

ASSESSING AND COMPARING QUALITY OF LIFE SCORES IN PATIENTS
WITH IRRITABLE BOWEL SYNDROME-DIARRHEA, IRRITABLE
BOWEL SYNDROME-CONSTIPATION, AND
IRRITABLE BOWEL SYNDROME-MIXED

By

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ABSTRACT

Irritable bowel syndrome (IBS) is a common gastrointestinal (GI) disorder that affects an estimated 1 in 10 people globally (Black & Ford, 2020). Since IBS is such a common GI disorder worldwide it is important to understand that impact it has on quality of life. This study assessed the differences in the effects of IBS on the quality of life in patients with each of the three types of IBS: IBS-D, IBS-C, and IBS-M. Potential respondents were recruited via social media using an online survey, which collected demographics and assessed the effects of IBS on quality of life. The survey was also emailed to FODMAP trained dietitians who were asked to share the survey with their patients. Data collection lasted for approximately 9 weeks. One hundred and ninety-two responses were analyzed. Descriptive statistics for demographic data were reported as frequencies and correlated to the quality of life subscale scores. An ANOVA was used to analyze the differences between the total quality of life scores and subscale scores among patients with IBS-D, IBS-C, and IBS-M. An ANOVA was also used to analyze the differences between total quality of life scores among the different races, education levels, and monthly spending on IBS. A t-test was used to analyze the differences between quality of life subscale scores among female and male patients. A p -value ≤ 0.05 indicated significance. A significant difference in total quality of life scores was found between groups based on how much money participants spend monthly on treatments for/managing their IBS symptoms ($F(4, 149) = 10.81, p = <0.01$). Significant differences

were found in quality of life subscales scores among IBS-M, IBS-C, and IBS-D patients in the interference with activities ($F(3, 178)= 5.83, p= 0.001$), body image ($F(3, 185)= 3.61, p= 0.014$), and health worry subscales ($F(3, 183)= 4.83, p= 0.003$).

Significant differences were also found in quality of life subscale scores among white, non-Hispanic; whites, Hispanic origin; and others (Native Americans, Asian/Pacific Islanders, multi-racial, and Asian Indians) in the dysphoria ($F(2, 181)= 3.86, p= 0.023$), social reaction ($F(2, 182)= 3.23, p= 0.042$), and relationships subscales ($F(2, 184)= 3.58, p= 0.030$). Further research is needed to validate these associations.

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CHAPTER 1

INTRODUCTION

Irritable bowel syndrome (IBS) is one of the most commonly diagnosed functional bowel disorders, affecting an estimated 1 in 10 people globally (Black & Ford, 2020). IBS is defined as abdominal pain or discomfort associated with at least 2 of the following symptom groups: symptoms associated with changes in frequency of defecation, symptom relief associated with defecation, and symptoms associated with changes in consistency of stool (Bohn et al., 2015; Endo, Shoji, & Fukudo, 2015; Simren, Palsson, & Whitehead, 2017). Symptoms associated with IBS include chronic bloating, gas, diarrhea, abdominal distention, constipation, and nausea (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). IBS seems to have a significant impact on the health-related quality of life of the patients who suffer from the syndrome (El-Salhy, 2012; Jamali et al., 2012; Singh et al., 2015).

Statement of the Problem

Irritable bowel syndrome has been found to negatively impact the quality of life of the patients who suffer from it (Agarwal & Spiegel, 2011; Cho et al., 2011; Jamali et al., 2012; Jerndal et al., 2010; Kopczyńska, Mokros, Pietras, & Małecka-Panas, 2018; Østgaard, Hausken, Gundersen, & El-Salhy, 2012; Wang et al., 2012). IBS-diarrhea (IBS-D) negatively impacts the quality of life of patients (Andrae, Patrick, Drossman, & Covington, 2013; Buono, Carson, & Flores, 2017). Little research evaluating the effects

of IBS-Constipation (IBS-C) and IBS-Mixed (IBS-M) specifically on quality of life has been conducted. One study comparing the quality of life in IBS-D patients versus IBS-C patients found that quality of life scores tend to be lower in patients with IBS-D than IBS-C (Singh et al., 2015). Additional research is necessary to examine the differences among quality of life in patients with IBS-D, IBS-C, and IBS-M.

Purpose

The purpose of this study was to examine the differences in the effects of IBS on the quality of life in patients with each of the three types of IBS: IBS-D, IBS-C, and IBS-M. The IBS-Quality of Life (IBS-QOL) questionnaire assesses quality of life using eight subscales: body image, dysphoria, interference with activities, healthy worry, food avoidance, social reactions, sexual health, and effect on relationships (Singh et al., 2015). This study also examined the quality of life score differences between genders, races, education levels, and monthly spending on IBS categories of patients with IBS-D, IBS-C, and IBS-M.

Hypotheses

The following hypotheses were tested:

1. There will be no significant difference in the quality of life scores among patients with IBS-D, IBS-C, and IBS-M.
2. There will be no significant difference in the quality of life scores between genders in patients with IBS-D, IBS-C, and IBS-M.
3. There will be no significant difference in the quality of life sub scores among patients with IBS-D, IBS-C, and IBS-M.

Justification

Approximately 10-20% of the global population is diagnosed with IBS with only 12% of those patients seeking healthcare or treatment for their IBS symptoms (Black & Ford, 2020; Saha, 2014). IBS is a frustrating condition for many patients due to the lack of effective treatment plans and the lack of visible signs of disease or damage in the digestive tract (Bertram et al., 2001; National Institute of Diabetes and Digestive and Kidney Diseases, 2017). According to Al Huthail (2013), many IBS patients feel dissatisfied with their perceived physician-patient relationship due to a feeling of being insufficiently educated about their condition and a lack of an adequate explanation for their symptoms. IBS patients also often feel that their concerns are not taken seriously by their physician and many report perceived uncaring attitudes from medical professionals (Bertram et al., 2001; Bjorkman, Simren, Ringstrom, & Ung, 2016; Hakanson et al., 2010). Due to this, many IBS patients fail to seek medical care because they feel a consultation with a physician will provide little help (Al Huthail, 2013). If more research is conducted investigating the quality of life of patients with IBS it is possible that physicians may approach these patients differently. More research about the quality of life in IBS patients may help physicians understand how much IBS impacts the life of patients, so they may be more understanding and willing to find ways to improve symptoms. There is limited research regarding the quality of life in patients with IBS-C and IBS-M, so this study is needed to provide additional data to the current body of research related to the quality of life of patients with IBS.

CHAPTER 2

REVIEW OF LITERATURE

Irritable bowel syndrome (IBS) is a common gastrointestinal (GI) disorder that affects an estimated 1 in 10 people globally (Black & Ford, 2020). The exact pathophysiology of IBS is unclear, but IBS is defined as a group of symptoms that occur together without any visible signs of disease or damage in the digestive tract (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). Despite the lack of physical damage in the digestive tract, IBS can significantly reduce quality of life with the same degree of impairment as major chronic diseases, like diabetes, congestive heart failure, kidney disease, and hepatic cirrhosis (El-Salhy, 2012). Quality of life with IBS has been found to be affected by psychiatric symptoms, GI symptoms, disease severity, and gender (Singh et al., 2015). The symptoms that commonly occur in IBS may include chronic abdominal pain, diarrhea, constipation, changes in bowel movements, abdominal distension, bloating, and gas. Symptoms and the severity of symptoms can vary drastically between patients (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). It is estimated that 41% of patients have mild IBS, 35% of patients have moderate IBS, and 25% of patients are considered to have severe IBS (Corsetti & Whorwell, 2017). Mild IBS is considered to include 1-3 symptoms, mild/intermittent abdominal pain, good health-related quality of life, occasional activity restriction (0-15

days per year), health care utilization 0-1 time per year, and lack of or mild psychological distress (Drossman et al., 2011). Moderate IBS is considered to include 4-6 symptoms, including moderate and frequent abdominal pain, fair health-related quality of life, 15-50 days of activity restriction per year, moderate psychological distress, and health care utilization 2-4 times per year. Severe IBS is considered to include 7 or more symptoms, poor health-related quality of life, >50 days of activity restriction per year, severe psychological distress, severe and constant abdominal pain, and health care utilization 5 or more times per year (Drossman et al., 2011). Frequency of symptoms can also vary among patients. Some patients may experience symptoms daily, while other patients may experience symptoms at intervals of weeks or months at a time (El-Salhy, 2012). IBS can be difficult to diagnose due to the lack of visible damage within the digestive tract. Typically, IBS is diagnosed by eliminating other GI disorders such as: ulcerative colitis, crohn's disease, diverticulitis, small intestinal bacterial overgrowth (SIBO), celiac disease, non-celiac gluten sensitivity, and lactose intolerance (Borghini, Donato, Alvaro, & Picarelli, 2017).

Prevalence of Irritable Bowel Syndrome

Approximately 12% of IBS patients seek healthcare related to the treatment of IBS (Saha, 2014). According to the World Gastroenterology Organization approximately 1/3 of IBS patients have IBS-diarrhea (IBS-D), 1/3 of patients have IBS-constipation (IBS-C), and 1/3 of patients have IBS-mixed with diarrhea and constipation (IBS-M) (Corsetti & Whorwell, 2017). In the United States, IBS affects approximately 15% of the population, but many patients do not seek health care for their condition (Qureshi et al., 2016). IBS-related care accounts for about 12% of primary care visits and 2.2 million

prescriptions. IBS is the most common diagnosis made by gastroenterologists in the United States (Qureshi et al., 2016). In Western countries IBS tends to be more common in women, while in Eastern countries IBS is not found to be more common in women than men. It has been hypothesized that IBS is under diagnosed in Asia and other Eastern countries (Saha 2014). Approximately 6.5%-10.1% of the Asian population meets the criteria for IBS (Chang, Lu, & Chen, 2010). Lovell and Ford (2012) collected data from studies conducted in Northern Europe and Southeast Asia. This meta-analysis found that IBS occurs more commonly in women than men and age was not a factor in diagnosis (Lovell & Ford, 2012). These results are different than results found by Pan, Chang, Su, and Tsai (2016), who found that the incidence of IBS significantly increased with age.

Anbardan et al. (2012) conducted a study examining gender in a sample of 144 patients with IBS in Tehran, Iran. These researchers found that 69.4% of the patients with IBS were female and 30.6% of the patients were male. These results align with the results from the meta-analysis conducted by Lovell and Ford (2012) and the study conducted by Pan, Chang, Su, and Tsai (2016) which found that IBS is more common in women than men. IBS-D was more common in men (38.6%), while IBS-C was more common in women (38%). Kosako, Akiho, Miwa, Kanazawa, and Fukudo (2018) conducted an internet survey of 30,000 Japanese IBS-C patients and abdominal discomfort, abdominal distention, and abdominal fullness were significantly more common in female subjects than male subjects. Abdominal distention and abdominal pain were also significantly more common in IBS-C patients aged 20-49 years than those aged 50-79 years (Kosako, Akiho, Miwa, Kanazawa, & Fukudo, 2018). Between 1995-2005, IBS was diagnosed in approximately 141,295 patients worldwide (Ladabaum et al., 2011). Of these 141,295

patients 74% were female and the mean age at time of diagnosis was 46 years. Internists made 68% of diagnoses, gastroenterologists made 13% of diagnoses, and others made 19% of diagnoses (Ladabaum et al., 2011).

Diagnosis of Irritable Bowel Syndrome

A variety of methods can be used to diagnose IBS including reviewing the patient's symptoms, reviewing the patient's medical history, evaluating the patient for warning signs of more severe conditions, performing a physical examination, and using the Rome IV Criteria (Lacy & Patel, 2017). The presence of additional functional GI disorders and extraintestinal disorders such as, fibromyalgia, migraines, gastroesophageal reflux disease (GERD), dyspepsia, and interstitial cystitis, may increase the likelihood of a positive IBS diagnosis (Lacy, 2016). Warning signs for more severe conditions include anemia, hematochezia, unintentional weight loss, and family history of colorectal cancer or inflammatory bowel diseases. The Rome IV Criteria were developed by an international panel of experts in the field of functional GI disorders. The Rome IV Criteria define IBS as a functional bowel disorder with chronic abdominal pain that is associated with a change in bowel habits. Diarrhea, constipation, or a mix of diarrhea and constipation are disordered bowel habits. The Rome IV Criteria are chronic abdominal pain at least 1 day per week over the last 3 months, associated with two or more of the following criteria: related to defecation, associated with a change in stool frequency, or associated with a change in appearance or form of stool (Endo, Shoji, & Fukudo, 2015; Simren, Palsson, & Whitehead, 2017). These criteria must be met over the previous 3 months and symptom onset must have occurred at least 6 months prior to diagnosis (Simren, Palsson, & Whitehead, 2017). The Rome III were previously used to diagnose

IBS and they are characterized by abdominal pain which improves with defecation and whose onset is associated with a change in frequency or form of stool and is not attributed to structural or biochemical abnormalities (Sandhu & Paul, 2014).

Irritable Bowel Syndrome-Constipation (IBS-C)

IBS can be divided into three different types based on the predominant change in bowel habits: IBS-constipation (IBS-C), IBS-diarrhea (IBS-D), and IBS-mixed (IBS-M) (Mearin et al., 2016). IBS-C can be compared to chronic constipation because both are functional bowel disorders. In IBS-C constipation, abdominal bloating, and abdominal distention are the predominant symptoms. IBS-C and chronic constipation are characterized by visceral hypersensitivity and abnormalities in gut motility (Nellesen, Yee, Chawla, Lewis, & Carson, 2013). IBS-C is characterized by abdominal discomfort or pain with disturbed defecation, while chronic constipation is simply characterized by sporadic and infrequent bowel movements, hard stools, straining, and feeling of incomplete bowel evacuation. Functional or chronic constipation (with or without IBS) can be classified according to the pathophysiological mechanism associated with the constipation including, functional defecatory disorders, slow colonic transit time, and normal colonic transit time. Approximately 5.2%-66% of IBS patients are considered to have IBS-C (Nellesen, et al., 2013). DiBonaventura, Sun, Bolge, Wagner, and Mody (2011) used data from the 2007 National Health and Wellness Survey to assess the effects of IBS-C on health-related quality of life on patients lives. IBS-C was associated with reduced health-related quality of life, increased work productivity loss, increased activity impairment, and greater use of healthcare resources. Patients with IBS-C also reported

significantly more doctors' appointments and emergency room visits when compared to patients without IBS-C (DiBonaventura, Sun, Bolge, Wagner, & Mody, 2011).

Irritable Bowel Syndrome-Diarrhea (IBS-D)

IBS-D is characterized by abdominal pain, loose or watery stools, abdominal bloating, and abdominal cramping (Buono, Carson, & Flores, 2017). Patients with IBS-D may also experience abdominal pain associated with frequent loose stools, a feeling of urgency not relieved by defecation, and mucus in the stool (Lacy, 2016). IBS-D symptoms can be infrequent and mild, moderate and occasionally bothersome, or severe enough to reduce the ability to have normal daily functioning (Lacy, 2016).

Approximately 0.8%-33.98% of IBS patients are considered to have IBS-D (Nellesen, Yee, Chawla, Lewis, & Carson, 2013). The pathophysiology of IBS-D is not exactly known, but dietary factors, accelerated transit through the gastrointestinal tract, visceral hypersensitivity, and abnormalities in the gut microbiota may contribute to the development of IBS-D (Lacy, 2016). Buono, Carson, and Flores (2017) examined the impact of IBS-D on health-related quality of life, work productivity, and daily activities, and found that IBS-D patients reported lower health-related quality of life compared to patients with asthma, gastroesophageal reflux disease (GERD), or migraines. These patients also reported more bodily pain, impaired social functioning, and worse mental health compared to patients with other chronic diseases (Buono, Carson, & Flores 2017). Singh et al. (2015), conducted a study examining the effect of IBS subtype on IBS-specific quality of life using the Irritable Bowel Syndrome-Quality of Life (IBS-QOL) questionnaire. Of the 243 IBS patients included in the study 22.2% had IBS-C, 23.1% had IBS-D, and 49.8% had IBS-M. Patients with IBS-D and IBS-M scored lower on IBS-

QOL and have increased food avoidance, effect on daily activities, and social relationship problems (Singh et al., 2015).

Irritable Bowel Syndrome-Mixed (IBS-M)

IBS-M is characterized by varying GI symptoms including both diarrhea and constipation (Su, Shih, Presson, & Chang, 2013). The most common symptoms associated with IBS-M include irregular bowel habits, bloating, and abdominal pain. Nausea has also been found to be significantly more common in patients with IBS-M than patients with IBS-D or IBS-C. Irregular bowel habits can be defined as less than 3 bowel movements per week or greater than 3 bowel movements per day (Su, Shih, Presson, & Chang, 2013).

Quality of Life with Irritable Bowel Syndrome

Many studies have found that IBS negatively impacts the quality of life of patient who experience symptoms (Buono, Carson, & Flores, 2017; DiBonaventura, Sun, Bolge, Wagner, & Mody, 2011; El-Salhy, 2012; and Singh et al., 2015). Symptom severity, anxiety, and depression have been associated with the overall IBS-QOL life score (Cho et al., 2011). Fear of GI symptoms has also been found to impact health-related quality of life in IBS patients (Lackner, Gudleski, Ma, Dewanwala, & Naliboff, 2014). Patients with worse bowel symptoms that occur more frequently have been found to have a lower health-related quality of life when compared to patients with mild, less frequent symptoms (Cho et al., 2011). Singh et al. (2015), found that patients with IBS-D and IBS-M have significantly lower IBS-QOL scores than patients with IBS-C. IBS-D and IBS-M patients reported greater interference with daily activities and had increased food

avoidance when compared to patients with IBS-C which impacted the overall IBS-QOL score (Singh et al., 2015). IBS can significantly reduce quality of life with the same degree of impairment as major chronic diseases, like diabetes, congestive heart failure, kidney disease, and hepatic cirrhosis (El-Salhy, 2012).

Economic Impact of Irritable Bowel Syndrome

Due to the high prevalence of IBS in the United States and an increased demand of health care related to the condition, approximately \$8 billion are spent on the medical costs of IBS patients per year (Qureshi et al., 2016). It is also estimated that an additional \$25 billion are wasted by IBS patients who have undergone unnecessary procedures such as: appendectomies, hysterectomies, cholecystectomies, and other surgical procedures due to the difficulty associated with diagnosing IBS (Qureshi et al., 2016). According to Ladabaum et al. (2011), endoscopic and radiologic testing were most commonly used by gastroenterologists prior to being diagnosed with IBS. Canavan and Card (2014) found that 15%-43% of patients diagnosed with IBS pay out of pocket for treatments (such as medications) for their symptoms. Approximately 48% of patients with IBS incur some costs each year related to their IBS. International annual cost estimates per patient: \$742-\$7,547 per year in the U.S.; \$116-\$409 per year in the UK; \$670-\$1,020 per year in France; \$259 per year in Canada; \$936 per year in Germany; \$310 per year in Norway; and \$92 per year in Iran (Canavan & Card, 2014). Doshi et al. (2014), conducted a retrospective analysis of health care costs associated with IBS in the United States and found that the mean health care costs for IBS patients was estimated to be \$11,182 annually. Over half of these costs were attributed to physician office visits and other outpatient services. The remainder of the costs were attributed to hospitalizations

(21.8%), prescriptions (19.1%), and ER visits (5.4%). Specific GI-related health care costs averaged \$4,456 per year (approximately 39.8% of all-cause health care costs) (Doshi et al., 2014). Corsetti & Whorwell (2017) facilitated a report with a pharmaceutical company that states the major cause for the economic burden placed by IBS on health care services and society is the less than ideal management of the condition.

A majority (90%) of consultations related to IBS are with a general practitioner and patients often repeatedly consult their general practitioner for management of IBS before being referred to a specialist (Corsetti & Whorwell, 2017). These primary care visits are estimated to account for 30% of total direct healthcare costs for IBS patients, while 25-30% of costs are attributed to inpatient healthcare. In the UK and US, patients diagnosed with IBS take an average of 8.5-21.6 days off work each year (Corsetti & Whorwell, 2017). According to a survey conducted by the American Gastroenterological Association, patients with IBS reported that their GI symptoms interfered with work productivity an average of 9 workdays per month and that they had to miss an average of 2 days of work per month due to IBS symptoms (Buono, Carson, & Flores, 2017). Productivity loss due to IBS amounts to an annual loss of \$748 per patient in Canada, \$335 per patient in the U.S., \$335 per patient in the UK, and \$812 per patient in Iran (Corsetti & Whorwell, 2017). Despite the significant impact on quality life caused by IBS, it has been reported that only 60% of employers recognize IBS as a valid reason for absence from work (Corsetti & Whorwell, 2017). According to the Irritable Bowel Syndrome with Constipation (IBIS-C) study conducted in the UK, France, Germany, Italy, Spain, and Sweden, 70% of the 104 IBS patients included in the study consulted a

general practitioner, 100% consulted a gastroenterologist, and 24% of patients required an emergency department visit or inpatient hospital stay (Yiannakou et al., 2015).

Additionally, 52% of patients required some type of diagnostic test, 90% took prescription drugs for IBS-C, 51% took sick leave due to their IBS symptoms, and 82% of patients incurred productivity losses (Yiannakou et al., 2015).

Triggers for Irritable Bowel Syndrome Symptoms

Irritable bowel syndrome symptoms can vary among patients and the factors that trigger symptoms also vary widely (Qin, Cheng, Tang, & Bian, 2014; Saha, 2014; Volta et al., 2016). Triggers for IBS symptoms may include food triggers, lifestyle triggers, or internal causes. Some patients may experience symptoms caused by only specific triggers or combinations of a variety of different triggers (Qin, Cheng, Tang, & Bian, 2014; Saha, 2014; Volta et al., 2016).

Food Triggers

Approximately 60% of IBS patients relate the occurrence of their symptoms with the consumption of certain foods and many of these patients report worsening of symptoms within 15 minutes to a few hours after eating a meal (Volta et al., 2016).

Monsbakken, Vandik, and Farup (2006) evaluated perceived food intolerances in IBS patients and found that 62% of participants limited or excluded certain foods from their diet and 12% were considered to have a nutritionally inadequate diet. El-Salhy et al. (2012), reported that the average diet of an IBS patient was low in calcium, magnesium, phosphorus, riboflavin, and vitamin A. Food related symptoms in IBS patients are typically referred to as food intolerances rather than food allergies because there is no

evidence of an allergic reaction mediated by immunoglobulin E in response to foods in IBS.

Non-celiac gluten sensitivity (NCGS) is defined as having gastrointestinal and extra-intestinal symptoms, without celiac disease or a wheat allergy, but symptoms are improved by following a gluten-free diet (Volta et al., 2016). NCGS is characterized by symptoms such as: diarrhea, abdominal pain, bloating, gas, headache, fatigue, attention-deficit/hyperactivity disorder, skin issues, or recurrent oral ulceration (Makharia, Catassi, & Makharia, 2015). Disorders related to gluten sensitivity or intolerance are recognized as commonly mimicking the symptoms of IBS (Makharia, Catassi, & Makharia, 2015). Physicians may perform celiac-specific serological tests in patients with suspected gluten sensitivity and if these tests are negative patients may be instructed to participate in a trial of a gluten/wheat free diet. If symptoms improve while the patient is on the gluten/wheat free diet a diagnosis of NCGS may be supported (Makharia, Catassi, & Makharia, 2015). In a double-blind randomized placebo-controlled study evaluating the effects of following a gluten free diet on symptoms in IBS patients, statistically significant differences, were found in overall symptoms among the gluten-containing group and placebo group (Shahbazkhani et al., 2015). Based on these results, the researchers concluded that many IBS patients may be sensitive to gluten (Shahbazkhani et al., 2015). A controlled-trial of a gluten-free diet in patients with IBS-D which found that participants consuming the gluten-containing diet had more bowel movements per day than the group following the gluten free diet (Vazquez-Roque et al., 2013). Despite having fewer bowel movements per day while following the gluten free diet, the

participants in the gluten free diet group did not experience a significant difference in stool form (Vazquez-Roque et al., 2013).

Fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAP) are another category of foods that have been associated with the onset of IBS symptoms (Barret & Gibson, 2012). FODMAPs are defined as short-chain carbohydrates that are not completely absorbed in the GI tract (de Roest et al., 2013). These carbohydrates are also highly fermentable, so this increases the osmotic load in the intestines. Increased delivery of water to the colon and increased gas production in the colon causes luminal distention. This luminal distention leads to symptoms such as altered GI motility, bloating, abdominal pain/discomfort, and gas (de Roest et al., 2013). Many fruits, vegetables, and grains typically deemed healthy foods that should be included in the diet are FODMAPs. Examples of FODMAPs are lactose, fructose, sorbitol, mannitol, fructo-oligosaccharides, and galacto-oligosaccharides (Varney et al., 2017). Foods are classified as high FODMAP containing, moderate FODMAP containing, and low FODMAP containing. High FODMAP foods can potentially lead to the worst IBS symptoms, while low FODMAP foods are often considered to be less likely to cause symptoms. Despite these generalizations, food triggers vary widely for IBS patients (Barrett & Gibson, 2012). Oligosaccharides are found in foods such as: wheat and rye products, nuts, legumes, onion, garlic, and artichokes. There is no an enzyme in the human body capable of completely breaking down fructans and galacto-oligosaccharides, so they are malabsorbed. They are highly fermentable, so gas is produced causing bloating, abdominal pain, and excessive flatulence. Lactose is the disaccharide FODMAP and it is found in dairy products such as: milk, yogurt, and soft

cheeses. Fructose is the monosaccharide FODMAP and it is found in many foods including apples, pears, watermelon, mango, honey, sugar snap peas, and high fructose corn syrup. Fructose is highly osmotic and draws water into the lumen. This luminal distension can cause abdominal pain, bloating, diarrhea, and altered GI motility (Barrett, 2017). Foods that contain polyols that might contribute to IBS symptoms include mushrooms, apples, pears, stone fruits, cauliflower, snow peas, and sugar-free chewing gum or mints. Polyols are slowly absorbed in the small intestine and can produce an osmotic effect similar to fructose (Barrett & Gibson, 2012).

Lifestyle Triggers

Psychological and emotional stress are important factors in the development of IBS and can exacerbate the severity of symptoms (Qin, Cheng, Tang, & Bian, 2014). IBS is often described as a functional illness that is influenced by social, psychological, and physiological factors (Lackner et al., 2010). Psychological stresses have a significant impact on intestinal sensitivity, secretion, motility, and permeability. Approximately 94% of patients with IBS also have some type of psychiatric disorder or mental health issue such as depression or generalized anxiety disorder (Gulewitsch et al., 2013). Panic disorder is present in 25-44% of IBS patients, generalized anxiety disorder is present in 32%, post-traumatic stress disorder is present in 36% of IBS patient, and major depressive disorder is present in 47% of IBS patients (Fadgyas-Stanculete, Buga, Popa-Wagner, & Dumitrascu, 2014). Stress can induce alterations in the neuro-endocrine-immune system pathway which act on the gut-brain axis and microbiota-gut-brain axis. These alterations can lead to exacerbation of IBS symptoms or symptom flare-ups (Qin, Cheng, Tang, & Bian, 2014). Additionally, the secretion of corticotropin-releasing factor

(CRF) can be stress-induced which may lead to disruptions in GI function. Immune system activation and low-grade inflammation also appear to be important in the development of IBS symptoms (O'Malley, Quigley, Dinan, & Cryan, 2011).

Stress and depression are related to IBS along with functional dyspepsia, and peptic ulcer disease (Lee et al., 2015). The incidence of IBS increased as stress levels increased (Lee et al., 2015). Mykletun et al. (2010), examined the prevalence of mood and anxiety disorders in IBS patients. The researchers found that 27.5% of patients with IBS also were currently suffering from a mood or anxiety disorder. Additionally, 50.5% of patients with lifetime IBS also reported having a lifetime psychiatric condition (Mykletun et al., 2010). Kabra and Nadkarni (2013) found similar results when evaluating the prevalence of depression and anxiety in IBS patients. Kabra and Nadkarni (2013) found that 37.1% of participants had an anxiety disorder and 31.4% of participants suffered from depression. They also found that IBS is significantly associated with low socio-economic status, lower education levels, and being single, divorced, or widowed (Kabra & Nadkarni, 2013). Gastrointestinal (GI) specific anxiety, which is anxiety related to GI symptoms and disorders, has been theorized to influence the quality of life and severity of symptoms in IBS patients (Gulewitsch et al., 2013; Jerndal et al., 2010). Jerndal et al. (2010), report that IBS patients have more severe GI specific anxiety when compared with healthy people. Severe GI specific anxiety is also associated with more severe GI symptoms, more severe generalized anxiety, lower socioeconomic status, and more severe depression (Jerndal et al., 2010; Kabra & Nadkarni, 2013).

Potential Internal Causes for IBS Symptoms

Potential underlying causes of IBS may include minor inflammatory bowel disease, serotonin dysregulation, small intestine bacterial overgrowth, and central dysregulation (Saha, 2014). Approximately 10% of IBS patients believe their IBS symptoms began after experiencing an infectious illness. Exposure to gastrointestinal infections can cause low-grade mucosal and systemic inflammation, which causes mucosal infiltration of immune cells, increased production of several cytokines, and an altered population of cells circulating through the bloodstream (Belmonte et al., 2012). Psychological stress has also been reported to be a factor that potentially induces immune activation (Ishihara et al., 2013). Serotonin dysregulation has been theorized to play a role in the onset of IBS (Saha, 2014). The 5-HT₃ and 5-HT₄ serotonin receptors play a significant role in controlling GI motility, sensation, and secretion (Spiller, 2001). Houghton et al. (2003), found that plasma 5-HT concentrations are elevated in IBS patients with diarrhea and reduced in IBS patients with constipation, especially in patients whose symptoms occur postprandially. Small intestinal bacterial overgrowth (SIBO) is seems to prevalent in IBS patients, but it remains unclear whether SIBO causes IBS (Spiegel, 2011). SIBO causes symptoms that mirror IBS symptoms such as: diarrhea, gas, bloating, constipation, nausea, abdominal pain, and fatigue. Moraru et al. (2014), found that 31.7% of IBS patients were diagnosed with SIBO. In this study SIBO was present in 45.7% of patients with IBS-D (Moraru et al., 2014). The central nervous system modulates gut secretions, motility, and blood flow, so central dysregulation may influence the onset of IBS symptoms (Mayer, Naliboff, & Craig, 2006).

Potential Treatments for Irritable Bowel Syndrome

Due to the variety of triggers and causes for IBS symptoms there are also a wide variety of potential treatments that may be used to manage IBS (Halmos, Power, Sheperd, Gibson, & Muir, 2013; Hussain & Quigley, 2006; Kong et al., 2005; Khanna, MacDonald, & Levesque, 2014; Trinkley & Nahata, 2014). Potential treatments may include medications, peppermint oil, dietary changes, specific dietary patterns, probiotics, and other alternative treatments. Many patients go through a trial and error process to determine the treatment regimen that works the best to control their symptoms and effective treatment regimens often vary between patients (Halmos, Power, Sheperd, Gibson, & Muir, 2013; Hussain & Quigley, 2006; Kong et al., 2005; Khanna, MacDonald, & Levesque, 2014; Trinkley & Nahata, 2014).

Medications

Currently there are no specific medications that are used as a first-line treatment for all patients with IBS (Trinkley & Nahata, 2014). Typically, when medications are prescribed for patients with IBS, the medication is chosen based on its efficacy for treating the patient's specific symptoms. For example, a patient suffering from chronic diarrhea or IBS-D will require a different medication than a patient suffering from chronic constipation or IBS-C (Trinkley & Nahata, 2014). According to Trinkley and Nahata (2014) there is evidence that supports the improvement of certain IBS symptoms with many different medications including: loperamide, psyllium husk, lubiprostone, linaclotide, amitriptyline, trimipramine, desipramine, citalopram, fluoxetine, paroxetine, dicyclomine, rifaximin, ketotifen, pregabalin, gabapentin, and octreotide. These medications fall into several categories and have many different mechanisms of action.

Citalopram, fluoxetine, and paroxetine are classified as selective serotonin reuptake inhibitors (SSRIs) and are typically used to treat anxiety and depression (Trinkley & Nahata, 2014). Amitriptyline, desipramine, and trimipramine are tricyclic antidepressants that have been shown to improve IBS symptoms in some patients. Antispasmodics such as dicyclomine and hyoscyamine have also been used in the treatment of IBS (Trinkley & Nahata, 2014). Antispasmodics cause decreased GI motility and ease GI muscle spasms, which can improve abdominal pain and cramping in IBS patients (Roblin et al., 2009). Loperamide is the only antidiarrheal that has been found to be effective in patients with IBS-D. Loperamide works by inhibiting peristalsis, reducing stool frequency, and improving stool consistency (Roblin et al., 2009). LinzessTM is a medication that has been approved by the FDA for use in patients with IBS-C (Rao et al, 2012). LinzessTM works by increasing the release of intestinal fluid, accelerating intestinal transit time, and reducing pain in the intestines, but LinzessTM also may cause diarrhea (Chey et al., 2012).

Peppermint Oil

Peppermint oil naturally causes relaxation of the smooth muscles located throughout the gastrointestinal system, so it has been researched regarding its potential role in the treatment of IBS (Khanna, MacDonald, & Levesque, 2014). Peppermint oil also has several other mechanisms of action including visceral sensitivity modulation, anti-inflammatory activity, anti-microbial effects, and improvement of psychosocial stress (Chumpitazi, Kearns, & Shulman, 2018). Based on the meta-analysis performed by Khanna, MacDonald, and Levesque (2014) peppermint oil was found to cause a significant improvement in IBS symptoms including abdominal pain. Peppermint oil has

also been found to be beneficial in the treatment of functional dyspepsia, functional abdominal pain, and post-operative nausea (Chumpitazi, Kearns, & Shulman, 2018).

Despite the potential positive effects of peppermint oil on IBS symptoms, heart burn has been identified as a potential negative side effect (Khanna, MacDonald, & Levesque, 2014).

Diets and Eating Patterns

Many diets that have been theorized and tested in the management of IBS symptoms, but one of the most popular is the low FODMAP diet (Halmos, Power, Sheperd, Gibson, & Muir, 2013). The low FODMAP diet is an elimination diet that limits consumption of fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs). Many of the foods that fall into these categories can trigger GI symptoms including gas, diarrhea, abdominal bloating, abdominal discomfort, and excessive flatulence (Gibson, 2017). The term “FODMAP” was developed by researchers at Monash University in Melbourne, Australia in 2004 (Gibson, 2017). The low FODMAP diet focuses on the elimination or limitation of many foods that are considered to contain high amounts of FODMAPs (Mitchell, Porter, Gibson, Barrett, & Garg, 2018). When this diet is initiated there is typically an elimination period that lasts approximately 3-8 weeks, then there is a reintroduction phase (Gibson, 2017). The reintroduction phase involves reintroducing certain foods one at a time for three days each. It is important that the reintroduction phase is conducted correctly so patients can identify specific foods that cause GI symptoms for themselves specifically (Gibson, 2017). Examples of foods that are limited on this diet include onions, garlic, apples, wheat products, milk, yogurt, soft cheeses, watermelon, cauliflower, green bell pepper, chickpeas, and soybeans. Examples

of foods that are suitable for this diet include carrots, celery, red bell pepper, sweet potato, blueberries, grapes, strawberries, hard cheeses, gluten-free products, lactose-free milk, and white potatoes (Mitchell, Porter, Gibson, Barrett, & Garg, 2018).

Eswaran, Chey, Han-Markley, Ball, and Jackson (2016) compared the effects of a low FODMAP diet versus a diet modified from the National Institute for Health and Care Excellence (mNICE) in patients with IBS-D. The diet modified from the mNICE guidelines included eating smaller meals more frequently, limiting caffeine and alcohol, and avoiding foods that are known to cause symptoms (Eswaran, Chey, Han-Markley, Ball, and Jackson, 2016). Approximately 52% of the participants in the low FODMAP diet group reported significant relief of their IBS-D symptoms, while 41% of the participants in the mNICE group reported significant relief of their IBS-D symptoms. The participants in the low FODMAP group also reported greater reductions in their average daily scores for abdominal pain, bloating, stool consistency, stool frequency, and urgency of bowel movements (Eswaran, Chey, Han-Markley, Ball, & Jackson, 2016). Staudacher, Whelan, Irving, and Lomer (2011) investigated the effects of a low FODMAP diet versus standard dietary guidelines for patients with IBS. The NICE guidelines were also used in this study and were the standard dietary guidelines for patients with IBS at this time. Approximately 76% of the patients in the low FODMAP group reported satisfaction with their symptom relief, while 54% of the patients in the standard group reported satisfaction with their symptom relief (Staudacher, Whelan, Irving, & Lomer, 2011). The patients in the low FODMAP group also reported significant improvements in abdominal pain (low FODMAP 85% versus standard 61%), bloating (low FODMAP 82% versus standard 49%), and flatulence (low FODMAP 87% versus standard 50%).

Despite the favorable results seen in many studies evaluating the efficacy of a low FODMAP diet there are concerns about the restrictiveness of the diet (Hill, Muir, & Gibson, 2017). There is concern that the low FODMAP diet may lead to a risk of inadequate intake of important nutrients and disordered eating patterns. There is also concern that long-term strict restriction of high FODMAP foods may induce a potentially unfavorable gut microbiota (a decrease in beneficial bacteria) due to the prebiotic actions found in fructans and galacto-oligosaccharides. (Hill, Muir, & Gibson, 2017). O’Keefe et al. (2017), evaluated the long-term effects of the low FODMAP diet on GI symptoms, food intake, patient acceptability of the diet, and healthcare utilization in IBS patients. Approximately 12% of participants reported satisfactory relief of symptoms at baseline, 61% at the short-term follow up appointment, and 57% at the long-term follow up appointment. At the long-term follow up appointment 82% of the participants continued to follow a low FODMAP diet that was adapted to their individual trigger foods. The low FODMAP group reported that the diet costed appreciably more than their typical diet and affected social eating habits (O’Keefe et al., 2017).

Alternative Treatments

Recent studies have found that 50% of IBS patients utilize complementary and alternative medicine (CAM) as treatment for their IBS symptoms (Hussain & Quigley, 2006; Kong et al., 2005). Herbal therapies, probiotics, turmeric, artichoke leaf extract, hypnotherapy, cognitive-behavioral therapy, relaxation techniques, acupuncture, and exercise have all been studied for their potential positive effects on IBS symptoms (Chey, Maneerattaporn, & Saad, 2011; Yoon, Grundmann, Koepp, & Farnell, 2011). Mind-body therapies, acupuncture, cognitive-behavioral therapy, probiotics, dietary changes, and

exercise are the most common CAM therapies that are sought out by IBS patients (Yoon, Grundman, Koepf, & Farnell, 2011). Mind-body therapies may potentially have a positive impact on the quality of life for IBS patients because many IBS patients have fears and anxiety related to their GI symptoms (Lackner, Gudleski, Ma, Dewanwala, & Naliboff, 2014). Many types of psychotherapy have been studied in IBS patients including cognitive-behavioral therapy, gut-directed hypnotherapy, psychodynamic psychotherapy, and mindfulness (Kinsinger, 2017). Cognitive-behavioral therapy has been the focus and has been tested in at least 20 published randomized controlled trials which conclude that cognitive-behavioral therapy is an effective way to improve IBS symptoms (Laird et al., 2016).

Probiotics are beneficial bacteria that are found naturally in the body, which have been studied in the treatment of IBS symptoms in patients (Roblin et al., 2009). Probiotics are defined as live, micro-organisms that can cause a health effect on the host when consumed in adequate amounts (Butel, 2014). Lactobacillus, Bifidobacterium, enterococcus, streptococcus, and leuconostoc are the most common strains of probiotics that are available commercially (Peyton & Greene, 2014). There are five criteria that must be met in order for a probiotic to be considered effective: 1) it must not be toxic or pathogenic; 2) it must produce a beneficial effect on the host; 3) it must contain a large number of viable micro-organisms per pill; 4) it must be able to survive the intestine, reproduce, maintain itself, and have intraluminal metabolic activity; and 5) it must stay viable while being stored and used (Dai, Zheng, Jiang, Ma, & Jiang, 2013). Probiotics have various actions and may improve IBS symptoms by decreasing bacterial overgrowth in the small intestine and improving the imbalance between the pro-inflammatory

cytokines and the anti-inflammatory cytokines (Peyton & Greene, 2014). Probiotics may also inhibit pathogen binding in the intestinal cells, enhance mucosal barrier function, effect colonic transit and motility, have an anti-inflammatory effect, reduce intestinal permeability and bacterial translocation, and function in metabolic reactions (Dai, Zheng, Jiang, Ma, & Jiang, 2013). The Treatment section of the IBS Clinical Practice Guidelines concluded that probiotics have the potential to improve multiple IBS symptoms and generally have been found to be effective in treating IBS patients (Whelan & Quigley, 2013).

A systemic review of randomized controlled trials investigating the use of exercise therapy in IBS patients which found that quality of life, anxiety, GI symptoms, and IBS-related comorbidities showed more significant symptom improvements with exercise therapy when compared to typical lifestyle maintenance (Zhou, Zhao, Li, Jia, & Li, 2018). Very few studies showed that exercise is as effective as medications or a low FODMAP diet for the treatment of IBS symptoms (Zhou, Zhao, Li, Jia, & Li, 2018). El-Sahey, Lillebo, Reinemo, Salmelid, and Hausken (2010), conducted a study evaluating the effects of a health program including patient education, diet management, probiotics, and exercise on the symptoms and quality of life of IBS patients and found that symptoms scores and quality of life scores were significantly improved at the completion of the program. Zhao, Ni, Zhang, and Tian (2019) conducted a similar study evaluating the effects of cognitive behavioral therapy combined with exercise on IBS-D patients. They found that a combination of cognitive behavioral therapy and exercise can have a positive impact on IBS patients (Zhao, Ni, Zhang, & Tian, 2019). These researchers concluded that to significantly improve symptoms and quality of life in IBS patients a

combination of treatments/therapies may need to be used (El-Sahey, Liilebo, Reinemo, Salemlid, & Hausken, 2010; Zhao, Ni, Zhang, & Tian, 2019).

CHAPTER 3

METHODS

The purpose of this study was to compare the quality of life scores for each specific type of IBS (IBS-D, IBS-C, and IBS-M). This study used an online survey design that included the validated Irritable Bowel Syndrome Quality of Life Questionnaire (IBS-QOL) (Rome Foundation, 2012). The IBS-QOL questionnaire was developed by the Rome Foundation who also developed the Rome IV IBS diagnostic criteria. The Rome Foundation works to develop and legitimize the diagnosis and treatment of disorders of gut brain interactions (DGBIs). The IBS-QOL questionnaire has been validated in several countries and is used to assess the impact of IBS and its treatment on quality of life. This survey is available in English as well as many other languages including French, Spanish, Italian, German, etc. The IBS-QOL questionnaire assesses quality of life in IBS patients using a total scale score and eight subscales including: body image, dysphoria, interference with activities, healthy worry, food avoidance, social reactions, sexual health, and effect on relationships. The author's scoring formulas that were used for calculations are included in Appendix B. The questionnaire was included in an online survey developed on Qualtrics™ software and was distributed through a link provided on various social media outlets including Facebook, IBS Support Groups on Facebook, and Instagram. The groups chosen included men and women, a variety of age groups, and a variety of racial groups. FODMAP diet

trained dietitians were also contacted and asked to share the survey with their patients. Demographic data including gender, age, household income, education level, health insurance status, country of residence, and race was also collected.

Institutional Review Board (IRB) approval was obtained from the Louisiana Tech University Human Use Committee.

Sample

Eligible participants for this study included persons who have been diagnosed by a physician to have IBS, are 18 years of age or older, and reside in the United States. Potential participants were excluded if they could not read and speak English (the survey was only provided in English), completed less than 50% of the survey, have not been diagnosed with IBS by a physician or if they have been diagnosed with additional gastrointestinal diseases (with similar symptoms) such as Crohn's Disease, Celiac Disease, or Ulcerative Colitis. The target sample size was 250 participants. Subjects were recruited via personal accounts on social media and the survey was posted in several large public IBS Support Groups that are present on Facebook. Approximately 130 FODMAP diet trained dietitians were also contacted and asked to share the survey with their patients.

Data Collection Instruments

Data collection was conducted via an online questionnaire using the Qualtrics software. The Irritable Bowel Syndrome Quality of Life Questionnaire (IBS-QOL) was included. A licensure agreement was provided by the Rome Foundation who developed the IBS-QOL Questionnaire, which was signed, and permission was given to use the IBS-

QOL Questionnaire for this study. The IBS-QOL questionnaire includes a total of 34 items which assess quality of life of IBS patients and includes eight subscales: body image or dysphoria, interference with activities, health worry, food avoidance, social reactions, sexual health, and effect on relationships. Eight items assess dysphoria, 7 items assess interference with activities, 4 items assess body image, 3 items assess food avoidance, 4 items assess social reactions, 2 items assess sexual health, 3 items assess effects on relationships, and 3 items assess health worry. The scores for the subscales could range from 0-100, while the total quality of life scores could be over 100.

Demographic information included gender, age, household income, education level, health insurance status, country of residence, how much spent monthly on IBS, and race. The link to the questionnaire was posted on the researcher's personal Facebook page, Instagram account, the Phi Mu National Connection Facebook group, and was shared to public IBS support groups on Facebook. Many of the participants were recruited from the public IBS support groups on Facebook. FODMAP diet trained dietitians were also contacted and asked to share the survey with their patients.

Data Collection Process

Institutional Review Board (IRB) approval was obtained from the Louisiana Tech University Human Use Committee. An introduction social media post describing the study (Appendix C) and a link that directs participants to the survey on the Qualtrics website was shared on social media outlets including the researcher's personal Facebook page, Instagram account, the Phi Mu National Connection Facebook group, and to the public IBS Support (Official) group on Facebook which currently has 72,300 members. FODMAP diet trained dietitians were also contacted and asked to share the survey with

their patients. Participants were able to provide consent for participation in the study by voluntarily completing the survey. The survey was open for approximately 9 weeks. Over the course of the 9 weeks several follow up posts were made on the researcher's personal Facebook page and the IBS Support Groups on Facebook to recruit more participants. After the survey was closed a technical error was found. It appeared that respondents were able to select multiple responses to the 34 statements included in the IBS Quality of Life Survey question matrix, which affected the ability to calculate quality of life scores and subscale scores for those responses. In the cases where multiple responses were selected the ones within 1 point of each other were averaged and those more than 1 point apart were designated as a missing value. As an incentive, all participants were provided the option to enter a drawing to win a \$25.00 Amazon gift card by providing their email or phone number on a separate survey that was not linked to their responses.

Data Analysis

The Scientific Package for Social Sciences (SPSS) BASE for Students was used for statistical analysis (SPSS Statistics for Windows, Version 26.0., 2017). Descriptive statistics for participants included age, race, and gender and were reported as frequencies and were correlated with the quality of life scale and subscales. Hypotheses one and three were tested using analysis of variance (ANOVA) test, hypothesis two was tested using a t-test. A p -value of 0.05 ($x \pm SD$; $p < .05$) was used to define statistical significance.

Surveys that were less than 50% complete were removed from the study data.

CHAPTER 4

RESULTS

Of the 293 responses to the survey, 192 responses were used for analysis. A total of 39 responses were excluded for not meeting study criteria. An additional 54 responses were excluded because the respondents have been diagnosed with another gastrointestinal disorder; and 14 responses were excluded because they had not been diagnosed with IBS by a physician. A total of 107 responses were excluded. There were 87 participants who were diagnosed with IBS-D, 36 with IBS-C, 63 with IBS-M, and six were not sure which type of IBS they have been diagnosed with.

Respondent Demographics

The majority of respondents were white, non-Hispanic (87.5%); female (92.2%); between the ages of 18-35 (78.1%); and had completed a college degree (75.6%) (Table 4-1). Of the total population, approximately 51.1% of respondents were between the ages of 18-25, 27.9% of respondents were between the ages of 26-35, 8.9% of respondents were between the ages of 36-45, 4.7% of respondents were between the ages of 46-55, and 7.4% were 56 or older. Since there were so few males that responded to the survey the data was also analyzed using females only (Table 4-2)

Table 4-1

Demographics of Study Participants (N=192)

Type of IBS	IBS-M <i>n</i> = 63 (%)	IBS-C <i>n</i> =36 (%)	IBS-D <i>n</i> =87 (%)	Total <i>n</i> =192 (%)
<u>Gender</u>				
Male	6 (9.5%)	3 (8.3%)	5 (5.7%)	14 (7.3%)
Female	57 (90.5%)	33 (91.7%)	81 (93.1%)	177 (92.2%)
Prefer Not to Answer	0 (0%)	0 (0%)	1 (1.1%)	1 (0.5%)
<u>Race</u>				
White, Non-Hispanic	54 (85.7%)	32 (88.9%)	76 (87.4%)	168 (90.3%)
White, Hispanic Origin	32 (3.2%)	4 (11.1%)	11 (12.6%)	17 (9.1%)
Other	7 (11.1%)	0 (0%)	0 (0%)	7 (3.8%)
<u>Age</u>				
18-25	27 (43.5%)	23 (63.9%)	43 (50%)	97 (51.1%)
26-35	21 (33.9%)	4 (11.1%)	27 (31.4%)	53 (27.9%)
36-45	7 (11.3%)	4 (11.1%)	5 (5.8%)	17 (8.9%)
46-55	0 (0%)	3 (8.3%)	6 (7%)	9 (4.7%)
56+	7 (11.3%)	2 (5.6%)	5 (5.8%)	14 (7.4%)
<u>Education</u>				
Some High School, no Diploma	0 (0%)	1 (2.9%)	0 (0%)	1 (0.06%)
High School Graduate or GED	5 (8.2%)	1 (2.9%)	5 (6.3%)	12 (6.7%)
Trade/Technical/Vocational Training	2 (3.3%)	0 (0%)	3 (3.8%)	5 (2.8%)
Some College Credit, no Degree	13 (21.3%)	3 (8.8%)	10 (12.7%)	27 (15.2%)
Associate Degree	4 (6.6%)	4 (11.8%)	5 (6.3%)	13 (7.3%)
Bachelor's Degrees	23 (37.7%)	14 (41.2%)	36 (45.6%)	76 (42.7%)
Master's Degree	11 (18.0%)	11 (32.4%)	15 (18.9%)	38 (21.3%)
Professional Degree (MD, DDS, PharmD, PhD, DCN)	3 (4.9%)	0 (0%)	5 (6.3%)	6 (3.4%)

Note. Some of the total numbers do not add up to 192 due to missing responses to survey questions.

Table 4-2

Demographics of Study Participants, Females Only (N=178)

Variable	IBS-M n= 81 (%)	IBS-C n=33 (%)	IBS-D n=57 (%)	Total n=178 (%)
<u>Race</u>				
White, Non-Hispanic	70 (86.4%)	30 (90.9%)	48 (84.2%)	155 (87.6%)
White, Hispanic Origin	11 (13.6%)	3 (9.1%)	2 (3.5%)	16 (9.1%)
Other	0 (0%)	0 (0%)	7 (12.3%)	7 (3.3%)
<u>Age</u>				
18-25	39 (48.1%)	22 (66.7%)	26 (46.4%)	87 (51.2%)
26-35	26 (32.9%)	3 (9.1%)	19 (33.9%)	48 (28.2%)
36-45	5 (6.2%)	4 (12.1%)	7 (12.5%)	16 (9.4%)
46-55	6 (7.4%)	3 (9.1%)	0 (0%)	9 (5.3%)
56+	5 (6.2%)	1 (3%)	4 (7.1%)	10 (5.9%)
<u>Education</u>				
Some High School, no Diploma	0 (0%)	1 (3.2%)	0 (0%)	1 (0.06%)
High School Graduate or GED	5 (6.8%)	0 (0%)	5 (9.1%)	10 (6.3%)
Trade/Technical/Vocational Training	2 (2.7%)	0 (0%)	2 (3.6%)	4 (2.5%)
Some College Credit, no Degree	8 (11%)	3 (9.7%)	11 (20%)	22 (13.8%)
Associate Degree	4 (5.5%)	3 (9.7%)	4 (7.3%)	11 (6.9%)
Bachelor's Degrees	35 (47.9%)	13 (41.9%)	20 (36.4%)	68 (42.5%)
Master's Degree	15 (20.5%)	11 (35.5%)	11 (20%)	37 (23.1%)
Professional Degree (MD, DDS, PharmD, PhD, DCN)	5 (6.8%)	0 (0%)	2 (3.6%)	7 (4.4%)

Note. Some of the total numbers do not add up to 178 due to missing responses to survey questions.

Total Quality of Life Scores

Valid t-tests could not be run as too few males responded to the survey. Data comparing the total quality of life scores among races, types of IBS, education levels, and monthly spending on IBS were analyzed using an ANOVA (Tables 4-3 & 4-4). There were no significant differences found between total quality of life scores between patients

with genders, races, types of IBS, and education levels (Table 4-3). A significant difference was found between the different groups based on how much money participants spend monthly on treatments for/managing their IBS symptoms ($F(4, 149)=10.81, p=0.000$) (Table 4-3). As spending increased, the total IBS-QOL score decreased. Data examining the effectiveness of Registered Dietitians in IBS patients was analyzed using a t-test. There were no significant differences found between patients who had seen a Registered Dietitian compared to patients who had not seen a Registered Dietitian and those who found a Registered Dietitian to be beneficial versus those who did not (Table 4-5).

Table 4-3

ANOVA Comparing Irritable Bowel Syndrome Quality of Life Scores between , Races, Types of IBS, Education Levels, and Monthly Spending Groups (N=164)

Variable	Number of Participants	Total IBS QOL Score Mean \pm SD	F	p-value
<u>Race</u>			1.28*	0.28
	White, Non-Hispanic	146	56.21 \pm 21.89	
	White, Hispanic Origin	14	47.40 \pm 21.74	
	Other	4	47.98 \pm 10.85	
<u>Type of IBS</u>			0.76*	0.52
	IBS-M	68	53.41 \pm 23.67	
	IBS-C	32	58.72 \pm 20.12	
	IBS-D	58	54.63 \pm 20.38	
<u>Education</u>			1.84*	0.08
	Some High School, no Diploma	1	75.00	
	High School Graduate or GED	11	37.37 \pm 29.93	
	Trade/Technical/Vocational Training	4	45.49 \pm 26.03	
	Some College Credit, no Degree	23	55.23 \pm 20.42	
	Associate Degree	12	61.27 \pm 23.79	
	Bachelor's Degrees	65	56.87 \pm 20.32	
	Master's Degree	31	60.92 \pm 16.64	
	Professional Degree (MD, DDS, PharmD, PhD, DCN)	7	54.83 \pm 27.43	
<u>Amount Spent Monthly on IBS</u>			10.81*	<0.0
	\$0-20	77	65.78 \pm 18.50*	
	\$21-50	44	50.51 \pm 20.91*	
	\$51-75	17	43.29 \pm 16.39*	
	\$76-100	9	43.09 \pm 20.45*	
	Over \$100	7	34.35 \pm 21.94*	

Note. Some of the total numbers do not add up to 164 due to missing responses to survey questions. One Participant selected "Prefer not to answer" for gender. Six participants answered "Not Sure" when asked what type of IBS. Seventeen participants did not answer the question regarding education level. Thirty-eight participants did not answer the question regarding amount spent monthly on IBS. *p < 0.05

Table 4-4

ANOVA Comparing Irritable Bowel Syndrome Quality of Life Scores between Races, Types of IBS, Education Levels, and Monthly Spending Groups; Females Only (N=153)

Variable	Number of Participants	Total IBS QOL Score Mean \pm SD	F	p-value
<u>Race</u>			1.15*	0.32
White, Non-Hispanic	135	55.92 \pm 22.27		
White, Hispanic Origin	14	47.40 \pm 21.74		
Other	4	47.98 \pm 21.77		
<u>Type of IBS</u>			1.05*	0.37
IBS-M	63	52.29 \pm 23.87		
IBS-C	31	59.33 \pm 20.15		
IBS-D	53	54.48 \pm 20.86		
<u>Education</u>			1.88*	0.077
Some High School, no Diploma	1	75.00		
High School Graduate or GED	11	37.37 \pm 29.93		
Trade/Technical/Vocational Training	3	43.87 \pm 31.63		
Some College Credit, no Degree	20	53.69 \pm 20.35		
Associate Degree	10	61.39 \pm 24.38		
Bachelor's Degrees	62	57.14 \pm 220.69		
Master's Degree	31	60.92 \pm 16.64		
Professional Degree (MD, DDS, PharmD, PhD, DCN)	6	50.37 \pm 27.12		
<u>Amount Spent Monthly on IBS</u>			10.69*	<0.01
\$0-20	75	65.49 \pm 18.65*		
\$21-50	40	48.70 \pm 20.29*		
\$51-75	15	42.67 \pm 17.39*		
\$76-100	7	42.65 \pm 23.41*		
Over \$100	7	34.35 \pm 21.94*		

Note. Some of the total numbers do not add up to 153 due to missing responses to survey questions.

Table 4-5

T-Test Examining the Effect of Registered Dietitian on Quality of Life Scores in Patients with IBS (N=156)

Variable	Number of Participants	Total IBS QOL Score Mean \pm SD	F	p-value
<u>Seen a Registered Dietitian</u>			0.49*	0.48
Have Seen	31	51.03 \pm 20.53		
Have Not Seen	125	56.19 \pm 22.35		
<u>Effectiveness of Registered Dietitian</u>			0.21	0.65
Beneficial	18	57.31 \pm 19.60		
Not Beneficial	10	43.24 \pm 20.13		

Note. Effectiveness of Registered Dietitian is a small population since only 31 respondents had seen a Registered Dietitian.

Quality of Life Subscale Scores

There were too few males to run statistics to analyze the differences in quality of life subscale scores between males and females.

The IBS quality of life subscale scores between patients with IBS-M, IBS-C, and IBS-D were analyzed using an ANOVA (Tables 4-6 & 4-7). Patients with IBS-M, IBS-C, and IBS-D were found to have a significant difference between their subscale scores for the interference with activities subscale ($F(3, 178) = 5.83, p = 0.001$). Significant differences between IBS-M, IBS-C, and IBS-D patients were also found in the body image ($F(3, 185) = 3.61, p = 0.014$) and healthy worry ($F(3, 183) = 4.83, p = 0.003$) subscales (Table 4-6). The results shown in (Table 4-6 & 4-7) reflect a negative impact of

IBS on quality of life to varying degrees in each of the subscales for IBS-M, IBS-C, and IBS-D.

The IBS quality of life subscale scores among races were analyzed using ANOVA (Tables 4-8 & 4-9). Significant differences between three subscale scores were found among white, non-Hispanic; whites, Hispanic origin; and others (native Americans, Asian/Pacific Islanders, Multi-racial, and Asian Indians). The three subscales were dysphoria ($F(2, 181)=3.86, p=0.02$), social reaction ($F(2, 182)=3.23, p=0.04$), and relationships ($F(2, 184)=3.58, p=0.030$) (Table 4-8).

Table 4-6

ANOVA Comparing Irritable Bowel Syndrome Quality of Life Subscale Scores between IBS-M, IBS-C, and IBS-D of the Total Population (N=181)

IBS QOL Subscale Score	Total n= 181 Mean \pm SD	IBS-M n=63 Mean \pm SD	IBS-C n=31 Mean \pm SD	IBS-D n=87 Mean \pm SD	F	p-value
Dysphoria	56.71 \pm 27.12	55.06 \pm 27.75	61.07 \pm 24.90	55.01 \pm 30.61	1.05*	0.37
Interference with Activities	52.19 \pm 25.65	50.69 \pm 52.74	65.77 \pm 22.39	45.11 \pm 24.12*	5.83*	0.00
Body Image	56.98 \pm 24.77	55.63 \pm 25.86	47.74 \pm 25.54	64.11 \pm 21.21*	3.61*	0.01
Health Worry	55.10 \pm 23.05	53.01 \pm 24.91	45.83 \pm 22.07	62.70 \pm 18.88*	4.83*	0.03
Food Avoidance	34.48 \pm 28.00	34.51 \pm 31.03	40.60 \pm 24.93	30.75 \pm 25.36	0.95*	0.41
Social Reaction	54.32 \pm 26.05	53.04 \pm 27.03	59.82 \pm 24.49	52.17 \pm 26.05	0.89*	0.44
Sexual	65.26 \pm 30.80	64.16 \pm 31.89	60.59 \pm 33.70	69.15 \pm 28.19	0.66*	0.58
Relationships	68.18 \pm 25.12	68.60 \pm 25.43	69.56 \pm 26.76	65.71 \pm 24.44	0.62*	0.60

Note. Six participants answered "Not Sure" when asked what type of IBS diagnosis.

*Significant at $p < 0.05$

Table 4-7

ANOVA Comparing Irritable Bowel Syndrome Quality of Life Subscale Scores between IBS-M, IBS-C, and IBS-D of Females Only (N=152)

IBS QOL Subscale Score	Total n= 152 Mean \pm SD	IBS-M n=63 Mean \pm SD	IBS-C n=36 Mean \pm SD	IBS-D n=53 Mean \pm SD	F	p-value
Dysphoria	56.85 \pm 27.66	54.52 \pm 28.19	62.78 \pm 24.46	54.98 \pm 28.15	1.30*	0.27
Interference with Activities	52.31 \pm 25.94	49.49 \pm 25.71	68.25 \pm 21.63	45.57 \pm 24.57*	6.67*	0.00
Body Image	56.11 \pm 24.84	54.38 \pm 25.61	48.48 \pm 26.56	62.89 \pm 21.60*	2.64*	0.05
Health Worry	54.70 \pm 22.79	52.54 \pm 24.29	46.21 \pm 22.95	61.98 \pm 18.72*	4.02*	0.01
Food Avoidance	34.24 \pm 28.29	33.54 \pm 31.04	40.28 \pm 25.47	31.36 \pm 26.14	0.74*	0.53
Social Reaction	54.00 \pm 26.15	52.10 \pm 27.18	61.91 \pm 24.24	51.17 \pm 25.84	1.538	0.21
Sexual	65.43 \pm 30.89	63.80 \pm 31.52	62.31 \pm 34.53	69.19 \pm 28.64	0.47	0.70
Relationships	68.75 \pm 25.04	69.12 \pm 24.84	61.97 \pm 26.34	65.15 \pm 25.16	0.91*	0.44

Note. Six participants answered "Not Sure" when asked what type of IBS diagnosis.

*Significant at $p < 0.05$

Table 4-8

ANOVA Comparing Irritable Bowel Syndrome Quality of Life Subscale Scores between Whites, Non-Hispanic, Whites, Hispanic, and Others of the Total Population (N=192)

IBS QOL Score	Total n= 192 Mean \pm SD	White, Non-Hispanic n=168 Mean \pm SD	White, Hispanic n=17 Mean \pm SD	Other n=7 Mean \pm SD	F	p-value
Dysphoria	56.71 \pm 27.12	58.74 \pm 26.32	44.24 \pm 30.67	38.39 \pm 26.19*	3.86*	0.02
Interference with Activities	52.19 \pm 25.65	53.45 \pm 25.60	43.81 \pm 24.83	39.29 \pm 25.56	1.77*	0.17
Body Image	56.98 \pm 24.77	57.27 \pm 24.57	47.79 \pm 24.99	56.98 \pm 24.77	2.82*	0.06
Health Worry	55.10 \pm 23.05	55.38 \pm 23.75	50.00 \pm 17.48	61.11 \pm 14.59	0.61*	0.54
Food Avoidance	34.48 \pm 28.00	35.66 \pm 27.73	27.45 \pm 31.7	23.81 \pm 23.78	1.19*	0.30
Social Reaction	54.32 \pm 26.05	56.13 \pm 25.72	41.91 \pm 24.88	40.63 \pm 28.98*	3.23*	0.04
Sexual Relationships	65.26 \pm 30.80	65.59 \pm 30.96	58.82 \pm 31.80	73.21 \pm 25.44	0.61*	0.54
	68.18 \pm 25.12	69.94 \pm 24.79	57.60 \pm 26.20	50.00 \pm 19.00*	3.58*	0.03

Note. The other category included Native American, Asian/Pacific Islander, Multi-Racial, Asian Indian, and other.

*Significant at $p < .05$

Table 4-9

ANOVA Comparing Irritable Bowel Syndrome Quality of Life Subscale Scores between Whites, Non-Hispanic, Whites, Hispanic, and Others of Females Only (N=153)

IBS QOL Score	Total n= 153 Mean \pm SD	White, Non-Hispanic n=135 Mean \pm SD	White, Hispanic n=14 Mean \pm SD	Other n=4 Mean \pm SD	F	p-value
Dysphoria	56.85 \pm 27.66	59.09 \pm 26.87	44.24 \pm 30.67	38.39 \pm 26.19*	3.838	0.02
Interference with Activities	52.31 \pm 25.94	53.68 \pm 25.83	43.37 \pm 25.71	39.29 \pm 25.56	1.81*	0.17
Body Image	56.11 \pm 24.84	56.21 \pm 24.58	48.05 \pm 25.79	75.00 \pm 21.65	2.63*	0.08
Health Worry	54.70 \pm 22.79	54.80 \pm 23.53	51.11 \pm 17.50	61.11 \pm 14.59	0.42	0.66
Food Avoidance	34.24 \pm 28.29	35.64 \pm 28.02	25.52 \pm 31.7	23.81 \pm 23.78	1.43*	0.24
Social Reaction	53.99 \pm 26.15	55.93 \pm 25.73	41.02 \pm 25.41	40.63 \pm 28.98*	3.25*	0.04
Sexual Relationships	65.43 \pm 30.89	65.71 \pm 30.99	59.38 \pm 32.76	73.21 \pm 25.44	0.53	0.59
	68.75 \pm 25.04	70.72 \pm 24.53	57.29 \pm 27.02	50.00 \pm 19.00*	3.95*	0.02

Note. The other category included Native American, Asian/Pacific Islander, Multi-Racial, Asian Indian, and other.

*Significant at $p < .05$

CHAPTER 5

DISCUSSION

This study examined the potential differences in quality of life scores between patients with IBS-M, IBS-C, and IBS-D. Approximately half of respondents to this survey suffer from IBS-D, while the smallest number suffer from IBS-C. Other studies have found that the percentage of IBS sufferers who have each type varies widely, but it is estimated that approximately 1/3 of IBS participants suffer from IBS-M, 1/3 suffer from IBS-C, and 1/3 suffer from IBS-D (Corsetti & Whorwell, 2017; Nellesen, et al., 2013; Singh et al., 2015).

A large majority of the respondents to this survey were female. These findings align with many other studies which have found that more females suffer from IBS than males (Anbardan et al.; Kosako, Akiho, Miwa, Kanazawa, & Fukudo, 2018; Ladabaum et al., 2011; 2012 Lovell & Ford, 2012; Pan, Chang, Su, & Tsai, 2016). The higher occurrence of IBS diagnosis in females may be associated with stress levels and emotional distress. According to the American Psychological Association (2012) women report higher stress levels and are more likely than men to report physical and emotional symptoms of stress. Psychological and emotional stress are very important factors in the development of IBS and severity of symptoms (Jerndal et al., 2010; Lackner et al., 2010 ;

Lee et al., 2015; Mykletun et al., 2010; Qin, Cheng, Tang, & Bian, 2014). Gulewitsch et al. (2013), reports that approximately 94% of IBS patients suffer from a psychological condition such as generalized anxiety disorder or depression. Additional studies have also found that a significant number of IBS patients suffer from psychological disorders and emotional stress (Kabra & Nadkarni, 2013; Mykletun et al., 2010). Males had lower mean scores in the dysphoria, interference with activities, food avoidance, sexual, and relationships subscale categories. Females had lower mean scores in the body image, health worry, and social reaction categories.

Slightly over half of the participants in this study were between the ages of 18-25 years, while another quarter were between the ages of 26-35 years. These results differ from other studies that have found the mean age of IBS diagnosis to be 46 years and that the incidence of IBS diagnosis increases with age (Ladabaum et al., 2011; Pan, Chang, Su & Tsai, 2016). The increased number of responses in the 18-25 category may be related to the way the survey was shared. Because personal social media was used, the education levels and ages of the respondents may not be reflective of the general IBS population. The survey was also shared to multiple IBS Support groups on Facebook that include members of all ages, so these groups likely contributed many of the responses from participants over the age of 25 years. The education levels of the respondents also may be related to how the respondents were recruited. A large majority of the participants had received some type of college degree. Many of the friends on the researcher's personal Facebook page have received a college degree, while all of the members of the sorority's national connection page were either in college or had graduated from college.

This study found that IBS had a negative impact of the quality of life of respondents. While the quality of life subscale scores varied between groups it was evident that IBS negatively impacted all patients in each of the eight subscale categories. The total IBS quality of life scores and subscale scores had a range of 0-100. Overall, the IBS-C group had the highest total quality of life scores (113.86 ± 27.37), only having lower subscale scores than the IBS-M or IBS-D groups in three categories (body image, health worry, and sexual). Lower scores in the body image category from patients with IBS-C may be related to abdominal distension and bloating which are the predominant symptoms of IBS-C (Nellesen, Yee, Chawla, Lewis, & Carson, 2013). Abdominal distension and bloating can significantly impact the outward appearance of the abdomen which often negatively impacts body image. IBS-C also may cause abdominal pain, nausea, and severe constipation (Nellesen, Yee, Chawla, Lewis, & Carson, 2013). These symptoms may contribute to health worry in patients with IBS-C because they may feel concerned about the reasons their bowels move slower than normal. Constipation, gas, bloating, pain, feelings that the bowels are unable to empty completely, and rectal bleeding (which can be attributed to straining due to difficulty during bowel movements) are also signs of colon cancer, bowel obstructions, and rectal cancer (Mayo Clinic, 2021). These symptoms can be frightening to patients especially if they are severe and chronic in nature.

Registered dietitians can potentially have a significant impact on the quality of life for patients with IBS. Many IBS patients attribute some of their GI symptoms to the consumption of certain foods. Since registered dietitians are experts in food and nutrition, they can work with patients to identify foods that may be causing issues, or they can help

them follow the low FODMAP diet if their symptoms are severe enough. Dietitians can become certified in the low FODMAP diet, so these dietitians specifically could be very beneficial. The quality of life scores for food avoidance were the lowest for each type of IBS showing that food avoidance has a significant impact on quality of life in IBS patients.

The IBS-D group had the lowest scores in the interference with activities, food avoidance, social reaction, and relationships subscales, indicating a higher impact of IBS-D on these subscales. They had the highest scores in the body image, health worry, and sexual subscales, indicating a lesser impact of IBS-D on these subscales. Increased bowel frequency and diarrhea can affect the abilities of patients to participate in normal daily activities such as, work, travel, and exercise (Lacy, 2016). One can assume that impaired abilities to participate in daily activities can have negative impacts on relationships and social interactions. Patients with IBS often contribute their GI symptoms with diet and certain foods. Patients with IBS-D report a lower quality of life related to the burden of food avoidance (Singh et al., 2015). The increased food avoidance in patients with IBS-D may be related to patient or physician driven diet changes aimed at reducing frequency and severity of symptoms. The IBS-M group quality of life subscale scores fell between the scores of the IBS-C and IBS-D groups in all categories. This is likely because patients with IBS-M experience both constipation and diarrhea, so their perceived quality of life may vary based on the symptoms currently being experienced.

A large majority of the study respondents were white, non-Hispanic (87.5%) which may be attributed to where participants were recruited from to complete the survey. Those of Hispanic origin made up 8.9% of the remaining survey respondents

while Native Americans, Asian/Pacific Islanders, multi-racial, and Asian Indians were grouped into the “Other” category which accounted for the last 3.6% of respondents. Significant differences were found between Hispanics; White, Non-Hispanics; and the other group for the dysphoria, social reaction, and relationships subscales. White, Hispanic respondents had higher mean scores than the two other groups in all three of these subscales. The lower mean subscale scores for respondents of Hispanic origin in the social reaction and relationship categories are interesting because it has been reported that people of Hispanic origin often feel obligated to ask for encouragement and advice about health issues from many family members (Caballero, 2011). These feelings of obligation and loyalty to their family may cause stress or emotional distress because they may feel they must consult family members prior to making health-related decisions (Caballero, 2011).

Respondents in the “Other” category had the lowest mean scores in the dysphoria, interference with activities, food avoidance, social reaction, and relationship subscales. The white, non-Hispanic group had the highest scores in the dysphoria, interference with activities, body image, food avoidance, social reaction, and relationships subscales. Many studies have found significant racial disparities in health care between white, non-Hispanic people and people of color, so these healthcare disparities may contribute to the higher quality of life subscale scores in white, non-Hispanic people (Cook, McGuire, & Zaslavsky, 2012; Lau, Lin, & Flores, 2012; Williams & Wyatt, 2015; Derose, Gresenz, & Ringel, 2011).

Monthly spending related to IBS treatment and symptom management also seems to contribute to quality of life in patients. A majority of the participants in this study

reported spending \$0-50 per month related to their IBS treatments, medications, etc. According to the American Psychological Association (2015), money is the leading cause of stress for Americans. Stress is likely the reason why total quality of life scores were lower in this study for participants who reported spending \$51 to over \$100 per month on IBS related costs. The higher spending related to IBS may also be related to severity of symptoms because they may be spending more on medications or treatments to manage symptoms, which may also contribute to the lower quality of life scores in this group. The total quality of life scores were the highest in the group who reported spending \$0-20 per month, while they were significantly lower in the group who reported spending over \$100 per month. Emotional and psychological stress are strongly related to the severity and development of IBS symptoms, so it is understandable that as financial burden increases, stress levels may also increase, which may increase severity of IBS symptoms causing reduced quality of life (Jerndal et al., 2010; Lackner et al., 2010 ; Lee et al., 2015; Mykletun et al., 2010; Qin, Cheng, Tang, & Bian, 2014).

Education levels of patients with IBS may also contribute to reported quality of life. In this study most of the groups with higher education levels reported higher total quality of life scores when compared to the groups with lower education levels. One exception is the “Some High School, no diploma” category which reported the highest total quality of life score out of all the groups, but there was only one respondent in that category so overall this may not be indicative of the quality of life of people in this group. The higher quality of life scores in the groups with higher education levels may be related to having more money or access to resources and healthcare to help manage IBS symptoms. In 2019 the U.S. Bureau of Labor reported that people with a college degree

earn an average of 61% more money than people without a college degree. Often employers that require a college degree offer health insurance to their employees (Abel & Deitz, 2014). Lack of adequate health insurance can lead to significant levels of insecurity for people, so this may also affect quality of life in IBS patients with lower education levels.

There were a few limitations to the current study. All survey responses were self-reported, so it is possible that some respondents may have contributed inaccurate data. It is also possible that respondents accidentally skipped certain questions or selected an incorrect answer choice. The use of an electronic survey also may have been geared toward the younger or more tech savvy population. Secondly, the survey was initially shared primarily on the social media platform of Facebook. While the survey was shared to a large number of IBS patients through IBS Support groups present on Facebook it is possible that many of the group members have group notifications turned off or do not check the group often for new posts. Another limitation of the survey recruitment being on social media is that the older IBS population may not have been reached. Late in the process of survey sharing many FODMAP diet trained dietitians were contacted and asked to share the survey link with their clients. Many of these dietitians agreed and shared the link, so it likely would have been very beneficial to utilize this recruitment method initially. Additionally, the respondents were primarily white, non-Hispanic and between the ages of 18-25 which is not reflective of the general population of IBS patients. There were only 14 male respondents out of the 192 total responses used for data analysis, so this limited the statistical analysis of the differences in quality of life scores between males and females.

This study also had several strengths. This study included many demographic questions along with the IBS Quality of Life questionnaire (IBS-QOL) questions that are not included in many previous studies using the IBS-QOL questionnaire. This study compared the quality of life total scores and subscores between all three types of IBS, while many studies focus on IBS-D and IBS-M. This study also compared the quality of life subscale scores between the different races which to date has not been seen in the literature using this questionnaire.

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BANK NAME: WELLS FARGO BANK, N.A.

BANK ADDRESS:

For Domestic (US) wires:

420 MONTGOMERY
STREET, SAN FRANCISCO,
CA 94104

For International wires:

525 MARKET STREET, *SAN FRANCISCO, CA 94105*

BANK PHONE: 919-881-6435

INCOMING WIRE ROUTING/ABA: 121000248

BENEFICIARY: ROME FOUNDATION

BENEFICIARY ACCOUNT

NUMBER: 2000057776084

BENEFICIARY ADDRESS: 14460 Falls of Neuse Rd. Ste. 149-116 Raleigh, NC 27614.

SWIFT CODE: **WFBIUS6S** (REQUIRED FOR INTERNATIONAL WIRES)

4. Proprietary Rights.

4.1. Ownership. Licensee acknowledges and agrees that the Content is and shall remain the exclusive property of ROME. Licensee shall not reproduce, copy, sell, sublicense, lease, display, perform, modify, transfer or distribute the ROME Content and any derivative works thereof, other than as expressly permitted by this Agreement.

4.2. Copyright Notice. All Content (including any promotional materials in which the Content or ROME Marks appear) shall bear the following copyright notice (or other reasonable notices requested by ROME):

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4.3. Trademark Usage. Neither party shall use any of the other's marks, logos or other identifiers ("Marks") in any manner, without the trademark owner's prior written approval. The parties reserve the right to review any proposed use of their respective Marks and to require changes in such further use, and the other agrees to comply with any such requirements. Each party acknowledges and agrees that: (i) it shall not use the other's Marks in a manner likely to diminish the Marks' commercial value; (ii) it shall not knowingly permit any third party to use the other's Marks unless authorized to do so in writing; (iii) it shall not knowingly use or permit the use of any mark, name, or image likely to cause confusion with the other's Marks; (iv) all goodwill associated with use of the Marks shall inure to the party owning the Marks; (v) the Marks are and shall remain the sole property of their owner; (vi) nothing in this Agreement shall confer in either party any license rights or right of ownership in the other's Marks (and Licensee shall not make any representation to that effect), or use the other's Marks in a manner that suggests that such rights are conferred.

4.4. Breach or Threatened Breach. In the event of a breach or a threatened breach of any of the provisions of this Section, Licensee acknowledges that a breach or threatened breach shall result in irreparable harm to ROME, and ROME shall be entitled to seek a preliminary injunction restraining any such person or entity from such breach. Nothing contained herein shall be construed as prohibiting ROME from pursuing such other remedies as may be available to ROME for any such breach.

5. Confidential Information.

5.1. Definition. Each party acknowledges that it may be exposed to certain information that is not generally known to the public and that would be considered confidential and proprietary by the other party ("**Confidential Information**"). Confidential Information includes, without limitation, all competitively sensitive or secret business, marketing and technical information disclosed by one party to another, such as proposed products and services, affiliate and customer lists, strategic and tactical business planning materials, sales and technical training materials, information disclosed in customer conferences, meetings and seminars, materials obtained from the password protected portion of any party's web sites or other web sites utilized in connection with this Agreement, source code, development-level documentation and similar technical information and the contents of this Agreement. **In addition, the financial terms of this Agreement shall be considered Confidential Information.** Confidential Information does not include such portions of any disclosed information which: (i) are or become generally available to the public other than as a result of a disclosure by a party or any of its agents, representatives, affiliates, employees or consultants in violation of its or their obligations of confidentiality hereunder; or (ii) become available to a party on a non-confidential basis from a source which is not prohibited from disclosing such information to that party by a legal, contractual or fiduciary obligation to the other party.

5.2. Confidentiality Obligation. Each party agrees that, with respect to received Confidential Information, it (i) shall protect such Confidential Information from unauthorized disclosure using the highest commercially reasonable standard of care, (ii) shall not disclose such Confidential Information to any third party except the party's lawyers, accountants, underwriters and other professionals, and (iii) shall not use such Confidential Information (other than as specifically authorized by this Agreement) without the prior written consent of the other party. These mutual obligations with respect to Confidential Information shall continue for the

shorter of five (5) years following the date of termination of this Agreement, or until such information becomes publicly known other than by breach of this Agreement by any party. Within five (5) calendar days after a party's request, or upon termination of this Agreement, all materials or media containing any Confidential Information shall either be returned to the originating party or destroyed by the other party, at the originating party's sole discretion, and each party agrees to certify its compliance with such obligation upon the request of the other party.

5.3. Compelled Disclosure. In the event that a party or anyone to whom that party transmits Confidential Information pursuant to this Agreement becomes legally compelled to disclose any of the Confidential Information ("**Compelled Party**"), the Compelled Party will provide the other party ("**Furnishing Party**") with prompt notice thereof so that the Furnishing Party may seek a protective order or other appropriate remedy or waive compliance with the provisions of this Agreement. In the event that such protective order or other remedy is not obtained by the Furnishing Party or the Furnishing Party waives compliance with the provisions of this Agreement, the Compelled Party will furnish or cause to be furnished only that minimum portion of the Confidential Information which the Compelled Party is legally required to furnish and will exercise commercially reasonable efforts to obtain reliable assurances that confidential treatment is accorded the Confidential Information so furnished.

6. Representations and Warranties.

6.1. ROME warrants and represents that it has the right and authority to enter into this Agreement and to grant the rights in the Content set forth herein, subject to the limitations and exclusions set forth herein; and that the Content does not and shall not infringe upon the rights or interests of any third party.

6.2. Licensee represents and warrants that it has the power and authority to enter into this Agreement and to perform its obligations and, upon execution and delivery hereof, this Agreement shall constitute the valid and binding obligations of Licensee enforceable in accordance with its terms.

6.3. CONTENT IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. LICENSEE EXPRESSLY AGREES THAT ITS RECEIPT AND USE OF THE CONTENT IS AT LICENSEE'S SOLE RISK, AND THAT THE ENTIRE RISK AS TO SATISFACTORY QUALITY, PERFORMANCE, ACCURACY AND EFFORT IS WITH LICENSEE. LICENSOR HEREBY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT TO THE CONTENT. LICENSOR SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY, AND THOSE ARISING FROM A COURSE OF DEALING OR USAGE OF TRADE.

7. Indemnification.

7.1. By ROME. ROME shall defend, indemnify and hold harmless Licensee from and against any claims, actions or demands, alleging or resulting from the breach of any of ROME's obligations, covenants, representations or warranties under this Agreement.

7.2. By Licensee. Licensee shall defend, indemnify and hold harmless ROME, its officers, employees, shareholders, directors, managers, members and suppliers, and those of its affiliates including parent companies and subsidiaries, from and against (i) any damages or liability of any kind arising from any use of Content other than the uses expressly permitted by this Agreement, and (ii) any claims, actions or demands, alleging or resulting from the breach of any of Licensee's obligations,

covenants, representations, or warranties under this Agreement.

8. Limitation of Liability.

8.1. Limitation of Liability. Other than the indemnification obligation set forth herein, ROME shall have no liability or responsibility for claims or actions caused by or arising from use, access, or display of the Content not in accordance with this Agreement, that arise out of Licensee equipment malfunction or negligence, or that arise from the use, access or display of the Content in conjunction with products, platforms, or materials not provided by Licensee in accordance with this Agreement. **NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY, IN NO EVENT WILL ROME BE LIABLE FOR ANY INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES ASSOCIATED WITH LOSS OF PROFITS, LOSS OF BUSINESS OPPORTUNITIES OR LOSS OF GOODWILL) EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR FOR ANY MATTER BEYOND ITS REASONABLE CONTROL, IN EACH CASE REGARDLESS OF THE FORM OF THE CLAIM OR THE THEORY OF RECOVERY. TOTAL CUMULATIVE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO ANY SUBJECT MATTER OF THIS AGREEMENT, REGARDLESS OF THE FORM OF THE CLAIM OR THE THEORY OF RECOVERY, WILL IN NO EVENT EXCEED US\$10,000.**

9. PROVISIONS RELATING TO THE FDA REGULATION

Pursuant to the U.S. regulation called the federal food drug and cosmetics act as amended by the generic drug enforcement act of 1992 (GDEA), ROME represents, warrants and covenants to Licensee as follows:

- (i) to the best of its knowledge at the time of signing the Agreement neither it nor any individual employed or engaged by ROME have ever been and are not currently
 - (a) under investigation for debarment or debarred by any relevant health authority for debarment action (as detailed in the section 306 of the GDEA of 1992),
 - (b) excluded by any relevant agency for debarment action (as detailed in the section 306 of the GDEA of 1992),
 - (c) otherwise disqualified or restricted by the FDA or any other regulatory authority, nor will ROME knowingly utilize any debarred, excluded or disqualified personnel to perform services hereunder;
- (ii) it will notify Licensee immediately in writing in the event any investigation or proceeding for debarment, exclusion or disqualification is initiated against ROME or any employee or personnel during the term of the Agreement or within one (1) year following its expiration or termination;
- (iii) its employees or contractors are, and will continue to be, qualified and have, and will continue to have, sufficient technical expertise to perform ROME's obligations under this Agreement and will require such for other personnel; if ROME, or any of its employees or contractors involved in the services, or any other person or organization used by ROME in connection with the services should become debarred, disqualified or excluded during the term of this Agreement or within one (1) year following its expiration or termination, provider agrees to notify Licensee promptly in writing.

10. MISCELLANEOUS

10.1 Survival. Sections of this Agreement relating to Confidential Information, Indemnification, Limitation of Liability, and Representations and Warranties shall survive the expiration or termination of this Agreement.

10.2 Waiver. Any waiver by either party of its rights under this Agreement shall not constitute a waiver of any other rights hereunder.

10.3 Assignment. Licensee shall not assign this Agreement or any of its rights hereunder or delegate any of its obligations hereunder except with the prior written consent of ROME, except if such assignment is made to the benefice of one of its affiliates.

10.4 Excusable Delay. If, for any reason beyond its control, either party is unable to comply with its responsibilities under this Agreement, then performance by that party shall be excused until the reason for such inability ceases to exist. In such circumstances, each party shall use its best efforts to comply with the essential portions of this Agreement. In the event that such inability shall exist for a period of at least thirty (30) days, the parties shall meet to negotiate a resolution of any such existing performance problems. If the parties fail to negotiate a resolution within thirty (30) days, the Agreement may be terminated at the option of either party.

10.5 Jurisdiction. Any legal action or proceeding concerning the validity, interpretation and enforcement of this Agreement, matters arising out of or related to this Agreement or its making, performance or breach, or related matters shall be brought exclusively in the federal or state courts of the State of North Carolina having jurisdiction, and all parties consent to the exclusive jurisdiction of those courts, waiving any objection to the propriety or convenience of such venues. The United Nations Convention on Contracts for the International Sale of Goods does not apply to or otherwise affect this agreement. The validity, interpretation and enforcement of this Agreement, matters arising out of or related to its making, performance or breach, and related matters shall be governed by the internal laws of the State of North Carolina (without reference to choice of law doctrine). Licensee agrees that service of process in any actions, controversies, and disputes arising from or relating to this Agreement may be effected by mailing a copy thereof by registered or certified mail (or any substantially similar form of mail), postage prepaid, to the other party however, nothing herein shall affect the right to effect service of process in any other manner permitted by law. The invalidity or unenforceability of any part of this Agreement shall not affect the validity or enforceability of the balance hereof.

10.6 Illegal Provision. If any covenant or other provision of this Agreement is invalid, illegal, or incapable of being enforced by reason of any rule of law, administrative order, judicial decision or public policy, all other conditions and provisions of this Agreement shall, nevertheless, remain in full force and effect. The parties shall make changes to this Agreement as are necessary to cure the invalidity, consistent with the original objectives of the parties.

10.7 No Partnership or Joint Venture. Nothing in this Agreement or the relations between the parties to this Agreement shall be construed to constitute a partnership or joint venture between or among the parties to this Agreement. Licensee shall have no right or authority to bind or obligate ROME in any manner whatsoever and shall not expressly or impliedly incur any liability or obligation on behalf of ROME.

10.8. Notices. Any notice or demand required or permitted by this Agreement shall be in writing and shall be deemed given when received by the parties at the address set forth above.

10.9. Counterpart Execution. This Agreement may be executed by the parties on any number of separate counterparts, and all such counterparts so executed constitute one agreement binding on all the parties notwithstanding that all the parties are not signatories to the same counterpart.

10.10. Entire Agreement. This Agreement contains the entire agreement and understanding between the parties and may not be modified or amended except by

written agreement executed by both of the parties.

IN WITNESS WHEREOF, each of the parties has caused a duly authorized officer or agent to execute this Agreement as of the dates set forth below.

ROME FOUNDATION, INC.

Hailey Hutchison
Registered Dietitian
8/21/2020

Johannah Ruddy M. Ed.
Executive Director
August 21, 202

APPENDIX B

DATA COLLECTION INSTRUMENT

AND

DATA COLLECTION INSTRUMENT SCORING INSTRUCTIONS

Quality of Life in Persons with IBS

Start of Block: Default Question Block

Q1 The following is a brief summary of the project in which you are asked to participate. Please read this information before continuing on to the survey.

PURPOSE OF STUDY/PROJECT: The purpose of this study is to examine the differences in the effects of irritable bowel syndrome (IBS) on the quality of life in patients with each of the three types of IBS: IBS-Diarrhea (IBS-D), IBS-Constipation (IBS-C), and IBS-Mixed (IBS-M).

PROCEDURE: You have been directed to this survey by clicking on the link provided via a social media post. The survey will take approximately 10-15 minutes to complete.

RISKS/ALTERNATIVE TREATMENTS: This is a descriptive study therefore there are no risks to subjects in the study. As with all online survey tools, the server may collect information and your IP address indirectly and automatically via “cookies”.

BENEFITS/COMPENSATIONS: There are no direct benefits to participating in this survey. I attest by clicking “Yes I am over 18 years of age and agree to participate in the study” below that I have read and understood the following description of the study “Assessing and Comparing Quality of Life Scores in Patients with Irritable Bowel Syndrome-Diarrhea, Irritable Bowel Syndrome-Constipation, and Irritable Bowel Syndrome-Mixed” and its purposes and methods. I understand that my participation and refusal to participate in this study will not affect my relationship with Louisiana Tech University. Further, I understand that I may withdraw at any time and refuse to answer any questions without penalty. Upon completion of the study, I understand that the aggregated results will be freely available to me upon request. I understand that the results of the material will be confidential, accessible only to the principal investigators, myself or a legally appointed representative. I have not been requested to waive nor do I wave any of my rights related to participating in this study.

If you have any questions or concerns about completing the survey or being in this study you may contact Hailey Hutchison, Graduate Student, at hutchison95@yahoo.com or Dr. Vicky Green, faculty advisor, at vgreen@latech.edu.

Members of the Human Use Committee of Louisiana Tech University may also be contacted if a problem cannot be discussed with the experimenters: Dr. Richard Kordal,

Director, Office of Intellectual Property & Commercialization Ph: (318) 257-2484, Email: rkordal@latech.edu

- Yes I am over the age of 18 and agree to participate in this survey (1)
- I do not agree to participate in the survey (2)

Skip To: End of Survey If The following is a brief summary of the project in which you are asked to participate. Please rea... = I do not agree to participate in the survey

Q2 Have you been diagnosed with Irritable Bowel Syndrome (IBS) by a physician?

- Yes (1)
- No (2)

Skip To: End of Survey If Have you been diagnosed with Irritable Bowel Syndrome (IBS) by a physician? = No

Q3 Have you been diagnosed with any other Gastrointestinal Disorders such as: Celiac disease, Ulcerative Colitis, Crohn's Disease?

- Yes (1)
- No (2)

Skip To: End of Survey If Have you been diagnosed with any other Gastrointestinal Disorders such as: Celiac disease, Ulcera... = Yes

Q4 Do you suffer from IBS-Mixed, IBS-Constipation, or IBS-Diarrhea?

- IBS-Mixed (1)
 - IBS-Constipation (2)
 - IBS-Diarrhea (3)
 - Other (4)
 - Not sure (5)
-

Q5 How long have you been experiencing IBS symptoms?

▼ less than 1 year (1) ... over 25 years (26)

Q6 How long have you been diagnosed with Irritable Bowel Syndrome (IBS)?

▼ less than 1 year (1) ... over 25 years (26)

Q7 Do you have a family history of Irritable Bowel Syndrome (IBS)?

- Yes (1)
 - No (2)
 - Not sure (3)
-

Q8 What is your sex?

- Male (1)
 - Female (2)
 - Other (3)
 - Prefer not to answer (4)
-

Q9 What is your race?

- White, Non-Hispanic origin (1)
 - White, Hispanic origin (2)
 - Black or African American, Non-Hispanic (3)
 - Black or African American, Hispanic Origin (4)
 - Native American or Alaskan Native (5)
 - Asian/Pacific Islander (6)
 - Asian Indian (7)
 - Middle Eastern (8)
 - Multi-racial (9)
 - Other (10)
-

Q10 What is your age?

▼ 18 (1) ... 90 (73)

Q11 Do you reside in the United States?

Yes (1)

No (2)

Q12 IBS Quality of Life Survey.

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

	Not at all (1)	Slightly (2)	Moderately (3)	Quite a bit (4)	A great deal (5)
I feel helpless because of my bowel problems. (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am embarrassed of the smell caused by my bowel problems. (2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am bothered by how much time I spend on the toilet. (3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel vulnerable to other illnesses because of my bowel problems. (4)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel fat because of my bowel problems. (5)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I feel like I'm losing control of my life because of my bowel problems. (6)

I feel my life is less enjoyable because of my bowel problems. (7)

I feel uncomfortable when I talk about my bowel problems. (8)

I feel depressed about my bowel problems. (9)

I feel isolated from others because of my bowel problems. (10)

I have to watch the amount of food I eat because of my bowel problems. (11)

Because of my bowel problems, sexual activity is difficult for me. (12)

I feel angry to I have bowel problems. (13)

I feel like I irritate others because of my bowel problems. (14)

I worry that my bowel problems will get worse. (15)

I feel irritable because of my bowel problems. (16)

I worry that people think I exaggerate my bowel problems. (17)

I feel I get less done because of my bowel problems. (18)

I have to avoid stressful situations because of my bowel problems. (19)

My bowel problems reduce my sexual desire. (20)

My bowel problems limit what I can wear. (21)

I have to
avoid
strenuous
activity
because of
my bowel
problems.
(22)

I have to
watch the
kind of food I
eat because
of my bowel
problems.
(23)

Because of
my bowel
problems I
have difficulty
being around
people I do
not know well.
(24)

I feel sluggish
because of
my bowel
problems.
(25)

I feel unclean
because of
my bowel
problems.
(26)

Long trips are
difficult for me
because of
my bowel
problems.
(27)

I feel
frustrated that
I cannot eat
when I want
because of
my bowel

problems.
(28)

It is important
to be near a
toilet because
of my bowel
problems.

(29)

My life
revolves
around my
bowel
problems.

(30)

I worry about
losing control
of my bowels.

(31)

I fear I won't
be able to
have a bowel
movement.

(32)

My bowel
problems are
affecting my
closest
relationships.

(33)

I feel that no
one
understands
my bowel
problems.

(34)

 

Q13 Since being diagnosed with IBS have you sought medical intervention?

- Yes (1)
- No (2)

Skip To: Q15 If Since being diagnosed with IBS have you sought medical intervention? = No

Q14 Have medical interventions been helpful or improved your symptoms?

- Yes (1)
- No (2)
- Unsure (3)

Q15 Have you been able to identify triggers for your IBS symptoms? (ex. Specific foods, stress, anxiety, etc)

- Yes (1)
- No (2)
- Unsure (3)

Skip To: Q17 If Have you been able to identify triggers for your IBS symptoms? (ex. Specific foods, stress, anxie... = No

Q16 What triggers have you identified? Select all that apply.

- Foods (1)
- Stress (2)
- Anxiety (3)
- Other (4) _____
-

Q17 Since being diagnosed with IBS have you made any changes to your diet?

- Yes (1)
- No (2)

Skip To: Q19 If Since being diagnosed with IBS have you made any changes to your diet? = No

Q18 Have these diet changes improved your IBS symptoms?

- Yes (1)
- No (2)
- Unsure (3)
-

Q19 Have you seen a Registered Dietitian or Nutritionist since being diagnosed with IBS?

- Yes (1)
- No (2)
- Unsure (3)

Skip To: Q22 If Have you seen a Registered Dietitian or Nutritionist since being diagnosed with IBS? = No

Skip To: Q22 If Have you seen a Registered Dietitian or Nutritionist since being diagnosed with IBS? = Unsure

Q20 What specific diet or diets did the Registered Dietitian or Nutritionist educate you about?

- Low FODMAP diet (1)
- Gluten Free (2)
- Other (3) _____
-

Q21 Did you find your discussion with the Registered Dietitian or Nutritionist beneficial?

- Yes (1)
- No (2)
- Unsure (3)
-

Q22 Do you have health insurance?

- Yes (1)
- No (2)
-

Q23 How much do you spend out-of-pocket monthly on medications or other treatments for IBS?

- \$0-20 (1)
 - \$21-50 (2)
 - \$51-75 (3)
 - \$76-100 (4)
 - over \$100 (5)
-

Q24 What is your total annual household income?

- Less than \$10,000 (1)
 - \$10,000 to \$19,999 (2)
 - \$20,000 to \$29,999 (3)
 - \$30,000 to \$39,999 (4)
 - \$40,000 to \$49,999 (5)
 - \$50,000 to \$59,999 (6)
 - \$60,000 to \$69,999 (7)
 - \$70,000 to \$79,999 (8)
 - \$80,000 to \$89,999 (9)
 - \$90,000 to \$99,999 (10)
 - \$100,000 to \$149,999 (11)
 - \$150,000 or more (12)
-

Q25 What is the highest degree or level of education you have completed?

- Less than high school (1)
 - Some high school, no diploma (2)
 - High school graduate, diploma or the equivalent (for example: GED) (3)
 - Trade/technical/vocational training (4)
 - Some college credit, no degree (5)
 - Associate degree (6)
 - Bachelor's degree (7)
 - Master's degree (8)
 - Doctor of Medicine (11)
 - Doctor of Dental Science (12)
 - Doctor of Pharmacy (13)
 - Doctor of Clinical Nutrition (14)
 - Other Professional degree (9)
 - Doctoral degree (PhD) (10)
-

Q26 How much do you weigh? Enter in pounds or kilograms.

_____ lbs (12)

_____ kgs (19)



Q27 How tall are you? Enter both feet and inches.

_____ Feet (1)
_____ Inches (2)
_____ OR Meters (3)

Q28 Thank you for completing this survey.

Q29 Do you want to enter a drawing to win a \$25 Amazon gift card?

- Yes (1)
 No (3)

Skip To: Q30 If Do you want to enter a drawing to win a \$25 Amazon gift card? = Yes

Q30 Click the link below to enter the drawing.

https://latechnd.iad1.qualtrics.com/jfe/form/SV_2oC9AdFoYePOcwB

End of Block: Default Question Block

Transforming and Computing Overall Score and Subscores of IBS-QOL

Summarized by J.B. Hu

IBS-QOL is a new survey instrument first developed in 1997 to assess health related quality of life [QOL] of patients afflicted with irritable bowel syndrome [IBS]. The instrument was co-developed by Donald L. Patrick, PhD, Douglas A. Drossman, MD, and Ihunnaya O. Frederick, in the United States. This summary is based on the User's Manual for the U.S. version of IBS-QOL authored and published by the three in May 1997.

The original U.S. version of the IBS-QOL contains 34 question items relating to symptoms of IBS. Each item, when answered by the patient, describes the respondent's feelings to a particular symptom. The magnitude of the respondent's feelings to each item is determined by the patient's selection of one of the five Likert-style responses labeled 1 through 5, where 1=Not at all, 2=Slightly, 3=Moderately, 4=Quite a bit, and 5=Extremely.

In data analysis, the five responses are transformed in order to obtain a 100-point overall score and eight 100-point subscales. The table below lists names [beginning with TOT_] of the total overall score and 8 subscales, their component items, and acronyms [beginning with IBS_] of the final 9 computed 100-point scores:

	Subscale Names and Description [total]	Sequential order of component items in the IBS-QOL	100-point Names
1	TOT-OV for Overall [34]	All 34 items	IBS_OV
2	TOT-DY for Dysphoria [8]	IBS01 IBS06 IBS07 IBS09 IBS10 IBS13 IBS16 IBS30	IBS_DY
3	TOT-IN for Interference With Activity [7]	IBS03 IBS18 IBS19 IBS22 IBS27 IBS29 IBS31	IBS_IN
4	TOT-BI for Body Image [4]	IBS05 IBS21 IBS25 IBS26	IBS_BI
5	TOT-HW for Health Worry [3]	IBS04 IBS15 IBS32	IBS_HW
6	TOT-FA for Food Avoidance [3]	IBS11 IBS23 IBS28	IBS_FA
7	TOT-SR for Social Reaction [4]	IBS02 IBS14 IBS17 IBS34	IBS_SR
8	TOT-SX for Sexual [2]	IBS12 IBS20	IBS_SX
9	TOT-RL for Relationship [3]	IBS08 IBS24 IBS33	IBS_RL

Step 1 in the transformation is to reverse code the responses, making 5=Not at all, 4=Slightly, 3=Moderately, 2=Quite a bit, and 1=Extremely. Manual reverse coding is cumbersome, but most statistical analysis packages for personal computers are equipped with different ways and shortcuts to the reverse coding.

Step 2 of the transformation calculates a summary total of the overall score and eight subscales by totaling up the reverse coded values of the component items in each of the 9 groups. For example, TOT-DY is obtained by adding up all the reverse coded values of IBS01 IBS06 IBS07 IBS09 IBS10 IBS13 IBS16 IBS30.

Step 3 computes the final 100-point scores using the following formulas:

	Final 100-point Score Names	Computation Formula	Explanation
1	IBS_OV =	$((TOT_OV - 34) / (136)) * 100$	- denotes subtraction / indicates division * means multiplication Note: No final score should exceed 100. Higher scores may mean a higher quality of life and a less degree of IBS symptoms and their impact.
2	IBS_DY =	$((TOT_DY - 8) / (32)) * 100$	
3	IBS_IN =	$((TOT_IN - 7) / (28)) * 100$	
4	IBS_BI =	$((TOT_BI - 4) / (16)) * 100$	
5	IBS_HW =	$((TOT_HW - 3) / (12)) * 100$	
6	IBS_FA =	$((TOT_FA - 3) / (12)) * 100$	
7	IBS_SR =	$((TOT_SR - 4) / (16)) * 100$	
8	IBS_SX =	$((TOT_SX - 2) / (8)) * 100$	
9	IBS_RL =	$((TOT_RL - 3) / (12)) * 100$	

For more details of calculating the scores or to obtain a copy of the original IBS-QOL questionnaire, the User's Manual, or other supporting materials, please contact any person listed below:

Douglas A. Drossman, MD University of North Carolina – Chapel Hill CB 7080 BioInformatics Building Chapel Hill, North Carolina 27599-7080 USA Tel: (919) 966-0141 Fax: (919) 966-8929	or	Donald L. Patrick, PhD Department of Health Services, H689 Box 357660, University of Washington Seattle, Washington 98195-7660 USA Tel: (206) 616-7393 Fax: (206) 616-3135
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APPENDIX C

LOUISIANA TECH HUMAN USE
COMMITTEE APPROVAL FORM



OFFICE OF SPONSORED PROJECTS

MEMORANDUM

TO: Ms. Hailey Hutchison and Dr. Vicky Green

FROM: Dr. Richard Kordal, Director of Intellectual Property & Commercialization (OIPC)
rkordal@latech.edu

SUBJECT: HUMAN USE COMMITTEE REVIEW

DATE: November 20, 2020

In order to facilitate your project, an EXPEDITED REVIEW has been done for your proposed study entitled:

HUC 21-039

"Assessing and Comparing Quality of Life Scores in Patients with Irritable Bowel Syndrome-Diarrhea, Irritable Bowel Syndrome- Constipation and Irritable Bowel Syndrome-Mixed"

The proposed study's revised procedures were found to provide reasonable and adequate safeguards against possible risks involving human subjects. The information to be collected may be personal in nature or implication. Therefore, diligent care needs to be taken to protect the privacy of the participants and to assure that the data are kept confidential. Informed consent is a critical part of the research process. The subjects must be informed that their participation is voluntary. It is important that consent materials be presented in a language understandable to every participant. If you have participants in your study whose first language is not English, be sure that informed consent materials are adequately explained or translated. Since your reviewed project appears to do no damage to the participants, the Human Use Committee grants approval of the involvement of human subjects as outlined.

Projects should be renewed annually. *This approval was finalized on November 20, 2020 and this project will need to receive a continuation review by the IRB if the project continues beyond November 20, 2021.* ANY CHANGES to your protocol procedures, including minor changes, should be reported immediately to the IRB for approval before implementation. Projects involving NIH funds require annual education training to be documented. For more information regarding this, contact the Office of Sponsored Projects.

You are requested to maintain written records of your procedures, data collected, and subjects involved. These records will need to be available upon request during the conduct of the study and retained by the university for three years after the conclusion of the study. If changes occur in recruiting of subjects, informed consent process or in your research protocol, or if unanticipated problems should arise it is the Researchers responsibility to notify the Office of Sponsored Projects or IRB in writing. The project should be discontinued until modifications can be reviewed and approved.

A MEMBER OF THE UNIVERSITY OF LOUISIANA SYSTEM

P.O. BOX 3092 • RUSTON, LA 71272 • TEL: (318) 257-5075 • FAX: (318) 257-5079

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