluated in a screening questionnaire to determine if those patients who report being diagnosed with IBS would meet the criteria for diagnosis, which includes stomach pain at least one day/week in the last three months and pain which comes with two or more of the following: is related to passing stool; a change in how often you pass stool; a change in form of stool.¹⁰ Participants were not excluded if they did not meet the criteria. Participants had to have regular internet access, own a smartphone, be willing to

purchase the Monash FODMAP app (\$9.99), and indicate readiness to change their diet as assessed via a TTM question designed to indicate their Stage of Change. Participants were recruited on a rolling basis from Texas Woman's University faculty, staff, and students through bulk emails; flyers were provided to gastroenterology and family medicine clinics, and counseling offices; and a flyer was advertised via the researcher's social media accounts. A link to the PsychData survey used to provide information on the study, collect informed consent, and screen participants was included on the flyer and in emails. Those participants from the "IBS and Diet" survey from June 2018 who indicated interest in future clinical trials were also be contacted via email and informed of the study.

Participants who linked to the survey were provided detailed information on the study and asked to complete the informed consent survey then to create their unique study PIN. Those who provided consent were then screened through a separate PsychData survey entitled "Irritable Bowel Syndrome and The Low FODMAP Diet Study Survey." Participants were excluded from the trial if they were pregnant or planned to become pregnant in the next six weeks, were institutionalized, had an acute GI episode within four weeks, co-existing gastrointestinal disease, eating disorders; food allergies, were currently taking or had taken within the previous four weeks the following medications: antibiotics, stool bulking agents, narcotic analgesics, probiotics or prebiotics, or lactulose; or followed one of the following diets in the prior four weeks: LFD, very low-carb, ketogenic, gluten free, or paleo.

Participants who were not screened out in the above survey were directed on to a linked survey (The FODMAP Fix Demographic Data Survey) where basic demographic data (year of birth, height, weight, gender, ethnicity) were collected. Participants continued on to an adapted Food Frequency Questionnaire (FFQ) based on the NHANES Food Questionnaire entitled “Food Frequency Questionnaire.”¹¹ Participants avoiding FODMAPs, as determined by screening with this questionnaire were excluded. Similar to Staudacher et al.,⁷ patients who follow a low-lactose diet were not excluded, but asked to maintain their current lactose intake. Next, remaining participants were then sent to a separate survey where they entered in their PIN and email. The email address was required to provide access to the online Canvas classroom where The FODMAP Fix program was housed. This survey was not linked to the previous surveys, thus it separated the identifiable information from any health-related data. Participants were informed that they would receive an email indicating whether they were in the control or intervention group.

Protection of Human Subjects

The study proposal was submitted to the Institutional Review Board of Texas Woman’s University, Denton Campus. Informed consent was obtained prior to the start of the survey via the Psychdata survey that provided information on the study, collected informed consent, and screened participants. The survey was anonymous and participants were not required to disclose their identities. Email addresses of those who were not screened out were collected through a separate survey in PsychData. Contact information for the PI and research advisor was included on the survey for participants, who had the

option to email their queries to researchers before, during, or after participating in the study. Participants could also contact the researcher through the Canvas LMS platform.

The most significant risk associated with this internet-based study is the potential loss of confidentiality. In an effort to minimize the risk of loss of confidentiality, several steps were taken. Immediately upon completion of the study, the electronic record of the Informed Consent was deleted. The file was printed and stored in the faculty mentor's office in a locked cabinet where it will be stored for five years. There was no opportunity for interaction between participants on the Canvas LMS, nor was identifying information ever posted. No health-related data was collected or stored on Canvas. The program included an optional, closed Facebook group that provided the only opportunity for interaction amongst participants. The loss of confidentiality with any information they chose to share and loss of anonymity was addressed in a Canvas announcement to participants reviewed by the IRB. Participants were not automatically enrolled, but provided instructions on how to join the group if they chose to do so. Data was not collected from Facebook interactions. Participants were notified that there was a potential risk of loss of confidentiality in all email, downloading, electronic meetings, and internet transactions. Participants were asked to download and utilize the Monash University app, which is not connected with location, contacts, photos, etc. Participants could choose to use the diary feature at their discretion to record their food intake and symptoms, but this is a feature of the app and in no way a requirement of the program. The app was completely independent of The FODMAP Fix program and is managed by Monash University. Participants also had the option of submitting food and symptom diaries to

the researcher via email for personalized feedback. However, this was not a program requirement. Participants were cautioned against electronic transmission of health-related data due to the potential loss of confidentiality.

Other risks associated with this study include the loss of time, loss of anonymity, embarrassment due to the sensitive nature of some questions on the IBS-QOL assessment, and fatigue due to the length of surveys and video. The IBS-QOL contains some sensitive questions related to bowel habits; however, this is a validated tool used in numerous research studies. The assessment was completed on PsychData and used a unique PIN to not identify the participant with the responses. Fatigue was a concern due to the number and length of assessments. To help alleviate this issue, participants were able to enter and exit the surveys. Also, while there were numerous videos, they were kept short (12 minutes maximum) to minimize fatigue.

Study Design

Day 0:

After obtaining participant's informed consent, participants were randomized into the control or intervention groups through an internet-based, research randomization program (www.randomizer.org). After randomization, the intervention group received access to the internet-based classroom hosted on a free version of the Canvas LMS, where The FODMAP Fix program is housed. Participants were then asked to complete the Introduction module, which provided an overview of the program and assessments, but gave no information on the diet.

The intervention group participated in The FODMAP Fix, a four-week internet- and module-based LFD education program. In addition to the brief introductory module, the program included four weekly modules on the elimination phase of the diet followed by an additional two weeks of instruction to reintroduce FODMAPs for the reintroduction and adapted phases of the LFD. Educational videos and downloadable resources were released in each module. The closed, moderated Facebook group was an optional feature made available in Module 1. It provided an opportunity for interaction with other participants and the RDN. Participants were asked to download the Monash University FODMAP Diet App to their smartphone. A video in Module 1 provided instructions on how to download and use the application. Participants were not required to prove they had downloaded the app to participate. The app is an important tool for the FODMAP diet, as it provides up-to-date food lists based upon Monash University's tests of FODMAP content.

The entire program, including time for assessments was designed to take participants no more than seven hours over the course of the four weeks to complete. The breakdown of the time estimated for each module was as follows:

Intervention Group: 7 hours total

- Introduction/Module 1: Maximum 2 hours
- Modules 2: Maximum 2 hours
- Module 3: Maximum 1 hour
- Module 4: Maximum 2 hours

Control Group: 3 hours total

- Introduction/Module 1: Maximum 1 hour
- Module 2: Maximum 1 hour
- Module 4: Maximum 1 hour

The intervention group was also asked to follow the elimination phase of the LFD for four weeks. Compliance to the diet was designed to assess by a question adapted from Staudacher, et al.⁷ at the conclusion of each module, as well as through a diet assessment using the FODMAP FFQ and 24-hour diet recall administered via the ASA24¹².

Participants randomized to the control group received notification via email that they have been accepted into the study. The email explained that they had been assigned to the control group and would receive access to The FODMAP Fix program after they complete the second round of assessments – around four weeks from the start of the study. The control group was asked to complete all health and nutrition assessments during the four-week study.

The primary outcome of interest was changes in IBS-SSS with secondary outcomes including IBS-QOL, reported compliance, FODMAP knowledge, and SE in regards to the participant's ability to follow the LFD. IBS-SSS, validated by Francis et al,¹³ is the gold standard in assessing the symptom severity of IBS.¹³ The scores ranges from 0 to 500 with a higher score indicating more severe symptoms. The survey covers topics relevant to IBS: abdominal pain intensity, abdominal pain frequency, abdominal distension, dissatisfaction with bowel habits, and how much IBS symptoms interfere in a patient's life. The IBS-QOL assessed quality of life assessment¹⁴ and is commonly used

to assess the impact of dietary interventions in people with IBS.^{7,15,16} Both the intervention and control groups were instructed via email to complete the following assessments after randomization: IBS-SSS, IBS-QOL, SE survey adapted from Bandura⁶, and the FODMAP knowledge quiz. Links to these assessments were provided in the email, as well as in the Canvas-based program for the intervention group.

Week 2:

After completion of Module 1, the intervention group was asked to retake the FODMAP quiz, 24-hour recall, and answer a question on compliance. The control group was requested to complete the online, 24-hour diet recall during week two.

Week 5, End of Treatment:

After completion of Module 4, participants were again asked to complete the adapted global symptom question, IBS-SSS, IBS-QOL, adapted FFQ 24-hour diet recall, adapted SE assessment, compliance question, and a program feedback form to assess The FODMAP Fix program. Participants were thanked for their participation. Module 5 included teaching on reintroduced FODMAPs into the diet and was released the day after assessments were due. Module 6 taught participants how to follow an adapted LFD. The researcher remained available to participants during these phases, but data was not collected on participants.

PHASE THREE: MODIFIED, TWO-WEEK TRIAL

Purpose and Hypothesis

Phase 3 was developed after recruitment and retention for Phase 2 participants failed. Recruitment for Phase 2 began in January of 2019 and lasted four months. A total

of 333 participants were screened; however, due to strict exclusion criteria, only 18 were enrolled. Of those enrolled, 10 were randomized to the control group and 8 to the intervention group. None of the control group and only three participants in the intervention group completed the study. In an effort to boost enrollment and improve retention, the original Phase 2 trial was revised and IRB approval was obtained for trial modifications and Phase 3 was launched.

Revised Hypothesis: A two-week trial of “The FODMAP Fix” in adult patients with IBS will result in significant improvements in pre/post scores as assessed by the IBS Symptom Severity Scale (IBS-SSS) and Quality of Life (IBS-QOL) instruments with a significance of $P < 0.05$.

Population and Sample

The revised study employed the same protections for human subjects as previously described for Phase 2. Exclusion criteria were reevaluated and revised to allow for greater enrollment, while still maintaining a high level of control. During Phase 2 enrollment, 270 potential participants were excluded because they had been on the LFD within the previous 4 weeks. The timeline was adjusted for the LFD and gluten-free diets to allow subjects to enroll if they had not followed those diets within two weeks. Other diets were removed as exclusions, including the low carb, keto, and paleo diets, since a significant source of FODMAPs are found in onion, garlic, mushrooms, and other non-starchy vegetables that are allowed on these diets. Enrollment was opened to include those self-diagnosed with IBS, instead of requiring participants to be physician-diagnosed, since studies show up to 76% of people with IBS never receive a formal

diagnosis.¹⁷ Participants were asked to indicate if they have IBS then asked whether they were self-diagnosed or diagnosed by a physician, nurse practitioner, or physician's assistant. Also, participants were no longer required to download the Monash FODMAP app, but encouraged to do so. Nine potential participants were excluded in Phase 2 because they stated they would not be willing to download the app, which costs \$7.99. It was reasoned that these participants may not yet understand the value of the app prior to watching the videos for the Introductory Module and Module 1, which emphasized the utility of the app. Recruitment for this trial expanded to include faculty, staff, and students from Abilene Christian University and Texas Tech University; additional family practice clinics; a paid Facebook advertisement; and list serves of American Society of Nutrition and the American Gastroenterological Association.

Study Design

The redesigned study was a non-randomized, prospective intervention, which sought to assess the effectiveness of an internet-based LFD education course (“The FODMAP Fix”) to improve symptoms in patients with IBS through repeated measures. Modifications to Phase 2 are detailed below. Enrollment into the program was done on a rolling basis as participants were accepted into the trial. Participants were enrolled in one of five groups in order to keep group size manageable and provide a real-world online group experience. The largest group had 23 participants. Participants who dropped out or did not accept the program invitation to early groups were invited to attend a later group.

The intervention period for Phase 3 was decreased from four to two weeks. This was in effort to improve compliance and completion rates. Total time for the intervention

also decreased from 7 hours for the program and assessments over four weeks to 3 1/2 hours over two weeks: 2 hours in week 1 and 1 1/2 hours in week 2. The control group was removed, since this group in Phase 2 was completely noncompliant, making this a nonrandomized trial. All screened participants who qualified were part of the intervention. Data analysis was done using paired *t*-test for pre/post analysis. Precedence for this study design was established by four previously published clinical trials.^{15,18-20} Participants in Phase 2 commented in the program evaluation that the assessments were lengthy, thus in an effort to improve retention and reduce fatigue the FFQ and both 24-hour recall surveys were removed from the analysis. Compliance to the LFD was assessed using the previously validated compliance question.⁷

Day 0:

Participants were emailed a link to complete the initial assessments, which included the IBS-SSS, IBS-QOL, an adapted SE assessment, and a FODMAP baseline knowledge quiz. All program assessments were housed on PsychData and accessed via a username and password of their choosing. Each assessment required the participant to include their unique study PIN. Participants were also granted access to the Canvas classroom where The FODMAP Fix program is hosted and asked to view the brief Introductory Module outlining the program. The assessments and FODMAP Quiz were also linked in the Introductory Module with a due date set the day prior to the release of Module 1.

Day 1: Module 1 was released and participants were asked to view the videos prior to starting the LFD on Day 2.

Day 2: Participants were requested to start implementing the LFD.

Day 4: Module 2 released

Day 8: Module 3 released

Day 11: Module 4 released

Day 15: End of Treatment:

Participants were requested to complete all assessments by the following day.

Final assessments included the adapted global symptom question, IBS-SSS, IBS-QOL, adapted SE assessment, compliance question, as well as a program feedback form to assess the format of The FODMAP Fix program. Similar to Staudacher, et al.,^{7,21} patients who report that they followed the diet at least 50% of the time were considered compliant.

STASTICAL ANALYSIS

Data was analyzed using SPSS version 25. A priori power analysis was conducted using G*Power 3.1.9 to determine the minimum sample size required to find statistical significance using a paired samples *t*-test. With a desired level of power set at .80, an alpha (α) level at .05, and a moderate effect size of .5 (*d*), it was determined that a minimum of 34 participants would be required to ensure adequate power.²²

“Responders” to the dietary intervention were determined by a reduction in IBS-SSS >50 points, which is considered to reflect a Minimum Clinically Important Difference (MCID).^{13,23} IBS-SSS scores were used to determine the severity category of the participant’s IBS: scores <75 were regarded as “in remission”, scores of 75-174 were

interpreted as “mild disease”, 175-299 as “moderate”, and 300 or greater as “severe” disease.¹³

CHAPTER IV

RESULTS

PHASE TWO: ORIGINAL, FOUR-WEEK, RANDOMIZED CONTROLLED TRIAL

After four months of recruitment, 333 potential participants were screened and only 18 qualified for the study. Most were disqualified because they had followed restricted diets within the last four weeks: 270 followed the LFD and 5 the very low carb. Eight people had taken pre- or probiotics within the last four weeks. Nine others refused to purchase the Monash FODMAP app. None of the 10 participants in the control group completed the pre- and post-assessments and only three of the eight participants in the intervention group completed both pre- and post-assessments. These very low enrollment and high attrition numbers prompted the researcher to reevaluate both the program and the study design. Modifications to the proposed design are detailed in the Methods and the results of the subsequent study “Phase 3” are detailed below.

PHASE THREE: MODIFIED, TWO-WEEK TRIAL

Subjects

While 135 people began the screening survey and provided informed consent, only 118 confirmed they had IBS and were between the ages of 18 and 65 years (Figure 1). Following screening, 52 subjects were invited to participate in the study and received links to the initial assessments and an invitation to The FODMAP Fix online course via email. Demographic data is described in Table 1.

Symptoms: Baseline

The ROME Foundation sets the criteria for the diagnosis of IBS. In 2016, the Foundation released the ROME IV diagnostic criteria, which includes recurrent abdominal pain, on average, at least 1 day/week in the last 3 months, associated with two or more of the following criteria with the percentage of participants who reported experiencing each:

- Related to passing stool: 51%
- Associated with a change in how often stool is passed: 36%
- Associated with a change in form (appearance) of stool: 42%

These criteria had to be fulfilled for the previous three months with symptom onset at least six months before diagnosis.¹ Thirty-five percent of invited participants fulfilled the ROME IV criteria for diagnosis of IBS through self-reporting.

Participants were also asked about other symptoms commonly associated with Functional Gastrointestinal Disorders.² In order to be consistent with ROME diagnostic criteria, participants were asked “Please choose which best describe your symptoms OVER THE LAST 3 MONTHS for any symptoms that have been present for at least six months” and asked to select all that applied to the following statements, which are followed by the percent that selected each.

- Bloating at least one day per week: 83%
- Constipation at least one day per week: 49%
- Diarrhea at least one day per week: 60%
- Excess gas at least one day per week: 77%

Significant correlations were found between ethnicity and IBS sub-type ($r = -.297, p = 0.03$). Also, significant was whether the participant fulfilled ROME IV criteria and IBS sub-type ($r = 0.32, p = 0.02$) and fulfilled ROME IV and BMI ($r = 0.35, p = 0.01$).

The average IBS-SSS score for the 34 participants who completed their initial assessments was classified as “moderate” in severity ($M=227\pm67.12$). There was a wide variation in SE scores based on a 100-point scale adapted from Bandura (2006) originally designed to assess a person’s SE to follow a low-fat diet. The mean score was 75.5 ± 24.25 with a range of 86 points.

Sixteen of the 52 participants who provided informed consent and were invited to join the course never accepted the invitation. Three participants accepted the course invitation, but never completed the initial assessments. Of those participants who accepted the course invitation and completed at least part of their initial assessments, only 15 participants completed both initial and final assessments (Figure 1).

Symptoms: Final Analysis

Data for the 15 participants included in the final analysis were checked for normality. Demographic data is described in Table 2. Forty percent of the 15 included in the final analysis met ROME IV criteria based on self-report of symptoms. Most (60%) were compliant with the LFD at least 50% of the time.

Descriptive statistics for IBS-SSS, IBS-QOL, and SE are shown in Table 3 and Figure 2. Initial and final mean IBS-SSS score fell within the “moderate” range for severity and remained similar before and after the intervention, though range of scores

and pre-/post-scores for some individuals was dramatic. Over half (53%) experienced an improvement in their IBS-SSS scores. IBS-QOL scores were much less variable with similar means between pre- and post-intervention, though, again, there was great intra-individual variability. Mean SE decreased slightly post-intervention from 59 to 56 on a scale of 1-100.

The IBS-QOL includes a several subscales. Table 4 provides a summary of the descriptive statistics for each sub-scale and Figure 3 provides a visual depiction.

Pre- and Post-Intervention Changes

Due to a lack of compliance with assessments and the high dropout rate, there were too few participants for an adequate power analysis to assess the effect of the diet on symptom severity, quality of life, or changes in SE. Table 5 shows the results of the paired samples t-test used to assess changes in pre- and post- intervention IBS-SSS, IBS-QOL and subscale, and SE scores. IBS symptom severity, as assessed by the IBS-SSS, did not change between the pre- and post-intervention assessments; however, again this analysis was underpowered. There was no correlation between IBS-subtype, compliance, and whether a participant was a “responder” (>50-point reduction in IBS-SSS scores; Bohn 2015) to the diet education program (Tables 6 and 7). There was no difference between the change in IBS-SSS scores and the time spent within The FODMAP Fix program on Canvas nor with the scores and how many modules the participant viewed in the program.

The FODMAP Fix program is hosted on a free version of Canvas – a learning management platform. Mean time spent on Canvas was 73 ± 71 minutes, which would not

include the time spent viewing videos. However, this number is likely not useful to understand engagement, as participants could have left Canvas open and left their device or moved to other websites or applications. A more useful tool to understanding engagement is evaluating the last module accessed by participants in the Access Reports found within the course. Unfortunately, as shown in Tables 8 and 9, there was no correlation between the time spent on Canvas nor the last module accessed and changes in IBS-SSS scores.

Knowledge of the LFD was assessed pre- and post-intervention by a five-question quiz. Table 10 displays descriptive data around mean scores and Table 11 highlights the results of the paired t-test which revealed that FODMAP knowledge scores improved significantly ($p = 0.01$) after The FODMAP Fix program.

A feedback survey to assess The FODMAP Fix program content and delivery was included in the final assessment. Most (66%) reported the online classroom format was easy or very easy to use and even more (73%) liked the module-based approach. When asked what they would change about this approach, the most common reply was more email reminders followed by providing the information more in advance of the start of the diet. The program was structured so that Module 1 videos were released the day prior to when participants were asked to begin the LFD to keep the experience similar to meeting with a RDN. Only one participant reported utilizing the closed Facebook group. When asked whether they thought the online, module-based approach would be more or less effective than a single, one-on-one, hour-long consultation with a Registered Dietitian, 73% stated it would be at least as effective or more effective. Only one

participant was dissatisfied with the length and number of videos included in the program. Two participants reported issues with technology. Participants were asked if they would recommend this program to others suffering from IBS and 13% ($n = 2$) stated “No” and the same number reported “Maybe”, while 73% stated they would recommend it.

COMPLIANCE ADDRESSED

Due to the low rate of completion of final assessments, two short surveys were developed and approved by the TWU IRB for follow-up. The first survey was sent to those who completed the screening and informed consent and provided their contact information, yet never accepted the invitation to The FODMAP Fix program. Of the 16 in this category, 6 responded. When asked why they did not accept the invitation the reasons were as follows: too busy – 2; felt the study was too confusing or difficult to navigate – 2; traveling during beginning of study and felt it too difficult to follow diet – 1; reported time and recommended Monash app cost were too much – 1. Two people reported technical issues – admitting it was confusion on their part. Two respondents stated they were experiencing significant stress, anxiety, or depression at the beginning of the study. Four of the six non-compliant participants reported mild IBS symptoms and the other two reported moderate symptoms at the beginning of the study.

The second survey was sent to those who accepted the FODMAP Fix invitation and began the program, but did not complete the final assessments. Eight of 15 responded. Only one person who responded had completed all four modules, five completed through Module 1, and two completed only the introductory module. Five of

the eight began the LFD. Two followed it less than one week, two followed it one to two weeks, one followed it the full two weeks. One person stopped because of traveling, three stopped because of lack of time or felt they were too busy.

Three participants reported the length of assessments affected their willingness to complete the program and three more said this was somewhat a factor. Three participants reported suffering from significant stress, anxiety, or depression at the start of the program with two more saying these conditions somewhat affected their decision. These participants reported mild (3) and moderate (5) symptoms. Interestingly, only one of these participants completed all four modules during the two weeks, seven of the eight would recommend the program to a friend.

CHAPTER V

DISCUSSION

An improvement in symptoms, as defined by IBS-SSS scores was seen in slightly over half (53%, $n = 8$) of participants in Phase 3 of a 100% online, LFD education program. Due to high dropout and non-usage rates, as well as a wide range of IBS-SSS scores, the study was underpowered to detect significant changes. Also, while changes in IBS-QOL, including subscales, and SE were assessed, these measures failed to provide valuable information due to the lack of power. Thus, neither Phases 2 nor 3 of the trial were able to answer the question of whether a two-week trial of “The FODMAP Fix” in adult patients with IBS would result in significant improvements in IBS-SSS and IBS-QOL assessing pre/post scores. However, many lessons were learned and insightful information was gained that will be beneficial for both practice and research going forward.

PROGRAM DESIGN

To accomplish the goal of improving symptoms and quality of life in patients with IBS, the “The FODMAP Fix” program was designed to promote HL and provide an LFD education program that was accessible, credible, affordable, and relatable to the target audience. A collaborative, multidisciplinary approach should be considered when addressing health literacy and health education specialists are uniquely equipped to offer support. Health outcomes can be significantly affected by the patient’s HL level.¹ One review found that lower HL was consistently associated with a number of factors,

including those that could directly affect patients with IBS, such as poorer medication adherence and ability to interpret labels and health messages.¹ HL can also help mediate disparities between racial groups.¹ Since IBS is prevalent across many ethnicities and demographic variables and can significantly impact HRQOL,² incorporating strategies to improve HL in this intervention was imperative. The LFD is complex and can be perceived as confusing as the diet eliminates many foods generally considered healthy. Using multimedia to present complex or confusing information can benefit those with low HL and improve access to education.³ Video, in particular, was chosen as a key component of this intervention as it is an effective tool to improve HL.^{4,5} The FODMAP Fix incorporated a variety of video styles to discourage fatigue. Several of the more technical presentations incorporated pictures, texts, and spoken word through a voiceover presentation, a method shown to be particularly beneficial for those with low HL.⁶ The use of video made the program more accessible to those with limited literacy levels, as video can decrease the burden on working memory.⁷ Accessibility of the educational component was also enhanced by the internet-based platform, which provided access to a trained RDN to those who might have otherwise been restricted due to location, lack of insurance, cost, or mobility. The Canvas LMS platform is a user-friendly platform used in secondary and college education as an online classroom. There were a few comments regarding difficulty with technology from those who accepted the invitation, but never joined and from those who completed the program. Because the same comments came from those who had never accessed the Canvas platform, as well as those who had, the issue may be attributed to digital literacy rather than the platform. Other studies have

included digital literacy assessments and/or trainings prior to enrollment or beginning the study.⁸ Incorporating a technology check and/or an optional basic training for computer or platform use could improve the program. Instruction was provided in the program for using the Monash FODMAP app and participants were directed on how to get additional training or have their app-related question answered.

Affordability was an important factor figured into the development of this program. Insurance coverage for nutrition consults for patients with IBS is lacking and many patients are unable or unwilling to pay out-of-pocket costs for an RDN consult. This unfortunate situation can increase the likelihood that a patient seeking information on the internet might come across outdated or incorrect LFD education. These patients might attempt to follow the diet based on the information they found online and determine that the diet does not work for them when, in fact, it could have if they had received accurate, current education. Due to the amount of free information available on the internet, online courses need to be affordable or they risk being overlooked. Prices for online diet education courses vary wildly with some LFD courses costing up to \$400.

IBS is a sensitive subject with potentially embarrassing symptoms. Many patients may delay seeking help from a physician for a year or more after they begin experiencing symptoms.⁹ An internet-based program allows patients the opportunity to get the nutrition help they need from a qualified professional in the comfort of their home or wherever they can get internet access. Similar to many health topics, the information on the LFD available on the internet varies widely in accuracy. Patients need a resource they can trust with their health, though many do not know where to look due to the plethora of

information available. Module 1 of the program reviewed the mechanisms of action for the LFD in patients with IBS to help provide patients background information in a manner that was easily understood. It was designed to establish trust and efficacy of the LFD by discussing the breadth of research on the LFD in patients with IBS, while alerting patients to the fact that while the diet works for most, it does not work for everyone. Lessons within the Introductory Module of The FODMAP Fix program established the presenter as an authority figure by providing her credentials and discussing her training in nutrition and the LFD. However, authority and competence are not enough to establish credibility.¹⁰ Trustworthiness or warmth of the presenter is a key component of credibility.¹⁰ Module 1 incorporated the use of narrative as the presenter shares her story of how the LFD affected her life including the initial struggle during the elimination phase of the diet. The use of narrative can improve relatability of the presenter, build trust, and increase SE.¹¹

Given the intentional design of the program to increase SE, the slight decrease in SE, as described in the Results, between the pre and post-assessments is intriguing. While the decrease was insignificant, it was hypothesized that the intervention would improve the scores. Since FODMAP knowledge increased significantly and a high percentage of participants said they would recommend this program, the decrease in SE was particularly interesting. Knowledge is a precondition for change, but it is insufficient on its own to change behavior.¹² This may help explain why an increase in knowledge in the present study did not result in corresponding diet compliance. One could theorize that the extent of education on this elimination diet could have decreased SE. Others have

proposed that participants with lower education began interventions intending to change their health behavior, but that their SE decreased after they received extensive information about the required changes.¹³ This may have also decreased their motivation to participate.^{13,14} Lower education levels could indicate those participants are less familiar with internet-based programs, affecting SE and attrition rates.^{13,14} Education level was not assessed in this study. Alternatively, the participant, upon learning about the number of foods they would be required to eliminate from their own diet and once they began practicing the elimination diet, may have found it much more difficult than they had anticipated before they were informed. Further research is needed to better understand if this change was purely by chance, given the low sample size, or if and why SE actually decreased as a result of this intervention.

The Cognitive Load Theory states that learning is first processed in working memory and that it is easier if elements can be learned successively rather than simultaneously.¹⁵ The LFD can be delivered in a variety of ways depending on the motivation of the learner. One approach is to eliminate one FODMAP group at a time, which could facilitate learning, as this would be a successive approach. However, the method used in The FODMAP Fix eliminated all high FODMAP foods at once and is the most researched. The cognitive load is potentially quite high in this program, as anyone with limited computer literacy is experiencing high-element interactivity because they are learning a complex diet and a new system.¹⁶ If computer literacy was addressed first, it would decrease the element interactivity and facilitate learning. The process of learning a

new skill (e.g. cooking) or new material (e.g. the LFD), can overload the capacity of an individual's working memory and result in a loss of SE.¹⁷

Kelder, Holscher, and Perry¹⁸ noted four factors known to influence SE: previous experience, vicarious experience, social persuasion, and emotional arousal. Throughout the program, a number of tactics were used to influence these factors in an effort to build SE. The use of narrative in the form of the presenter sharing her story targeted vicarious experience and emotional arousal, as she shared both triumphs and pitfalls of her own experience. The closed Facebook group was intended to provide an opportunity for social persuasion. However, this group had very limited enrollment and none of the participants commented or posted in the forum beyond "liking" posts from the researchers. Social persuasion could have also been built in through discussion forums within the LMS. Participants could have been encouraged to post new tips or recipes there or pose questions to the group. Kelder, Holscher, and Perry¹⁸ also noted that self-mastery is typically the strongest influencer in the formation of SE. Opportunities for self-mastery included the built-in self-assessments in the form of quizzes and case studies, which encouraged participants to review the information again if they were unsure of their answers. The program could be improved with more opportunities to "master" elements of the diet or Monash app. This could be accomplished by participants sharing successes when choosing low FODMAP options from restaurants, including additional "how to" videos on cooking low FODMAP foods and asking participants to try at home and share their experience, providing opportunities for participants to upload photos of low

FODMAP foods they prepared, or participants reporting hidden ingredients they found on seemingly benign foods. Participant sharing could also improve social persuasion.

ENGAGEMENT

Tailored and customized online programs and interventions tend to result in more favorable outcomes than “plug and play” versions.¹⁹⁻²¹ While this study included options for both a closed Facebook group and diet feedback, engagement by participants in these options was limited. Only one participant opted to join the Facebook group and two others submitted diet and symptom information for personalized feedback. Participants were not asked if they had a Facebook account, so the limited engagement may have resulted in a low number of account holders. Also, participants were alerted to the loss of anonymity associated with a Facebook group, which, given the sensitive nature of IBS, may have also attributed to low rates of participation. One way to allow for interaction while protecting anonymity would have been to use the discussion board forum on the Canvas LMS. Since participants were enrolled with their PIN, which was not linked to identifying information, they may have been more likely to participate.

Time spent on The FODMAP Fix program on Canvas ranged from 6 to 280 minutes, which would not include the time participants spent viewing the externally linked YouTube videos where the majority of the content was delivered. The great variation in time spent on the LMS is attributed to the early discontinuation of some participants (one participant only viewed the introductory module and never opened another), while others were very engaged with the program. Also, time spent does not necessarily indicate engagement, as it is possible that some left the browser opened and

walked away from their computer or worked on other projects online which would have caused the time to continue to accumulate. Most participants viewed all the modules, which may have resulted in the significant increase in scores of the FODMAP quiz used to assess a change in knowledge of the LFD. This was a higher level of engagement than achieved by some previous studies.²²

Brusk and Bensely²² assessed engagement of online nutrition education lessons in WIC participants and found the typical user completed less than two lessons. Previous assessments of engagement and outcomes in online dietary interventions found greater engagement is also associated with retention and positive change in a key outcome of the intervention.²³⁻²⁵ Program exposure is an important factor in determining the impact of internet-based programs.²⁶ Tailoring programs can also lead to increased engagement.^{23,24} However, not all tailored programs result in better outcomes than static programs. Genugten et al.²⁷ reported no differences in outcomes in an online weight management intervention and suggested that “sub-optimal” use of the interactive system could have been the reason for the lack of effect. Increased engagement has been associated with increases in completion rates of outcome survey, which is essential to research studies.²³ While the modules of The FODMAP Fix program were static, tailored content was available to those who chose to engage with the researcher through the Facebook group or the diet and symptom diaries. Participants who completed the diaries were provided personalized recommendations and individual support. All participants were made aware of this option, but only two chose to participate.

IMPORTANCE OF INTERNET-BASED DIET EDUCATION

As the rates of chronic disease continue to climb, accessible and affordable diet education to address the root causes of these conditions and assist in treatment is vital. The United States has limited insurance coverage of RDNs, the most qualified professionals to provide disease-related diet advice. In addition, most physicians are not referring out to RDNs, and many are not comfortable providing diet advice themselves – or lack the time to do so. Thus, patients are often left to discern complicated diets from a pamphlet or what information they can gather online.

Technology or internet-based programs provide a tremendous opportunity for mass reach of credible nutrition education. RDNs would benefit from training programs incorporating more education on health behavior theories, effective communication strategies, and how to maximize technology to promote gains in nutrition knowledge amongst the public.

LIMITATIONS

This study includes a number of limitations. The high dropout rate amongst participants provided an inadequate sample size and significantly limited data analysis. More than half of participants did not complete the post-intervention assessments. Attrition is a significant problem in internet-based education of all forms.²⁸ One review of 7 health-related, tailored internet-based, interventions reported dropout rates of 28 to 86%.¹³ Brindal et al. reported 40% attrition in the first week followed by 20% in subsequent weeks in an online weight-loss intervention.²⁴ Incentives at a similar level to the \$20 Amazon.com e-gift card offered in this study has previously been shown to

increase retention rates,²⁹ thus the high dropout rate was particularly disappointing. Also, the results are not generalizable due to the low rate of male participation and the lack of ethnic diversity in the sample. The use of a single presenter, a white female, may have negatively affected engagement as participants may not be able to relate to the individual. When individuals can identify with the character or source of information in the narrative, they are more likely to become absorbed into the story or engaged in the program and are more easily persuaded by the message.¹¹

A significant proportion of the participants were not compliant with the diet with several reporting less than 25% compliance. Reasons for the abnormally high dropout rate were assessed in follow-up questionnaires and emails from participants to the researcher, which indicated stressful life events affected some participants. In an effort to decrease assessment fatigue, this study did not include anxiety or depression scales, which could have provided additional information on dropout or compliance rates. Participants reported that email or text reminders would have been helpful.

The initial IBS-SSS scores were relatively low (median = 210 ± 78.25) in this trial compared with other, similar trials assessing the LFD.³⁰⁻³² Thus, it was less likely that the dietary intervention would result in a comparable improvement in symptoms or QOL similar to other trials. There was also great variability in the initial and final IBS-SSS (ranging from mild to severe disease), IBS-QOL, and SE scores between participants.

Other factors limit interpretation of the data. The utility of the global symptom question was lost as it was included in early rounds of the initial program assessments, but not included in later rounds due to researcher error. Age was not verified nor was it

specifically asked. Participants were only asked to confirm if they were between 18 to 65 years old. When analyzing the data for the needs assessment (Phase 1 of the trial) a few participants were excluded because, though they had indicated they were between 18 to 65 years old, their year of birth revealed that they were older. Socioeconomic status and education were not included in the original trial design, yet could have provided useful information. Also, notably, this study was predominantly female and menstruation was not accounted for in the timing of the program or via survey questions. Menstruation has significant effects on IBS symptoms and may have affected the results of this study.^{33,34} This is particularly problematic in a two week trial that only assessed changes in symptoms pre- and post-intervention. A low recruitment rate and complete lack of compliance for the control group in an earlier version of this trial necessitated the change from a placebo-controlled trial to a prospective trial in which the changes in assessment scores were measured pre- and post-intervention. While not ideal, this approach was also used by four previous trials on the LFD to assess changes in IBS symptoms.^{30,32,35,36}

FUTURE DIRECTIONS

Research-based Recommendations

The gold standard for dietary interventions is a double-blind, placebo-controlled, randomized trial. This study was originally designed as a four-week intervention with a wait-listed control group. Due to the low rate of enrollment resulting from necessary exclusion criteria and a completely non-compliant control group, this approach was abandoned in favor of a shorter trial using pre-/post-assessments instead of a control group comparison. Ideally, a study investigating the effectiveness of an internet-based

LFD education program would be compared against a face-to-face arm in which the same information was delivered by an RDN in the format of a traditional diet consult.

Blinding for dietary interventions is notoriously difficult. This is especially true in the case of an elimination diet used in a population with symptoms that are sensitive to stress. Future trials would ideally utilize a sham diet to help control for the stress of an elimination diet and improve blinding. Staudacher, et al.³⁷ established eight criteria for the development of a sham diet for dietary interventions. The diet would need to be delivered in the same format as the intervention diet with similar resources and level of detail while excluding the same number of foods as the treatment diet.

Several participants contacted the researcher via email and others expressed via the survey that stressful life events prevented them from being compliant with the diet or the program. Future trials of the LFD should always include evaluations of extra-intestinal, including anxiety, depression, and fatigue using validated scales such as the Hospital Anxiety and Depression Scale (HADS)³⁸ and the Fatigue Impact Scale (FIS)³⁹. IBS symptoms can be significantly impacted by stress, anxiety, and depression (REF). A strict elimination diet, such as the LFD, has the potential to induce these conditions in some and could, in turn, worsen symptoms.

Trials assessing changes in IBS-SSS symptom scores should ideally be powered to evaluate changes by IBS-subtype. Patients on the LFD who predominantly experience constipation, may fare worse on the LFD.³⁷ One patient in the original, four-week, controlled trial dropped out during the first week of the diet due to worsening

constipation; however, both participants with constipation-predominant IBS in this trial had slightly improved symptom scores.

Goal setting, an important skill in any nutrition education intervention was not incorporated in this trial. Behavior change requires that an individual be able to exercise self-direction, including goal setting.⁴⁰ Planning ahead and goal setting by participants can help bridge the intention-action gap, as well as help maintain action in nutrition education programs.⁴⁰ Goal setting would be appropriate to incorporate into the introductory module of program to increase mindfulness of participants and decrease mental burden when faced with food choices.⁴⁰ To facilitate goal setting and planning, introductory modules can provide videos or podcasts and worksheets to walk participants through the process. Participants could be encouraged to download these sheets and keep them in places where they can be reminded of their goals and personal objectives. Health coaches or certified health education specialists could serve as a valuable resource in helping participants craft their personal goals and develop a plan to meet them.

Improving Attrition and Non-usage in Technology-based Interventions. The average attrition for four separate LFD intervention trials was 16%; however, a more conservative attrition rate of 20% was used to calculate the sample size for this trial.^{32,36,37,41} While it was expected that the convenience and anonymity offered by an internet-based program that dealt with a potentially sensitive condition would decrease attrition, the attrition rate should have been based on those of other e-health interventions and not face-to-face trials. Online interventions and courses have high attrition rates in general. Massive Open Online Courses (MOOC) have large enrollment figures, but often

very low completion rates ranging from 0.7% to 52% with a median of 12.6%⁴² and e-health interventions attrition rates as high as 60 to 80% are common⁴³. The rates vary according to course length, start date, and assessment type with shorter, recent courses with automatic grading resulting in improved rates.⁴²

Most available data focus on MOOCs and academic courses with little information assessing course completion rates for diet-related interventions. However, a recent meta-analysis, published after the completion of this trial, reported on engagement, adherence, and behavior change in online dietary interventions compiled data from 21 studies including 7,455 adults and 19 different e-health interventions.⁴³ Fourteen of the 19 trials reported improvements in dietary interventions and 12 studies reported significant changes in at least one targeted dietary behavior. However, many studies lacked engagement and non-usage attrition data. Most studies with low attrition rates included notification or reminder systems to encourage participation. This trial included reminders, sent as announcements through Canvas via email, to complete assessments during the two weeks, but not the modules that were released every 3-4 days. Non-usage rates were rarely reported, but authors noted their importance in understanding engagement with the intervention. This is especially important when there is an incentive to complete assessments, as was the case in this study. One participant in the final group of 15 only completed the introductory module, thus never received the LFD education component. Slightly over half (53%, $n = 8$) participants completed all four modules and 5 participants only completed modules 1 and 2, which were released in Week 1. A better approach might be to incentivize participants while encouraging program compliance

would be to provide incremental incentives of value given after each module is completed and the researcher verifies engagement or after mini assessments are completed during the course of the program. Another option is through a badge- or star-based system that would award their progress as they progress through the modules, while withholding the incentive of value until the end.

Early attrition is a problem in e-learning and the present study was no exception. One study reported that at least 35% of online learners drop-out before submitting their first assignment, suggesting a learner's initial experience with the online program or classroom can have a significant impact on a decision to drop out.⁴⁴ The complexity of initial tasks in the program, especially for a first-time online learner, and the cognitive overload that may result from multiple learning curves can contribute to early attrition.¹⁷ Sixteen participants passed the screening for Phase 3 and were invited to the program, yet never accepted the invitation. The screening process involved multiple online surveys, which may have contributed to cognitive overload. The two of the six participants who were early dropouts and responded to a follow-up survey reported they believed the study was too difficult to navigate. This interesting finding may indicate low levels of computer or digital literacy among some participants. Digital literacy goes beyond basic computer skills and includes "a large variety of complex cognitive, motor, sociological and emotional skills, which users need in order to function effectively in digital environments."⁴⁵ Limited digital literacy can cause those new to online learning to experience apprehension about their ability to handle the challenges of an online learning environment.⁴⁶

While internet-based interventions are increasingly common, such interventions are limited by the technology literacy of the participants. Two subjects who completed the study and others who dropped out expressed that the use of technology hindered their compliance. Going forward, internet-based interventions should ideally incorporate a technology proficiency check as a potential inclusion criterion or offer a tutorial on the specific technology and programs utilized before the intervention commences.⁸

Internet-based intervention programs should also consider the participant's "readiness for online learning" as an important factor in determining their persistence.⁴⁷ Bernard, et al.⁴⁷ studied the prerequisites of online learning predictive of achievement success. They determined there are four dimensions of "readiness":

1. Online skills, including basic computing, internet and written communication;
2. Self-management of learning and learning initiative, including time and organizational management skills;
3. Beliefs about online learning, including whether it is as effective as classroom instruction and if it is effective in helping learners achieve their goals; and,
4. Engagement with the instructor and/or other students, including the timeliness of feedback or grades, support and collaboration.

Of these four factors, two significantly predicted achievement: beliefs about online learning and self-management/initiative. The present study did not assess beliefs about online learning prior to the study, but did ask participants in the program assessment if

they felt that the program would be as effective as a one-on-one meeting with an RDN. Most (73%) reported it would be at least as effective, indicating they saw validity in the online learning model. Future interventions should include a screening question or, at minimum, a baseline assessment question on whether they believed online learning could be at least as effective as face-to-face approaches. If the present study had used this question as a screen, it could have potentially decreased the dropout rate. Tools to assess self-management and learning initiative could be used to screen those for internet-based interventions or to determine who should be targeted for pre-intervention programs to improve self-management skills and initiative.

While understanding retention and non-usage is important for developing more effective internet-based programs, additional studies are also needed that compare these programs to traditional, face-to-face education where participants are also evaluated on their compliance to the provided instruction. Studies utilizing this approach are limited, particularly in interventions involving diet education. Also, future e-health studies should include both the dropout rate and non-usage rate with additional insight as to the level of engagement when available.

Increased contact with participants through phone and/or email contact and updates to the program website are associated with more average log-ins to e-health intervention websites.⁴⁸ In the present study, the burden of contact was on the participant to obtain tailored feedback and increased engagement through the Facebook group or diet and symptom diary. To encourage more log-ins in 100% online interventions, it might be more helpful to have the dietitian or a health coach or certified health educator contact

participants directly asking if they have questions or concerns then continuing to follow-up as needed. Text message reminders were suggested by participants as a way to improve The FODMAP Fix program and would be an easy, low cost way to potentially improve engagement. Text messages could not only remind participants when assessments are due or modules open, but could be used to encourage and provide daily tips to overcoming the challenge of limited choices to improve SE. Customized or tailored text messages are significantly associated with greater intervention efficacy, as are those that incorporate a decreasing frequency – rather than a fixed frequency – over the life of the intervention.⁴⁹ Studies that include peer or counselor support tend to have higher levels of engagement with the program website.⁴⁸ Intervention studies could include required weekly or module-based discussion boards to facilitate peer support and support from the researcher. These boards could also contribute to collective efficacy if participants are encouraged to share “wins” via photos of new recipes they tried and enjoyed, unsuspecting high FODMAP ingredients they uncovered by reading labels, tips for dining out, etc. Also, weekly online chats in discussion forums or a live Q&A via webinar (with a call-in option) could increase engagement and support between the researcher and participants. Another option to increase engagement is to offer the material via podcast, as audio can be more accessible than video for many. Also, participants benefit when they can relate to the presenter or narrator, especially when the content is delivered via video.¹¹ Video-based nutrition or health education programs should use the needs assessment to understand their target audience and use presenters with whom the audience is likely to relate to maximize effectiveness of narratives in the

communication plan.¹¹ Involving participants early as co-creators of narrative- and picture-based materials for health education programs is another approach that not only increases engagement, but also improves HL.⁵⁰

Behavior Theory. Behavior change theory (BCT) also plays an important role in the success of online dietary interventions with more studies reporting significant results when they based their intervention on a BCT.^{43,51} Studies combining multiple theories or constructs may have larger effects than those focusing on a single theory.⁵¹ This study only enrolled participants who were identified as being at least in the Preparation Stage of the Transtheoretical Model (TTM) or Stages of Change Model, one of the most commonly used BCTs in diet and health interventions.^{43,51} This model was developed by Prochaska and DiClemente and is based on the notion that change is a process, not an event.⁵² In this model, an individual goes through a progressive series of five stages to make a change in behavior, though individuals can relapse into previous stages. Individuals in the Preparation Stage intend to take action usually within the coming month.⁵³ These individuals are appropriate to recruit for action-oriented programs, such as The FODMAP Fix where participants could join within days of screening or choose to join a round of enrollment later in that month.

SE is an important construct of the TTM and is defined as the confidence an individual has in their ability to take action.⁵⁴ A high level of SE could be important when initiating any dietary change, but particularly a strict elimination diet. The potential cognitive overload of those unaccustomed to e-learning could have also impacted SE. Internet-based programs should seek to assess the digital literacy of interested

participants and ensure that they have levels of SE regarding their ability to participate in online learning or provide training that sufficiently prepares the participant with the required skills and confidence needed to engage in an e-health program. Combining SE and the TTM in future studies, particularly in elimination diet interventions, has the potential to improve compliance and outcomes. Future research should investigate how SE differs pre- and post- between both traditional dietary interventions versus an elimination diet, as well as traditional, face-to-face delivery of diet education compared to an online course such as The FODMAP Fix.

Practice-based Recommendations

Many of the above-mentioned recommendations for improving future research can also be practically applied to developing better LFD and IBS and/or internet-based health or nutrition programs, particularly in regards to strategies to decrease attrition. Since this was the first study to assess an internet-based LFD education program for people with IBS, there is much work needed in this space. While the present trial focused on the elimination phase of the diet, there are few studies investigating the reintroduction and adapted phases, particularly in US populations. An internet-based reintroduction program could be an important tool to assist those who have started the LFD. Research is clear that there are potential long-term implications to following the LFD as indicated by short-term changes from the elimination phase of the LFD, including changes to the gut microbiome and metabolome.⁵⁵ Also, the diet limits a number of nutrients and could compromise the long-term nutritional profile of a patient's diet. Individuals with gastrointestinal disorders who change their diet may be at an increased risk for disordered

eating. Gastrointestinal symptoms that are individuals relate to food may result in food aversions and altered eating habits.⁵⁶ Programs need to not only encourage reintroduction, but also provide support from qualified professionals to those who may have developed or compounded disordered eating habits. Care should be taken to ensure a variety of food is included in the diets of those with IBS to maximize nutrient intake, including high FODMAP foods rich in beneficial prebiotics. Given the number of potential pitfalls of the LFD, any internet-based program should be created by or developed in coordination with an RDN trained on the LFD.

Internet-based e-health programs should be created from a public health perspective and based on theories of health education. Failing to do so only increases the amount of unreliable health promotion programs available on the internet and, if these programs are created by RDNs or other healthcare professionals, it threatens to discredit otherwise qualified professions. While there is an opportunity to create online programs to enhance revenue for practitioners, the focus should be on creating meaningful programs designed to maximize engagement, encourage completion, and promote behavior change. Practitioners to program development should also apply recommendations for increasing engagement and decreasing attrition in interventions. Finally, practitioners should also build evaluation tools into the beginning stages of program development. Following these recommendations from lessons learned in this study can help future researchers and practitioners develop effect internet-based nutrition and health promotion programs.

CHAPTER VI

CONCLUSION

In summary, while over half of participants experienced reductions in their IBS-SSS these differences were not significant and some patients experienced worsening of symptoms. Without a control group or adequately powered study, conclusions cannot be drawn from the data. The LFD is effective in alleviating IBS symptoms in 50-80% of people with IBS. Estimates of the size of the US population with some form of IBS are estimated at over 20%, but unfortunately, many of these neither are diagnosed nor meet with an RDN. New, innovative approaches are needed to meet the nutrition education needs for these patients, but also for an increasingly disease-burdened population that could benefit from credible, affordable, and accessible dietary interventions.

Key components of any innovative approach to nutrition education will include the use of technology and HBT, both of which can aid in improving HL. Tactics that decrease the working memory and cognitive load of participants can be helpful in improving HL. Specifically, in internet-based programs, the use of video, visuals, and the spoken word can be beneficial in improving HL. New online learners or those with limited digital literacy benefit from pre-intervention training that both provides the skill and confidence they need to engage in an online nutrition education course. If participants lack HL, not only are they more likely to dropout from a study or program, they experience decreased HRQOL. Public health programs targeting even well-educated

individuals should incorporate tactics to improve HL, as disease complexity and symptom burden can decrease the HL level of anyone.

Individuals often turn to the internet for information on nutrition and health-related topics before connecting with a physician or RDN. Creating thoughtfully designed programs, based on a needs assessment and a thorough understanding of the audience that incorporates multiple HBTs in constructive ways is important, but only if the programs are engaging and accessible. Attrition and non-usage remains an issue with internet-based programs. RDNs have the responsibility to create programs designed to improve public health. As nutrition education and promotion professionals, we must own our role as nutrition experts and develop education programs that are innovative and broaden access to affordable healthcare. Insurance coverage for RDN consultations, even in the critical care setting, is limited and physician referrals are still lagging behind the need and opportunity. If we are to contribute to the fight against obesity and the burden of chronic disease in America and around the world, we must develop new, strategic approaches that are accessible and affordable to the public. We cannot wait for systems to change. People need not only the knowledge we possess, but they need help in understanding how to apply it and tools to boost their SE to make lasting behavior changes.

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CHAPTER III

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APPENDIX A

TABLES

Table 1. Demographics of Invited Participants, <i>n</i> = 52	
	No. (%)
Gender	
Female	46 (88)
Male	3 (6)
Unspecified	3 (6)
Race/ethnicity	
Caucasian	38 (71)
Black/African American	4 (8)
Other	11 (21)
BMI	27.93±7.37
Diagnosis	
Self-diagnosed	28 (54)
MD/DO, NP, PA	24 (46)
IBS Sub-type	
Constipation	12 (23)
Diarrhea	22 (42)
Mixed	18 (35)

Table 2. Demographics of Participants Who Completed Assessments, <i>n</i> = 15	
	No. (%)
Gender	
Female	14 (93)
Male	1 (7)
Race/ethnicity	
Caucasian	14 (93)
Other	1 (7)
BMI	27.1±6.3
Diagnosis	
Self-diagnosed	6 (40)
MD/DO, NP, PA	9 (60)
IBS Sub-type	
Constipation	2 (13)
Diarrhea	9 (60)
Mixed	4 (27)

Table 3.Pre-/Post-Intervention Assessments, $n = 15$

	<i>Mean</i>	<i>Median</i>	<i>SD</i>	<i>Minimum</i>	<i>Maximum</i>
Initial IBS-SSS	215.80	210.00	78.25	95.00	400.00
Final IBS-SSS	218.20	230.00	121.52	30.00	420.00
Initial IBS-QOL	78.93	72.00	22.21	46.00	133.00
Final IBS-QOL	78.27	76.00	27.85	48.00	131.00
Initial SE ^a	59.13	56.00	22.67	14.00	93.00
Final SE ^a	55.73	49.00	24.03	25.00	96.00

^aSE=Self-efficacy

Table 4.
IBS-QOL Subscales, $n=15$

	<i>Mean</i>	<i>SD</i>	<i>Minimum</i>	<i>Maximum</i>
Dysphoria Initial	18.07	7.23	8.00	31.00
Dysphoria Post	17.60	9.01	8.00	34.00
Activity Interference Initial	15.93	5.47	9.00	28.00
Activity Interference Post	15.07	5.73	10.00	25.00
Body Image Initial	9.93	3.20	5.00	17.00
Body Image Post	10.33	3.85	5.00	18.00
Health Worry Initial	7.00	2.42	4.00	13.00
Health Worry Post	6.87	2.88	3.00	14.00
Food Avoid Initial	10.13	3.89	4.00	15.00
Food Avoidance Post	10.47	3.58	4.00	15.00
Social Reaction Initial	9.00	3.30	4.00	16.00
Social Reaction Post	8.73	3.58	5.00	16.00
Sexual Initial	3.60	2.16	2.00	10.00
Sexual Post	3.73	2.28	2.00	10.00
Relationships Initial	5.27	1.58	4.00	10.00
Relationships Post	5.33	2.13	3.00	11.00

Table 5.Paired Samples Test: Changes Post to Pre, $n = 15$

	<i>Mean</i>	<i>SD</i>	95% Confidence Interval of the Difference		<i>t</i>	<i>df</i>	<i>Sig. (2- tailed)</i>
			Lower	Upper			
IBS-SSS	2.40	96.34	-50.95	55.75	.10	14.00	.92
IBS-QOL	-.67	16.57	-9.84	8.51	-.16	14.00	.88
Self-efficacy	-3.40	22.50	-15.86	9.06	-.59	14.00	.57
Dysphoria	-.64	4.97	-3.51	2.23	-.48	13.00	.64
Interference in Daily Activity	-.87	3.23	-2.65	.92	-1.04	14.00	.32
Bod Image	.40	3.52	-1.55	2.35	.44	14.00	.67
Health Worry	-.13	2.42	-1.47	1.20	-.21	14.00	.83
Food Avoidance	.33	2.94	-1.30	1.96	.44	14.00	.67
Social Reaction	-.27	2.12	-1.44	.91	-.49	14.00	.63
Sexual	.13	1.73	-.82	1.09	.30	14.00	.77
Relationship	.07	1.16	-.58	.71	.22	14.00	.83

Table 6.

Descriptive Statistics: Responder Status, Sub-type, Diet Compliance

	<i>Mean</i>	<i>Std. Deviation</i>	<i>N</i>
How would you describe your IBS type? ^a	2.13	.640	15
Responder Y/N ^b	.2857	.46881	14
Compliant with diet - yes or no ^c	.6429	.49725	14

^aIBS subtype: 1=Constipation; 2=Diarrhea; 3=Mixed^bResponder? 0=No; 1=Yes^cCompliant with diet? 0=No; 1=Yes**Table 7.**

Correlations Between Responder Status, Sub-type, and Diet Compliance

	How would you describe your IBS type?	Responder Y/N	Compliant with diet - yes or no
How would you describe your IBS type? ^a	1	-.076	.167
		.796	.569
	15	14	14
Responder Y/N ^b	-.076	1	.184
	.796		.546
	14	14	13
Compliant with diet - yes or no ^c	.167	.184	1
	.569	.546	
	14	13	14

^aIBS subtype: 1=Constipation; 2=Diarrhea; 3=Mixed^bResponder? 0=No; 1=Yes^cCompliant with diet? 0=No; 1=Yes

Table 8.

Correlation Between Changes in IBS-SSS and Time Spent in Course

		Change IBS-SSS	Time on Canvas in minutes
Change in IBS-SSS	Pearson Correlation	1	-.035
	Sig. (2-tailed)		.902
	N	15	15
Time on Canvas in minutes	Pearson Correlation	-.035	1
	Sig. (2-tailed)	.902	
	N	15	15

Table 9.

Correlations Between Changes in IBS-SSS and the Last Module Accessed

			IBS-SSS change	Last module accessed
Spearman's rho	Change IBS- SSS	<i>r</i>	1.00	.195
		Sig. (2-tailed)	.	.486
	Last module accessed	<i>r</i>	.2	1.00
		Sig. (2-tailed)	.49	.

Table 10.Paired T-test on FODMAP Knowledge Samples Statistics, $n = 12$

	<i>Mean</i>	<i>SD</i>	<i>SEM</i>
FODMAP Quiz Pre	2.75	1.96	0.57
FODMAP Quiz Post	4.08	1.38	0.40

Table 11.Paired T-test on FODMAP Knowledge, $n = 12$

	<i>M</i>	<i>SD</i>	<i>SEM</i>	95% Confidence Interval of the Difference		<i>t</i>	<i>df</i>	<i>Sig. (2- tailed)</i>
				Lower	Upper			
FODMAP Quiz Pre/Post	-1.33	1.56	0.45	-2.32	-0.34	-2.97	11.00	0.01

APPENDIX B

PHASE 1: NEEDS ASSESSMENT SURVEY, POSTER WITH RESULTS

The Effect of Diet on Irritable Bowel Syndrome Symptoms and Its Role in the Treatment Plan

Rachel Adams, MS, RDN/LD¹ and K. Shane Broughton, PhD¹

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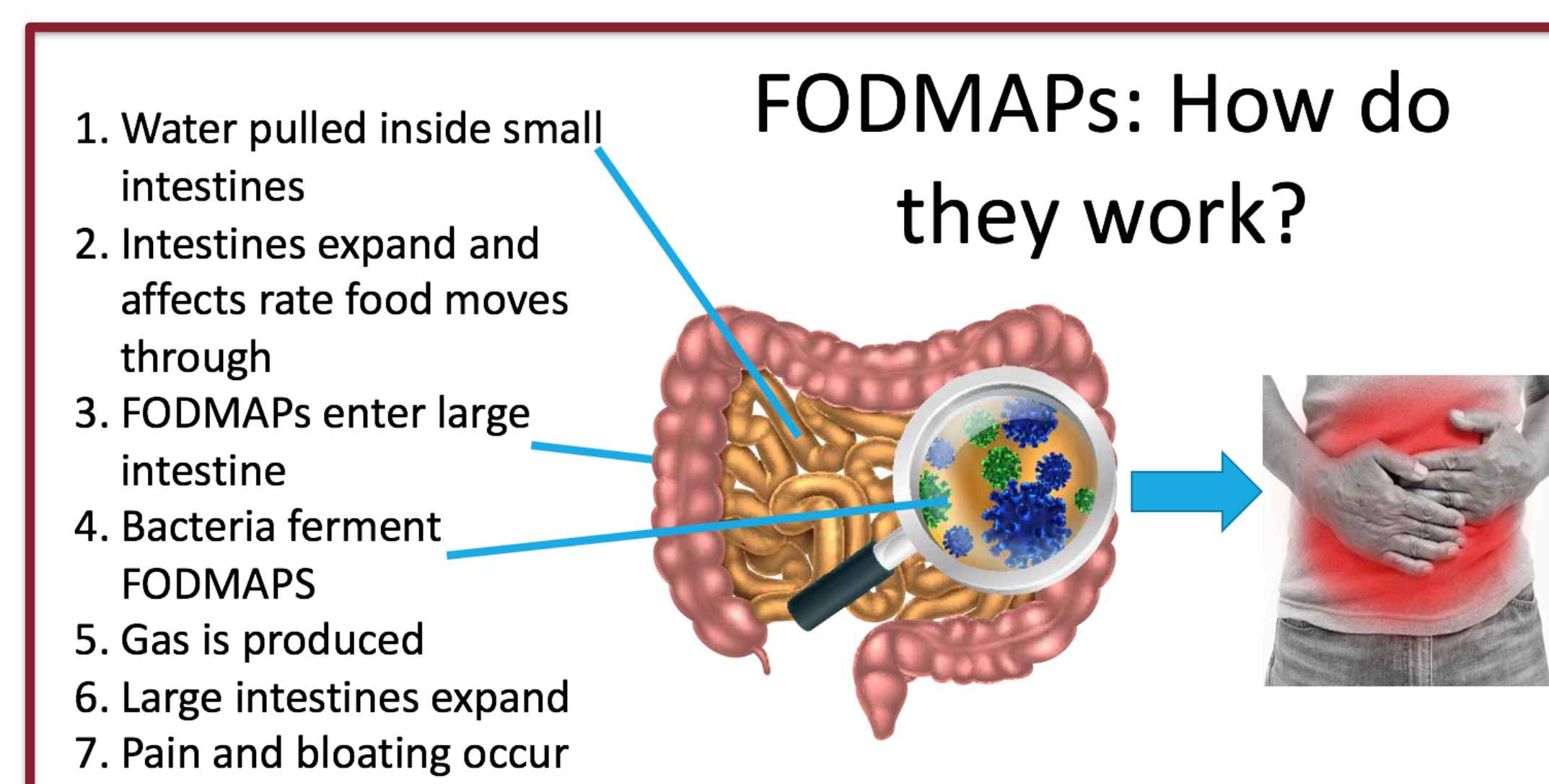
Aim

The primary aim of this research survey was to determine to what extent patients with Irritable Bowel Syndrome (IBS) relate their symptoms to diet and what role diet has in their treatment plan. Data from this survey informed the development an internet-based, Low FODMAP Diet (LFD) education program to treat symptoms of IBS. The survey also served as a recruiting tool for an ongoing research study to test the effectiveness of the internet-based LFD education program.

Introduction

An estimated 12% of North Americans have Irritable Bowel Syndrome (IBS) and most are women.¹ However, this figure could be an underestimation as **76.6% people with IBS are never formally diagnosed**.² IBS is the most commonly diagnosed gastrointestinal disorder.³ Pharmacological treatment for IBS is only marginally effective. The **Low FODMAP Diet (LFD)** is an treatment for IBS symptoms and is used increasingly in the clinical setting.⁵

The LFD diet leads to a beneficial clinical response in 50%–80% of IBS patients.⁴ The term FODMAP stands for “Fermentable, Oligosaccharides, Disaccharides, Monosaccharides, and Polyols”.⁵ Most studies seeking to establish the efficacy of the diet include limited diet teaching and often provide supplemental handouts for additional information.

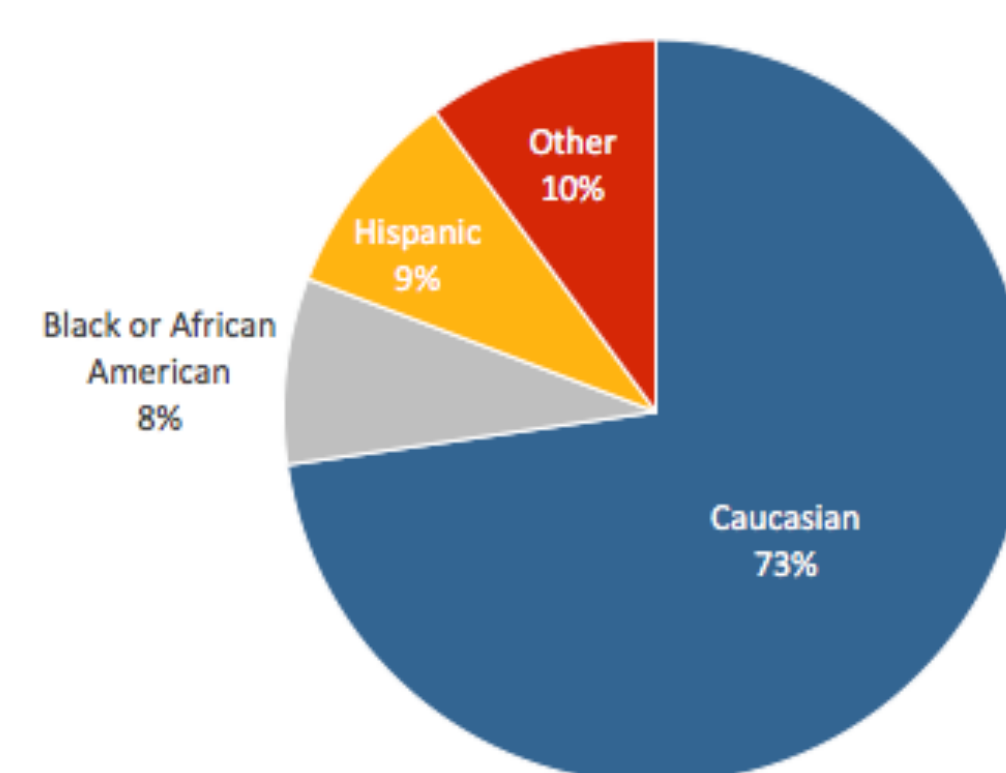


Registered dietitians (RDNs) are the most appropriate choice for continued LFD education delivery⁶, but barriers, including lack of physician referrals, poor insurance coverage, and a lack of adequately trained RDNs prevent patients from receiving needed education.

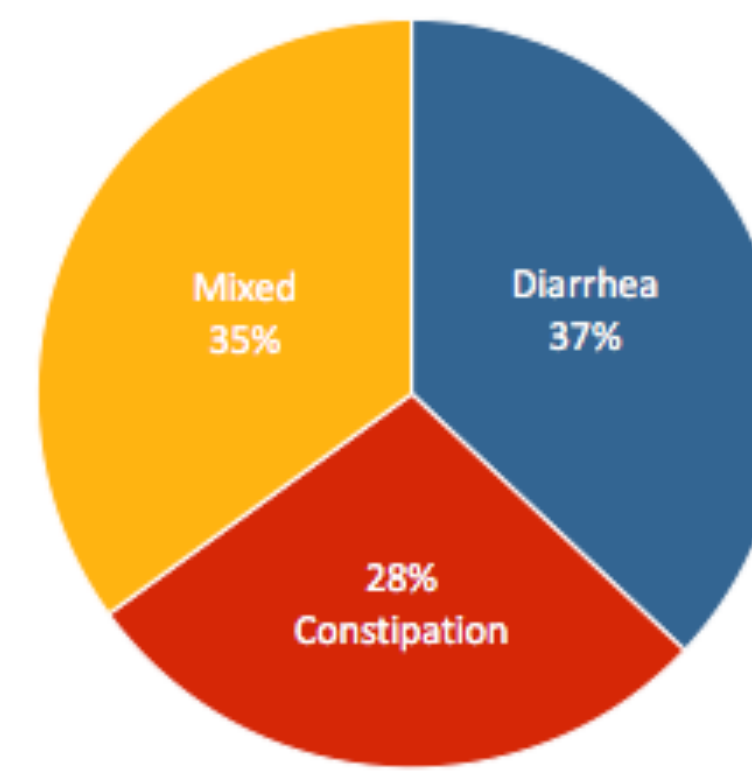
Developing a diet education program requires a needs assessment of the population. An effective program should address participant knowledge, skill, and attitude about their condition and the proposed diet intervention. This survey provided important information for a LFD education program for women, in particular, with IBS.

Results

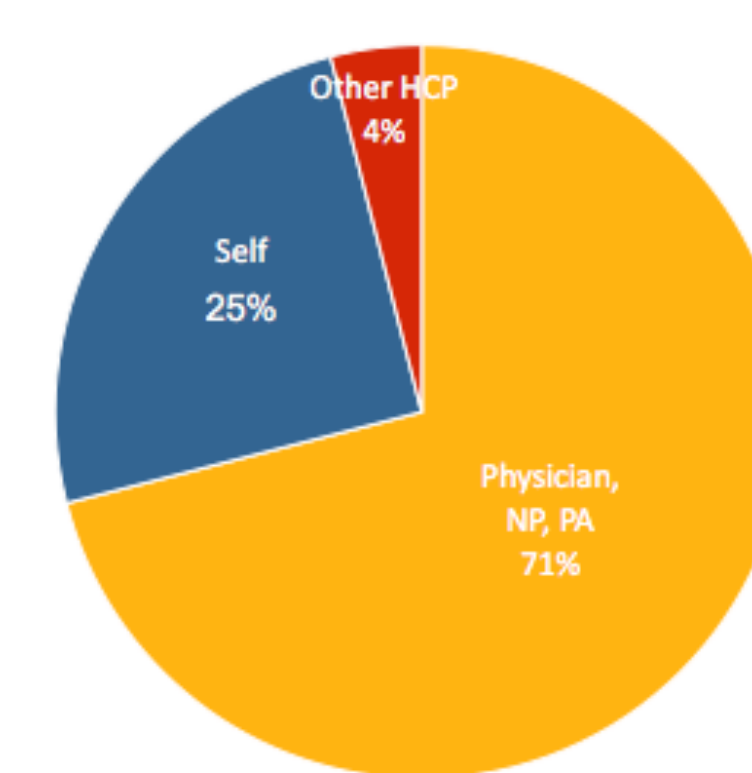
148 completed surveys and 12 partial responses submitted. 93% of respondents were female. Ages ranged from 19 to 65 years with an average age of 36 years.



Race



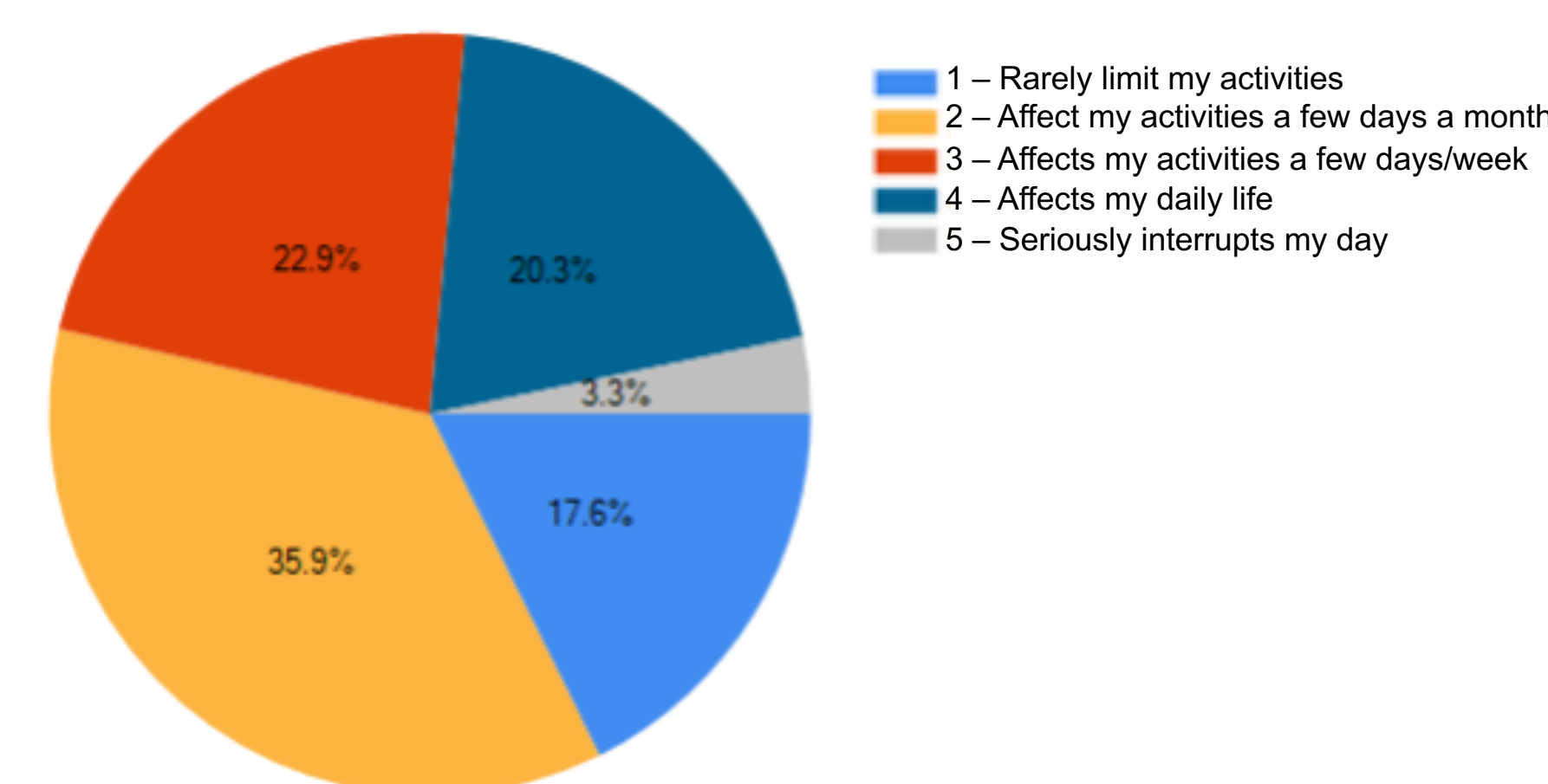
IBS-Subtype



Who diagnosed you?

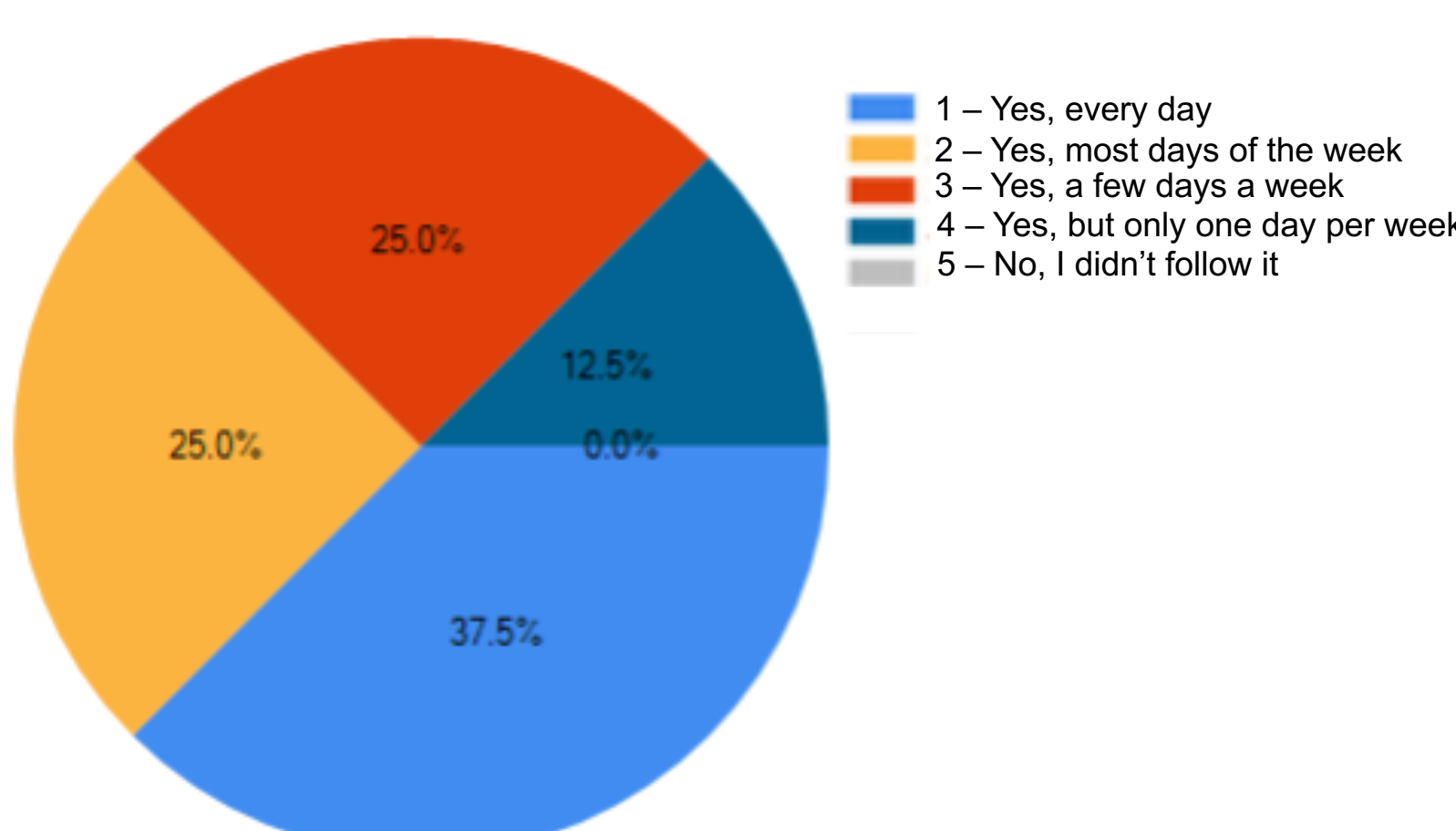
- 57% of participants believe their IBS symptoms are related to what they eat with another 33% who are unsure.
- 92% attempted to manage their IBS with dietary changes and 81% currently avoid foods due to perceived sensitivities.
- Many patients report avoiding foods high in FODMAPs including wheat, dairy, soy, foods high in fructose, onions, garlic, and corn, but not following the LFD.**
- 55% reported that their doctor prescribed a specific diet or changes to their current diet to help manage their IBS.
- The most common RDN diet advice included avoidance of FODMAPs, caffeine, alcohol, gas producing foods (beans, cabbage, onions), and to eat smaller, more frequent meals.

How do your IBS symptoms affect your life in an average week?



Only 6.8% of those who saw a physician were referred to a RDN for their IBS.

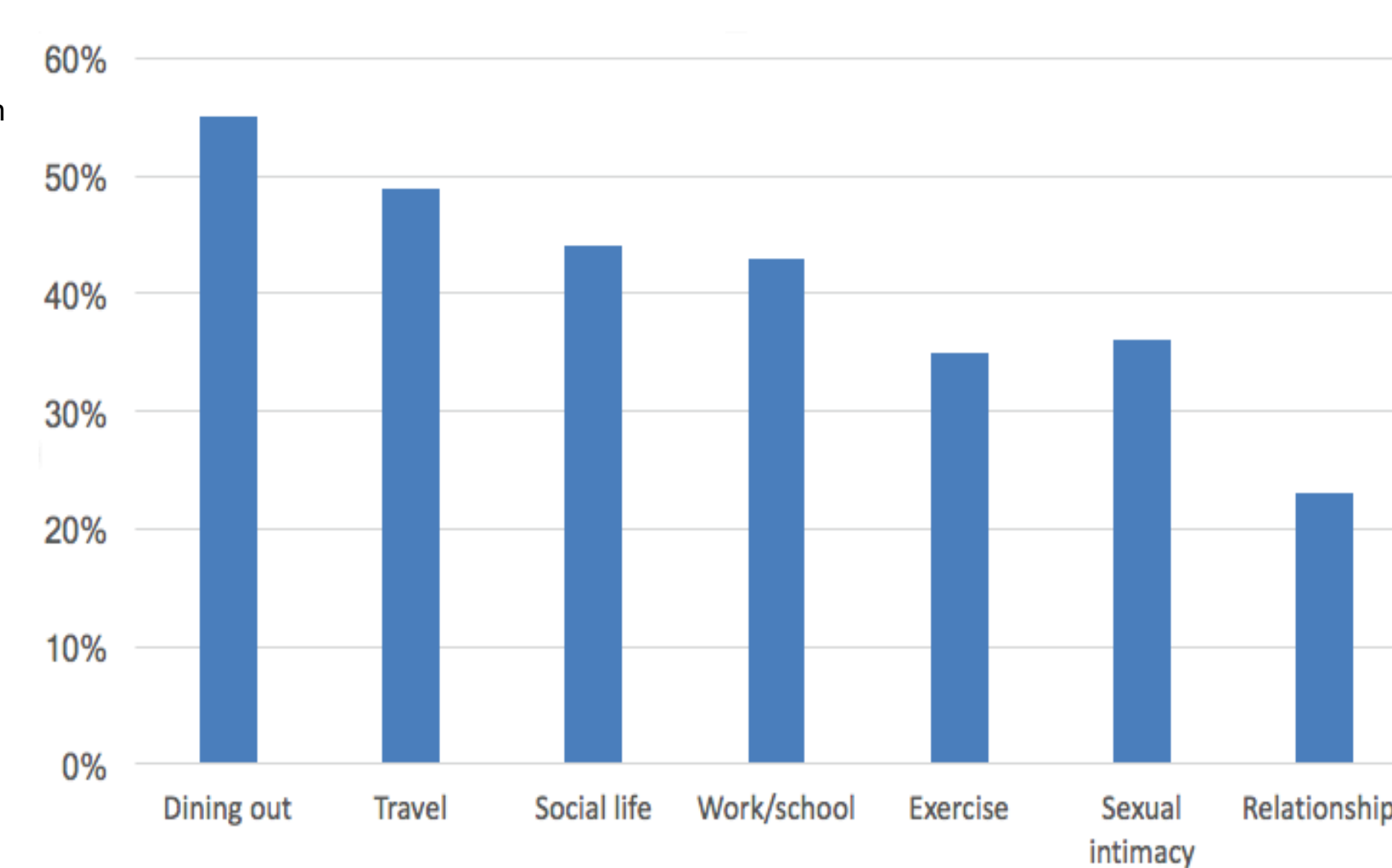
Did you follow your RDN's advice?



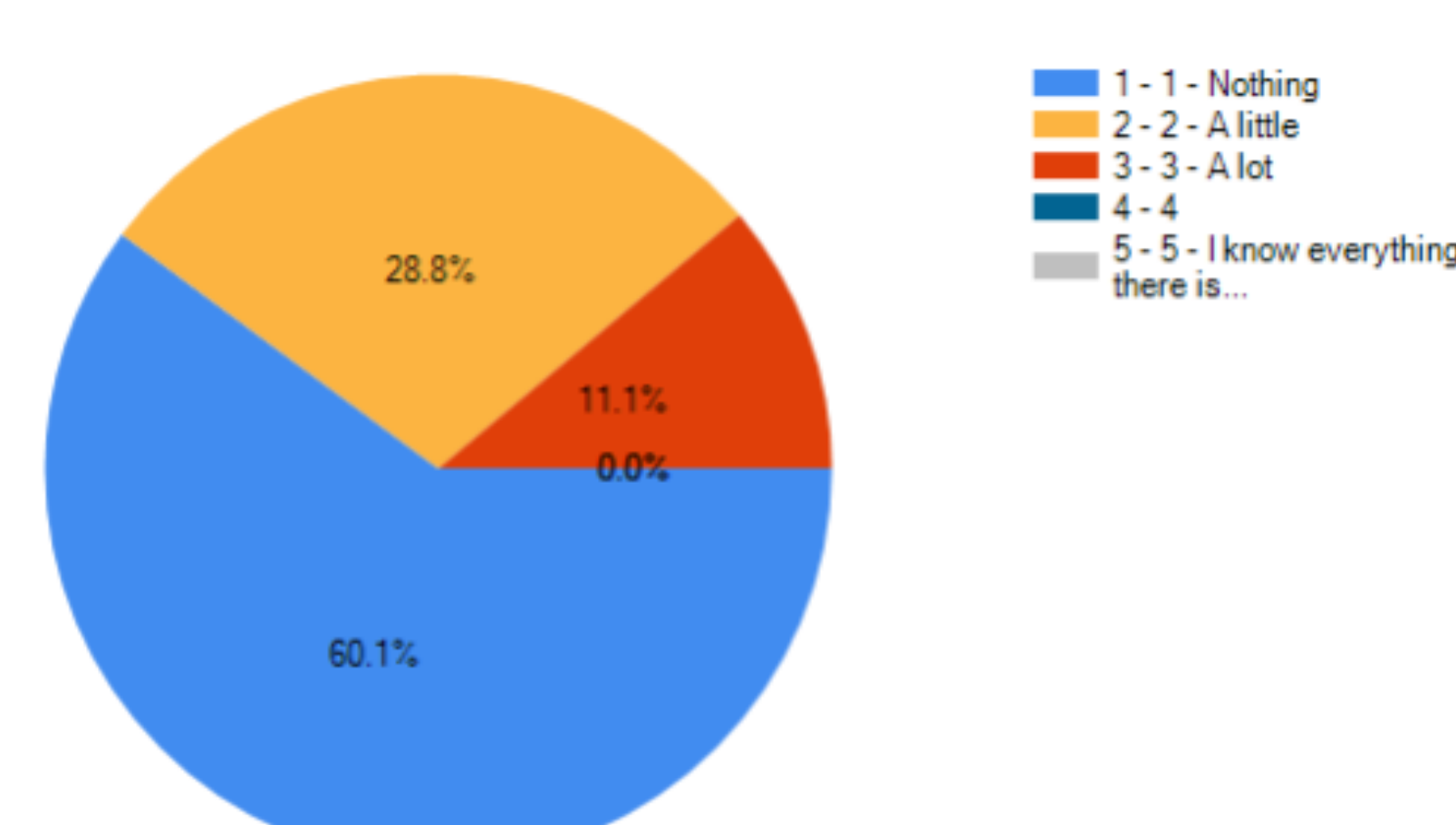
29% reported the diet advice “really helped my symptoms”, 71% “helped a little”

Diet changes had best effect on gas, stomach pain, and bloating with a moderate effect on diarrhea and variable on constipation.

IBS symptoms cause “moderate” or “major” affect on QOL



How much do you know about the LFD?



34% had followed the LFD, 19% currently followed the LFD. Most who stopped the diet reported that it was either too difficult or they had little symptom relief.

Methodology

Adults 18 to 65 years of age with self-reported IBS were prospectively recruited to an online questionnaire study on IBS and diet administered through PsychData. Participants were recruited through an email announcement to Texas Woman's University students, faculty, and staff and through the researcher's social media accounts. Self-reported demographic, medical, and personal decision making data around diet were collected from each participant.

Discussion & Conclusion

- Most believe their IBS symptoms are related to diet.
- Many physicians are not addressing diet in the context of IBS.
- Very few physicians refer patients to RDNs for IBS.
- IBS sufferers are largely self-managing their symptoms with diet and avoiding foods due to perceived sensitivities.
- The LFD is underutilized.
- There is a need for enhanced physician and RDN education on the LFD.

Further Studies

A prospective trial assessing the effectiveness of a two-week, four module LFD diet education program is currently underway. The study will be complete by July 1, 2019.

References

1. Chey, Kurlander, & Eswaran, S. (2015). *JAMA*. 2015; 313(9), 949-958.
2. Hungin, et al. *Aliment Pharmacol & Ther*. 2005; 21(11):1365-1375.
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6. O'Keeffe M, Lomer MC. *J Gastroenterol and Hepatol*. 2017;32:23-6.

Acknowledgements

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APPENDIX C

THE FODMAP FIX PROGRAM STRATEGY PLANNING GUIDE, CONTENT OUTLINES, AND EXAMPLE

The FODMAP Fix Strategy Planning Guide		
Program Activity	Mediator	Strategy
Introductory Module Videos		
Welcome	Perceived benefit	Motivational message
Module overview	Outcome expectations	Setting expectations for program content, outcomes, requirements
Assessments overview	Outcome expectations	Setting expectations for program outcomes, requirements
Conclusion	Reinforcement	Reinforce key messages
Module 1 Videos		
Intro to Module 1	Perceived benefit	Motivational message
LFD Introduction	Perceived benefit of taking action	Show evidence of taking action with LFD
How to Use Monash App	Self-efficacy	Developing skills
High FODMAP Foods: Category 1 and Self-Check Quiz	Self-efficacy	Developing knowledge; Reinforce learning via self-assessment
High FODMAP Foods: Category 2 and Self-Check Quiz	Self-efficacy	Developing knowledge; Reinforce learning via self-assessment
Narrative: Rachel Adams	Self-efficacy	Narrative of individual with IBS who had success on LFD to incite emotional arousal; motivational message; role modeling
High FODMAP foods: Category 3 and Case Study	Self-efficacy	Developing knowledge; Analyzing/critically evaluating issues
Conclusion to Module 1	Reinforcement	Reinforce key messages
Module 1 Resources		
High/low FODMAP Foods Table	Information environment	Reinforce knowledge
Recipe e-Book	Food/nutrition skills	Developing knowledge and skills
Food and Symptom Diary	Engagement; Self-regulation	Used throughout the program to enhance self-regulation; analyzing/critically evaluating symptoms and foods; provides opportunity to connect directly with RDN
Optional Facebook Group	Engagement; Social modeling; Social persuasion	Opportunity to develop social support/persuasion; provides opportunity to connect directly with RDN
Module 2 Videos		
Intro to Module 2	Perceived benefit	Motivational message

Dining Out	Social norm; self-efficacy	Developing knowledge; Addresses “new normal” of making specific requests at restaurants
Grocery Shopping and Reading Labels	Food/nutrition skills	Encouraged participant to share video with primary cook/grocery shopper (environmental support)
Recipe hacks	Food/nutrition skills	Developing knowledge/skills; Encouraged participant to share video with primary cook/grocery shopper (environmental support)
Conclusion to Module 2	Reinforcement	Reinforce key messages
Module 2 Resources		
Dining Out Cards	Self-efficacy; Social norm	Teaching how to be a personal advocate; normalizing restaurant requests
Recipe Hacks	Self-efficacy; Food/nutrition skills	Developing knowledge/skills
Grocery Shopping Helper	Self-efficacy; Food/nutrition skills	Developing knowledge/skills
Low FODMAP Menu Choices	Self-efficacy; Food/nutrition knowledge	Developing knowledge
Module 3 Videos		
Intro to Module 3	Perceived benefit	Motivational message
FODMAP Mess-ups and Mistakes	Self-efficacy; Self-regulation	Developing knowledge; Creating personal food policies around FODMAPs
Trouble Shooting Symptoms	Self-efficacy; Self-regulation	Developing knowledge; Creating personal food policies around FODMAPs
Conclusion to Module 3	Reinforcement	Reinforce key messages
Module 4 Videos		
Intro to Module 4	Perceived benefit	Motivational message
Quick and Easy Breakfast Ideas	Food/nutrition skills; self-efficacy	Developing knowledge; role modeling
Granola Balls Demonstration	Self-efficacy	Food demonstration; Developing skills
Fast and Cheap Lunch and Dinners	Food/nutrition skills; self-efficacy	Developing knowledge; role modeling
Conclusion to Module 4	Reinforcement	Reinforce key messages

The FODMAP Fix: Plan (4-week Program)

Elimination Phase

Screening

- FODMAP FFQ

Introduction (Baseline assessments)

- 3 videos

Assessments:

- IBS QOL
- IBS SSS
- 24-hour recall
- FODMAP Quiz

Module 1: FODMAP Basics

- 7 videos
- Food and symptom diary

Resources:

- High and Low FODMAP foods tables
- Recipe eBook

Module 2: Dining out and cooking at home

- 6 videos
- FODMAP FFQ or 3-day food record
- Self-efficacy assessment
- FODMAP Quiz

Resources:

- Dining out cards: FODMAPs to avoid
- Recipe hacks: seasoning, dressing, dips, and marinades recipes, pasta sauce recipe
- Grocery Shopping Helper
- Low FODMAP Menu Choices

Module 3: Mess-ups and Trouble Shooting

- 4 videos

Module 4: Overcoming Food Boredom – New LFD menus and recipes

- 6 videos

Assessments:

- IBS QOL
- IBS SSS
- FODMAP FFQ
- Self-efficacy assessment
- Internet-based program feedback

The FODMAP Fix: Plan (2-week Program)

Elimination Phase

Screening

- FODMAP FFQ

Introduction (Baseline assessments)

- 4 videos

Assessments:

- IBS-QOL
- IBS-SSS

Module 1: FODMAP Basics

- 8 videos
- Food and symptom diary

Resources:

- High and Low FODMAP foods tables
- Low FODMAP Mini Recipe eBook

Module 2: Dining out and cooking at home

- 6 videos
- Food and symptom diary

Resources:

- Dining out cards: FODMAPs to avoid
- Recipe hacks: seasoning, dressing, dips, and marinades recipes, pasta sauce recipe
- Grocery Shopping Helper
- Menus with high FODMAP foods highlighted

Module 3: Mess-ups and Trouble Shooting

- 4 videos
- Food and symptom diary

Module 4: Overcoming Food Boredom – New LFD menus and recipes

- 6 videos

Assessments:

- IBS-QOL
- IBS-SSS
- Self-efficacy assessment
- Internet-based program feedback
- FODMAP Quiz

Video Plan: The FODMAP Fix

11 Voiceover PPTs, 14 Videos, 1 Video +PPT

Introduction to The FODMAP Fix

1. Welcome
2. Module overview
3. Assessments overview
4. Conclusion

Module 1: FODMAP Basics

1. Intro to Module #1
 - a. What it will cover
 - b. Resources available
 - c. Module #1 participant expectations
2. Low FODMAP Diet introduction
3. How to use the Monash App
4. High FODMAP foods to avoid by category – Group 1
 - a. Bread, cereal, rice, and pasta
 - b. Vegetables
 - c. Fruits
 - d. Dairy
 - e. Self-assessment: quiz
5. High FODMAP foods to avoid by category – Group 2
 - a. Beans, nuts, vegetarian substitutions
 - b. Meat, fish, eggs
 - c. Beverages
 - d. Self-assessment: quiz
6. Narrative: Rachel Adams
7. High FODMAP foods to avoid by category – Group 3
 - a. Condiments
 - b. Sweets and treats
 - c. Self-assessment: Case study
8. Module #1 Wrap-up
 - a. Highlights of what we covered
 - b. Where to get help – resources
 - c. What is due and when

Module 2: Dining out and cooking at home

1. Intro to Module #2
 - a. What it will cover
 - b. Resources available
 - c. Module #2 participant expectations
2. Dining out

- a. Top tips
 - b. Checking menus online in advance
 - c. Making special requests
- 3. Grocery shopping and reading labels
 - a. Key words on packages (breaded, fried, spicy)
 - b. Where to search for ingredients list
 - c. What sections to avoid at the supermarket (frozen fried, pastas, salsas)
- 4. Recipe hacks
 - a. Homemade seasoning mixes
 - b. FODMAP-free flavor: garlic oil, lactose free milk, green onion tops
- 5. Module #2 Wrap-up
 - a. Highlights of what we covered
 - b. Where to get help – resources
 - c. What is due and when

Module 3: Mistake and Trouble Shooting

- 1. Intro to Module #3
 - a. What it will cover
 - b. Resources available
 - c. Module #3 participant expectations
- 2. FODMAP mess-ups and mistakes
 - a. What to do when you eat a red food or a little too much of a yellow
 - b. Dining out and realize you've been served something high in FODMAPs
- 3. Trouble shooting symptoms
 - a. Symptoms were better, but now worse
 - b. Haven't improved at all
- 4. Module #3 Wrap-up
 - a. Highlights of what we covered
 - b. Where to get help – resources
 - c. What is due and when

Module 4: Overcoming Food Boredom – New LFD Menus and Recipes

- 1. Intro to Module #4
 - a. What it will cover
 - b. Resources available
 - c. Module #4 participant expectations
- 2. Quick and easy ideas for breakfast
- 3. Grab and go LFD snacks
 - a. What to avoid
 - b. Interesting snack ideas
- 4. Granola balls recipe video with Rachel and Caroline

5. Fast and cheap LFD options for lunch and dinner
 - a. Drive through best bets
 - b. Easy ideas for home
6. Module #4 Wrap-up
 - a. Highlights of what we covered
 - b. What is due and when

Link to a video sample from The FODMAP Fix, Module 4: Granola Balls:
<https://www.youtube.com/watch?v=b8X-MEhUxrM>

Screen Shot: Example of Module Layout

The screenshot displays the Canvas LMS interface for a course. On the left is a dark sidebar with navigation icons and labels: Home, Account, Dashboard, Courses, Calendar, Inbox, Commons, and Help. To the right of the sidebar is a light gray navigation menu with links: Home, Announcements, **Modules** (highlighted in blue), Assignments, Discussions, Grades, People, Pages, Files, Syllabus, Outcomes, Quizzes, Conferences, Collaborations, and Settings. The main content area shows the 'Modules' section. At the top right of this section are two buttons: 'View Progress' and '+ Module'. The modules are listed in a light gray box with a vertical green bar on the left. Each module has a header with a dropdown arrow, a green checkmark, a plus button, and a three-dot menu button. The modules are: 1. **Introduction**: Contains 'Start Here!', 'First FODMAP Quiz' (May 27 | 5 pts), and 'Introductory Videos'. 2. **Module 1: FODMAP Basics**: Contains 'Module 1 Videos', 'FODMAP Food Lists.pptx', 'Low FODMAP Mini Recipe eBook.pdf', and 'Food and Symptom Diary'. 3. **Module 2: Dining Out and Cooking at Home**: Contains 'Module 2 Videos' and 'FODMAP Fix - Recipe Hacks.docx'. Each item in the list has a green checkmark and a three-dot menu button.

Module	Item	Status	Actions
Introduction	Start Here!	✓	⋮
	First FODMAP Quiz May 27 5 pts	✓	⋮
	Introductory Videos	✓	⋮
Module 1: FODMAP Basics	Module 1 Videos	✓	⋮
	FODMAP Food Lists.pptx	✓	⋮
	Low FODMAP Mini Recipe eBook.pdf	✓	⋮
	Food and Symptom Diary	✓	⋮
Module 2: Dining Out and Cooking at Home	Module 2 Videos	✓	⋮
	FODMAP Fix - Recipe Hacks.docx	✓	⋮



THE FODMAP FIX

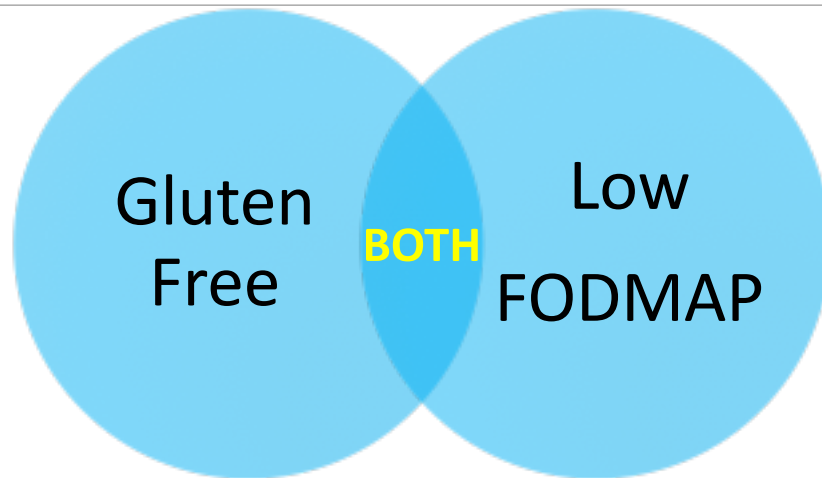
Module 1

Lesson 4

As a result of today's lesson, you will...

1. Learn how to choose low FODMAP foods over high ones.
2. Start the LFD by removing most of the high FODMAP foods from your diet over the next 2-3 days.
3. Be more confident that you can follow the LFD than you were before the lesson.
4. Find that your IBS symptoms improve over the next 2-3 days as you start the diet.

Smart FODMAP Swaps



Swaps: Bread, Cereal, and Pasta

High FODMAP	Low FODMAP
Wheat-based bread (whole wheat, white, oatmeal, etc.)	Gluten-free white bread (not multigrain), sourdough bread (avoid commercially prepared)
Flour tortillas	Corn tortillas
Granola, corn*, rice crisps, or wheat flake cereal	Gluten-free corn flake cereal, specialty low-FODMAP cereal
Instant or quick oats (more than ½ cup)	Rolled or “old fashioned” oats
Regular pasta or spaghetti noodles, gnocchi, couscous	Brown rice or quinoa pasta or noodles, gluten free couscous

Swaps: Vegetables

High FODMAP	Low FODMAP
Asparagus	Greens, spinach, kale,
Broccoli stalks	Broccoli heads
Brocolini heads	Brocolini stalks or whole (1/2 cup)
Cauliflower	Squash: Spaghetti, yellow, or zucchini
Corn (more than ½ cob)	Potato
Garlic	Fennel, Ginger
Mushrooms: button, Shitake, portabello	Oyster mushroom
Onion, leek, shallots	Green tops of spring onion or scallion
Peas: sugar snap, snow	Green beans
Celery	Cucumber, carrots

Swaps: Fruits

High FODMAP	Low FODMAP
Seed fruits: Apples, pears, watermelon	Grapes, kiwi, cantaloupe, honeydew melon
Stone fruits: apricots, cherries, peaches, plums, nectarines	
Citrus: Grapefruit, mango	Pineapple, oranges, clementines, lemons, limes
Berries: Blackberries, boysenberries (>5 berries), blueberries (> ¼ cup), raspberries (> than ½ cup)	Strawberries
Avocado or Guacamole	1/8 Avocado, 2T guacamole (no onion, garlic)
Banana, ripe or browning	Banana, firm; dried banana chips
Pomegranate	Kiwi fruit
Figs	
Dried fruit (>1 Tbsp raisins,	

Swap: Dairy and Dairy Alternatives

High FODMAP	Low FODMAP
Milk and cream: Dairy (cow), buttermilk, evaporated milk, and goat's milk	Lactose-free: non-flavored variety (skim, 2%, etc.)
Milk: Dairy-free: oat, soy, coconut (except canned for cooking)	Almond, rice, hemp, macadamia, quinoa
Dairy-based yogurt	Lactose-free, coconut or goat milk-based
Kefir	
Custard	Made with lactose-free milk
More than 1 serving of cream cheese, ricotta, sour cream, or ice cream (> ½ cup)	Small servings or lactose-free versions

Quick Check

1. Any bread labeled "gluten-free" is a safe bet on the LFD. True or False?

FALSE

2. Some types of onion are okay. True or False?

TRUE

3. Dried fruits are always off limits on the Low FODMAP diet. True or False?

FALSE

APPENDIX D

IRB APPLICATION AND APPROVED ASSESSMENTS, IRB APPROVAL LETTER, AND MODIFICATION APPROVAL LETTERS

PHASE 1:
IRB FORMS, APPROVAL LETTER, FLYER, AND SURVEY

Texas Woman's University Institutional Review Board

Application for Exempt Review

For office use only:

Protocol #: _____

Name of Principal Investigator (PI): Rachel Adams Phone: 940-393-2977

Status: ☐ faculty ☒ student ☐ staff ☐ other : _____ E-mail: _____

Department: NFS

Colleague ID# (this is the 7-digit # on your ID): _____

Title of Study: IBS and the FODMAP Diet Survey

If the PI is a student, provide the following information for the faculty advisor:

Name of advisor: K. Shane Broughton E-mail: kbroughton@twu.edu

TWU Department: Nutrition and Food Science

Estimated beginning date of study: ^{#1} 4/16/2018 Estimated duration of study 1 month

Campus (Denton, Dallas, or Houston) Denton

Type of Project : ☐ thesis ☐ professional paper ☐ dissertation ☐ class project
(check all that apply) ☐ faculty research ☐ pilot ☒ other Needs Assessment

Has project has been submitted for funding (internal or external)? ☐ yes ☒ no
If yes, funding source: _____

Signatures:

Principal Investigator (PI): Signature certifies that the investigator has primary responsibility for all aspects of the research project.

Principal Investigator

Date

Faculty Research Advisor (for student research only): Signature certifies that the faculty member has read, reviewed, and approved the content of the application and is responsible for the supervision of this research study.

Faculty Research Advisor

Date

Academic Administrator: Signature certifies that the administrator has read, reviewed, and approved the content of the application.

Academic Administrator (Department Chair, Program Director, or Associate Dean)

Date

CRITERIA FOR CLAIMING EXEMPT STATUS

If your study meets one or more of the criteria for an exempt review as noted below, complete this application form. If none of the items below apply to your study, you must complete the application form to the Institutional Review Board for expedited and full review studies. If you have any questions or want more detail about the following exempt categories, you may refer to the [45 CFR 46.101](#) or contact the IRB.

Please check, from the following list, the reason(s) you are claiming exempt status.

- ☐ Research involving normal educational practices.

Although the study may involve minors, this type of research may receive an exempt review, if the IRB receives:

1. a COMPLETE exempt application;
2. assurance of maintaining confidentiality of participants; and
3. a letter from the principal (or other appropriate school official), which contains the following items:
 - the name of the researcher;
 - title and description of project;
 - assurance that the proposed procedures are a part of normal instruction techniques, curricula, or classroom management techniques; and
 - a statement that data will be collected and analyzed as part of a research project.

- ☒ Research involving cognitive, diagnostic, aptitude, or achievement tests, surveys, interviews, or observation of public behavior, **unless** the participants can be identified **and** any disclosure of the responses could reasonably place the participants at risk (i.e., anonymous surveys, surveys that do not involve a sensitive topic or utilize a vulnerable population, interviews that do not involve a sensitive topic or utilize a vulnerable population). For anonymous questionnaires, the following statement must be placed at the top of the questionnaire in lieu of an informed consent form: *"The return of your completed questionnaire constitutes your informed consent to act as a participant in this research."*

- ☐ Research involving the collection or study of existing data.

- ☐ Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs.

- ☐ Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

METHODOLOGY

Please refer to instructions when completing this form. The application must be typed using a font no smaller than 11-point.

1. Describe the purpose of study, including research questions and/or hypotheses.

It is estimated that 12% of North Americans have Irritable Bowel Syndrome (IBS) primarily are women (Chey & Kurlander, 2015). However, this figure could be an underestimate of total prevalence as 76.6% people with IBS are never formally diagnosed (Hungin, Chang, Locke, Dennis, & Barghout, 2005) and estimates including this population go up to 20% (Canavan, West, & Card, 2014). IBS is the most commonly diagnosed gastrointestinal disorder (Ikechi, Fischer, DeSipio, & Phadtare, 2017). IBS is a heterogeneous disorder that affects all races and ethnicities and socioeconomic levels; however, it does appear to affect women more commonly than men (Lovell & Ford, 2015).

The Low FODMAP Diet (LFD) is a potential treatment for symptoms associated with IBS. Research into the mechanism of action and efficacy of the diet have increased rapidly since it was first postulated by Drs. Gibson and Shepherd (2005). The LFD is also increasingly used in the clinical setting (Staudacher & Whelan, 2017). However, it is unclear whether physicians are routinely recommending the diet and/or referring patients to Registered Dietitian/Nutritionists for management.

Purpose of the survey: The survey will serve as part of a needs assessment for the development of my dissertation project – an internet-based FODMAP diet education program for adults (18-65 years old) with Irritable Bowel Syndrome (IBS), as well as a recruiting tool for future research on the FODMAP diet and IBS.

Research questions to be addressed:

1. What is the rate of self- versus physician-diagnosed IBS and estimate what percentage of each potentially fulfill ROME IV diagnostic criteria?
2. How does Irritable Bowel Syndrome (IBS) affect diet and food purchasing decisions?
3. How are healthcare practitioners (physicians, nurse practitioners, and physician assistants) managing IBS and are they discussing diet changes with these patients or referring them to Registered Dietitian/Nutritionists?
4. What percentage of people with IBS have other related conditions?

2. Participant Information:

- a. Description of participants in study:

Adults 18-65 with self-reported Irritable Bowel Disease (IBS) living within the United States.

- b. Approximate number of participants: 130

- c. Vulnerable populations as participants (check all that apply):

Prisoners ☐
Pregnant women ☐
Fetuses / neonates ☐
Minors..... ☐

NOTE: Researchers must comply with the federal mandate to report child abuse. See instructions for details.

- d. Age (or age range) of participants: 18-65

Provide the rationale for inclusion/exclusion on the basis of age:

The internet-based diet education program for my dissertation will be designed for adults, thus minors are not included in the survey.

Adults over 65 are more likely to have additional conditions or issues with gut motility which could affect the program outcome.

Ahmed, T., & Haboubi, N. (2010). Assessment and management of nutrition in older people and its importance to health. *Clinical Interventions in Aging*, 5, 207–216.

- e. Sex of participants ☐ Male ☐ Female ☒ Both

Provide the rationale for inclusion/exclusion on the basis of sex:

- f. Participants will be excluded based on ethnicity: ☐ Yes ☒ No

If yes, provide a description of the exclusion criteria and the rationale for using these criteria:

- g. List and provide rationale for any other inclusion/exclusion criteria:

Patients who report self- and physician-diagnosed IBS will be included in the survey, as some research estimates that 76.6% of people with IBS are never formally diagnosed.

Hungin, A.P.S., Chang, L., Locke, G.R., Dennis, E.H., & Barghout, V. (2005). Irritable Bowel Syndrome in the United States: prevalence, symptom patterns and impact. *Alimentary pharmacology & therapeutics*, 21(11), 1365-1375.

3. Describe the participant recruitment process in detail. Attach any recruitment materials or scripts.

Participants will be recruited via bulk email from TWU students, faculty, and staff, as well as from researcher's social media account. The email and social media recruitment message will request participants between 18 and 65 years of age who have IBS. A link to the Psychdata survey will be included.

4. Research Procedures:

- a. Describe in detail the research procedures:

The emails sent to TWU students, faculty members and staff, as well as social media messages will contain a link to the Psychdata survey. Self-reported demographic, medical, and personal decision making data around diet will be collected from each participant. Once a participant completes the survey, they will be asked if they would like to be contacted for participation in any future IBS and diet-related research studies. Contact information for the PI and research advisor will be included on the survey for participants. They will have the option to email their queries to either researchers before, during or after participating in the survey.

b. Is video recording a part of the study? ☐ Yes ☒ No

With sound ☐ Without sound ☐

c. Is audio recording a part of the study? ☐ Yes ☒ No
If you answered "yes" to question #4a or 4b, describe the purpose of the recording and who will have access to these recordings.

The recording is for the transcription of the focus group interviews.

d. Is internet / email a part of the study? ☒ Yes ☐ No
If you answered "yes" to question #4c, describe how the internet and/or email will be used.

Mass emails will be sent via the university server for recruitment to all potential participants. Social media accounts of the PI will be used to recruit participants with a link to the survey. Participant responses on the surveys will be recorded on Psychdata, an online survey software tool. At the end of the study, the data will be downloaded on Microsoft Excel for further analysis.

Participants will have the option to email their queries to the researchers who will respond via the same channel.

5. What is the time commitment for the participants? Include the number of sessions, maximum time commitment per session, and the maximum cumulative time commitment.

Survey will take a maximum of 20 minutes. This study will not have a face-to-face component.

Data will be collected from February to March 2018.

6. Site / location of the study.

a. Will participants be affiliated with a specific non-TWU agency, institution, or organization? ☐ Yes ☒ No

If yes:

Name of the site(s)?

*Affiliation of the **principal investigator** to this site(s)?*

*Affiliation of the **participants** to this site(s)?*

Agency approval letters are required by the IRB before data can be collected at a site. If you answered "yes" to 6a, attach the signed agency approval letter on letterhead from each agency. If agency approval cannot be obtained prior to submitting the IRB application, explain here.

- b. Describe the setting of the study (i.e. physical location, surroundings, privacy aspects, etc.)

The survey will be housed on the internet-based Psycdata website. The surveys will be anonymous and participants will not be required to disclose their identities. However, they will have the option to interact with researchers via emails.

7. Explain the potential risks to the human participants involved in this research. All risks must be identified and listed on the consent form (if applicable).

Risk of loss of confidentiality: There is a possible risk for loss of confidentiality in this study. Confidentiality will be in place throughout the survey but may be lost in case of interaction between participants and researchers via emails. Participants will not be required to disclose their identities.

Researchers will not discuss contents of this interaction/ emails with anyone outside the research team.

Loss of time: Participants will take a maximum of 20 min to complete the online survey. The survey is designed to take a minimal amount of time.

The survey if left incomplete, will reset and participant will not be able to resume where they left off.

8. Because the academic component of TWU is classified as a non-covered HIPAA entity, identifiable health or health-related data cannot be transmitted electronically. You must be able to answer "no" to at least one of the following questions in order for your study to be approved.

Does this research involve health or health-related data? ☒ Yes ☐ No
If yes, are the data identifiable? ☐ Yes ☒ No
If yes, will data be transmitted electronically? ☒ Yes ☐ No

9. Provide a list of all research team members other than the investigator and faculty advisor.

A current **human subjects** training certificate (less than 3 years old) must be on file for the investigator, advisor, and all research team members before an exemption letter will be sent. These training certificates may be sent directly to the IRB separately or attached to this application in the attachment section.

Name TWU 7-digit Colleague ID # (if applicable) Email Address: TWU Department or Name of Other Institution Role on Project	
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Name TWU 7-digit Colleague ID # (if applicable) Email Address: TWU Department or Name of Other Institution Role on Project	
--	--

Name TWU 7-digit Colleague ID # (if applicable) Email Address: TWU Department or Name of Other Institution Role on Project	
--	--

Name TWU 7-digit Colleague ID # (if applicable) Email Address: TWU Department or Name of Other Institution Role on Project	
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(Attach additional sheets if necessary)

10. List and describe all attachments (Include forms, scripts, flyers, consent forms, agency approval letters, human subjects training certificates, signed confidentiality agreement forms, referral lists, surveys, questionnaires, or any other instrument used in the study.) Attachments should be listed below in the same order in which they are attached.

1. Survey questions
2. Recruitment flyer for posting on social media and to be sent out via email to TWU faculty, students, and staff
3. Human subjects training certificates

SUBMISSION INSTRUCTIONS

The application should be submitted to the appropriate campus IRB.

Denton and Dallas

Mail the signed original to the address below. If electronic submission is preferred, combine all parts of application into single .pdf document and email to irb@twu.edu. If the application is submitted electronically as a fully signed .pdf, the original copy is not required.

TWU's Office of Research & Sponsored Programs
Institutional Review Board
PO Box 425619
Denton, TX 76204-5619

Applications may also be hand delivered to the Denton campus ACT 7th floor or the Dallas campus Office of Research IHSD 8th floor.

Houston

All parts of the application (including the signed cover page and appendices in order) should be combined into one single .pdf or Word document and emailed to irb-houston@twu.edu. The original copy is not required. If you have any difficulty with preparing a .pdf file, please contact the Houston Office of Research via email for assistance.

RESPONSE TIMES

Upon receipt of the application, the investigator will receive an email notification that the application has been received and that it is being processed as an exempt study. Applicants can expect to receive a response from the IRB regarding the review within two weeks. Note that this time-frame is an estimate and additional time may be required during certain times of the academic calendar (i.e., summer, semester breaks, and holidays).



Institutional Review Board

Office of Research and Sponsored Programs
P.O. Box 425619, Denton, TX 76204-5619
940-898-3378
email: IRB@twu.edu
<http://www.twu.edu/irb.html>

DATE: April 3, 2018

TO: Ms. Rachel Adams
Nutrition & Food Sciences

FROM: Institutional Review Board (IRB) - Denton

Re: Exemption for IBS and the FODMAP Diet Survey (Protocol #: 20050)

The above referenced study has been reviewed by the TWU IRB (operating under FWA00000178) and was determined to be exempt from further review.

If applicable, agency approval letters must be submitted to the IRB upon receipt PRIOR to any data collection at that agency. Because a signed consent form is not required for exempt studies, the filing of signatures of participants with the TWU IRB is not necessary.

Although your protocol has been exempted from further IRB review and your protocol file has been closed, any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any adverse events or unanticipated problems. All forms are located on the IRB website. If you have any questions, please contact the TWU IRB.

cc. Dr. Shane Broughton, Nutrition & Food Sciences



Institutional Review Board

Office of Research and Sponsored Programs
P.O. Box 425619, Denton, TX 76204-5619
940-898-3378
email: IRB@twu.edu
<http://www.twu.edu/irb.html>

DATE: April 24, 2018

TO: Ms. Rachel Adams
Nutrition & Food Sciences

FROM: Institutional Review Board - Denton

Re: *Notification of Approval for Modification for IBS and the FODMAP Diet Survey (Protocol #: 20050)*

The following modification(s) have been approved by the IRB:

The survey has been modified for readability. The nature of the content has not changed, but the text has been modified to read at a 6th grade reading level.

cc. Dr. Shane Broughton, Nutrition & Food Sciences



Institutional Review Board

Office of Research and Sponsored Programs
P.O. Box 425619, Denton, TX 76204-5619
940-898-3378
email: IRB@twu.edu
<http://www.twu.edu/irb.html>

DATE: May 23, 2018

TO: Ms. Rachel Adams
Nutrition & Food Sciences

FROM: Institutional Review Board - Denton

Re: *Notification of Approval for Modification for IBS and the FODMAP Diet Survey (Protocol #: 20050)*

The following modification(s) have been approved by the IRB:

Per recommendations by the CRDA, few modifications and questions have been added to better quantify variables.

cc. Dr. Shane Broughton, Nutrition & Food Sciences

Texas Woman's University

Irritable Bowel Syndrome and Diet Study

Irritable Bowel Syndrome (IBS) is the most common functional gastrointestinal disorder. It affects both women and men is found across ethnicities and ages.

To qualify for this study, you must be:

- Between 18 – 65 years old, living in the US
- Believe you have IBS or have been diagnosed by a physician/nurse practitioner/physician's assistant

- As a participant of this study you will be asked to fill out a survey via the online service PsychData.
- You will be asked a series of questions pertaining to your personal health experience with IBS and other potentially related conditions, whether IBS has affected your diet, and how you manage your IBS.
- Your participation is completely voluntary and confidential. Submission of the completed survey constitutes your informed consent to act as a participant in this study. You may choose to cancel the survey at any time and not submit.
- The survey must be taken all at once as responses will not be saved until the survey is submitted.
- The survey will take about 15 minutes to complete.

If you are interested in participating in this survey, please follow this link:
<https://www.psychdata.com/s.asp?SID=181821>

Your participation in this study will help further our understanding of IBS and diet and enable future program development and research.

If you have questions about the study or would like to receive an email with the link to the survey, please contact:
Radams15@twu.edu

Thank you for your interest in this study. Your participation in this survey is voluntary.

The purpose of this research survey is to see how Irritable Bowel Syndrome (IBS) affects diet and food purchasing decision, if doctors are talking about diet with IBS patients, and find out how often people with IBS have related illnesses. This survey will be used to help develop a diet education program for people with IBS.

The survey will take about **15 minutes** to complete.

Please note: Submitting this survey means you are giving your informed consent to be a part of this research.

This survey does not include any of your personal information that could be used to identify you. The confidentiality of emails cannot be guaranteed. Please do not include any sensitive information in email.

Only individuals who are 18 to 65 years of age should complete this survey.

I am between 18 and 65 years of age.

☐ Yes

☐ No

----- Question Logic -----

(If 'no' checked)

We appreciate your effort, time, and participation!!

Thank you!!

----- Question Logic -----

(If 'yes' checked)

I have Irritable Bowel Syndrome (IBS).

☐ Yes

☐ No

----- Question Logic -----

(If 'no' checked)

We appreciate your effort, time, and participation!!

Thank you!!

----- Question Logic -----

(If 'yes' checked)

The last page of this survey will ask if you want to participate in IBS-related research studies in the future. If interested, please check the box on that page. This will lead you to another page where you will be able to enter your name and email. Your information will not be shared and will only be seen the researchers only and will be used to notify you when the research begins.

Please note: Participating in future research is voluntary. You can change your mind at any time.

Your identity along with contact details will not be linked to your survey responses.

Please email Principal Investigator, Rachel Adams or Faculty Advisor, K. Shane Broughton if you have any questions.

Rachel Adams: radams15@twu.edu

Shane K. Broughton: Kbroughton@twu.edu

----- Page Break -----

1. To which gender to you most identify?

- ☐ Female
- ☐ Male
- ☐ Transgender Female
- ☐ Transgender Male
- ☐ Not Listed or Prefer Not to Respond

2. Ethnicity:

- ☐ Black or African American
- ☐ Native American or Alaska Native
- ☐ South Asian (From Afghanistan, Bangladesh, Bhutan, India, Nepal, Maldives, Pakistan or Sri Lanka)
- ☐ East Asian (From China, Hong Kong, Macau, Japan, Taiwan, North/ South Korea or Mongolia)
- ☐ Native Hawaiian or Pacific Islander
- ☐ Middle Eastern (From Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Saudi Arabia, Palestine, Turkey, or Yemen)
- ☐ Caucasian (non-Hispanic)
- ☐ Hispanic
- ☐ Scandinavian (From Denmark, Norway, Sweden, Finland, or Iceland)
- ☐ Other: _____

3. What is the highest level of education? (Please select only one)

- | | |
|---|---|
| <input type="checkbox"/> Less than a high school diploma | <input type="checkbox"/> High school graduate |
| <input type="checkbox"/> Some college or technical training | <input type="checkbox"/> Associate's degree or equivalent |
| <input type="checkbox"/> Bachelor's degree | <input type="checkbox"/> Graduate degree |

4. What year were you born?

5. Who diagnosed you with IBS:

- ☐ I diagnosed myself
- ☐ I was diagnosed by a doctor (or Nurse Practitioner/Physician's Assistant)
- ☐ Other healthcare professional

If diagnosis was made by doctor...

5.A. Do you take medication prescribed by your doctor to treat IBS?

- ☐ Yes
- ☐ No

If Yes,

5.A.1 How satisfied are you with this treatment?

- ☐ 5 – Very satisfied
- ☐ 4
- ☐ 3 – Somewhat satisfied
- ☐ 2
- ☐ 1 – Not satisfied

5.B. Did your doctor prescribe a specific diet or changes to your current diet to help manage your IBS?

- ☐ Yes
- ☐ No

5.C. Did your physician/nurse practitioner/physician's assistant refer you to a Registered Dietitian/Nutritionist for a diet to help with your IBS symptoms?

- ☐ Yes
- ☐ No

If Yes,

5.C.1 Did you meet with a Registered Dietitian/Nutritionist?

- ☐ Yes
- ☐ No

5.D. Please select what advice your doctor or dietitian gave you about your diet.

- ☐ Eat smaller, more frequent meals
- ☐ Eat less fatty foods
- ☐ Eat more fiber
- ☐ Avoid alcohol
- ☐ Avoid coffee
- ☐ Avoid foods with gluten (wheat and wheat-based products)
- ☐ Avoid food and drinks with artificial sweeteners or sugar alcohol (sorbitol, mannitol, etc.)
- ☐ Avoid foods that might cause gas (beans, cabbage, onions, etc.)
- ☐ Avoid foods high in FODMAPs
- ☐ Other _____
- ☐ No advice was given

5.E. Did you follow your doctor or dietitian's diet advice?

- ☐ 1 – Yes, everyday
- ☐ 2 – Yes, most days of the week
- ☐ 3 – Yes, a few days a week
- ☐ 4 – Yes, but only one day per week or less
- ☐ 5 – No, I didn't follow the advice

If yes...

5.E.1 What effect did the diet changes have on your IBS symptoms?

- ☐ 1 – Really helped my symptoms
- ☐ 2 – Helped my symptoms a little
- ☐ 3 – No change to my symptoms
- ☐ 4 – My symptoms became a little worse
- ☐ 5 – My symptoms became much worse

5.E.2 (MATRIX QUESTION)

How did the diet affect these symptoms?

Bloating

Gas

Stomach pain

Constipation

Diarrhea

- ☐ 1 – Really helped
- ☐ 2 – Helped a little
- ☐ 3 – No change

- ☐ 4 – A little worse
- ☐ 5 – Much worse

If no...

5.E.3 What was the main reason you choose not to follow the diet advice?

- ☐ I don't believe my symptoms are diet related
- ☐ I don't think changing my diet will do that much good
- ☐ I don't have the time
- ☐ I don't have the money to follow it
- ☐ Didn't seem worth it
- ☐ Medication helps manage my IBS just fine

If self-diagnosed...

5.F. Have you tried to manage your IBS with changes to your diet?

- ☐ Yes
- ☐ No

6. Please choose which best describe your symptoms over the last three months:

- ☐ Stomach pain at least 1 day per week that is related to passing stool.
- ☐ Stomach pain at least 1 day per week that is associated with changes how often you pass stool.
- ☐ Stomach pain at least 1 day per week that is related to a change in form (consistency) of stool.
- ☐ Bloating at least one day per week.
- ☐ Constipation at least one day per week.
- ☐ Diarrhea at least one day per week.
- ☐ Excess gas at least one day per week.

7. Do you believe your IBS symptoms are related to what you eat?

- ☐ Yes
- ☐ No
- ☐ Unsure

8. Choose which answer best describes how your IBS symptoms affect your life in an average week

- ☐ 1 – My symptoms rarely limit my activities
- ☐ 2 – My symptoms limit my activities, but only a few days per month
- ☐ 3 – My symptoms limit my activities a few days per week
- ☐ 4 – My symptoms affect my daily life
- ☐ 5 – My symptoms seriously affect my day

9. (MATRIX QUESTION)

How much do your symptoms affect the following?

Work or school

Social life

Dining out

Exercise

Sexual Intimacy

Travel

Relationships

- ☐ 1 – No affect
- ☐ 2 – Minor negative affect
- ☐ 3 – Neutral
- ☐ 4 – Moderate affect
- ☐ 5 – Major affect

10. How long have you had IBS?

- ☐ Less than 12 months
- ☐ 1 to 5 years
- ☐ Between 5 and 10 years
- ☐ Greater than 10 years

11. What type of IBS bowel-related symptoms do you most often experience?

- ☐ Diarrhea
- ☐ Constipation
- ☐ Both Constipation and Diarrhea

12. Have you been diagnosed with any of the following? Please select all that apply.

- ☐ Inflammatory Bowel Disease (Crohn's, Ulcerative colitis)
- ☐ Celiac Disease
- ☐ Food Allergies
- ☐ Depression
- ☐ Anxiety
- ☐ Seasonal Allergies/Hayfever/Allergic Rhinitis
- ☐ Asthma
- ☐ Food Allergies
- ☐ Eczema

13. On a scale of 1- 5, how much you know about the Low FODMAP Diet?

- ☐ 1 – Nothing
- ☐ 2 – A little
- ☐ 3 – A lot

If 2 to 5 chosen...

12.A. Have you followed the Low FODMAP Diet?

- ☐ Yes
- ☐ No

If Yes...

12.A.1 How long has it been since you were on the Low FODMAP Diet or the Adapted FODMAP Diet?

- ☐ 1, I currently follow the diet
- ☐ 2, I followed it within the last 3 months
- ☐ 3, I followed it within the 4 to 12 months
- ☐ 4, It has been over a year since I followed the diet

If 2 to 4 chosen...

12.A.2 Why did you stop the diet?

- ☐ 1, It didn't help my symptoms
- ☐ 2, I only had minor relief from my symptoms and it wasn't worth it
- ☐ 3, It was too difficult
- ☐ 4, I'm feeling better and no longer need it
- ☐ 5, Other _____

14. Do you have seasonal allergies or hayfever?

- ☐ Yes
- ☐ No

15. Do you have asthma?

- ☐ Yes
- ☐ No

16. Do you suffer from anxiety?

- ☐ Yes
- ☐ No

17. Do you suffer from depression?

- ☐ Yes
- ☐ No

18. Do you have food allergies?

- ☐ Yes
- ☐ No

19. Do you avoid certain foods due to sensitivities?

- ☐ Yes
- ☐ No

If yes,

18.A. Please select all the foods you avoid due to sensitivities.

- ☐ Gluten (wheat products)
- ☐ Lactose (dairy products)
- ☐ Soy
- ☐ Caffeine
- ☐ Fructose (including high fructose corn syrup)
- ☐ Other _____

20. How often do you read food labels when choosing foods to buy?

- ☐ 1, Always
- ☐ 2, Sometimes
- ☐ 3, Never

21. On a scale of 1 to 5, please rate how helpful or confusing you find food labels.

- ☐ 1, Very confusing
- ☐ 2, Somewhat confusing
- ☐ 3, I feel neutral about reading food labels
- ☐ 4, Somewhat helpful
- ☐ 5, Very helpful
- ☐ I don't read food labels

22. How often do you eat at a sit-down restaurant (not fast food)?

- ☐ Less than once a week
- ☐ Every 5 to 7 days
- ☐ Every 2 to 4 days
- ☐ Daily

23. How many times per week do you eat fast food?

- ☐ Less than once a week
- ☐ Every 5 to 7 days
- ☐ Every 2 to 4 days
- ☐ Daily

24. How often do you prepare meals (including making any meal at home)?

- ☐ Less than once a week
- ☐ Every 5 to 7 days
- ☐ Every 2 to 4 days

☐ Daily

25. Are you the primary grocery shopper in your household?

☐ Yes

☐ No

26. Are you the primary cook at home?

☐ Yes

☐ No

27. Does anyone else in your home have IBS?

☐ Yes

☐ No

28. Would you follow a diet that eliminates a number of foods, if it could help your IBS symptoms?

☐ I do not intend to in the next 6 months

☐ I intend to change my diet in the next 6 months

☐ I intend to change my diet in the next 30 days

☐ I have been following a special diet for less than 6 months

☐ I have been following a special diet for 6 months or longer

-----Next Page: Option for potential future research volunteers-----

☐ Please check the box if you are interested in participating in future research studies on a diet to help relieve IBS symptoms.

-----Question Logic-----

(If box checked)

Please follow given link to a website where you can provide your contact information. We will notify you of research opportunities.

Participation in these studies is voluntary. You can change your mind at any time

<Link to website>

If participant identified as “Self-diagnosed”:

PHASE 2 & 3:
IRB FORMS, APPROVAL LETTER, MODIFICATIONS, FLYER, ASSESSMENTS

If you believe you have IBS and have not seen a physician about your symptoms, talk to your doctor to confirm diagnosis and explore treatment options.

**We appreciate your effort, time, and participation.
Thank you!**

(If box not checked)

**We appreciate your effort, time, and participation.
Thank you!**

Texas Woman's University Institutional Review Board

Application for Expedited and Full Review

For office use only:

Protocol #: _____

Name of Principal Investigator (PI): Rachel Adams Phone: 940-393-2977

Status: ☐ faculty ☒ student ☐ staff ☐ other : _____ E-mail: radams15@twu.edu

Department: Nutrition and Food Science

Colleague ID# (this is the 7-digit # on your ID): 0556839

Title of Study: The effectiveness of an internet-based low FODMAP diet education course to improve symptoms in patients with IBS

If the PI is a student, provide the following information for the faculty advisor:

Name of advisor: Shane Broughton E-mail: kbroughton@twu.edu

TWU Department: Nutrition and Food Science

Estimated beginning date of study: 1/3/2019 Estimated duration of study 4 weeks

Campus (Denton, Dallas, or Houston) Denton Level of review: ☒ expedited ☐ full

Type of Project : ☐ thesis ☐ professional paper ☒ dissertation ☐ class project
(check all that apply) ☐ faculty research ☐ pilot ☐ other _____

Has project has been submitted for funding (internal or external)? ☐ yes ☒ no
If yes, funding source: _____

Signatures:

Principal Investigator (PI): Signature certifies that the investigator has primary responsibility for all aspects of the research project.

Rachel Adams 11/19/18
Principal Investigator Date

Faculty Research Advisor (for student research only): Signature certifies that the faculty member has read, reviewed, and approved the content of the application and is responsible for the supervision of this research study.

K. S. R. 11/20/18
Faculty Research Advisor Date

Academic Administrator: Signature certifies that the administrator has read, reviewed, and approved the content of the application.

K. S. R. 11/20/18
Academic Administrator (Department Chair, Program Director, or Associate Dean) Date

METHODOLOGY

Please refer to instructions when completing this form. The application must be typed using a font no smaller than 11-point.

1. Describe the purpose of study, including research questions and/or hypotheses.

Irritable Bowel Syndrome (IBS) is the most commonly diagnosed gastrointestinal disorder and the seventh most common diagnosis in primary care (AGA, 2015; Ikechi, Fischer, DeSipio, & Phadtare, 2017). IBS affects around 20% of the population in America with most patients being women (Canavan, West, & Card, 2014).

The Low FODMAP Diet (LFD) is a treatment for symptoms associated with IBS. FODMAPs are “Fermentable, Oligosaccharides, Disaccharides, Monosaccharides, and Polyols”, which can be difficult to digest for people with IBS (Gibson & Shepherd, 2005). Research into the mechanism of action and efficacy of the diet have increased rapidly and the LFD is increasingly used in clinical settings (Staudacher & Whelan, 2017). A review of current literature reported that the LFD diet leads to a positive clinical response in 50%–80% of patients with IBS (Staudacher & Whelan, 2017). The LFD typically includes an elimination phase of two days to six weeks followed by gradual reintroduction of FODMAPs (Schumann, et al. 2017).

Key challenges of the diet are that it is both restrictive and difficult to implement. Most studies that have sought to establish the efficacy of the diet include very limited diet instruction and often provide supplemental handouts for information. There are few dietitians in the U.S. who are trained on the elimination and reintroduction phases of this diet, as this research originated in Australia and is relatively recent. Registered Dietitian/Nutritionists (RDN) have provided LFD education in clinical studies and researchers support that these clinicians are the most appropriate choice for continued LFD education delivery (O’Keefe & Lomer, 2017). However, meeting with a dietitian for a one-on-one consult could be costly, as many insurance providers will not cover a RDN consult for IBS. A novel approach is an internet-based LFD education program led by a RDN that would increase accessibility, decrease cost to the patient, and provide an increased level of education and support. Rachel Adams is a Registered Dietitian/Nutritionist trained on the LFD by Monash University. After completing needs assessment of the population in May/June 2018 through the (IRB approved) “Irritable Bowel Syndrome and Diet Study” (IRB #20050), Rachel created the “The FODMAP Fix”, an internet- and module-based LFD education program.

Purpose: The primary aim of this study is to determine if a four-week trial of the elimination phase of the Low FODMAP Diet (LFD) delivered through an internet- and module-based program (“The FODMAP Fix”) developed by a RDN trained on the LFD will improve symptoms and quality of life in patients with Irritable Bowel Syndrome (IBS). IBS Symptom Severity Scale (IBS-SSS), Quality of Life (IBS-QOL) indices, a self-efficacy efficacy survey, and a global symptom question will be used to assess outcomes. Changes in these indicators will be compared against a control group who will be completing the same assessments to determine if the online delivery method is effective in improving IBS symptoms.

Hypothesis: A four-week trial of “The FODMAP Fix” in adult patients with IBS will result in significant improvements in IBS Symptom Severity Scale (IBS-SSS), Quality of Life (IBS-QOL), and self-efficacy indices and a global symptom question by assessing pre/post scores and when compared to the control group’s changes.

References:

- American Gastroenterological Association. (2015). IBS in america: Survey summary findings 2015. <http://www.multivu.com/players/English/7634451-aga-ibs-in-america-survey/docs/survey-findings-pdf-635473172.pdf>. Accessed September 24, 2018.
- Canavan, C., West, J., Card, T. (2014). The epidemiology of irritable bowel syndrome. *Clinical Epidemiology*. 6:71.
- Gibson, P.R., Shepherd, S.J. (2005). Personal view: food for thought–western lifestyle and susceptibility to Crohn's disease. The FODMAP hypothesis. *Alimentary Pharmacology & Therapeutics*. 21(12):1399-409.
- Ikechi, R., Fischer, B.D., DeSipio, J., Phadtare, S. (2017). Irritable bowel syndrome: Clinical manifestations, dietary influences, and management. *Healthcare*. 5(2):21.
- O'Keeffe, M., Lomer, M.C. (2017). Who should deliver the low FODMAP diet and what educational methods are optimal: a review. *J Gastro and Hepatology*. 32:23-6.
- Schumann, D., Langhorst, J., Dobos, G., Cramer, H. (2018). Randomised clinical trial: Yoga vs a low-FODMAP diet in patients with irritable bowel syndrome. *Aliment Pharmacol Ther*. 47(2):203-211.
- Staudacher, H.M., Whelan, K. (2017). The low FODMAP diet: Recent advances in understanding its mechanisms and efficacy in IBS. *Gut*. 313750.

2. Participant Information:

- a. Description of participants in study:

Adults 18-65 who self-report being diagnosed with Irritable Bowel Syndrome by a physician, physician's assistant, or nurse practitioner. Participants must have regular access to the internet and own a smartphone capable of downloading the Monash University FODMAP app.

- b. Approximate number of participants: 63

- c. Vulnerable populations as participants (check all that apply):

Prisoners ☐
Pregnant women ☐
Fetuses / neonates ☐
Minors..... ☐

NOTE: Researchers must comply with the federal mandate to report child abuse. See instructions for details.

- d. Age (or age range) of participants: 18-65 years

Provide the rationale for inclusion/exclusion on the basis of age:

The internet-based diet education program is designed for adults, thus minors are not included in the survey. Adults over 65 are more likely to have additional conditions or issues with gut motility which could affect the program outcome.

Ahmed, T., & Haboubi, N. (2010). Assessment and management of nutrition in older people and its importance to health. *Clinical Interventions in Aging*, 5, 207–216.

- e. Sex of participants ☐ Male ☐ Female ☒ Both

Provide the rationale for inclusion/exclusion on the basis of sex:

- f. Participants will be excluded based on ethnicity: ☐ Yes ☒ No

If yes, provide a description of the exclusion criteria and the rationale for using these criteria:

- g. List and provide rationale for any other inclusion/exclusion criteria:

Exclusion Criteria:

Pregnant; not free-living; co-existing gastrointestinal disease; eating disorders; food allergies; are currently taking or have taken within the previous four weeks the following medications: antibiotics, stool bulking agents, narcotic analgesics, probiotic or prebiotic supplements, or lactulose; or followed one of the following diets in the prior four weeks: LFD, very low-carb, ketogenic, gluten free, or paleo; already avoiding FODMAPs, as identified by the an adapted FFQ based on the NHANES Food Questionnaire. Patients who already follow a low lactose diet will not be excluded and instead asked to maintain their current lactose intake, similar to Stauchacher, et al., 2017.

Many patients with IBS are already following restrictive/elimination diets, as they realize their symptoms are food related. The above mentioned diets must be excluded in order to determine if the LFD presented in The FODMAP Fix is effective.

NHANES Food Questionnaire.

<https://epi.grants.cancer.gov/diet/usualintakes/FFQ.English.June0304.pdf> Accessed October 18, 2018.

Staudacher HM, Lomer MC, Farquharson FM, Louis P, Fava F, Franciosi E, Scholz M, Tuohy KM, Lindsay JO, Irving PM, Whelan K. A diet low in FODMAPs reduces symptoms in patients with irritable bowel syndrome and a probiotic restores Bifidobacterium species: a randomized controlled trial. *Gastroenterology*. 2017 Oct 1;153(4):936-47.

3. Describe the participant recruitment process in detail. Make sure that you attach any recruitment materials or scripts in the attachment section.

Participants will be recruited via bulk email from TWU students, faculty, and staff, as well as from researcher's social media account, and local gastroenterology clinics. Those participants from the IBS and Diet survey from June 2018 who indicated interest in future clinical trials will also be contacted and informed of the study. The email and social media recruitment message will request participants between 18 and 65 years of age who have IBS. A link to the Psychdata screening survey will be included.

4. Research Procedures:

- a. In the space below, describe in detail the research procedures (do not use an attachment):

This will be a randomized, controlled trial with repeated measures summarized into pre-/post-treatment measurements.

The FODMAP Fix is an internet- and module-based Low FODMAP Diet education program created by a Registered Dietitian Nutritionist trained on the Low FODMAP Diet (LFD). It is a publicly available program. One video-based module will be released each week as part of The FODMAP Fix program beginning with a brief "Introduction" module followed by four weekly modules of diet education. The program includes a weekly video series and ancillary materials to support the videos. The program will require participants to follow the LFD, a well-researched diet for people with IBS, for four weeks.

Screening: Potential participants are screened through a PsychData brief survey. They will be excluded from the trial if they are pregnant; not free-living; have had an acute GI episode within four weeks; co-existing gastrointestinal disease; eating disorders; food allergies; are currently taking or have taken within the previous four weeks the following medications: antibiotics, stool bulking agents, narcotic analgesics, probiotics or prebiotics, or lactulose; or followed one of the following diets in the prior four weeks: LFD, very low-carb, ketogenic, gluten free, or paleo. Also, patients avoiding FODMAPs, as determined by screening with an adapted Food Frequency Questionnaire (FFQ) based on the NHANES Food Questionnaire will be excluded. Similar to Staudacher et al., 2017, patients who follow a low-lactose diet will not be excluded, but asked to maintain their current lactose intake. At the end of the FFQ, participants will be provided information about the study and asked to click a link that would serve as their informed consent. Contact information and basic demographic information (year of birth, height, weight, gender, ethnicity) will be collected. Participants will be informed that they will receive a link via email to the Canvas classroom to begin the study once eligibility is confirmed.

Day 0: After obtaining participant's informed consent and the researcher is able to confirm the participant has not inadvertently avoided FODMAPS by review of the FFQ, participants will receive a unique and randomly assigned PIN that will be issued to complete all health-related forms in Psychdata to protect confidentiality. Participants will also be randomized into the control or intervention groups. After randomization, the intervention group will receive access to the internet-based classroom hosted on Canvas where The FODMAP Fix program will be housed. Participants will be asked to complete the Introduction module, which introduces the program, but provides no information on the diet. Both the intervention and control groups will be instructed to complete the following assessments after randomization: Irritable Bowel Syndrome Symptom Severity Scale (IBS-SSS), Irritable Bowel Syndrome Symptom Quality of Life (IBS-QOL), a Food Frequency Questionnaire adapted from the NIH's Diet History

Questionnaire, self-efficacy survey adapted from Bandura, 2006, and the FODMAP knowledge quiz.

Week 2: After completion of Module 1, participants in the intervention group will retake the FODMAP quiz, 24-hour recall, and answer a question on compliance.

Week 5: End of Treatment: After participants have completed Module 4 they will again complete the adapted global symptom question, IBS-SSS, IBS-QOL, adapted FFQ, 24-hour diet recall, adapted self-efficacy assessment, compliance question, as well as a program feedback form to assess the format of The FODMAP Fix program. This data will be collected and analyzed. Dietary compliance will be analyzed using FFQ and 24-hour diet recall by scoring the number of high FODMAP foods consumed in the assessments and using the 24-hour recall as a guide for portion sizes on the most commonly consumed foods. This data will be compared against participant's reported compliance. This data will be compared against participant's reported compliance.

References:

National Institutes of Health, Applied Research Program, National Cancer Institute. Diet History Questionnaire, Version 3.0. 2018.

Bandura, A. (2006). Guide for constructing self-efficacy scales. Self-efficacy beliefs of adolescents. 5(307-337).

National Cancer Institute: Division of Cancer Control and Population Sciences. Automated Self-administered 24 hour Dietary Assessment Tool (ASA24).
<https://epi.grants.cancer.gov/asa24/> Accessed November 12, 2018.

Staudacher HM, Lomer MC, Farquharson FM, Louis P, Fava F, Franciosi E, Scholz M, Tuohy KM, Lindsay JO, Irving PM, Whelan K. A diet low in FODMAPs reduces symptoms in patients with irritable bowel syndrome and a probiotic restores Bifidobacterium species: a randomized controlled trial. Gastroenterology. 2017 Oct 1;153(4):936-47.

b. Is video recording a part of the study? ☐ Yes ☒ No

With sound ☐ Without sound ☐

c. Is audio recording a part of the study? ☐ Yes ☒ No

If you answered "yes" to question #4b or 4c, describe the purpose of the recording and who will have access to these recordings.

d. Is internet / email a part of the study? ☒ Yes ☐ No

If you answered "yes" to question #4d, describe how the internet and/or email will be used.

Mass emails will be sent via the university server for recruitment of potential participants. Social media accounts of the PI will be used to recruit participants. Participant responses to all health-related surveys will be through Psychdata, an online survey software tool. Identifying

information will not be used, but rather an assigned PIN. At the end of the study, the data will be downloaded onto SPSS for further analysis.

The FODMAP Fix is an online program that will be housed on Canvas and includes an optional, closed Facebook page where users can interact with each other and the PI/RDN. These interactions will be moderated by the PI of the study.

Participants will have the option to email their queries to the researchers who will respond via the same channel.

5. What is the time commitment for the participants? Include the number of sessions, maximum time commitment per session, and the maximum cumulative time commitment.

There is an introductory module which will describe the program plus initial assessments, which should in total take no more than two hours.

Each of the below includes the time required for The FODMAP Fix program and assessments associated with this trial.

Module 1: Maximum 2 hours of participant's time

Modules 2 and 3: Maximum 1 hour each

Module 4: Maximum 2 hours

6. Site / location of the study.

- a. Will participants be affiliated with a specific non-TWU agency, institution, or organization? ☐ Yes ☒ No

If yes:

Name of the site(s)?

*Affiliation of the **principal investigator** to this site(s)?*

*Affiliation of the **participants** to this site(s)?*

Agency approval letters are required by the IRB before data can be collected at a site. If you answered "yes" to 6a, attach the signed agency approval letter on letterhead from each agency. If agency approval cannot be obtained prior to submitting the IRB application, explain here.

- b. Describe the setting of the study (i.e. physical location, surroundings, privacy aspects, etc.)

Internet-based education and assessments that participants can access at their convenience from any computer, tablet, or smart phone. Assessments will be completed using a PIN on Psychdata to protect confidentiality. Access to the Canvas classroom is unique to the individual. The Canvas classroom will not be interactive between participants. The only interactive component between participants is the optional, closed Facebook group.

POTENTIAL RISKS AND PROTECTION OF PARTICIPANTS

7. Explain the potential risks to the human participants involved in this research. All risks must be identified and listed on the consent form (if applicable).

RISK	STEPS TO MINIMIZE RISK
Loss of confidentiality	Risk is addressed in consent form; Identifying information will be kept in a password protected file on Google drive and not saved on a PC. All health-related surveys are conducted on Psychdata. No interaction between participants on Canvas nor is identifying information ever posted.
RISK	STEPS TO MINIMIZE RISK
Nutritional deficiencies	Program discusses nutritionally sound substitutions for foods eliminated, provides recipes, and offers online support with RDN.
RISK	STEPS TO MINIMIZE RISK
Loss of time	Total time lost during the study should not exceed 8 hours. Videos have been kept short and only necessary assessments are included.
RISK	STEPS TO MINIMIZE RISK
Quality of life due to the nature of the elimination diet	The FODMAP Fix is designed to minimize frustration with the elimination diet by providing recipes, tips, and menus that will assist participants in following the LFD.

(Use continuation pages if necessary)

8. Will participants be told about the intent of the study prior to participating? ..☒ Yes ☐ No
If "no," provide an explanation of why deception is necessary and the debriefing method to be used to fully inform the participants of the study's intent.

9. Explain when and how the participants will be given the opportunity to ask questions.

The FODMAP Fix includes a closed Facebook group where questions relevant to the group (e.g. is a recipe or food low FODMAP) that will be monitored daily by RDN. For technical questions and personal concerns, participants will be able to contact the PI (also a RDN) through email. A food and symptom diary will also be submitted weekly and the PI will provide feedback.

10. Identifiable Data

Outline the steps to ensure the confidentiality of identifiable data. Identifiable data includes documents, audio and video recordings, electronic data, and blood or other human specimens.

- a. Explain what identifiable data, if any, will be collected.

Participants name, email, gender, ethnicity, and year of birth will be collected.

- b. Where will identifiable data be stored? (Specify precise location, preferably in a locked file cabinet with limited access.)

Identifiable data will be stored in Psychdata during the study period. The informed consent survey with identifying information will be printed and kept in a locked file in faculty mentor's office after analysis is complete. Downloaded files will be permanently deleted.

- c. Give the date that identifiable data will be destroyed (mm/dd/yy). If identifiable data will be stored for an indefinite period of time, please explain.

The consent form with identifying data will be stored indefinitely after the close of the study to allow for follow-up studies in the locked file in faculty mentor's office.

- d. Identify specific ways that identifiable data will be destroyed at the end of this period of time.

- e. Because the academic component of TWU is classified as a non-covered HIPAA entity, identifiable health or health-related data cannot be transmitted electronically. You must be able to answer "no" to at least one of the following questions in order for your study to be approved.

Does this research involve health or health-related data? ☒ Yes ☐ No
 If yes, are the data identifiable? ☐ Yes ☒ No
 If yes, will data be transmitted electronically? ☒ Yes ☐ No

BENEFITS/REMUNERATION

- 11. What will the participant receive for taking part in the study (i.e., financial remuneration, free services, access to information, and access to an intervention)? If there are none, state below that there are no direct benefits to the participant.**

Free diet education, access to a RDN, recipes, and print materials will be provided to participants, two weeks of instruction on how to apply the adapted version of the LFD, and feedback from the RDN on their food and symptom diary. Participants will also receive a \$20 gift card to amazon.com

12. What are the generalizable benefits of this study? (e.g., *contribution to knowledge in field*).

Internet-based low FODMAP diet education, if proven effective, could improve public health by providing a low-cost, broad-reach approach approach to providing medical nutrition therapy

13. Explain when and how the participants will be provided with the results of the study.

Participants will be contacted through an announcement in the Canvas classroom to inform them of the study outcome.

INFORMED CONSENT PROCEDURES

14. Written Informed Consent

- a. Explain the PROCESS you will use to obtain informed consent.

Participants who complete the FFQ will be automatically transferred to an informed consent screening survey. Information about the specific nature of the trial will be provided followed by the following: "I agree to participate in the IBS and Low FODMAP Diet Study. I understand that I may be asked to follow the low FODMAP diet, a diet that eliminates a number of foods that might be a part of my usual diet, for four weeks. I agree to complete the required assessments and follow the online program "The FODMAP Fix", which will be provided by the researcher." Participant will select either "Yes, I agree" or "No, I do not want to participate in this study".

- b. Unless there are unusual circumstances, investigators are required to document informed consent by obtaining the participant's signature (or the signature of their parent or guardian) on a written consent form. Explain when and how that signature will be obtained. Explain where the signed consent forms will be stored (specify precise location, preferably in a locked file cabinet with limited access), how long the signed consent forms will be kept, and identify specific ways that the signed consent forms will be destroyed at the end of this period of time. Note that a copy of the signed consent forms will need to be placed on file with the IRB when the study file is closed.

As this is a 100% online study, consent will be obtained through a PsychData survey, as described above. Informed consent surveys will be kept on the PsychData system indefinitely for follow-up research.

- c. If you will not use a written consent form, provide a detailed rationale and explain how informed consent will be obtained

See above.

RESEARCH TEAM MEMBERS

15. Provide a list of all research team members other than the investigator and faculty advisor.

A current **human subjects** training certificate (less than 3 years old) must be on file for the investigator, advisor, and all research team members before an approval letter will be sent. These training certificates may be sent directly to the IRB separately or attached to this application in the attachment section. If a current training certificate is already on file with the IRB, there is no need to attach another copy.

Name TWU 7-digit Colleague ID # (if applicable) Email Address: TWU Department or Name of Other Institution Role on Project	
Name TWU 7-digit Colleague ID # (if applicable) Email Address: TWU Department or Name of Other Institution Role on Project	
Name TWU 7-digit Colleague ID # (if applicable) Email Address: TWU Department or Name of Other Institution Role on Project	
Name TWU 7-digit Colleague ID # (if applicable) Email Address: TWU Department or Name of Other Institution Role on Project	

(Attach additional sheets if necessary)

ATTACHMENTS

16. List and describe all attachments (Include forms, scripts, flyers, consent forms, agency approval letters, human subjects training certificates, signed confidentiality agreement forms, referral lists, surveys, questionnaires, or any other instrument used in the study.) Attachments should be listed below in the same order in which they are attached.

Human Subject Training Certificates: R. Adams, K. Broughton
Promotional Flyer
IBS-SSS
IBS-QOL
Global symptom question
Compliance question
FODMAP knowledge quiz
Adapted Food Frequency Questionnaire
Adapted self-efficacy survey

SUBMISSION INSTRUCTIONS

The application should be submitted to the appropriate campus IRB.

Denton and Dallas

Mail the signed original to the address below. If electronic submission is preferred, combine all parts of application into single .pdf document and email to irb@twu.edu. If the application is submitted electronically as a fully signed .pdf, the original copy is not required.

TWU's Office of Research & Sponsored Programs
Institutional Review Board
PO Box 425619
Denton, TX 76204-5619

Applications may also be hand delivered to the Denton campus ACT 7th floor or the Dallas campus Office of Research IHSD 8th floor.

Houston

All parts of the application (including the signed cover page and appendices in order) should be combined into one single .pdf or Word document and emailed to irb-houston@twu.edu. The original copy is not required. If you have any difficulty with preparing a .pdf file, please contact the Houston Office of Research via email for assistance.

RESPONSE TIMES

Upon receipt of the application, the investigator will receive an email notifying them that the application has been received, the level of review that the application has been assigned, and the protocol number that has been assigned. Applicants can expect to receive a response from the IRB regarding the review within three weeks for an expedited application and within two weeks from the date of the meeting for a full review application. Note that these times are estimates and additional time may be required during certain times of the academic calendar such as summer, semester breaks, and Holidays.

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Kenneth Shane Broughton (ID: 989636)
- **Institution Affiliation:** Texas Woman's University (ID: 1959)
- **Institution Email:** kbroughton@twu.edu
- **Institution Unit:** Nutrition and Food Sciences
- **Phone:** 9408983715

- **Curriculum Group:** Biomedical Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 18999930
- **Completion Date:** 14-Mar-2016
- **Expiration Date:** 14-Mar-2019
- **Minimum Passing:** 80
- **Reported Score*:** 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Texas Woman's University Institutional Page (ID: 14186)	11-Mar-2016	No Quiz
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	11-Mar-2016	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	29-Aug-2008	3/3 (100%)
History and Ethics of Human Subjects Research (ID: 498)	29-Aug-2008	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	10-Sep-2008	5/5 (100%)
Informed Consent (ID: 3)	17-Nov-2008	4/4 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	17-Nov-2008	4/4 (100%)
Records-Based Research (ID: 5)	17-Nov-2008	2/2 (100%)
Genetic Research in Human Populations (ID: 6)	17-Nov-2008	2/2 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	14-Mar-2016	4/5 (80%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	17-Nov-2008	4/4 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	17-Nov-2008	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	17-Nov-2008	3/3 (100%)
FDA-Regulated Research (ID: 12)	17-Nov-2008	4/5 (80%)
Research and HIPAA Privacy Protections (ID: 14)	14-Mar-2016	3/5 (60%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	17-Nov-2008	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	17-Nov-2008	2/2 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k26B2573B-83A7-4CBD-9F36-0A5692A1CD07-18999930

Collaborative Institutional Training Initiative (CITI Program)

Email: support@citiprogram.org

Phone: 888-529-5929

Web: <https://www.citiprogram.org>



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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Kenneth Shane Broughton (ID: 989636)
- **Institution Affiliation:** Texas Woman's University (ID: 1959)
- **Institution Email:** kbroughton@twu.edu
- **Institution Unit:** Nutrition and Food Sciences
- **Phone:** 9408983715

- **Curriculum Group:** Biomedical Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 18999930
- **Report Date:** 21-Apr-2017
- **Current Score**:** 94

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	29-Aug-2008	7/7 (100%)
Texas Woman's University Institutional Page (ID: 14186)	11-Mar-2016	No Quiz
Informed Consent (ID: 3)	17-Nov-2008	4/4 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	17-Nov-2008	4/4 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	29-Aug-2008	3/3 (100%)
Records-Based Research (ID: 5)	17-Nov-2008	2/2 (100%)
Genetic Research in Human Populations (ID: 6)	17-Nov-2008	2/2 (100%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	17-Nov-2008	4/4 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	17-Nov-2008	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	17-Nov-2008	3/3 (100%)
FDA-Regulated Research (ID: 12)	17-Nov-2008	4/5 (80%)
Research and HIPAA Privacy Protections (ID: 14)	14-Mar-2016	3/5 (60%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	17-Nov-2008	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	17-Nov-2008	2/2 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	10-Sep-2008	5/5 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	11-Mar-2016	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	14-Mar-2016	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k26B2573B-83A7-4CBD-9F36-0A5692A1CD07-18999930

Collaborative Institutional Training Initiative (CITI Program)

Email: support@citiprogram.org

Phone: 888-529-5929

Web: <https://www.citiprogram.org>



Completion Date 25-Oct-2017
Expiration Date 24-Oct-2020
Record ID 24871276

This is to certify that:

Rachel Adams

Has completed the following CITI Program course:

Social & Behavioral Research - Basic/Refresher (Curriculum Group)
Social & Behavioral Research - Basic/Refresher (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Texas Woman's University



Verify at www.citiprogram.org/verify/?w97b9ad11-6ce5-4a4c-b4ec-198080d2d52f-24871276

Texas Woman's University

Irritable Bowel Syndrome and the Low FODMAP Diet Study

Irritable Bowel Syndrome (IBS) is very common. Affecting both women and men across ethnicities and ages. Your participation will help us understand how to relieve IBS symptoms.

To qualify for this study, you must be:

- Between 18 – 65 years old, living in the US
- Diagnosed with IBS by a physician/nurse practitioner/physician's assistant

- As a participant of this study you will first be asked to fill out an online screening survey. The survey should take no more than 15 minutes.
- Your participation is completely voluntary and confidential. Submission of the completed survey constitutes your informed consent to act as a participant in this study.
- The study includes four weekly modules with videos and downloadable resources, a closed Facebook group allowing interaction with a Registered Dietitian, and two weeks of additional support for the second phase of the diet. **Similar programs on the internet are valued at up to \$400.**
- The program should take no more than two hours weekly for four weeks.
- Participants will be assigned to one group with immediate access to The FODMAP Fix and the other group will receive access a month later.
- During the diet program, you will be asked to remove some commonly eaten foods from your diet. Food is NOT provided in the program.
- Participants who complete the four-week study will be given a **\$20 Amazon.com gift card. Participation is limited, so register soon!**

If you are interested in participating in this survey, please follow this link:

XXXXXXXXXX

If you have questions about the study or would like to receive an email with the link to the survey, please contact: Radams15@twu.edu

There is a potential risk of loss of confidentiality in all email, downloading, electronic meetings and internet transactions.

Irritable Bowel Syndrome and The Low FODMAP Diet Study Survey

You may exit and reenter this survey and your progress will be automatically saved.

Your participation is completely voluntary and confidential.

Please note: Submitting this survey means you are giving your informed consent to be a part of this research. You may choose to cancel the survey at any time and not submit.

The FODMAP Fix is a four-week internet-based low FODMAP diet education program. As a participant in this study you will be randomly assigned to one of two groups: intervention or control. You will be notified of your assignment within a week of completing this survey.

Participants randomized to the intervention group will be granted access to The FODMAP Fix at the start of the study and asked to **strictly follow the low FODMAP diet for four weeks**. The program will guide you and provide suggestions for foods to swap with those you might normally eat. The food itself is NOT included in this program. If you are randomized to the control group, you will be granted access to the program at the conclusion of the study (four weeks from the start date). You will be asked to follow your normal diet during the study period.

Both groups will be required to complete diet and health assessments throughout the four-week study.

The FODMAP Fix will consist of four weekly modules with videos and numerous resources for you to download, a closed Facebook group where, if you choose, you can interact with a Registered Dietitian trained on the low FODMAP diet, and an additional two weeks of support for the second phase of the low FODMAP diet. Similar programs on the internet are valued at up to \$400.

The FODMAP Fix program should take one to two hours per week over the four weeks.

If you have questions about the study, please contact the investigator Rachel Adams, MS, RDN at Radams15@twu.edu or the faculty advisor Shane Broughton, Ph.D kbroughton@twu.edu

There is a potential risk of loss of confidentiality in all email, downloading, electronic meetings and internet transactions. Please do not include any sensitive information in email communications.

***1)**

I agree to participate in the IBS and Low FODMAP Diet Study. I understand that I may be asked to follow the low FODMAP diet, a diet that eliminates a number of foods that might be part of my usual diet, for four weeks. I agree to complete the required assessments and follow the online program "The FODMAP Fix", which will be provided by the researcher.

☐ Yes, I agree to participate. [Value=1]

☐ No, I do not agree to participate. [Value=2]

2) Please provide a 6 digit study ID# that is made up of the following: Initial of first and last name, two digit day of birth, two digit month of birth. As an example, Jane Doe's birthday is August 6. Her study ID# would be JD0608.

***3)** I am 18 to 65 years of age.

☐ Yes
[Value=1]

☐ No
[Value=2]

***4)** Have you been diagnosed with Irritable Bowel Syndrome (IBS) by a physician, nurse practitioner, or physician's assistant?

☐ Yes
[Value=1]

☐ No
[Value=2]

-----Page Break-----

In the past four weeks, have you followed any of the following diets or eating plans?

***5)** Low FODMAP diet

☐ Yes [Value=1]

☐ No [Value=2]

***6)** Very low carbohydrate

☐ Yes [Value=1]

☐ No [Value=2]

***7)** Ketogenic

☐ Yes [Value=1]

☐ No [Value=2]

- *8) Gluten free
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *9) Paleo
- ☐ Yes [Value=1]
- ☐ No [Value=2]

-----Page Break-----

During the past four weeks have you taken any of the following:

- *10) Antibiotics
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *11) Narcotic analgesics
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *12) Stool bulking agent
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *13) Prebiotic or probiotic supplements
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *14) Lactulose
- ☐ Yes [Value=1]
- ☐ No [Value=2]

-----Page Break-----

- *15) Are you pregnant or planning to become pregnant in the next six weeks?
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *16) Are you living in a hospital, rehabilitation facility, nursing home, or long-term care facility?
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *17) Do you currently have an eating disorder?
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *18) Have you been diagnosed by a physician for food allergies? This does not include home testing kits for food allergies/hypersensitivities.
- ☐ Yes [Value=1]
- ☐ No [Value=2]

- *19) Have you been diagnosed with another gastrointestinal disorder besides Irritable Bowel Syndrome, such as Crohn's disease or Ulcerative Colitis?
- ☐ Yes [Value=1]
- ☐ No [Value=2]

-----Page Break-----

*20) Do you have a smartphone (Apple or Android)?

- ☐ Yes [Value=1]
☐ No [Value=2]

*21) Are you willing to download an application to your phone that will cost \$7.99, but will be required for you to participate in this study?

- ☐ Yes [Value=1]
☐ No [Value=2]

*22) Do you have regular access to the internet either through your smartphone or a computer?

- ☐ Yes [Value=1]
☐ No [Value=2]

*23) Would you be willing to follow a diet that eliminates a number of foods, if it could help relieve IBS symptoms?

- ☐ I do not intend to change my diet in the next 6 months [Value=1]
☐ I intend to change my diet within the next 2 to 6 months [Value=2]
☐ I intend to change my diet in the next 30 days [Value=3]

Question Logic

If **[I do not intend to change my diet in the next 6 mo...]** is selected, then skip to question **[GO TO END OF SURVEY]**

If **[I intend to change my diet within the next 2 to 6...]** is selected, then skip to survey **[#183851]**, question **[after #1, Text]** (See "Edit Logic" for details)

If **[I intend to change my diet in the next 30 days...]** is selected, then skip to survey **[#183851]**, question **[after #1, Text]** (See "Edit Logic" for details)

-----Page Break-----

-----Automatic Page Break-----

Irritable Bowel Syndrome and The Low FODMAP Diet Study Survey

Thank you!

For maximum confidentiality, please close this window.

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The FODMAP Fix Informed Consent

*1) What is your first and last name?

*2) What is your email address? This will only be used to contact you for the purposes of this study

*3) What year were you born?

*4) What is your gender?

- ☐ Female [Value=1]
☐ Male [Value=2]
☐ Transgender Female [Value=3]
☐ Transgender Male [Value=4]
☐ Not listed or prefer not to provide [Value=5]

*5) Ethnicity:

- ☐ Black or African American [Value=1]
☐ Native American or Alaska Native [Value=2]
☐ South Asian (from Afghanistan, Bangladesh, Bhutan, India, Nepal, Maldives, Pakistan, or Sri Lanka) [Value=3]
☐ East Asian (from China, Hong Kong, Macau, Japan, Taiwan, North/South Korea or Mongolia) [Value=4]
☐ Native Hawaiian or Pacific Islander [Value=5]
☐ Middle Eastern (from Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Saudi Arabia, Palestine, Turkey or Yemen) [Value=6]
☐ Caucasian (non-Hispanic) [Value=7]
☐ Scandinavian (from Denmark, Norway, Sweden, Finland or Iceland) [Value=8]
☐ Other (please specify) [Value=9]

*6) How tall are you?

*7) What is your weight (in pounds)?

*8) How would you best describe your IBS type?

- ☐ Constipation [Value=1]
☐ Diarrhea [Value=2]
☐ Both constipation and diarrhea [Value=3]

9) Please choose which best describe your symptoms OVER THE LAST 3 MONTHS for any symptoms that have been present for at least six months. (Select ALL that apply).

- ☐ Stomach pain on average at least 1 day per week that is related to passing stool. [Checked=1]
☐ Stomach pain on average at least 1 day per week that is associated with changes how often you pass stool. [Checked=1]
☐ Stomach pain on average at least 1 day per week that is related to a change in form (consistency) of stool. [Checked=1]
☐ Bloating at least one day per week. [Checked=1]
☐ Constipation at least one day per week. [Checked=1]
☐ Diarrhea at least one day per week. [Checked=1]
☐ Excess gas at least one day per week. [Checked=1]

-----Automatic Page Break-----

The FODMAP Fix Informed Consent

Thank you!

For maximum confidentiality, please close this window.

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Food Frequency Questionnaire

This survey is adapted from: National Institutes of Health, Applied Research Program, National Cancer Institute. Diet History Questionnaire, Version 3.0. 2018.

*1) What is your FODMAP Fix study ID#? (Initial of first and last name, two digit day of birth, two digit month of birth)

-----Page Break-----

What beverages did you drink?

Over the **past month**, how often did you drink the following beverages?

Please select one answer per beverage.

	Never	1 time in the past month	2-3 times in the past month	1-2 times per week	3-4 times per week	5-6 times per week	1 time per day	2-3 times per day	4-5 times per day	6 or more times per day
*2) Tomato juice or vegetable juice	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*3) Other 100% fruit juices or 100% fruit juice mixtures (such as apple, pineapple, or others)	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*4) Milk (including cow or goat milk, or flavored milks)	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*5) Milk, lactose free	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*6) Soy, oat, or coconut milk	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*7) Kefir or yogurt-based drinks	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*8) Milk-based meal replacement or high-protein beverages (including Boost, Muscle Milk,	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*9) Soda or pop	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*10) Coconut water	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*11) Beer or wine	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*12) Rum or rum-based mixed drinks	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*13) Coffee, caffeinated or decaffeinated (including brewed coffee, instant coffee, or	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*14) Espresso drink mixtures, caffeinated or decaffeinated (including latte, mocha, cappuccino, etc.)	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*15) Chai or oolong tea	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*16) Chamomile, fennel, dandelion or herbal blend tea	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*17) Kombucha	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]

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What fruits did you eat?

Over the **past month**, how often did you eat the following fruits.

Please select one asnwer per fruit.

1 time in 2-3 times 1-2 times 3-4 times 5-6 times 1 time per 2-3 times 4-5 times 6 or more

	the past month	in the past month	per week	per week	per week	day	per day	per day	times per day
*18) Apples or applesauce	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*19) Apricot (fresh or canned)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*20) Avocado or guacamole	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*21) Bananas, ripe	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*22) Bananas, green or not yet ripe	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*23) Blueberries, blackberries, boysenberries, cherries, or raspberries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*24) Dried fruit (such as prunes or raisins)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*25) Figs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*26) Grapefruit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*27) Mango (fresh, canned, or frozen)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*28) Nectarine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*29) Oranges, tangerines, or clementines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*30) Pears (fresh, canned, or frozen)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*31) Peaches, nectarines, or plums	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*32) Pomegranate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]
*33) Watermelon or honeydew melon	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]

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What vegetables, potatoes, and beans did you eat?Over the **past month**, how often did you eat the following vegetables, potatoes, nuts, or beans?

Please select one answer per food.

	Never	1 time in the past month	2-3 times in the past month	1-2 times per week	3-4 times per week	5-6 times per week	1 time per day	2-3 times per day	4-5 times per day	6 or more times per day
*34) Artichoke, canned	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*35) Artichoke, fresh or pickled in oil	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*36) Asparagus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*37) Beans, green	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*38) Beets, canned or pickled	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*39) Broccoli, head only	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*40) Broccoli, stalk only	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*41) Broccoli, whole	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*42) Brussels sprouts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]

*43) Butternut squash	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*44) Cauliflower	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*45) Celery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*46) Corn (fresh or canned)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*47) Garlic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*48) Mushrooms	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*49) Onion, including white, yellow, spring onion, shallots, or scallion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*50) Peas, green, sugar snap, or snow; including fresh, canned, or frozen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*51) Potato, sweet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*52) Potato, white	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*53) Zucchini	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*54) Beans or lentils, including, black, chickpeas, garbanzo, kidney, navy, or pinto	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*55) Meat replacement made with soy, lentils, or beans (such as false chicken nuggets, lentil or bean burger)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*56) Tofu	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*57) Almonds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*58) Cashews	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*59) Peanuts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*60) Pistachios	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]

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What bread, cereal, rice, and pasta did you eat?In the **past month**, how often did you eat the following bread, cereal, rice, or pastas?

Please select one answer per food.

	Never	1 time in the past month	2-3 times in the past month	1-2 times per week	3-4 times per week	5-6 times per week	1 time per day	2-3 times per day	4-5 times per day	6 or more times per day
*61) Wheat bran or germ	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*62) Bread, wheat, white, pumpernickel, or rye	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*63) Bread, sourdough	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*64) Bread, gluten-free, multigrain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*65) Bread, gluten-free, white	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*66) Granola	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*67) Cereal, rice crisps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*68) Cereal, wheat flake-based	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]

*69) Cereal, dried fruit-added	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*70) Cereal, corn flake	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*71) Cereal, muesli	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*72) Couscous	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*73) Couscous, gluten-free	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*74) Pasta, wheat-based	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*75) Pasta, lentil- or bean-based	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*76) Pasta, rice- or quinoa-based	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*77) Pasta, gnocchi	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*78) Tortillas, corn	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*79) Tortillas, flour, cassava or coconut flour-based	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]

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What meat, eggs, and fish did you eat?

-----Page Break-----

What snacks did you eat?In the **past month**, how often have you eaten the following snack foods?

Please select one answer per food.

	Never	1 time in the past month	2-3 times in the past month	1-2 times per week	3-4 times per week	5-6 times per week	1 time per day	2-3 times per day	4-5 times per day	6 or more times per day
*80) Yogurt, cow milk-based	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*81) Yogurt, lactose-free, coconut, almond, or goat milk-based	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*82) Bar, cereal or granola	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*83) Cookies (not gluten-free)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*84) Cake (not gluten-free)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*85) Brownies (not gluten-free)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*86) Chips, potato or corn, salted	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*87) Chips, potato, sour cream and chive flavor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*88) Energy bar	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*89) Rye crisps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*90) Trail mix with dried fruit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]
*91) Fruit-flavored snacks or roll-ups	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]	[Value=6]	[Value=7]	[Value=8]	[Value=9]	[Value=10]

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What condiments did you eat?

In the **past month**, how often did you eat the following condiments?

Please select one answer per food.

	Never	1 time in the past month	2-3 times in the past month	1-2 times per week	3-4 times per week	5-6 times per week	1 time per day	2-3 times per day	4-5 times per day	6 or more times per day
*92) Barbeque sauce	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*93) Ketchup	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*94) Salsa	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*95) Pesto	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*96) Marinara sauce	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*97) Alfredo sauce	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*98) Queso	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*99) Ranch dip or dressing	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*100) Jelly/jam	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]
*101) Honey or agave nectar	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=10]

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Food Frequency Questionnaire

Thank you!

For maximum confidentiality, please close this window.

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IBS - Symptom Severity Scale (IBS-SSS)

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IBS-SSS contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: <https://eprovide.mapi-trust.org/>

Francis CY, Morris J, Whorwell PJ. The irritable bowel severity scoring system: a simple method of monitoring irritable bowel syndrome and its progress. Aliment Pharmacol Ther. 1997 Apr

INSTRUCTIONS

This survey is designed to enable us to record and monitor the severity of your IBS. It is to be expected that your symptoms might vary over time, so please try and answer the questions based on how you currently feel (i.e., over the last ten days or so). All information will be kept in strict confidence.

1. For questions where a number of different responses are a possibility please circle the response appropriate to you.
2. Some questions will require you to write in an appropriate response.
3. Some questions require you to put a cross on a line which enables us to judge the severity of a particular problem.

***1)** FODMAP Fix ID Number (Initial of first and last name, two digit day of birth, two digit month of birth)

***2)** To which gender do you most identify?

- Female [Value=1]
- Male [Value=2]
- Transgender Female [Value=3]
- Transgender Male [Value=4]
- Not listed or prefer not to respond [Value=5]

***3)** Do you currently suffer from abdominal pain?

☐ Yes [Value=1]

☐ No [Value=2]

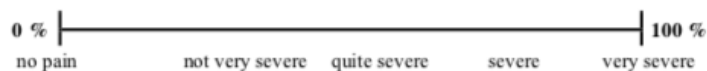
Question Logic

If **[Yes]** is selected, then skip to question **[#4]**

If **[No]** is selected, then skip to question **[#6]**

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***4)** If yes, how severe is your abdominal (stomach) pain? Please enter a number from 0 to 100 based on the scale below.



***5)** Please indicate the number of days that you get the pain in every ten days. For example, if you enter 4 it means that you get pain 4 out of 10 days. If you get pain every day enter 10.

***6)** Do you currently suffer from abdominal distention* (bloating, swollen or tight stomach)? (*women, please ignore distension related to your periods)

☐ Yes [Value=1]

☐ No [Value=2]

Question Logic

If **[Yes]** is selected, then skip to question **[#7]**

If **[No]** is selected, then skip to question **[#8]**

-----Page Break-----

IBS - Quality of Life (IBS-QOL)

PLEASE READ THIS CAREFULLY

On the following pages you will find statements concerning bowel problems (irritable bowel syndrome) and how they affect you.

For each statement, please choose the response that applies best to you and **circle** the number of your response.

If you are unsure about how to respond to a statement, please give the best response you can. **There are no right or wrong responses.**

Your responses will be kept strictly confidential.

If you have any questions, please contact:

Rachel Adams at radams15@twu.edu

The IBS-QOL was developed by Donald L. Patrick, Ph.D. at The University of Washington, Douglas A. Drossman, MD at The University of North Carolina, Novartis Pharmaceuticals Corporation, and Novartis Pharma AG. Authors hold joint copyright over the IBS-QOL and all its translations.

***1)** Please provide your FODMAP Fix participant ID#.

***2)** To which gender do you most identify?

- ☐ Female [Value=1]
☐ Male [Value=2]
☐ Transgender Female [Value=3]
☐ Transgender Male [Value=4]
☐ Not listed or prefer not to identify [Value=5]

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About how you feel

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

Please select one answer for each question. If not applicable, please choose "NOT AT ALL".

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
*3) I feel helpless because of my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*4) I am embarrassed by the smell caused by my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*5) I am bothered by how much time I spend on the toilet.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*6) I feel vulnerable to other illnesses because of my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*7) I feel fat/bloated because of my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*8) I feel like I'm losing control of my life because of my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*9) I feel my life is less enjoyable because of my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*10) I feel uncomfortable when I talk about my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*11) I feel depressed about my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*12) I feel isolated from others because of my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*13) I have to watch the amount of food I eat because of my bowel problems.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
*14) Because of my bowel problems, sexual activity is difficult for me.	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]
I feel angry that I have bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	[Value=1]	[Value=2]	[Value=3]	[Value=4]	[Value=5]
*15)					
*16) I feel like I irritate others because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*17) I worry that my bowel problems will get worse.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*18) I feel irritable because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*19) I worry that people think I exaggerate my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*20) I feel I get less done because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*21) I have to avoid stressful situations because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*22) My bowel problems reduce my sexual desire.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*23) My bowel problems limit what I can wear.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*24) I have to avoid strenuous activity because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*25) I have to watch the kind of food I eat because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*26) Because of my bowel problems, I have difficulty being around people I do not know well.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*27) I feel sluggish because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*28) I feel unclean because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*29) Long trips are difficult for me because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*30) I feel frustrated that I cannot eat when I want because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*31) It is important to be near a toilet because of my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*32) My life revolves around my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*33) I worry about losing control of my bowels.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*34) I fear that I won't be able to have a bowel movement.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*35) My bowel problems are affecting my closest relationships.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*36) I feel that no one understands my bowel problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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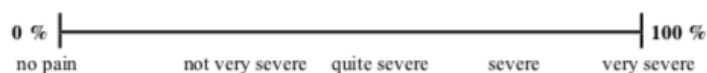
IBS - Quality of Life (IBS-QOL)

Thank you!

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- *7) If yes, how severe is your abdominal distension/tightness? Please enter a number between 0 to 100 based on the scale below.



- *8) How satisfied are you with your bowel movements? Please enter a number between 0 to 100 based on the scale below.



- *9) Please indicate how much your Irritable Bowel Syndrome is affecting or interfering with your life in general. Please select a number from 0 to 100 based on the scale below.



-----Page Break-----

- *10) What is the maximum number of times you have a bowel movement per day?

- *11) What is the maximum number of times you have a bowel movement per week?

- *12) What is the maximum number of times you have a bowel movement per month?

- *13) What is the minimum number of times you have a bowel movement per day?

- *14) What is the minimum number of times you have a bowel movement per week?

- *15) What is the minimum number of times you have a bowel movement per month?

Are your bowel movements ever:

	Often	Occasionally	Never
*16) Normal	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]
*17) Hard	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]
*18) Very thin (like string)	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]
*19) In small pieces (like rabbit pellets)	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]
*20) Mushy (like oatmeal)	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]

★21) Watery

☐
[Value=1]

☐
[Value=2]

☐
[Value=3]

Do you ever:

	Yes	No
★22) Pass mucus (or slime or jelly) with your bowel movements	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]
★23) Pass blood with your bowel movements	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]
★24) Have to hurry/rush to the toilet to have a bowel movement	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]
★25) Strain to have a bowel movement	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]
★26) Feel you haven't emptied your bowel completely after you have had a bowel movement	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]

-----Page Break-----

★27) In the last year, approximately how many weeks were you absent from work due to IBS? (Enter 52 if you have given up work completely because of IBS)

★28) In the last year, approximately how many weeks were you at work suffering from IBS?

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IBS - Symptom Severity Scale (IBS-SSS)

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Global IBS Symptom Relief Question

Did you have adequate relief of your IBS symptoms over the past seven days?

Staudacher HM, Lomer MC, Farquharson FM, Louis P, Fava F, Franciosi E, Scholz M, Tuohy KM, Lindsay JO, Irving PM, Whelan K. A diet low in FODMAPs reduces symptoms in patients with irritable bowel syndrome and a probiotic restores *Bifidobacterium* species: a randomized controlled trial. *Gastroenterology*. 2017 Oct 1;153(4):936-47.

Utility of global symptom question:

Irvine EJ, Tack J, Crowell MD, et al. Design of treatment trials for functional gastrointestinal disorders. *Gastroenterology*. 2016;150(1469–1480):e1461.

Compliance Assessment Question

“In the last week, I have followed the low FODMAP diet...”

- Never/rarely (<25% of the time)
- Sometimes (25- 50% of the time)
- Frequently (51-75% of the time)
- Always (76-100% of the time)

Adapted from: Staudacher HM, Lomer MC, Farquharson FM, Louis P, Fava F, Franciosi E, Scholz M, Tuohy KM, Lindsay JO, Irving PM, Whelan K. A diet low in FODMAPs reduces symptoms in patients with irritable bowel syndrome and a probiotic restores Bifidobacterium species: a randomized controlled trial. *Gastroenterology*. 2017 Oct 1;153(4):936-47.

FODMAP Self-efficacy Assessment

This survey is adapted from: Bandura, A. (2006). Guide for constructing self-efficacy scales. Self-efficacy beliefs of adolescents. 5(307-337).

- *1) What is your 6 character FODMAP Fix study ID#? (Initial of first and last name, two digit day of birth, two digit month of birth)

A number of situations are described below that can make it hard to stick to an elimination diet. Please rate in each of the blanks on the column how certain you are that you can stick to an elimination diet on a **regular basis** for four weeks.

Rate your degree of confidence by selecting one choice for each question below:

	0 Cannot do at all	1	2	3	4	5 Modera tely can do	6	7	8	9	10 Highly certain can do
*2) During holiday times	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*3) Eating at a friend's house for dinner	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*4) Preparing meals for others	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*5) Eating at a restaurant	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*6) When angry or annoyed	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*7) When very hungry	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*8) Feel like celebrating with others	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*9) When you are entertaining visitors	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*10) During vacations	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]
*11) When you have to prepare your own meals	<input type="radio"/> [Value=1]	<input type="radio"/> [Value=2]	<input type="radio"/> [Value=3]	<input type="radio"/> [Value=4]	<input type="radio"/> [Value=5]	<input type="radio"/> [Value=6]	<input type="radio"/> [Value=7]	<input type="radio"/> [Value=8]	<input type="radio"/> [Value=9]	<input type="radio"/> [Value=1 0]	<input type="radio"/> [Value=1 1]

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FODMAP Self-efficacy Assessment

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The Low FODMAP Diet Quiz

1. Low FODMAP Diet is based on the principle that certain_____ can cause IBS symptoms.
 - a. Proteins
 - b. Sugars and fiber
 - c. Oils
 - d. Chemicals
2. Which of the following foods is high in FODMAPs?
 - a. Strawberries
 - b. Avocado
 - c. Orange
 - d. Spinach
3. Which of the following is NOT key word you need to watch on food labels if you are following a low FODMAP diet?
 - a. Lactose
 - b. Sorbitol
 - c. Glucose
 - d. High fructose corn syrup
4. What ingredient on a package of taco seasoning would indicate that it might be high in FODMAPs?
 - a. Oregano
 - b. Chili powder
 - c. Cumin
 - d. Onion powder
5. Which would probably be a good choice when ordering fast food?
 - a. Hamburger: lettuce, tomato, mustard with no bun
 - b. Chicken strips
 - c. Grilled chicken sandwich
 - d. Southwest salad with salsa dressing

**Institutional Review Board**

Office of Research and Sponsored Programs

P.O. Box 425619, Denton, TX 76204-5619

940-898-3378

email: IRB@twu.edu<https://www.twu.edu/institutional-review-board-irb/>

DATE: January 17, 2019

TO: Ms. Rachel Adams
Nutrition and Food Sciences

FROM: Institutional Review Board (IRB) - Denton

Re: Approval for The Effectiveness of an Internet-Based Low FODMAP Diet Education Course to Improve Symptoms in Patients with IBS (Protocol #: 20358)

The above referenced study has been reviewed and approved by the Denton IRB (operating under FWA00000178) on 1/16/2019 using an expedited review procedure. This approval is valid for one year and expires on 1/16/2020. The IRB will send an email notification 45 days prior to the expiration date with instructions to extend or close the study. It is your responsibility to request an extension for the study if it is not yet complete, to close the protocol file when the study is complete, and to make certain that the study is not conducted beyond the expiration date.

If applicable, agency approval letters must be submitted to the IRB upon receipt prior to any data collection at that agency. A request to close this study must be filed with the Institutional Review Board at the completion of the study. Because you do not utilize a signed consent form for your study, the filing of signatures of subjects with the IRB is not required.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any adverse events or unanticipated problems. All forms are located on the IRB website. If you have any questions, please contact the TWU IRB.

cc. Dr. Shane Broughton, Nutrition and Food Sciences
Graduate School



Institutional Review Board

Office of Research and Sponsored Programs

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email: IRB@twu.edu

<https://www.twu.edu/institutional-review-board-irb/>

DATE: February 15, 2019

TO: Ms. Rachel Adams
Nutrition and Food Sciences

FROM: Institutional Review Board - Denton

Re: Notification of Approval for Modification for The Effectiveness of an Internet-Based Low FODMAP Diet Education Course to Improve Symptoms in Patients with IBS (Protocol #: 20358)

The following modification(s) have been approved by the IRB:

1. The PI will include physicians' offices and counseling centers as recruitment sites.
2. Nutrilink has granted the researchers access to their listsrv to which a recruitment email/flyer will be sent.
3. In addition to emailing the TWU campus for recruitment, the PI will also post the flyer around campus.

cc. Dr. Shane Broughton, Nutrition and Food Sciences



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DATE: March 28, 2019

TO: Ms. Rachel Adams
Nutrition and Food Sciences

FROM: Institutional Review Board - Denton

Re: Notification of Approval for Modification for The Effectiveness of an Internet-Based Low FODMAP Diet Education Course to Improve Symptoms in Patients with IBS (Protocol #: 20358)

The following modification(s) have been approved by the IRB:

Recruitment will be expanded to students, faculty, and staff at other universities where the research team has connections.

cc. Dr. Shane Broughton, Nutrition and Food Sciences



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email: IRB@twu.edu

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DATE: April 12, 2019

TO: Ms. Rachel Adams
Nutrition and Food Sciences

FROM: Institutional Review Board - Denton

Re: *Notification of Approval for Modification for The Effectiveness of an Internet-Based Low FODMAP Diet Education Course to Improve Symptoms in Patients with IBS (Protocol #: 20358)*

The following modification(s) have been approved by the IRB:

1. Decrease intervention period from 4 to 2 weeks. This is in an effort to improve compliance and completion rates. Trials of the low FODMAP diet have shown significant results within just 48 hours. Total time will decrease from 7 hours for the program and assessments over four weeks to 3 1/2 hours over two weeks: 2 hours in week 1 and 1 1/2 hours in week 2.
2. Paleo, keto, and low carb diets will not be excluded as some of the foods highest in FODMAPs (garlic and onions) are allowed and frequently consumed on these diets. Time since exclusion diets were followed will be decreased from 4 to 2 weeks to match intervention period.
2. Remove the control group. All screened participants will be part of the intervention. A pre/post analysis using a paired t-test will be completed. This is similar to four previous studies on the low FODMAP diet. The control group thus far has been completely non-compliant with survey completion.
3. Open enrollment to self-diagnosed IBS, instead of requiring participants to be physician-diagnosed. Patients will be asked to indicate if they have IBS then asked whether they were self-diagnosed or diagnosed by a physician, nurse practitioner, or physician's assistant. Studies show up to 75% of people with IBS never receive a formal diagnosis. This will hopefully increase my recruitment. Diagnosis type will be correlated with the ROME diagnostic criteria in the final analysis. I will add a statement in the survey directing participants to consult with a physician if they indicate they are experiencing "red flag" symptoms (see attached survey).
4. Food Frequency and the 24 hour recall surveys will be removed from the analysis. This is in an effort to improve compliance that may have suffered in original data collection from survey fatigue. This will decrease the maximum time required over two weeks. Compliance will be assessed using the previously approved (and validated) compliance question presented in the original IRB submission.

cc. Dr. Shane Broughton, Nutrition and Food Sciences



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940-898-3378

email: IRB@twu.edu

<https://www.twu.edu/institutional-review-board-irb/>

DATE: May 28, 2019

TO: Ms. Rachel Adams
Nutrition and Food Sciences

FROM: Institutional Review Board - Denton

Re: Notification of Approval for Modification for The Effectiveness of an Internet-Based Low FODMAP Diet Education Course to Improve Symptoms in Patients with IBS (Protocol #: 20358)

The following modification(s) have been approved by the IRB:

The PI will follow-up with participants who did not complete their final assessments to try to determine if the issue was the burden of the assessments, the diet, or the education program. The questions will be sent as a link to a PsychData survey.

cc. Dr. Shane Broughton, Nutrition and Food Sciences

APPENDIX E
CURRICULUM VITAE

Rachel Adams, MS, RD, LD

EDUCATION

2014-2015, 2017-2019, Texas Woman's University, Denton, TX

Ph.D. Candidate, Nutrition, 4.0 GPA

Graduate Research Assistant (January 2017 – August 2017)

Graduate Teaching Assistant (May 2015 – December 2017)

2000-2002, Tufts University, Boston, MA

MS: Nutrition Communication

Graduate Research Assistant (January 2001 – May 2001)

Internship: Edelman Public Relations (May 2001 – September 2001)

2001-2002, Simmons College, Boston, MA

Accredited Dietetic Internship

1996-2000, Abilene Christian University, Abilene, TX

BS: Food, Nutrition and Dietetics; Minor: Business Administration

Magna Cum Laude

EXPERIENCE

Eat Well Global

Consultant (March 2018 – Present)

- Lead planning, marketing, execution, and analysis of webinar series for global client.

Nestlé Health Sciences

Medical Affairs, Consultant (January 2017 – Present)

- Created science-based strategy for rebranding flagship product, including creation of an evidence review and development and substantiation of new product claims.

Clinical Sciences, Consultant (January 2015 – December 2015)

- Published a narrative review on the insulinotropic effects of whey protein to support messaging for the expanded use of an existing key product.
- Developed and presented a Continuing Education Unit (CEU) presentation on glycemic management for two key audiences: a national webinar of health care practitioners and a live presentation to an estimated 300 dietitians and physicians at the Puerto Rico Nutrition and Dietetics Conference and Exhibition.

Abilene Christian University

Adjunct Faculty (August 2014 – 2017)

- Instructor for undergraduate courses: Nutrition and Wellness, Nutrition Through the Lifecycle

Nestlé Nutrition

Integrated and Consumer Marketing, Consultant (June 2013 – January 2015)

Medical Scientific Liaison, Consultant (November 2010 – July 2014)

BabyNes Global Team on US Assignment, Consultant (January 2014 – July 2014)

Clinical Communication Specialist (November 2005 – November 2010)

- Managed the Speakers Bureau Program, including training of speakers, presentation development, and presiding over national teleconferences. Tripled the size of the Speakers Bureau in less than three years.
- Developed and enhanced relationships with Key Opinion Leaders (KOLs) to showcase Nestlé's research and development, and identified opportunities for cross collaboration.
- Identified and vetted investigators for clinical research collaborations.
- Responsible for updating key stakeholders, as well as all CEU and Speakers Bureau presentations, with the latest relevant medical and nutrition research.
- Assisted in the development of marketing and social media materials for both consumer facing and health care professional audiences for a global team's US launch, including developing the Twitter strategy and CRM email content for pediatricians.
- Translated clinical studies into training, marketing, and CEU materials, and trained medical sales representatives on clinical data.
- Conducted comparative analysis of competitive studies to garner insights and create talking points to address issues for Nestle representatives and physician speakers.
- Reported on competitive activity, market trends, and changes in hospital/physician access and opportunities to senior sales and medical, scientific, and regulatory leadership.
- Served as creative and content consultant for gerber.com.
 - Responsible for creating aggregate consumer and medical content and relevant assets for the site.
 - Reviewed, edited, and substantiated creative and content plans for gerber.com consumer facing videos.
 - Served as liaison between the Integrated Marketing team and Medical, Scientific and Regulatory Unit.

Infant Nutrition Representative (March 2004 – June 2007)

- Exceeded both 100% and stretch sales goals every year.
- Presented at both National and Regional Sales meetings on topics in clinical research and sales skills.

Wise Regional Health System

Clinical Dietitian (September 2002 – March 2004)

- Served as the clinical dietitian for both the outpatient and inpatient settings.
- Developed and managed the employee weight management program.

INVITED PRESENTATIONS

American Medical Writer's Association, November 2019, "Using Narratives to Improve Health Literacy and Communicator Credibility" (Upcoming)

The ROME Foundation Mentoring Program at Digestive Diseases Week, May 2019, "100% Online Low FODMAP Diet Education Program for Irritable Bowel Syndrome"

Texas Academy of Nutrition and Dietetics Annual Conference and Exhibition, April 2019, "Expand Your Reach: Creating Budget-Friendly, Online Courses"

Puerto Rico Academy of Nutrition and Dietetics Annual Conference and Exhibition, August 2017, "The Insulinotropic Effects of Whey Protein"

Texas Woman's University, April 2013, "The Tipping Point for Childhood Obesity"

Abilene Christian University, Center for Building Community, 2010, 2011, 2017. Career Planning and Work-Life Balance

SUNY Stony Brook, Winthrop-University Hospital, Allergy and Immunology Fellows, 2010 "Pediatric Allergy: Prevalence and Risk Reduction"

Georgetown University, Family Practice Residents and Fellows, 2009, "Probiotics and Infant Formula"

Morristown Memorial/Goryeb Children's Hospital, Gastroenterology Residents and Fellows, 2008, "Probiotics and Infant Formula"

SUNY Downstate, Gastroenterology Fellows, 2007, "Pediatric Allergy: Prevalence and Risk Reduction"

SELECTED PUBLICATIONS

Adams R, Broughton KS. The Effect of Diet on Irritable Bowel Syndrome Symptoms and Its Role in the Treatment Plan. *In Press*.

Adams R, Broughton KS. Insulinotropic Effects of Whey: Mechanisms of Action, Recent Clinical Trials, and Clinical Applications. *Ann Nutr Metab*. 2016;69(1):56-63. doi: 10.1159/000448665.

Buchanan-Adams R. Using FITS to Understand Consumption Patterns in a Critical Period for the Development of Childhood Obesity. Pediatric Nutrition Practice Group's (PNPG) *The Building Blocks for Life*. 2011; 34(2):13-18.

Robbins S, Meyers R (Ed.) *Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*, 2nd Edition. Chicago: American Dietetic Association, 2011. (*Advisor/Liaison*)

ACCOLADES

Texas Woman's University: Experiential Student Scholar Award, Summer 2018, Fall/Spring 2018-2019; Moore-Khourie Award, 2017, 2018-2019

American Society for Nutrition: Top Reviewer, *Advances in Nutrition*, 2018

Nestle: Gold Star, 2010, 2011; Sales Innovation, 2006; Very Best Spirit. 2005

CERTIFICATES

Low FODMAP Diet Training, Monash University, 2018

Essential Skills, American Medical Writers Association, 2014

PROFESSIONAL ORGANIZATION MEMBERSHIP

American Gastroenterological Association, 2019 - Present

Academy of Nutrition and Dietetics, 1999 – Present

American Medical Writers Association, 2013 – Present; Southwest Chapter Secretary, 2014

American Society for Nutrition, 2016 – Present; Nutrition Translation Research Interest Group Advisory Board, Doctoral Student Representative

SERVICE

Professional/Academic:

Tufts University, Friedman School of Nutrition, Science, and Policy, Social Justice, Inclusion, and Diversity, Faculty Sub-committee, Member 2018 – Present

Ad hoc Reviewer, *American Journal of Clinical Nutrition*, 2015 – Present

Ad hoc Reviewer, *Advances in Nutrition*, 2015 – Present

Civic:

Acts 4 Others/United 4 Hope, Board of Directors, 2012 – Present; Board Secretary, 2013 – Present, Fundraiser Planning Committee Member, 2015 – Present

Decatur Public Library, After-School STEAM Program Co-Director, January 2019 – Present

Decatur Church of Christ, Local Outreach Committee Co-Chair, 2017 – Present; Global Missions Committee Member 2014 – Present; Children's Education Committee Member 2014 – 2016

Texas Agri-life Extension Service, "Dinner Tonight", Planning Committee Member and Speaker 2013 – 2017

Mothers of Preschoolers (MOPs), Invited presentation on infant and toddler feeding, 2018

School Health Advisory Committee, Decatur ISD, Member 2015 – 2018

Fit-N-Wise Wellness and Rehabilitation Center, Nutrition Lecturer 2015