

THE EFFECTS OF THE GLUTEN-FREE FAD DIET  
ON ADULTS WITH CELIAC DISEASE

A thesis submitted to the faculty of  
San Francisco State University

In partial fulfillment of  
the requirements for  
the Degree

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Master of Arts

In

Family and Consumer Sciences

by

Tiffany Laurel Torok

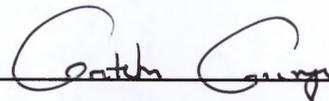
San Francisco, California

Spring, 2017

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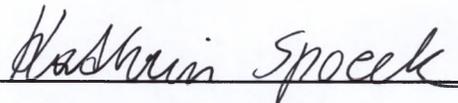
## CERTIFICATION OF APPROVAL

I certify that I have read *The Effects of the Gluten Free Fad Diet on Adults With Celiac Disease* by Tiffany Laurel Torok, and that in my opinion this work meets the criteria for approving a thesis submitted in partial fulfillment of the requirement for the degree Master of Arts in Family and Consumer Sciences at San Francisco State University.



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Gretchen George, PhD, RD  
Graduate Advisor, Assistant Professor



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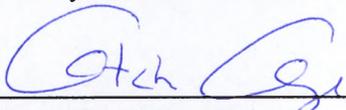
Kathrin Spoeck, MA, RD  
Lecturer

THE EFFECTS OF THE GLUTEN-FREE FAD DIET ON ADULTS WITH CELIAC  
DISEASE

Tiffany Laurel Torok  
San Francisco, California  
2017

The purpose of this study was to determine if the gluten-free fad diet has an effect on the quality of life of individuals with celiac disease. A survey was disseminated through the National Foundation for Celiac Awareness. A total of 841 qualified participants who were over 18 years of age with biopsy-confirmed celiac disease responded. The results of the study show that the gluten-free fad diet negatively affects the quality of life of this group. Nearly half (46%) of the participants felt that their condition was not taken seriously by the general public and 11% felt socially stigmatized as a result. Furthermore, 24% of the participants did not feel that restaurant personnel understand that cross-contamination can make them sick and 23% feel that there are more cross-contamination issues as a result of the gluten free fad diet.

I certify that the abstract is a correct representation of the content of this thesis.

  
\_\_\_\_\_  
Chair, Thesis Committee

5/24/17  
\_\_\_\_\_  
Date

## PREFACE AND/OR ACKNOWLEDGEMENTS

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## **Introduction**

### **Overview of Celiac Disease**

Celiac disease, an autoimmune disease triggered by the ingestion of gluten in genetically susceptible individuals, occurs in approximately 1% of the American population (Gujral, Freeman, & Thomson, 2012). Currently, the only treatment available to keep the disease in remission is strict adherence to a gluten-free diet, eliminating all sources of dietary gluten including cross-contamination over 50 mg/day, or less in more sensitive individuals (Fasano & Catassi, 2012). The gluten-free diet is difficult to maintain and adherence to the diet can cause numerous quality of life issues in this population, impacting individuals' social life, work, and travel (Hall, Rubin, & Charnock, 2009). Those with celiac disease are at a higher risk of developing osteoporosis, infertility issues, cancers of the blood, intestinal cancers, additional autoimmune diseases, anemia, and other related health conditions when adherence is poor (Rampertab, Pooran, Brar, Singh, & Green, 2006).

### **Statement of the problem**

The recent increase in the gluten-free food market is primarily fueled by fad dieters who feel that eating gluten-free will help with weight loss or to treat numerous conditions that research has not shown to be true (Gaesser & Angadi, 2012). According to the US based market research group Mintel, nearly half of Americans view the gluten-free diet as a fad while as many as one in four Americans avoid dietary gluten (Mintel, 2015). This dietary trend has led to backlash against the gluten-free diet, with the diet

being ridiculed across social media as well as mainstream media outlets such as Instagram, Vine, Facebook, and popular television shows such as South Park and the Tonight Show with Jimmy Fallon (Swerdloff, 2015). As Alice Bast, founder of National Foundation for Celiac Awareness (now Beyond Celiac) and well known celiac disease advocate, wrote in a recent article in the Huffington Post “Celebrities, various companies and, now, presidential candidates are making it increasingly difficult for people who need a gluten-free diet to be taken seriously” (Bast, 2016). Furthermore, personal narratives about the negative effects of the gluten-free fad diet on individuals with celiac disease is being addressed on mainstream media outlets such as The Boston Globe (Swidey, 2015).

### **Significance of the study**

Currently, there is little to no research exploring how the gluten-free fad diet affects the quality of life of individuals with biopsy confirmed celiac disease. This pilot study is the first of its kind to try to address this issue. Further research into this topic can help to determine if methods to help improve dietary compliance exist or to assist with the development of alternative treatment options. Therefore, it is important to understand how this new dietary trend is affecting the quality of life of individuals with celiac disease.

## **Literature Review**

### **Description of Celiac Disease**

Celiac disease is a genetic autoimmune disease that can develop at any point in life. The immune response in celiac disease is elicited by the ingestion of gluten,

particularly the gliadin component of gluten, found in grains such as wheat, rye, and barley. Once ingested, gluten causes inflammation that alters the integrity of the tight junction system of the intestinal lining in people with celiac disease (Green & Cellier, 2007). In a normally functioning small intestine, the intestinal lining is responsible for both absorption of nutrients via intestinal villi and serves as protection from antigens and bacteria or other pathogens (Ulluwishewa et al., 2011). When the intestines are damaged during the immune response in celiac disease, macromolecules such as gluten permeate into the submucosa of the gut. People with celiac disease have a certain class of genes known as HLA-DQ2 and/or HLA-DQ8. When the gluten molecule passes through the submucosa, it is acted on by transglutaminase 2, which converts glutamine residues into negatively charged glutamate residues, which then binds to the HLA antigen presenting cells of class II DQ2 or DQ8 (Figure 1). Then, specific CD4 T cells recognize those cells as invaders and begin an autoimmune attack, causing crypt hyperplasia and villous atrophy in patients with celiac disease (Tonutti & Bizzaro, 2014).

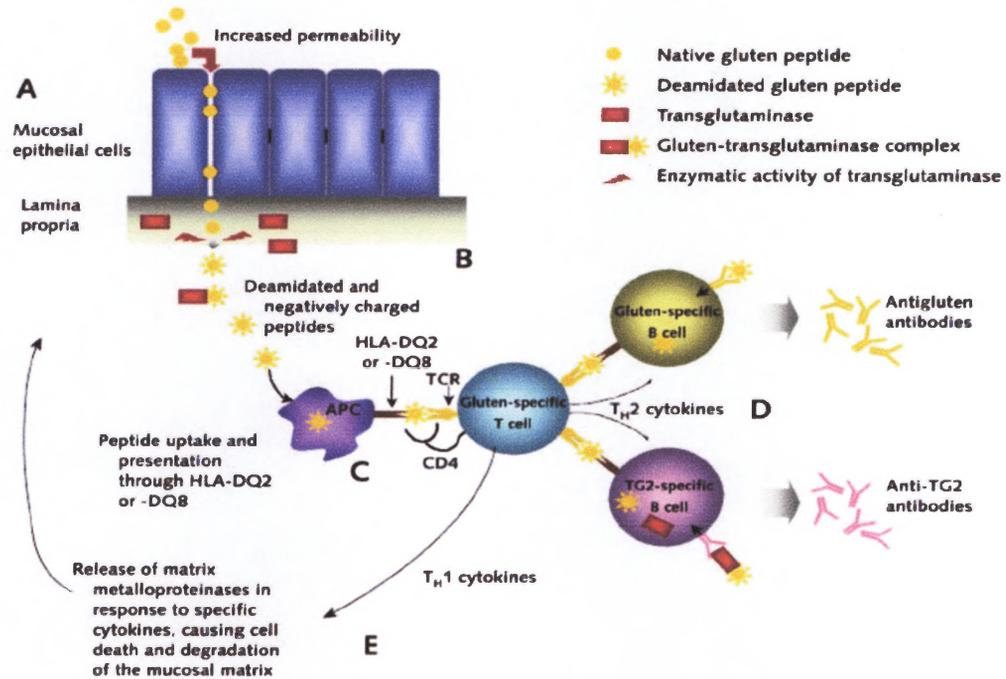


Figure 1. Simplified schematic of the possible HLA-DQ2– DQ8 and immune response in celiac disease (Alaedini & Green, 2005)

Villous atrophy is measured using the Marsh scale, a tool designed to define the severity of intestinal damage seen in patients with celiac disease. A Marsh score of 1 represents mild damage to the intestinal villi and a score of 3c represents complete atrophy and blunting of the intestinal villi (Figure 2). As the damage progresses, symptoms become more severe and associated comorbidities such as malnutrition and intestinal cancers may develop. When severe damage to the intestinal villi occurs, it causes malabsorption of nutrients, ultimately leading to malnutrition (Tonutti & Bizzaro, 2014).

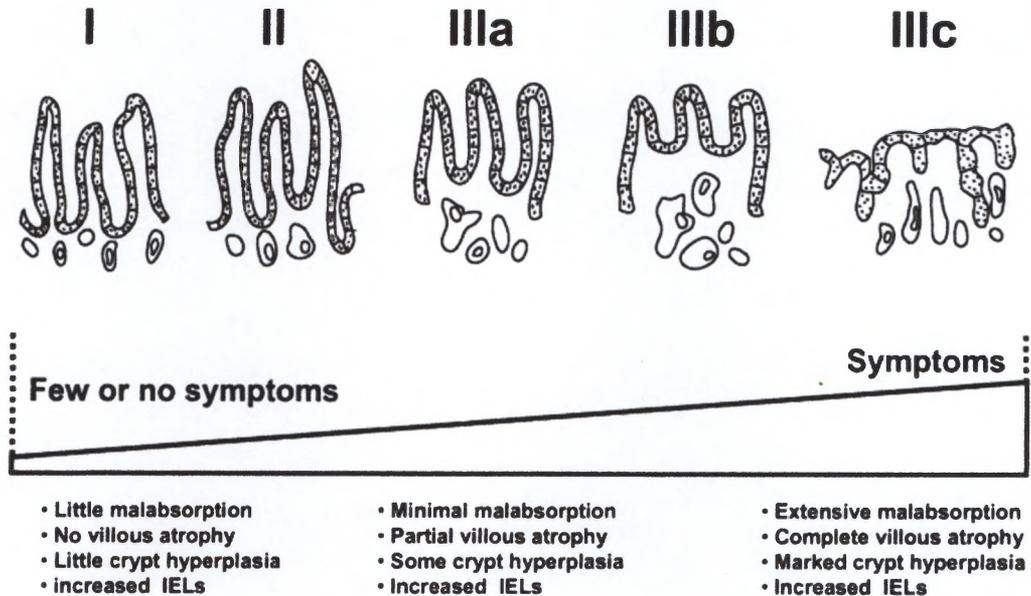


Figure 2. Marsh Score for villous damage seen in celiac disease (Rostom, Murray, & Kagnoff, 2006)

Celiac disease can cause a wide range of symptoms such as abdominal pain, anemia, vomiting, diarrhea, constipation, gas, anorexia, weight gain or loss, abdominal distension, failure to thrive, irritability, fatigue, headache, and others (Tonutti & Bizzaro, 2014). However, celiac disease can also be asymptomatic or latent, presenting with no symptoms or symptoms not gastrointestinal related. Celiac disease can be suspected when the individual has another autoimmune disease or related condition, such as iron deficiency anemia, type I diabetes, or autoimmune thyroid disease. The accompaniment of another autoimmune disease occurs in approximately 30% of people with celiac disease, whereas the prevalence of autoimmune disease in the general population is only 3% (Reilly & Green, 2012).

**Prevalence of celiac disease.**

Celiac disease affects less than 1% of the American population or approximately 1 in 133 people (Reilly & Green, 2012). Worldwide, it is most common in the Saharawi people in North Africa with a prevalence rate of 5.6%. The lowest rate of 0.3% is found in Germany (Reilly & Green, 2012). Celiac disease is found in many cultures worldwide and is prevalent in India, the Middle East, countries in Northern Africa, and China (Fasano & Catassi, 2012). The disease is commonly under-diagnosed and is more common in women than men, first-degree relatives of individuals with celiac disease, and individuals with other autoimmune diseases or related conditions (Fasano & Catassi, 2012).

**Diagnosis of celiac disease.**

Celiac disease causes numerous detectable histological and serological changes. As noted earlier, celiac disease causes a blunting of intestinal microvilli and crypt hyperplasia. Additionally, given its autoimmune nature, celiac disease also causes antibodies to be produced including serum tissue transglutaminase IgA and IgG as well as endomysial antibodies (Reilly & Green, 2012). The gold standard of diagnosis of celiac disease is a duodenal biopsy graded on the Marsh scale with serum blood work showing the presence of these antibodies (Kav & Sivri, 2012).

Prior to the 1980's, celiac disease was described as a pediatric condition presenting with diarrhea, steatorrhea, and weight loss (Reilly & Green, 2012). However, in recent years, diagnosis in adulthood is becoming more common, with presentations of

non-diarrheal symptoms on the rise. As Rampertab et al. (2006) described, there was a decrease in the proportion of patients with celiac disease who presented with diarrhea, from 91.3% of patients diagnosed prior to 1981 down to 37.2% of patients diagnosed after 2000. There was an increase in the number of patients diagnosed by screening methods from 0% prior to 1996 to 15.2% in individuals diagnosed between 1996 and 2000. There was no change in the number of patients who presented with bone disease, anemia, or who were diagnosed incidentally by endoscopy for other reasons. Patients were diagnosed at an older age after 1980 and malignancy had declined from 22% prior to 1980 to 5% between 1996 and 2000.

Furthermore, Rampertab et al found that there was a negative linear trend in how long patients suffered from symptoms prior to diagnosis. Although there was an improvement in the delay of diagnosis, there was no improvement in delay of diagnosis for those patients presenting with diarrhea. After comparison of patients with or without diarrheal symptoms, there was no significant difference in the age at presentation of symptoms. The majority of patients in this study were diagnosed after 1995, which may have skewed the results. This study showed that asymptomatic presentation of celiac disease has become more common as more adults are being diagnosed by screening after a family member has been diagnosed (Rampertab et al., 2006).

Due to celiac disease being an autoimmune condition that causes both malabsorption and malnutrition, there are often numerous comorbidities that accompany the diagnosis. Individuals with celiac disease are at a higher risk of developing

osteoporosis, infertility issues, cancers of the blood, intestinal cancer, additional autoimmune diseases, anemia, impaired splenic function, neurologic disorders, ulcerative jejunoileitis, and other related health conditions (Rampertab et al., 2006) (Fasano and Catassi, 2012). The disease has been known to lead to depression, anxiety, and social phobia due to its restrictive and challenging nature of treatment.

### **Treatment of Celiac Disease**

Currently, the only treatment for celiac disease is lifelong adherence to a gluten-free diet, although there are numerous therapies being studied and developed (Plugis & Khosla, 2015). Dietary management is challenging for individuals with celiac disease mainly due to the proliferation of gluten in modern processed foods as well as the issue of cross-contamination (Smith & Goodfellow, 2011). The gluten-free diet excludes foods made with wheat, rye, barley, and cross-contaminated oats. Since the majority of processed foods are made with wheat, the gluten-free diet excludes most processed foods.

#### **The gluten-free diet.**

Gluten is defined as a protein complex, specifically the combination of two proteins glutenin and gliadin, and is found in wheat, rye, and barley. However, due to modern processing and storage techniques utilized by food production companies, many processed foods are not safe for individuals with celiac disease due to cross-contamination issues, including most oats. When a product is processed on the same equipment as another product, miniscule amounts of all ingredients may be present in both products. Since the passage of the Food Allergen Labeling and Consumer Protection

Act of 2004, the FDA requires food manufacturers to declare when a food has one of the eight top allergens in it, those allergens being wheat, peanuts, tree nuts, eggs, milk, soy, fish, and shellfish (Derr, 2006). However, since gluten is not only a part of wheat but is also present in barley and rye, food manufacturers do not have to declare if gluten itself is present in the food. Recently, since the passage of the gluten-free labeling act, if a food manufacturer is claiming that a food is gluten-free on its label, that food has to be tested to be under 20 parts per million (ppm) (*Progressive Digital Media Food News*, 2013).

Additionally, individuals with celiac disease must avoid cross-contamination by ensuring that their food is not prepared on the same surfaces as gluten-containing foods. This means that someone with celiac disease cannot have food that has been fried in the same fryer, toasted in the same toaster, or baked in pans that gluten-containing foods have previously been baked in (Welstead, 2015). The threshold for permissible cross-contamination of gluten in the gluten-free diet varies from individual to individual, ranging from 10 mg to 50 mg (Fasano & Catassi, 2012). Since the threshold for gluten is small, individuals with the disease have to remain vigilant about controlling for this concern, ensuring that foods are not prepared on the same surface or often times not prepared in the same facility.

| <b>Safe Ingredients and Foods for Individuals with Celiac Disease</b> |                 |                   |
|---|-----------------|-------------------|
| <b>Amaranth</b>   | <b>Nuts</b>     | <b>Fruits</b>     |
| <b>Arrowroot</b>  | <b>Potatoes</b> | <b>Vegetables</b> |

|   |                               |                                 |
|---|-------------------------------|---------------------------------|
| <b>Buckwheat</b>  | <b>Quinoa</b>                 | <b>Distilled Liquor</b>         |
| <b>Cassava</b>  | <b>Rice (brown and white)</b> | <b>Wine</b>                     |
| <b>Corn</b>   | <b>Sorghum</b>                | <b>Unprocessed Meats</b>        |
| <b>Flax</b>   | <b>Soy</b>                    | <b>Eggs</b>                     |
| <b>Beans</b>  | <b>Tapioca</b>                | <b>Dairy</b>                    |
| <b>Corn Tortillas</b>   | <b>Rice Cakes</b>             | <b>Corn Starch</b>              |
| <b>Millet</b>   | <b>Teff</b>                   | <b>Plain Yogurt</b>             |
| <b>Questionable Ingredients and Foods for Individuals with Celiac Disease</b> |                               |                                 |
| <b>Natural Flavor</b>   | <b>Artificial Flavor</b>      | <b>Bouillon Cubes</b>           |
| <b>Carmel Color</b>   | <b>Starch</b>                 | <b>Brown Rice Syrup</b>         |
| <b>Dextrin</b>  | <b>Modified Food Starch</b>   | <b>Imitation Fish</b>           |
| <b>Maltodextrin</b>   | <b>Worcestershire</b>         | <b>Cold cuts/processed Meat</b> |
| <b>Rice Mixes</b>   | <b>Seitan</b>                 | <b>Seasoning Mixes</b>          |
| <b>French Fries</b>   | <b>Gravy</b>                  | <b>Soups</b>                    |
| <b>Salad Dressings</b>  | <b>Cereals</b>                | <b>Mayonnaise</b>               |
| <b>Oats</b>   | <b>Flavored Yogurt</b>        | <b>Molded Cheeses (Bleu)</b>    |
| <b>Chips</b>  | <b>Processed Cheese</b>       | <b>Imitation Meat</b>           |
| <b>Unsafe Ingredients and Foods for Individuals with Celiac Disease</b>       |                               |                                 |
| <b>Barley Malt or Malt</b>  | <b>Wheat</b>                  | <b>Triticale</b>                |

|                           |                                 |                         |
|---------------------------|---------------------------------|-------------------------|
| <b>Malt Vinegar</b>       | <b>Barley</b>                   | <b>Semolina</b>         |
| <b>Soy Sauce</b>          | <b>Rye</b>                      | <b>Bromated Flour</b>   |
| <b>Malt Syrup/Extract</b> | <b>Spelt</b>                    | <b>Durum Flour</b>      |
| <b>Malt Flavoring</b>     | <b>Kamut</b>                    | <b>Enriched Flour</b>   |
| <b>Malted Beverages</b>   | <b>Einkorn</b>                  | <b>Farina</b>           |
| <b>Bulgur</b>             | <b>Hydrolyzed Wheat Protein</b> | <b>Brewer's Yeast</b>   |
| <b>Most Breads</b>        | <b>Muffins</b>                  | <b>Pancakes</b>         |
| <b>Beer</b>               | <b>White flour</b>              | <b>Graham Flour</b>     |
| <b>Flour Tortillas</b>    | <b>Farro</b>                    | <b>Phosphated Flour</b> |

Table 1: Safe and unsafe foods for individuals with celiac disease (Gluten Intolerance Group, 2017)

#### **Treatment burden of celiac disease.**

As noted in a recent observational study by Shah et al. (2014), the burden of following the gluten-free diet is very high when compared to most other chronic diseases. During this study, participants were recruited from the Celiac Center at Beth Israel Deaconess Medical Center in Boston, MA. A survey was administered to individuals with celiac disease, hypertension, diabetes mellitus, congestive heart failure, end-stage renal disease on dialysis, gastroesophageal reflux disease, irritable bowel syndrome, and inflammatory bowel disease that met qualifying criteria. The survey evaluated treatment burden, adherence to treatment, and treatment barriers of the various conditions. The participants rated their difficulty following treatment, perceived importance of following

the treatment, disease-specific health, and overall health. The celiac group was compared to the non-celiac comparison group. Surveys were collected from 341 celiac participants and 368 non-celiac participants.

The treatment burden reported by the celiac participants averaged 44.9 points on a scale of 0 to 100 with 0 being very easy and 100 being very difficult. The average treatment burden reported by the other cohort was 33.01 ( $p < 0.001$ ). However, when the results were analyzed by condition, the group with end-stage renal disease requiring dialysis had the highest treatment burden compared to the other groups. In contrast, the celiac group reported a very high perceived importance to adhering to the gluten-free diet (93.80,  $p < 0.001$ ), as well as a high rating of disease-specific health (81.61,  $p = 0.004$ ). The researchers concluded that the perceived treatment burden of celiac disease was higher than that of most other chronic conditions. Furthermore, having a high treatment burden is a predictor of poor adherence to the gluten-free diet (Shah et al., 2014).

#### **Adherence to the gluten-free diet.**

There are numerous contributing factors that cause individuals with celiac disease to have varying adherence to the gluten-free diet. A study in 2014 by Dowd, Tamminen, Jung, Case, McEwan, and Beauchamp in England assessed these issues and determined that motives for adherence to a strict gluten-free diet were having a diagnosis of celiac disease, experiencing symptoms when consuming gluten, concerns about long-term health, hitting rock bottom, experiencing pain, having family members follow a gluten-free diet, and needing to gain or lose weight. Only 21 of the 203 participants gave

explanations for not adhering to the gluten-free diet. These reasons included “feeling like they were not very sensitive”, which made them feel open to taking chances, “not being very careful when eating out”, a “love for the taste of gluten-containing foods”, “difficulty eating gluten-free while traveling”, the “expense of the gluten-free diet”, and “consuming gluten when drinking alcohol.” A “desire to lose weight” and a “feeling of hitting rock bottom” were the top two reasons for adhering to the gluten-free diet in terms of self-reported accidental and purposeful gluten ingestion in the past week. However, those individuals who reported pain as the motivation to following a gluten-free diet were the most likely to report purposeful gluten consumption. Finally, individuals who reported that long-term health and having celiac disease were their motivation for adherence had the highest occurrence of accidental gluten ingestion (Dowd et al., 2014).

As Saisbury and Mullan demonstrated in 2011 by using the Theory of Planned Behavior, the benefits of adhering to a strict gluten-free diet appeared to be a bigger motivator for adherence than the disadvantages. Worrying about what others think or about possibly inconveniencing others was found to be associated with poorer adherence. Also, the belief that it is easy to eat a balanced diet while maintaining strict adherence to being gluten-free was found to lead to poorer adherence to the gluten-free diet. The theory of planned behavior was able to significantly predict intention to adherence as well as actual adherence (Sainsbury & Mullan, 2011).

Adherence to the gluten-free diet can be very difficult for individuals with celiac disease. It is hard to assess actual rates of strict adherence because as of yet, there is no

consensus for what strict adherence to the gluten-free diet entails. A 2009 systematic review by Hall, Rubin, and Charnock, analyzed articles published between 1980 and 2007 that pertained to adults with celiac disease. It was found that adherence rates ranged from 44% to 90% when expertly assessed and from 42% to 91% when self-reported. In all but two studies, adherence and education or socioeconomic factors were unrelated. Adults who were diagnosed in childhood tended to have lower rates of adherence. Additionally, gender did not appear to play a role in adherence rates. Poor knowledge of the gluten-free diet appeared to result in lower rates of adherence; however, noncompliance was not necessarily due to a knowledge deficit. No difference in the rates of adherence between screen-detected and symptom-detected celiac disease was found. However, one study found a significant negative correlation between compliance and malabsorption with the most severe cases having better dietary compliance. The cost, complexity, and restrictive nature of the gluten-free diet did not appear to affect adherence levels. Membership to a support or advocacy group was found to increase adherence. The ability to follow the gluten-free diet while traveling, dining out, and at work or social events was significantly related to adherence. Hall, Rubin, and Charnock did not find evidence that quality of life was related to compliance. Up to 60% of individuals included in this study were found to be partially non-adherent to strictly following a gluten-free diet. Factors that affect the individual's adherence include cognitive, emotional, and sociocultural influences, membership to a support or advocacy

group, and regular follow up by a dietitian. Additionally, severity of malabsorption and symptoms may be related to better adherence (Hall, Rubin & Charnock, 2009).

**Complimentary pharmacological treatments currently being tested.**

One reason the gluten-free diet is difficult to follow is due to cross-contamination issues and the use of gluten in many processed foods. Therefore, complementary pharmacological treatments are currently being researched to help reduce the long-term effects of gluten exposure in patients with celiac disease. Driven primarily by celiac disease advocacy groups and by individuals who have celiac disease, there is a market for complementary treatments. Most of these treatments do not offer a cure for celiac disease, but rather an additional treatment aimed at reducing symptoms and immunological response, thus decreasing the risk of cross-contamination. A complementary pharmacological treatment could help ease the treatment burden of the gluten-free diet and potentially improve the quality of life of this group of people, likely reducing the stress of having to worry about cross-contamination.

One medication appears to be the most promising adjunct pharmacological treatment currently being studied. ALV003, is a combination of two recombinant enzymes that specifically act to attenuate gluten particles. When taken at the time of ingestion of up to two grams of gluten, or the amount in half a slice of bread, ALV003 has been shown to prevent gluten-induced injury to the small intestine in patients with biopsy-confirmed celiac disease. Since this medication can attenuate up to two grams of

gluten, it shows promise in treating accidental gluten ingestion in addition to cross-contamination (Lahdeaho et al., 2014).

A 2014 study of ALV003 by Lahdeaho et al. established an appropriate amount of dietary gluten to use to test the medication by conducting trials of three groups of adults with biopsy-confirmed celiac disease. The three groups were assigned to ingest 1.5 g, 3 g, or 6 g of dietary gluten in the form of breadcrumbs. The researchers determined that 2 g of gluten would be appropriate for this study design. Next, 41 participants were recruited and randomly assigned to a treatment or placebo group. After adjusting for dropouts or serological baseline measures that were abnormal, the total number of participants included 16 in the treatment group and 18 in the placebo group. The participants were asked to complete a gastrointestinal symptom rating scale, a Bristol stool chart, a celiac disease quality of life questionnaire, a visual analog scale, and a form that evaluated their knowledge of the gluten-free diet. Additionally, the participants were provided with meal and drug dosing diaries. The participants, caretakers, study personal, and data managers were all blinded to who was in each group. For six weeks the participants consumed 2 g of gluten in the form of breadcrumbs at the same major meal each day while taking their assigned medication. Intestinal biopsies and serological tests were performed at baseline and following the challenge.

After the post-study biopsies were examined, the researchers used Chi-square to analyze the difference in villous height to crypt depth ratio as well as immunological markers. Thirteen of the 16 participants in the treatment group showed no significant

damage to their villi ( $p = 0.2499$ ), whereas the placebo group did show significant reduction in mean villous height ( $n = 18$ ,  $p = 0.0007$ ). When the groups were compared, the treatment group's villous height to crypt depth ratio was higher than the placebo group ( $p = 0.0002$ ). Additionally, the treatment group did not show a significant increase in immunological markers ( $p = 0.4271$ ), but the placebo group did ( $p = 0.0002$ ). One participant in both groups showed serological changes in celiac-specific antibodies. However, the majority of the participants from both groups experienced gastrointestinal symptoms (Lahdeaho et al., 2014). The medication is currently in stage three of clinical trials in Finland.

Another medication that has shown promising results in mice is BL-7010, a non-absorbable polymer taken prior to ingesting gluten that binds with dietary gliadin in the intestinal lumen, preventing it from being acted upon by digestive enzymes, thus preventing the breakdown into peptides that elicit an immune response (McCarville et al., 2014). A double blind, placebo-controlled, dose escalation study was completed in 2014 with a study group of 40 patients, although the results were not published in a scholarly journal. According to the drug manufacturer, BioLineRx, the medication does not affect vitamin absorption and is specific to the gliadin molecule in sequestration (Biolinerx, ND). Further information will be needed to assess the efficacy of this medication for the human adult celiac population.

Another medication that has begun human clinical trials in the United States is a synthetic peptide called Larazotide Acetate. This medication is the first of its kind to

claim to prevent the opening of the tight junctions of the small intestines, thus reducing the immunological response seen in individuals with celiac disease. In a dose-ranging, randomized, placebo-controlled study published in 2012 by a team of researchers that specialize in celiac disease, this medication appeared to reduce symptoms experienced during a gluten challenge (Kelly et al., 2012). This study included 167 patients with celiac disease who had been following a gluten-free diet for at least six months and did not have any severe complications such as refractory sprue, additional chronic intestinal disease, HIV or hepatitis B or C. The study also excluded participants who were pregnant, lactating, on immunosuppressive medications, or on medications that interfered with intestinal permeability or digestion. The subjects were placed into four treatment groups including a placebo group and three groups that received larazotide acetate in either 1, 4, or 8 mg doses given 15 minutes prior to meals. All groups were given 900 mg of gluten with their meals to total 2.7 g of gluten a day in the form of two capsules. Additionally, placebo capsules containing cornstarch were provided during a run-in period. The researchers utilized a urine test called the LAMA (lactulose to mannitol) ratio as a marker for efficacy of the medication. In individuals with celiac disease, the LAMA ratio is increased as intestinal permeability increases with a breakdown of the tight junction barrier. In addition to the LAMA ratio, the researchers also utilized serum anti-tTG IgA and IgG antibodies to assess for immunological response. Lastly, patients were evaluated using questionnaires about their gastrointestinal symptoms and psychological well being. The researches concluded that although taking larazotide acetate with the

amount of gluten typically ingested during accidental exposure does reduce gastrointestinal symptoms and immune response in individuals with celiac disease, it failed to reduce the LAMA ratio by any statistical significance (Kelly et al., 2012).

According to a recent review by Plugis and Khosla (2015), there are a number of additional therapies currently being developed to treat celiac disease. These therapies include glucocorticoids, gluten detoxifying oral proteases, gluten sequestering polymers such as the aforementioned BL-7010, zonulin antagonists such as larazotide acetate, gluten tolerization through vaccination, probiotics, and hookworm infection. Additionally undergoing preclinical studies are methods that can block transcellular gliadin transport, ways to block interleukin-15, inhibition of transglutaminase 2, gene suppression of HLA-DQ2 or HLA-DQ8, suppression of T cells, therapies to target celiac-specific B cells, and other ways to block intestinal lymphocyte homing in response to gluten ingestion. Furthermore, the study of the genome of individuals with celiac disease may hold the key for future treatments (Plugis & Khosla, 2015).

### **Quality of Life**

Quality of life is a measure of an individual's emotional and physical well being as it relates to their personal experience of life (Theofilou, 2013). Numerous factors can affect quality of life and oftentimes, individuals with chronic diseases experience a lower rating of quality of life than individuals who do not have chronic diseases (Theofilou, 2013).

### **Celiac disease specific quality of life tool.**

Celiac disease has been known to affect quality of life. Prior to 2009, health related quality of life studies on individuals with celiac disease were assessed utilizing a generalized health-related quality of life tool (Dorn et al., 2009). However, the generalized health-related quality of life tool did not capture the impact that celiac disease and the gluten-free diet has on the quality of life of those with the disease. Given the unique nature of celiac disease, a disease specific quality of life tool needed to be developed.

In 2009, Dorn et al., developed a new better tool for assessing the quality of life for individuals with celiac disease, the celiac-specific quality of life tool (CD-QOL). In order to develop the CD-QOL, the researchers first conducted two focus groups (n=12) to collect ideas about the specific nature of their disease and the impact it had on their lives. Then, other patients with celiac disease and experts in the field reviewed the ideas that were elicited during the focus groups. Those ideas were translated into questions that could be answered using a five-point Likert rating scale. This questionnaire was then administered to 44 different participants who had celiac disease. The questions that majority of the respondents answered were moderately to significantly bothersome were not changed and the remaining questions underwent further review to either be reworded or excluded from the survey. A final 24-question survey was developed and administered to 387 participants. A final celiac-specific quality of life tool with 20 questions was developed. Four of the final 24 questions were eliminated due to redundancy, poor correlation with the total score, or because they contributed little variance to the factor

analysis. The areas of quality of life that were most affected individuals with celiac disease were limitations, dysphoria, health concerns, and inadequate treatment.

Validity was determined by having a subset of participants from the final group answer further surveys including the self-related health survey, the sickness impact profile survey, the brief symptom inventory, and the average daily abdominal pain questionnaire. The researchers found that individuals with lower psychological distress, less abdominal pain, less daily impairment, and higher self-related health survey scores had a higher quality of life. The CD-QOL instrument developed during this study was a unique validated tool that could be useful in evaluating the quality of life of individuals with celiac disease on a gluten-free diet (Dorn et al., 2009).

**Factors that affect quality of life.**

Several studies exist that assess the quality of life of individuals with celiac disease. Celiac disease is unique in its treatment and given the restrictive nature of the gluten-free diet, the treatment can impact several aspects of quality of life of those who are afflicted with the disease as well as those in the person's life. Researchers have assessed the quality of life of individuals with celiac disease to try to find ways to improve areas of treatment or support.

Lee et al. (2012) showed that having celiac disease and following the gluten-free diet negatively impacted the quality of life, especially in the social domain. The researchers sent recruitment letters to 40 American celiac support groups requesting

participation. Two thousand surveys were subsequently sent to members of 30 of the support groups.

The surveys were self-reported and used a Standard Quality of Life questionnaire as well as celiac-specific questions that are part of a validated disease-specific quality of life tool. The survey focused mainly on dietary compliance and social areas of life such as travel, home life, self-perception of health, social activities, and eating away from home. In addition to the participants with celiac disease, surveys were sent to family members of the participants to be used as controls, although they only filled out the Standard Quality of Life portion of the survey. Participants were required to have biopsy-confirmed celiac disease, follow a gluten-free diet, and be over 19 years of age. In total, 1743 surveys were returned from individuals who met the inclusion criteria.

When compared to the control population, the participants with celiac disease had similar ratings of overall quality of life with lower ratings of health perception. However, the responses to the disease and diet specific questions showed that celiac disease and its dietary management had a negative impact, especially in the social domain, on quality of life. Almost half of the participants responded that having celiac disease affected their interactions with family, friends, and other social groups. Females appeared to be more affected in the social domain than males. Dining out was found to be the most affected social activity with approximately one quarter of the respondents who had been diagnosed in the past two to five years stated that they did not dine out at all. Travel was also negatively affected by the gluten-free diet, although it appeared to have less of an

effect the longer the individual had been diagnosed. The respondents reported high compliance to the gluten-free diet; however, most admitted to intentional non-compliance during social activities (Lee et al, 2012).

Additionally, celiac disease has an expansive effect on the lives of those living with the condition as evidenced by a survey conducted by Black and Orfila (2011). A group of 146 biopsy-confirmed individuals in the UK filled out self-administered questionnaires that addressed their quality of life and dietary habits as well as a food frequency questionnaire. The food frequency questionnaire was analyzed to determine if the participants were compliant with the restrictions of the gluten-free diet or if they were possibly experiencing cross-contamination. Self-reported compliance with the gluten-free diet was found to be very high at 96%, with the other 4% admitting that they did not always follow a gluten-free diet at social activities. However, it was also determined by the food frequency questionnaire that as many as 44% of the participants ate cereals that were not gluten-free and labeled as containing barley. Most of the respondents found that complying with the restrictions was difficult. While three quarters of the respondents did not avoid travel, 63% of them did bring their own food with them when they did. More than half of the study participants reported that they avoided dining out at least some of the time and that they feel left out of social situations. Additionally, 43% of the respondents worried about the safety of food if they had to stay in a hospital. As many as 40% of the respondents felt depressed some of the time due to having celiac disease and a similar portion of the participants stated that they felt emotionally upset, usually due to

feeling excluded or embarrassed as a result of their condition. Only 28% of the respondents stated that they experience pain as a result of celiac disease; however, only 37% felt energetic all or most of the time. The authors concluded that while dietary compliance was high, celiac disease had an expansive effect on the lives of those living with the condition due to the numerous social and daily activities that were affected by the management of the disease. Additionally, the authors concluded that unintentional gluten consumption may be common amongst individuals with celiac disease residing in the UK (Black & Orfila, 2011).

A 2013 cross-sectional study by Paarlahti, Kurppa, Ukkola, Collin, Huhtala, Maki, and Kaukinen assessed the quality of life of individuals with celiac disease in Finland to determine which factors contribute to persistent symptoms and a reduction in the quality of life. In this study, the researchers recruited a total of 596 adults with biopsy-confirmed celiac disease. The participants answered a gastrointestinal symptom survey, as well as a healthy related quality of life survey. In addition to the self-administered surveys, a physician or nurse with expertise in celiac disease interviewed the participants. Demographic data, clinical presentation at diagnosis, and data regarding comorbidities was also obtained. A control group of 110 healthy subjects was also interviewed in the same manner. The researchers found that the celiac group had more symptoms on the gastrointestinal symptom survey than the control group ( $p= 0.003$ ). Additionally, the celiac group reported lower quality of life scores than the control group ( $p= 0.05$ ). Furthermore, individuals with persistent gastrointestinal symptoms

experienced a greater reduction in quality of life than those who were asymptomatic ( $p < 0.001$ ). The researchers concluded that individuals with celiac disease who are following a gluten-free diet experience a reduction in health-related quality of life (Paarlahti et al., 2013).

Further research suggests that a decrease in the quality of life of individuals with celiac disease is found worldwide. A recent survey study that included individuals with celiac disease from Australia in 2013 highlights the effects of the gluten-free diet on the quality of life of individuals with celiac disease. The researchers first tested the survey in a group of 390 individuals, then validated the survey in a second group of 189 individuals. Those researchers found that there was a significant correlation between reduced quality of life and improved gluten-free diet adherence, thus those individuals who followed the gluten-free diet more strictly experienced a greater reduction in their quality of life ( $p < 0.001$ ) (Sainsbury, Mullan, & Sharpe, 2013).

A study from Canada in 2012 found many difficulties individuals with celiac disease experience as a result of following a gluten-free diet. These difficulties include but are not limited to: purchasing gluten-free foods, gluten-free food preparation, eating with family/friends, eating in restaurants, eating at school/work, and traveling (Zarkadas et al., 2012). A review of international literature on the quality of life of individuals with celiac disease in 2015 found that individuals with celiac disease report having to sacrifice experiences, which can impact quality of life. Additionally, the same review found that quality of life is negatively impacted by the gluten-free diet in individuals with

asymptomatic celiac disease, but quality of life improves for individuals who had symptomatic celiac disease (Ciacci & Zingone, 2015).

### **The Gluten-free Fad Diet**

The gluten-free fad diet is defined in this study as the self-imposed adherence to a gluten-free diet for reasons other than celiac disease (suspected or confirmed), irritable bowel syndrome, a confirmed wheat or gluten allergy, or non-celiac gluten sensitivity, outside of medical direction from a doctor or registered dietitian. A scholarly timeline for the beginning and subsequent proliferation of the gluten-free fad diet does not exist, and thus the author has relied on anecdotal evidence to try to establish a timeline. According to a USA today article titled *Gluten-free Diets Gaining in Popularity*; gluten-free dieting had become a “fad” sometime around 2008 (Painter, 2008). However, anthropologist Lauren Moore from the University of Kansas, argues that the gluten-free diet began to become popular amongst individuals who do not have celiac disease sometime around 2011, although interest in celiac disease in America has risen dramatically since 2003 (Moore, 2014). Since then books have been published touting the unfounded dangers of gluten. One such book, *Grain Brain*, written in 2013 by a neurologist, Dr. Perlmutter, made claims that eating grains causes dementia, attention deficit and hyperactivity disorder, headaches, depression and other illnesses. Another book published in 2014 called *Wheat Belly: Lose the Weight, and Find Your Path Back to Health* by cardiologist William Davis, claimed that over 100 million Americans experience adverse reactions to wheat. These books became popular with individuals seeking a cure to all that ails them

(Perlmutter, 2013; Davis, 2014). Numerous celebrities such as Oprah Winfrey, Jenny McCarthy, Zoe Deshanel, and Gweneth Paltrow also began to promote the gluten-free diet for weight loss or general well-being (Piccalo, 2010).

However, public perception of the gluten-free diet has recently shifted with the diet now being ridiculed in mainstream and social media. Jimmy Kimmel, a late night talk show host, had a segment on his show in 2014 where he asked people off the street “what is gluten?” and subsequently made light of their responses (Friedman, 2014). Another anecdotal article, written in 2014 on the Washington Post, noted that backlash against the gluten-free diet had begun, and that individuals with celiac disease had begun to notice that people were not taking their condition seriously and that others were eating gluten-free at their own convenience (McCarthy, 2014). A 2015 online article on National Public Radio featured interviews with multiple individuals who have celiac disease and discussed how they felt the gluten-free fad diet was affecting them, with many feeling that their condition was not taken seriously in the wake of the fad diet (Fell, 2015). In a 2015 Food Market Forecast by the Chicago-based consumer market research group Mintel, nearly half of the respondents viewed the gluten-free diet as a fad. This shift of public perception may have negative effects on those individuals with celiac disease who rely on an uncontaminated gluten-free diet to treat their disease. However, empirical evidence about these effects does not yet exist.

#### **Prevalence of the gluten-free fad diet.**

According to Mintel's 2015 market forecast, nearly half of Americans think that the gluten-free diet is a fad, up from 33% in 2013 (Mintel, 2015). As the report states, 25% of consumers eat gluten-free foods at least some of the time. The percentage of those consuming gluten-free foods has risen 67% in the past couple years (Mintel, 2015).

#### **Reasons why people choose to eat gluten-free.**

There are many reasons consumers choose to follow a gluten-free diet. Some individuals self-restrict gluten from their diet for perceived health, wellness, and weight loss reasons (Gaesser & Angadi, 2012). When questioned by Mintel, 37% of consumers responded that they follow a gluten-free diet because they perceive it to be good for their health and 16% state that they think gluten is "bad for you." Of those questioned, only 11% follow a gluten-free diet at the suggestion of a healthcare professional, although it is not stated if those professionals were doctors or registered dietitians (Mintel, 2015).

According to a review by pediatric gastroenterologist, Dr. Pietzak in 2012, there are several disorders for which the gluten-free diet is used as a therapeutic treatment, although the gluten-free diet has not been shown to be an effective treatment for all of these conditions. Aside from celiac disease, Pietzak reports that individuals with a confirmed wheat allergy, gluten sensitivity, dermatitis herpetiformis, gluten ataxia, irritable bowel syndrome, and autism spectrum disorder also utilize the gluten-free diet as treatment for their conditions. The conditions in which the gluten-free diet has been well established to be a treatment for include celiac disease, and its related conditions dermatitis herpetiformis and gluten ataxia, and wheat allergy. Research has been

inconclusive for non-celiac gluten sensitivity, as well as irritable bowel syndrome, and autism spectrum disorders (Pietzak, 2012).

Non-celiac gluten sensitivity, a recently recognized condition, is currently being researched. In one recent 2013 review of human clinical studies, in vitro, and animal studies, researchers found that though the evidence in animal studies suggests that gliadin can increase intestinal permeability, induce cellular apoptosis, and cause changes in neuromotor function, when it comes to human clinical studies, the evidence is inconclusive (Biesiekierski, Muir, & Gibson, 2013). Of interest are two studies by the same group of researchers. The first study, by Biesiekierski et al in 2012, appeared to show evidence of gluten being a trigger. However, during the second study, the researchers were unable to reproduce their results. A very high placebo response was found in both studies (Biesiekierski et al., 2011, Biesiekierski et al., 2013).

Additionally, recent research in Australia points to dietary exclusion of gluten on the basis of relief of gastrointestinal symptoms without a formal diagnosis or recommendation from a medical professional. The most commonly reported gastrointestinal symptoms reported by this study group, in order of reported prevalence, include gas or bloating, abdominal pain, lethargy, constipation or diarrhea, heartburn, and skin issues such as rashes or itching. Most of the participants reported getting their information about wheat avoidance from a non-medical source. Approximately 38% of the participants reported being formally diagnosed with another food allergy. The researchers found that the profile of the individuals who avoided wheat outside of the

direction of a medical professional included being female, less trusting of conventional medicine, and being more likely to seek out complementary medical treatment (Golley, et al., 2014).

### **Research Question**

This research study sought to answer the question, What are the effects of the gluten-free fad diet on the quality of life of American adults with biopsy confirmed celiac disease?

### **Definition of Terms**

*Crypt hyperplasia* – an increase in the proliferation of simple, branched, tubular invaginations at the base of the intestinal villi in the submucosal layer

*Villous atrophy* – the flattening of intestinal microvilli as the result of immune system damage to the intestinal mucosa

*Marsh scale* – a measure of the histological findings of an intestinal biopsy used to diagnose celiac disease

*Steatorrhea* – the presence of an abnormal amount of fat in feces as the result of decreased absorption of fat in the intestines

*Strict gluten-free diet* – the elimination of all sources of dietary gluten including cross-contamination over 50 mg/day

*Gluten-free fad diet* - the self-imposed adherence to a gluten-free diet for reasons other than celiac disease (suspected or confirmed), irritable bowel syndrome, a confirmed

wheat or gluten allergy, or non-celiac gluten sensitivity, outside of medical direction from a doctor or registered dietitian

*Quality of life* - measure of an individual's emotional and physical well being as it relates to their personal experience of life

*Dermatitis herpetiformis* – a disease of the skin, presenting as a chronic blistering rash of the skin on the shoulders, elbows, buttocks, and back of the thighs

*Gluten ataxia* – a neurological condition involving the involuntary coordination of muscle movements as a result of immunologic damage to the cerebellum, posterior spinal columns, and peripheral nerves in response to ingestion of gluten in sensitive individuals

*Irritable bowel syndrome*- a chronic intestinal condition that is diagnosed by exclusion of other gastro-intestinal diseases, which causes recurrent abdominal pain coupled with diarrhea or constipation, often triggered by stress, depression, or anxiety

*Celiac disease* – genetic, chronic autoimmune disease resulting in chronic enteritis and villous atrophy secondary to gluten sensitivity that causes malabsorption and malnutrition

*Autism spectrum disorder* – a neurodevelopmental disorder that causes impairment in the afflicted individual's ability to communicate and interact with others, resulting in impairment in occupation, behavior, and social functioning

*Wheat allergy* – an immunoglobulin E mediated response to the ingestion of wheat protein that causes hives, eczema, or gastrointestinal symptoms

*Non-celiac gluten sensitivity* – a clinical presentation of gastrointestinal symptoms triggered by the ingestion of gluten in individuals in which celiac disease or a true wheat

allergy have been ruled out and symptoms have been found to be relieved after dietary exclusion of gluten.

## **Method**

### **Research Design**

This cross-sectional, mixed-methods research study utilized quantitative methods in the form of an anonymous online questionnaire as well as qualitative methods in the form of one free answer question.

### **Participants**

The participant inclusion criteria included of American adults (>18 years old) with biopsy-confirmed celiac disease who had been following a gluten-free diet for a minimum of three months and were on the emailing list for the National Foundation for Celiac Awareness. No specified race, gender, or socioeconomic class was recruited for, the main inclusion criteria were age, diagnosis, and access to the Internet. Participants were excluded from the study if they noted self-diagnoses, or were diagnosed with only blood work or an elimination diet, as well as being under 18 years of age and not American. The study was anonymous and the researcher did not know the participants.

### **Recruitment**

The study participants were recruited through the National Foundation for Celiac Awareness (NFCA), one of the largest not-for-profit celiac support organizations in the United States of America. Utilizing a voluntary opt-in for research email list, the NFCA sent an email blast requesting participation in the research study. In addition to the email blast, a Facebook post was sent to the 139,327 individuals that “like” their Facebook group and eventually reached over 17,000 individuals on that site.

### **Instrumentation**

This study utilized two sets of questions through one anonymous online questionnaire. The first survey, the Celiac-Specific Quality of Life Tool (CD-QOL), was developed and validated at the University of North Carolina Chapel Hill's Medical School and has been utilized in numerous quality of life studies (Dorn, et al, 2009). The survey consists of twenty questions using a Likert scale.

In addition to the CD-QOL, the primary researcher of this study developed ten more questions regarding the participant's perception of the gluten-free diet as a fad and its effect on the participants. A registered dietitian, who was diagnosed with celiac disease nine years prior to the study, developed this portion of the survey using her own personal experience of living with the disease. Having the unique perspective of having been diagnosed prior to the proliferation of the diet for means other than treating celiac disease, the researcher had multiple discussions with other individuals with celiac disease and was able to form questions regarding the effect of the fad diet on individuals who are required to follow the diet to treat their chronic disease. A dietetic intern who was diagnosed with celiac disease three years prior to the study, in addition to two other registered dietitians who do not have celiac disease and are therefore unbiased to the questions, reviewed the survey and changes were made to eliminate bias from questions. Nine of the ten questions were rated on the Likert scale and the final question was a free-answer question that limited the participant's responses to a few sentences.

### **Data Collection**

The NFCA was contacted to request their participation in the recruitment of study participants. After agreeing to be a part of the study, the NFCA sent an email blast to their list serve with the recruitment letter and a link to the survey as well as posting the link to the survey to their Facebook page. Participants received the email requesting their participation and either chose to participate or not participate by clicking the link to the survey or ignoring the link to the survey. Those interested clicked the link to the survey and read a consent form before moving on to the qualification questions. The interested participants answered a few demographic questions as well as questions about celiac disease such as when they were diagnosed, how they were diagnosed, and how long they have been following a gluten-free diet. Qualified participants were then asked to continue the survey and filled out the celiac-specific quality of life questionnaire. Next, the participants moved on to answer the specific questions regarding the gluten-free diet. Lastly, the participants had the opportunity to answer one free-answer question regarding how they feel about other individuals following the gluten-free diet. The participants had the option to opt out of the survey at any time by closing their web browser. Upon completion of the survey, the participants exited their web browser. Data was collected through a survey powered by Qualtrics survey software. At the end of six weeks, the survey was closed.

### **Data Analysis**

Demographic data such as age and gender was analyzed for prevalence and characteristics. The survey data sets were itemized according the portions of the survey

that were part of the CD-QOL, the gluten-free fad diet portion, and the free-answer question. Furthermore, the data sets were itemized according to the age of the participants and the length of time they have been living with the disease as well as if they strictly follow the gluten-free diet or do not strictly follow the gluten-free diet. The researcher used Chi-square to assess if these factors affect the respondent's quality of life or their opinions about the gluten-free fad diet. Data was analyzed on the statistic software program, SPSS version 24. The questions with a  $p < 0.05$  were determined to be statistically significant.

To qualitatively analyze the free-answer question, the researcher used Grounded Theory. First, the researcher read all of the responses and determined categories that emerged. Next, similar categories were combined into major categories. The researcher and an assistant, without influence from each other, then separately tallied the responses that corresponded with the thematic categories and the totals were averaged. Lastly, themes were categorized into negative, positive, and neutral themes.

## Results

### Demographic Data

A total of 912 participants responded to the online survey. After exclusion questions were asked, a total of 841 qualified to complete the survey. Of the 841 qualified respondents, 69 (8%) participants were male, 770 (92%) were female, and 2 (<0%) preferred not to answer. When asked about dietary compliance, 812 (97%) participants self-reported strict adherence to the gluten-free diet, while 29 (3%) participants self-reported that they do not strictly follow a gluten-free diet. When asked about when they were diagnosed, 13 (2%) participants reported diagnosis under three months ago, 81 (10%) reported diagnosis three months to one year ago, 383 (46%) reported diagnosis one to five years ago, 194 (23%) reported diagnosis six to ten years ago, 85 (10%) reported diagnosis 11 to 15 years ago, 32 (4%) reported diagnosis 16 to 20 years ago, and 52 (6%) reported diagnosis 21 years or more ago. Although all of the 841 qualified participants answered that they were over the age of 18, 819 chose to respond to what age they were with 103 (13%) participants being 18-25 years old, 177 (22%) being 26-35 years old, 202 (25%) being 36-45 years old, 180 (22%) being 46-55 years old, and 157 (19%) being 56 years old or older (n=819).

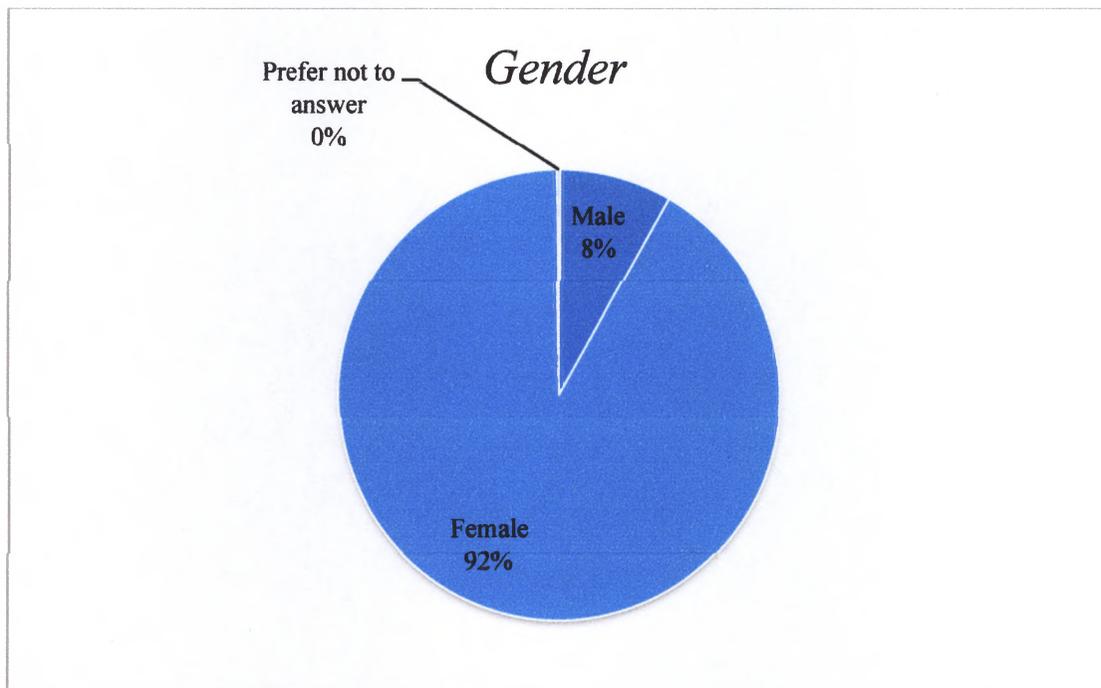


Chart 1: Gender composition of respondents

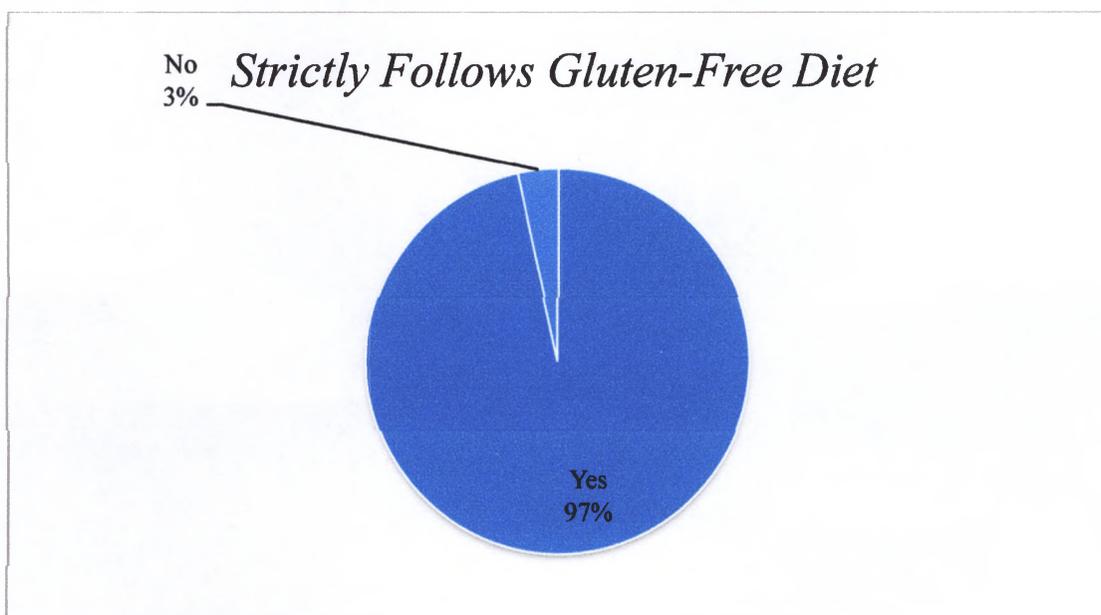


Chart 2: Gluten-free diet adherence in respondents

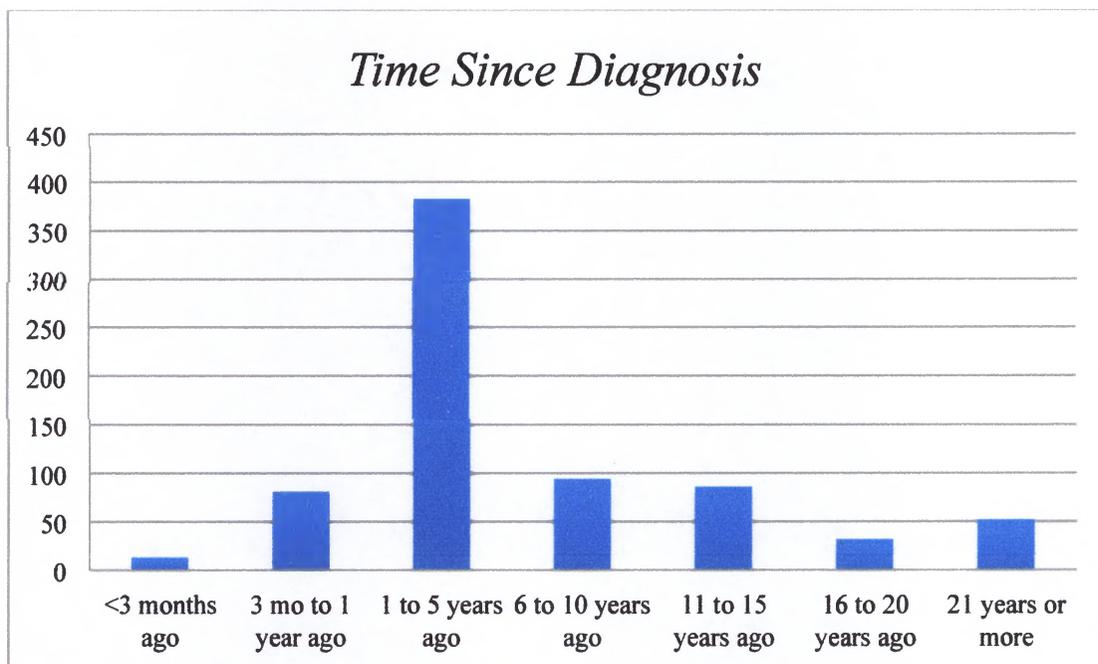


Chart 3: Time since diagnosis of celiac disease of the respondents

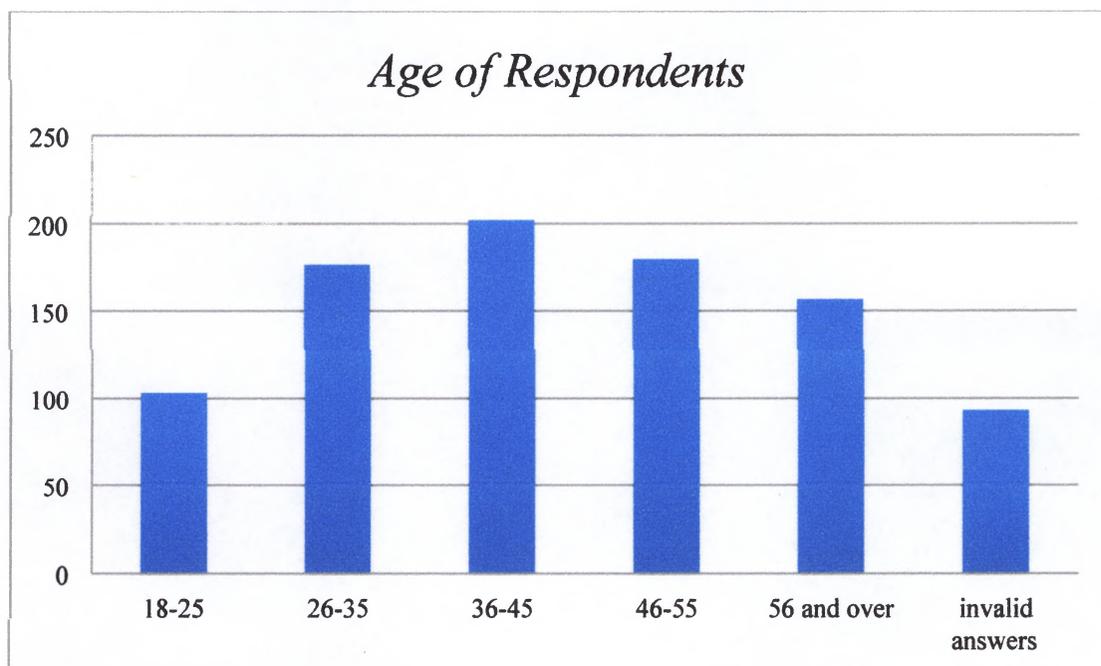


Chart 4: Age of respondents

## CD-QOL

The next portion of the survey consisted of a celiac disease-specific quality of life tool (CD-QOL) developed by a team of researchers at the University of North Carolina Chapel Hill medical school. The CD-QOL consists of 20 questions with Likert scale responses: not at all, slightly, moderately, quite a bit, and a great deal. The first question was preceded by the phrase “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 fill in the box that best describes your feelings.” Since respondents were allowed to opt out of any question they did not feel like answering or end the survey when they needed, there were varying responses to each question.

The first question asked respondents to rate the phrase “I feel limited by this disease” on the Likert scale. Of 830 responses, 31 (4%) participants responded “not at all”, 196 (24%) participants responded “slightly”, 289 (35%) participants responded “moderately”, 203 (25%) participants responded “quite a bit”, and 111 (13%) participants responded “a great deal.” The next question asked respondents to rate the phrase “I feel worried that I will suffer from this disease.” Of 825 responses, 100 (12%) participants responded “not at all”, 242 (29%) participants responded “slightly”, 259 (31%) participants responded “moderately”, 150 (18%) participants responded “quite a bit”, and 74 (9%) participants responded “a great deal.” The next question asked participants to respond to the phrase “I feel concerned that this disease will cause other health problems.” Of 822 responses, 34 (4%) participants responded “not at all”, 172 (21%) participants

responded “slightly”, 261 (32%) participants responded “moderately”, 222 (27%) participants responded “quite a bit”, and 133 (16%) participants responded “a great deal.”

The fourth question stated: “I feel worried about my increased risk of cancer from the disease.” Of 817 responses, 104 (13%) participants responded “not at all”, 210 (26%) participants responded “slightly”, 246 (30%) participants responded “moderately”, 148 (18%) participants responded “quite a bit”, 109 (13%) participants responded “a great deal.” The next question stated: “I feel socially stigmatized for having this disease.” Of 823 responses, 103 (13%) participants responded “not at all”, 222 (27%) participants responded “slightly”, 193 (24%) participants responded “moderately”, 160 (19%) participants responded “quite a bit”, and 145 (18%) participants responded “a great deal.” The sixth question stated: “I feel like I am limited in eating meals with coworkers.” Of 822 responses, 39 (5%) participants responded “not at all”, 222 (27%) participants responded “slightly”, 193 (24%) participants responded “moderately”, 160 (19%) participants responded “quite a bit”, and 145 (18%) participants responded “a great deal.”

The next question stated: “I feel like I am not able to have special foods like birthday cake and pizza.” Of 820 responses, 132 (16%) participants responded “not at all”, 162 (20%) participants responded “slightly”, 169 (21%) participants responded “moderately”, 164 (20%) participants responded “quite a bit”, and 193 (24%) responded “a great deal.” Next, the participants answered “I feel that the diet is sufficient treatment for my disease.” Of 817 responses, 94 (12%) participants responded “not at all”, 119 (15%) participants responded “slightly”, 235 (29%) participants responded “moderately”,

192 (24%) participants responded “quite a bit”, and 177 (22%) participants responded “a great deal.” When asked to rate “I feel that there are not enough choices for treatment” on the Likert scale, 813 participants responded. Of those 813 responses, 136 (17%) participants responded “not at all”, 139 (17%) participants responded “slightly”, 170 (21%) participants responded “moderately”, 192 (24%) participants responded “quite a bit”, and 177 (22%) participants responded “a great deal.”

The next question stated: “I feel depressed because of my disease.” Of 816 responses, 285 (35%) participants responded “not at all”, 280 (34%) participants responded “slightly”, 149 (18%) participants responded “moderately”, 71 (9%) participants responded “quite a bit”, and 31 (4%) participants responded “a great deal.” When asked to rate the phrase: “I feel frightened by having this disease”, 814 participants responded. Of those 814 responses 326 (40%) participants responded “not at all”, 279 (34%) participants responded “slightly”, 141 (17%) participants responded “moderately”, 43 (5%) participants responded “quite a bit”, and 25 (3%) participants responded “a great deal.” Next, the participants rated on the Likert scale the phrase: “I feel like I don’t know enough about the disease. Out of 815 responses, 393 (48%) participants responded “not at all”, 259 (32%) participants responded “slightly”, 111 (14%) participants responded “moderately”, 35 (4%) participants responded “quite a bit”, and 17 (2%) participants responded “a great deal.” Next, the survey asked the participants to rate on the Likert scale the phrase: “I feel overwhelmed about having the disease.” Of 814 responses, 296 (36%) participants responded “not at all”, 272 (33%) participants responded “slightly”,

137 (17%) participants responded “moderately”, 76 (9%) participants responded “quite a bit”, and 33 (4%) participants responded “a great deal.”

The survey then asked participants to rate the phrase “I have trouble socializing because of my disease” on the Likert scale. Out of 185 responses, 260 (32%) participants responded “not at all”, 251 (31%) participants responded “slightly”, 148 (18%) participants responded “moderately”, 96 (12%) participants responded “quite a bit”, and 60 (7%) participants responded “a great deal.” Next, participants were asked to rate the phrase: “I find it difficult to travel or take long trips because of my disease” on the Likert scale. A total of 815 participants responded with 97 (12%) participants responded “not at all”, 206 (25%) participants responded “slightly”, 194 (24%) participants responded “moderately”, 162 (20%) participants responded “quite a bit”, and 156 (19%) participants responded “a great deal.” Next, participants rated the phrase: “I feel like I cannot live a normal life because of my disease” on the Likert scale. Of 816 responses, 228 (28%) participants responded “not at all”, 271 (33%) participants responded “slightly”, 143 (18%) participants responded “moderately”, 100 (12%) participants responded “quite a bit”, and 74 (9%) participants responded “a great deal.” The participants then rated the phrase: “I feel afraid to eat out because my food may be contaminated” on the Likert scale. A total of 810 participants responded to this question; 37 (5%) participants responded “not at all”, 171 (21%) participants responded “slightly”, 201 (25%) participants responded “moderately”, 171 (21%) participants responded “quite a bit”, and 230 (28%) participants responded “a great deal.”

Next, participants rated the phrase: “I feel worried about the increased risk of one of my family members having celiac disease” on the Likert scale. Of 813 responses, 94 (12%) participants responded “not at all”, 182 (22%) participants responded “slightly”, 211 (26%) participants responded “moderately”, 177 (22%) participants responded “quite a bit”, and 149 (18%) participants responded “a great deal.” The participants then rated the phrase: “I feel like I think about food all the time” on the Likert scale. Of 813 responses, 169 (21%) participants responded “not at all”, 175 (22%) participants responded “slightly”, 170 (21%) participants responded “moderately”, 169 (21%) participants responded “quite a bit”, and 130 (16%) participants responded “a great deal.” The last question asked the participants to rate on the Likert scale the phrase: “I feel concerned that my long-term health will be affected.” Of 812 responses, 62 (8%) participants responded “not at all”, 195 (24%) participants responded “slightly”, 235 (29%) participants responded “moderately”, 205 (25%) participants responded “quite a bit”, and 115 (14%) participants responded “a great deal.”

The researcher used Chi-square to determine if time since diagnosis has an effect on quality of life. The researcher compared those diagnosed under three months prior to the survey, three months to one year prior to the survey, one year to five years prior to the survey, six years to ten years prior to the survey, eleven to fifteen years prior to the survey, sixteen to twenty years prior to the survey, and twenty one years or more prior to the survey. Eighteen of the twenty questions were significantly significant and showed

that the length of time since diagnosis can negatively affect quality of life. The results from these questions are listed below in table 2.

| The Effect of Length of Time Since Diagnosis on Quality of Life of Individuals With Celiac Disease           |           |                |              |               |                |                |           |
|--|-----------|----------------|--------------|---------------|----------------|----------------|-----------|
| <i>Question: I feel limited by this disease</i>  |           |                |              |               |                |                |           |
|  | <3 months | 3 mo to 1 year | 1 to 5 years | 6 to 10 years | 11 to 15 years | 16 to 20 years | 21 years  |
|  | n (%)     | n (%)          | n (%)        | n (%)         | n (%)          | n (%)          | n (%)     |
| Not at all   | 1 (7.7)   | 2 (2.5)        | 8 (2.1)      | 6 (3.1)       | 6 (7.1)        | 4 (12.5)       | 4 (7.7)   |
| Slightly   | 0         | 10 (12.3)      | 77 (20.1)    | 58 (29.9)     | 25 (29.4)      | 11 (34.4)      | 15 (28.8) |
| Moderately   | 6 (46.2)  | 28 (34.6)      | 144 (37.6)   | 58 (29.9)     | 29 (34.1)      | 11 (34.4)      | 13 (25)   |
| Quite a bit  | 2 (15.4)  | 25 (30.9)      | 92 (24)      | 49 (25.3)     | 14 (16.5)      | 6 (18.8)       | 15 (28.8) |
| A great deal   | 4 (30.8)  | 14 (17.3)      | 57 (14.9)    | 21 (10.8)     | 11 (12.9)      | 0              | 4 (7.7)   |
| Total n  | 13        | 79             | 378          | 192           | 85             | 32             | 51        |
| n= 830   |           |                |              |               |                |                |           |
| chi-square 51.563***   |           |                |              |               |                |                |           |
| ***p=0.001   |           |                |              |               |                |                |           |
| Note: Number in parenthesis represents the percentage of the number of individuals responding for each group |           |                |              |               |                |                |           |
| <i>Question: I feel worried that I will suffer from this disease</i>   |           |                |              |               |                |                |           |
|  | <3 months | 3 mo to 1 year | 1 to 5 years | 6 to 10 years | 11 to 15 years | 16 to 20 years | 21 years  |
|  | n (%)     | n (%)          | n (%)        | n (%)         | n (%)          | n (%)          | n (%)     |
| Not at all   | 1 (7.7)   | 2 (2.5)        | 32 (8.4)     | 31 (16)       | 11 (12.9)      | 7 (21.9)       | 16 (30.8) |

|              |          |           |            |           |           |           |           |
|--------------|----------|-----------|------------|-----------|-----------|-----------|-----------|
| Slightly     | 1 (7.7)  | 26 (32.1) | 99 (25.8)  | 59 (30.4) | 35 (41.2) | 11 (34.4) | 11 (21.2) |
| Moderately   | 6 (46.2) | 25 (30.9) | 133 (34.7) | 56 (28.9) | 15 (17.6) | 12 (37.5) | 12 (23.1) |
| Quite a bit  | 2 (15.4) | 18 (22.2) | 81 (21.1)  | 30 (15.5) | 13 (15.3) | 1 (3.1)   | 5 (9.6)   |
| A great deal | 3 (23.1) | 7 (8.6)   | 32 (8.4)   | 16 (8.2)  | 9 (10.6)  | 1 (3.1)   | 6 (11.5)  |
| Total n      | 13       | 78        | 377        | 192       | 83        | 31        | 50        |

$n= 825$

chi-square \*\*\*65.610

\*\*\* $p=0.000$

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

*Question: I feel concerned that this disease will cause other health problems*

|              | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|--------------|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
|              | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 1 (7.7)      | 1 (1.2)           | 7 (1.8)         | 9 (4.6)          | 6 (7.1)           | 3 (9.4)           | 7 (13.5)  |
| Slightly     | 3 (23.1)     | 12 (14.8)         | 73 (19.1)       | 43 (22.2)        | 21 (24.7)         | 9 (28.1)          | 11 (21.2) |
| Moderately   | 2 (15.4)     | 27 (33.3)         | 124 (32.4)      | 62 (32)          | 20 (23.5)         | 11 (34.4)         | 15 (28.8) |
| Quite a bit  | 2 (15.4)     | 23 (28.4)         | 111 (29)        | 45 (23.2)        | 23 (27.1)         | 7 (21.9)          | 11 (21.2) |
| A great deal | 5 (38.5)     | 15 (18.5)         | 62 (16.2)       | 31 (16)          | 13 (15.3)         | 1 (3.1)           | 6 (11.5)  |
| Total n      | 13           | 78                | 377             | 190              | 83                | 31                | 50        |

$n= 822$

chi-square \*41.032

\* $p=0.017$

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

| <i>Question: I feel worried about my increased risk of cancer from the disease</i>                           |              |                   |                 |                  |                   |                   |           |
|--|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
|  | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|  | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 2 (15.4)     | 4 (4.9)           | 42 (11)         | 19 (9.8)         | 15 (17.6)         | 7 (21.9)          | 15 (28.8) |
| Slightly   | 2 (15.4)     | 20 (24.7)         | 92 (24)         | 58 (29.9)        | 20 (23.5)         | 9 (28.1)          | 9 (17.3)  |
| Moderately   | 2 (15.4)     | 25 (30.9)         | 118 (30.8)      | 58 (29.9)        | 20 (23.5)         | 8 (25)            | 15 (28.8) |
| Quite a bit  | 2 (15.4)     | 15 (18.5)         | 73 (19.1)       | 33 (17)          | 16 (18.8)         | 5 (15.6)          | 4 (7.7)   |
| A great deal   | 5 (38.5)     | 13 (16)           | 48 (12.5)       | 22 (11.3)        | 12 (14.1)         | 2 (6.3)           | 7 (13.5)  |
| Total n  | 13           | 77                | 373             | 190              | 83                | 31                | 50        |
| <i>n= 817</i>  |              |                   |                 |                  |                   |                   |           |
| chi-square *39.700   |              |                   |                 |                  |                   |                   |           |
| *p=0.023   |              |                   |                 |                  |                   |                   |           |
| Note: Number in parenthesis represents the percentage of the number of individuals responding for each group |              |                   |                 |                  |                   |                   |           |
| <i>Question: I feel socially stigmatized for having this disease</i>   |              |                   |                 |                  |                   |                   |           |
|  | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|  | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 1 (7.7)      | 8 (9.9)           | 40 (10.4)       | 16 (8.2)         | 17 (20)           | 10 (31.3)         | 11 (21.2) |
| Slightly   | 1 (7.7)      | 15 (18.5)         | 102 (26.6)      | 57 (29.4)        | 21 (24.7)         | 7 (21.9)          | 19 (36.5) |
| Moderately   | 5 (38.5)     | 15 (18.5)         | 89 (23.2)       | 46 (23.7)        | 21 (24.7)         | 11 (34.4)         | 6 (11.5)  |
| Quite a bit  | 2 (15.2)     | 17 (21)           | 78 (20.4)       | 43 (22.2)        | 8 (9.4)           | 4 (12.5)          | 8 (15.4)  |
| A great deal   | 4 (30.8)     | 23 (28.4)         | 67 (17.5)       | 29 (14.9)        | 17 (20)           | 0                 | 5 (9.6)   |

| Total n   | 13           | 78                | 376             | 191              | 84                | 32                | 49        |
|---|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
| <p><math>n= 823</math></p> <p>chi-square ***58.897</p> <p>***<math>p=0.000</math></p> <p>Note: Number in parenthesis represents the percentage of the number of individuals responding for each group</p> |              |                   |                 |                  |                   |                   |           |
| <i>Question: I feel like I am limited in eating meals with coworkers</i>  |              |                   |                 |                  |                   |                   |           |
|   | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|   | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all  | 0            | 4 (4.9)           | 5 (1.3)         | 10 (5.2)         | 5 (5.9)           | 7 (21.9)          | 8 (15.4)  |
| Slightly  | 1 (7.7)      | 5 (6.2)           | 46 (12)         | 24 (12.4)        | 20 (23.5)         | 7 (21.9)          | 11 (21.2) |
| Moderately  | 2 (15.4)     | 9 (11.1)          | 75 (19.6)       | 29 (14.9)        | 19 (22.4)         | 6 (18.8)          | 10 (19.2) |
| Quite a bit   | 4 (30.8)     | 23 (28.4)         | 112 (29.2)      | 61 (31.4)        | 14 (16.5)         | 7 (21.9)          | 8 (15.4)  |
| A great deal  | 6 (46.2)     | 37 (45.7)         | 138 (36)        | 66 (34)          | 26 (30.6)         | 5 (15.6)          | 12 (23.1) |
| Total n   | 13           | 78                | 376             | 190              | 84                | 32                | 49        |
| <p><math>n= 822</math></p> <p>chi-square ***80.768</p> <p>***<math>p=0.000</math></p> <p>Note: Number in parenthesis represents the percentage of the number of individuals responding for each group</p> |              |                   |                 |                  |                   |                   |           |
| <i>Question: I feel like I am not able to have special foods like birthday cake and pizza</i>   |              |                   |                 |                  |                   |                   |           |
|   | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |

|   | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
|---|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
| Not at all  | 1 (7.7)      | 10 (12.3)         | 38 (9.9)        | 36 (18.6)        | 23 (27.1)         | 12 (37.5)         | 12 (23.1) |
| Slightly  | 1 (7.7)      | 9 (11.1)          | 80 (20.9)       | 37 (19.1)        | 17 (20.0)         | 8 (25)            | 10 (19.2) |
| Moderately  | 1 (7.7)      | 22 (27.2)         | 79 (20.6)       | 40 (20.6)        | 14 (16.5)         | 4 (12.5)          | 9 (17.3)  |
| Quite a bit   | 3 (23.1)     | 14 (17.3)         | 81 (21.1)       | 34 (17.5)        | 16 (18.8)         | 6 (18.8)          | 10 (19.2) |
| A great deal  | 7 (53.8)     | 23 (28.4)         | 98 (25.6)       | 43 (22.2)        | 13 (15.3)         | 2 (6.3)           | 7 (13.5)  |
| Total n   | 13           | 78                | 376             | 190              | 83                | 32                | 48        |
| <p><math>n= 820</math></p> <p>chi-square ***54.748</p> <p>***<math>p=0.000</math></p> <p>Note: Number in parenthesis represents the percentage of the number of individuals responding for each group</p> |              |                   |                 |                  |                   |                   |           |
| <i>Question: I feel depressed because of my disease</i>   |              |                   |                 |                  |                   |                   |           |
|   | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|   | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all  | 2 (15.4)     | 20 (24.7)         | 119 (31.1)      | 65 (33.5)        | 37 (43.5)         | 14 (46.9)         | 27 (51.9) |
| Slightly  | 5 (38.5)     | 22 (27.2)         | 130 (33.9)      | 73 (37.6)        | 25 (29.4)         | 14 (43.8)         | 11 (21.2) |
| Moderately  | 2 (15.4)     | 21 (25.9)         | 76 (19.8)       | 31 (16)          | 12 (14.1)         | 2 (6.3)           | 5 (9.6)   |
| Quite a bit   | 3 (23.1)     | 11 (13.6)         | 32 (8.4)        | 17 (8.8)         | 6 (7.1)           | 0                 | 2 (3.8)   |
| A great deal  | 1 (7.7)      | 4 (4.9)           | 17 (4.4)        | 3 (1.5)          | 3 (3.5)           | 0                 | 3 (5.8)   |
| Total n   | 13           | 78                | 374             | 189              | 83                | 31                | 48        |
| <p><math>n= 816</math></p> <p>chi-square **44.442</p> <p>**<math>p=0.007</math></p>   |              |                   |                 |                  |                   |                   |           |

| Note: Number in parenthesis represents the percentage of the number of individuals responding for each group |              |                   |                 |                  |                   |                   |           |
|--|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
| <i>Question: I feel frightened by having this disease</i>  |              |                   |                 |                  |                   |                   |           |
|  | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|  | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 1 (7.7)      | 15 (18.5)         | 137 (35.8)      | 75 (38.7)        | 47 (5.3)          | 19 (59.4)         | 32 (61.5) |
| Slightly   | 6 (46.2)     | 32 (39.5)         | 134 (35)        | 71 (36.6)        | 23 (27.1)         | 9 (28.1)          | 4 (7.7)   |
| Moderately   | 3 (23.1)     | 18 (22.2)         | 70 (18.3)       | 30 (15.5)        | 9 (10.6)          | 3 (9.4)           | 8 (15.4)  |
| Quite a bit  | 2 (15.4)     | 8 (9.9)           | 19 (5)          | 10 (5.2)         | 3 (3.5)           | 0                 | 1 (1.9)   |
| A great deal   | 1 (7.7)      | 5 (6.2)           | 12 (3.1)        | 2 (1)            | 2 (2.4)           | 0                 | 3 (5.8)   |
| Total n  | 13           | 78                | 372             | 188              | 84                | 31                | 48        |
| n= 814   |              |                   |                 |                  |                   |                   |           |
| chi-square ***67.212   |              |                   |                 |                  |                   |                   |           |
| ***p=0.000   |              |                   |                 |                  |                   |                   |           |
| Note: Number in parenthesis represents the percentage of the number of individuals responding for each group |              |                   |                 |                  |                   |                   |           |
| <i>Question: I feel like I don't know enough about the disease</i>   |              |                   |                 |                  |                   |                   |           |
|  | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|  | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 3 (23.1)     | 18 (22.2)         | 150 (39.2)      | 111 (57.2)       | 60 (70.6)         | 22 (68.8)         | 29 (55.8) |
| Slightly   | 5 (38.5)     | 24 (29.6)         | 141 (36.8)      | 49 (25.3)        | 20 (23.5)         | 8 (25)            | 12 (23.1) |
| Moderately   | 1 (7.7)      | 20 (24.7)         | 60 (15.7)       | 22 (11.3)        | 1 (1.2)           | 1 (3.1)           | 6 (11.5)  |

|              |          |           |          |         |         |    |         |
|--------------|----------|-----------|----------|---------|---------|----|---------|
| Quite a bit  | 0        | 11 (13.6) | 15 (3.9) | 6 (3.1) | 2 (2.4) | 0  | 1 (1.9) |
| A great deal | 4 (30.8) | 4 (4.9)   | 8 (2.1)  | 0       | 1 (1.2) | 0  | 0       |
| Total n      | 13       | 77        | 374      | 188     | 84      | 31 | 48      |

$n= 815$

chi-square \*\*\*149.903

\*\*\* $p=0.000$

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

*Question: I feel overwhelmed about having the disease*

|              | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|--------------|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
|              | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 2 (15.4)     | 8 (9.9)           | 119 (31.1)      | 78 (40.2)        | 45 (52.9)         | 17 (53.1)         | 27 (51.9) |
| Slightly     | 2 (15.4)     | 24 (29.6)         | 134 (35)        | 64 (33)          | 24 (28.2)         | 13 (40.6)         | 11 (21.2) |
| Moderately   | 4 (30.8)     | 19 (23.5)         | 71 (18.5)       | 29 (14.9)        | 10 (11.8)         | 1 (3.1)           | 3 (5.8)   |
| Quite a bit  | 3 (23.1)     | 20 (24.7)         | 33 (8.6)        | 13 (6.7)         | 4 (4.7)           | 0                 | 3 (5.8)   |
| A great deal | 2 (15.4)     | 6 (7.4)           | 16 (4.2)        | 5 (2.6)          | 1 (1.2)           | 0                 | 3 (5.8)   |
| Total n      | 13           | 77                | 373             | 189              | 84                | 31                | 47        |

$n= 814$

chi-square \*\*\*96.048

\*\*\* $p=0.000$

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

*Question: I have trouble socializing because of my disease*

|  | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|--|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
|  | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 1 (7.7)      | 18 (22.2)         | 108 (28.2)      | 65 (33.5)        | 33 (38.8)         | 16 (50)           | 19 (36.5) |
| <i>Slightly</i>  | 5 (38.5)     | 21 (25.9)         | 117 (30.5)      | 55 (28.4)        | 25 (29.4)         | 10 (31.3)         | 18 (34.6) |
| Moderately   | 1 (7.7)      | 18 (22.2)         | 79 (20.6)       | 33 (17)          | 11 (12.9)         | 2 (6.3)           | 4 (7.7)   |
| Quite a bit  | 3 (23.1)     | 11 (13.6)         | 40 (10.4)       | 26 (13.4)        | 10 (11.8)         | 3 (9.4)           | 3 (5.8)   |
| A great deal   | 3 (23.1)     | 10 (12.3)         | 30 (7.8)        | 9 (4.6)          | 5 (5.9)           | 0                 | 3 (5.8)   |
| Total n  | 13           | 78                | 374             | 188              | 84                | 31                | 47        |
| <i>n</i> = 815   |              |                   |                 |                  |                   |                   |           |
| chi-square *39.476   |              |                   |                 |                  |                   |                   |           |
| * <i>p</i> =0.024  |              |                   |                 |                  |                   |                   |           |
| Note: Number in parenthesis represents the percentage of the number of individuals responding for each group |              |                   |                 |                  |                   |                   |           |
| <i>Question: I find it difficult to travel or take long trips because of my disease</i>                      |              |                   |                 |                  |                   |                   |           |
|  | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|  | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 0            | 5 (6.2)           | 44 (11.5)       | 20 (10.3)        | 14 (16.5)         | 5 (15.6)          | 9 (17.3)  |
| <i>Slightly</i>  | 0            | 15 (18.5)         | 83 (21.7)       | 61 (31.4)        | 22 (25.9)         | 11 (34.4)         | 14 (26.9) |
| Moderately   | 6 (46.2)     | 18 (22.2)         | 87 (22.7)       | 43 (22.2)        | 19 (22.4)         | 9 (28.1)          | 12 (23.1) |
| Quite a bit  | 1 (7.7)      | 19 (23.5)         | 86 (22.5)       | 39 (20.1)        | 9 (10.6)          | 3 (9.4)           | 5 (9.6)   |
| A great deal   | 6 (46.2)     | 21 (25.9)         | 73 (19.1)       | 25 (12.9)        | 20 (23.5)         | 3 (9.4)           | 8 (15.4)  |
| Total n  | 13           | 78                | 373             | 188              | 84                | 31                | 48        |
| <i>n</i> = 815   |              |                   |                 |                  |                   |                   |           |

chi-square \*\*46.636

\*\*p=0.004

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

*Question: I feel like I cannot live a normal life because of my disease*

|              | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|--------------|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
|              | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 0            | 8 (9.9)           | 94 (24.5)       | 57 (29.4)        | 32 (37.6)         | 17 (53.1)         | 20 (38.5) |
| Slightly     | 4 (30.8)     | 24 (29.6)         | 132 (34.5)      | 65 (33.5)        | 23 (27.1)         | 8 (25)            | 15 (28.8) |
| Moderately   | 2 (15.4)     | 25 (30.9)         | 61 (15.9)       | 31 (16)          | 13 (15.3)         | 5 (15.6)          | 6 (11.5)  |
| Quite a bit  | 6 (46.2)     | 10 (12.3)         | 53 (13.8)       | 23 (11.9)        | 6 (7.1)           | 0                 | 2 (3.8)   |
| A great deal | 1 (7.7)      | 11 (13.6)         | 33 (8.6)        | 13 (6.7)         | 10 (11.8)         | 1 (3.1)           | 5 (9.6)   |
| Total n      | 13           | 78                | 373             | 189              | 84                | 31                | 48        |

n= 816

chi-square \*\*\*67.806

\*\*\*p=0.000

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

*Question: I feel afraid to eat out because my food may be contaminated*

|            | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years |
|------------|--------------|-------------------|-----------------|------------------|-------------------|-------------------|----------|
|            | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)    |
| Not at all | 0            | 0                 | 14 (3.7)        | 6 (3.1)          | 5 (5.9)           | 6 (18.8)          | 6 (11.5) |

|              |          |           |           |           |           |          |           |
|--------------|----------|-----------|-----------|-----------|-----------|----------|-----------|
| Slightly     | 1 (7.7)  | 11 (13.6) | 68 (17.8) | 47 (24.2) | 24 (28.2) | 8 (25)   | 12 (23.1) |
| Moderately   | 3 (23.1) | 22 (27.2) | 84 (21.9) | 58 (29.9) | 21 (24.7) | 5 (15.6) | 8 (15.4)  |
| Quite a bit  | 3 (23.1) | 15 (18.5) | 91 (23.8) | 29 (14.9) | 15 (17.6) | 9 (28.1) | 9 (17.3)  |
| A great deal | 6 (46.2) | 30 (37)   | 115 (30)  | 46 (23.7) | 18 (21.2) | 3 (9.4)  | 12 (23.1) |
| Total n      | 13       | 78        | 372       | 186       | 85        | 31       | 47        |

$n= 810$

chi-square \*\*60.237

\*\*\* $p=0.000$

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

*Question: I feel worried about the increased risk of one of my family members having celiac disease*

|              | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|--------------|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
|              | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 1 (7.7)      | 7 (8.6)           | 40 (10.4)       | 21 (10.8)        | 11 (12.9)         | 3 (9.4)           | 11 (21.2) |
| Slightly     | 0            | 15 (18.5)         | 79 (20.6)       | 44 (22.7)        | 18 (21.2)         | 14 (43.8)         | 12 (23.1) |
| Moderately   | 3 (23.1)     | 22 (27.2)         | 98 (25.6)       | 51 (26.3)        | 22 (25.9)         | 9 (28.1)          | 6 (11.5)  |
| Quite a bit  | 4 (30.8)     | 18 (22.2)         | 93 (24.3)       | 35 (18)          | 20 (23.5)         | 3 (9.4)           | 4 (7.7)   |
| A great deal | 5 (38.5)     | 16 (19.8)         | 62 (16.2)       | 37 (19.1)        | 12 (14.1)         | 2 (6.3)           | 15 (28.8) |
| Total n      | 13           | 78                | 372             | 188              | 83                | 31                | 48        |

$n= 813$

chi-square \*41.925

\* $p=0.013$

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

*Question: I feel like I think about food all the time*

|              | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|--------------|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
|              | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all   | 0            | 10 (12.3)         | 60 (15.7)       | 43 (22.2)        | 25 (29.4)         | 11 (34.4)         | 20 (38.5) |
| Slightly     | 1 (7.7)      | 16 (19.8)         | 82 (21.4)       | 42 (21.6)        | 17 (20)           | 7 (21.9)          | 10 (19.2) |
| Moderately   | 4 (30.8)     | 16 (19.8)         | 83 (21.7)       | 34 (17.5)        | 19 (22.4)         | 5 (15.6)          | 9 (17.3)  |
| Quite a bit  | 2 (15.4)     | 21 (25.9)         | 85 (22.2)       | 40 (20.6)        | 12 (14.1)         | 2 (6.3)           | 7 (13.5)  |
| A great deal | 6 (46.2)     | 15 (18.5)         | 63 (16.4)       | 28 (14.4)        | 10 (11.8)         | 6 (18.8)          | 2 (3.8)   |
| Total n      | 13           | 78                | 373             | 187              | 83                | 31                | 48        |

$n = 813$

chi-square \*\*51.186

\*\* $p = 0.001$

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

*Question: I feel concerned that my long-term health will be affected*

|            | <3<br>months | 3 mo to 1<br>year | 1 to 5<br>years | 6 to 10<br>years | 11 to 15<br>years | 16 to 20<br>years | 21 years  |
|------------|--------------|-------------------|-----------------|------------------|-------------------|-------------------|-----------|
|            | n (%)        | n (%)             | n (%)           | n (%)            | n (%)             | n (%)             | n (%)     |
| Not at all | 0            | 2 (2.5)           | 21 (5.5)        | 15 (7.7)         | 9 (10.6)          | 5 (15.6)          | 10 (19.2) |
| Slightly   | 3 (23.1)     | 15 (18.5)         | 82 (21.4)       | 53 (27.3)        | 21 (24.7)         | 10 (31.3)         | 11 (21.2) |
| Moderately | 4 (30.8)     | 23 (28.4)         | 112 (29.2)      | 55 (28.4)        | 20 (23.5)         | 9 (28.1)          | 12 (23.1) |

|  |          |           |           |           |           |          |           |
|--|----------|-----------|-----------|-----------|-----------|----------|-----------|
| Quite a bit  | 3 (23.1) | 21 (25.9) | 109 (2.5) | 40 (20.6) | 22 (25.9) | 6 (18.8) | 4 (7.7)   |
| A great deal   | 3 (23.1) | 16 (19.8) | 49 (12.8) | 25 (12.9) | 10 (11.8) | 1 (3.1)  | 11 (21.2) |
| Total n  | 13       | 77        | 373       | 188       | 82        | 31       | 48        |
| <i>n</i> = 812<br><i>chi-square</i> **43.853<br>** <i>p</i> =0.008<br>Note: Number in parenthesis represents the percentage of the number of individuals responding for each group |          |           |           |           |           |          |           |

Table 2. Comparison of length of time on the gluten-free diet on quality of life

Additionally, the CD-QOL responses comparing those who strictly follow the gluten-free diet and those who do not strictly follow the gluten-free diet were analyzed using Chi-square. Four questions were statistically significant, showing the effect that following the gluten-free diet or not following the gluten-free diet has on quality of life. The answers are shown in table 3 below.

|   |                  |    |                 |     |
|---|------------------|----|-----------------|-----|
| The Effect of Strictly Following the Gluten-free Diet on Quality of Life of Individuals With Celiac Disease |                  |    |                 |     |
| <i>Question: I feel concerned that this disease will cause other health problems</i>                        |                  |    |                 |     |
|   | Strictly follows |    | Does not follow |     |
|   | n                | %  | n               | %   |
| Not at all  | 30               | 4% | 4               | 14% |

|              |     |     |    |     |
|--------------|-----|-----|----|-----|
| Slightly     | 165 | 21% | 7  | 24% |
| Moderately   | 253 | 32% | 8  | 28% |
| Quite a bit  | 219 | 28% | 3  | 10% |
| A great deal | 125 | 16% | 7  | 24% |
| Total n      | 792 |     | 29 |     |

chi-square \*11.389

\*p=0.023

| <i>Question: I feel like I don't know enough about the disease</i> |                  |     |                 |     |
|--|------------------|-----|-----------------|-----|
|  | Strictly follows |     | Does not follow |     |
|  | n                | %   | n               | %   |
| Not at all   | 385              | 49% | 8               | 29% |
| Slightly   | 250              | 32% | 8               | 29% |
| Moderately   | 107              | 14% | 4               | 14% |
| Quite a bit  | 29               | 4%  | 6               | 21% |
| A great deal   | 15               | 2%  | 2               | 7%  |
| Total n  | 786              |     | 28              |     |

chi-square \*\*\*25.765

\*\*\*p=0.000

| <i>Question: I find it difficult to travel or take long trips because of my disease</i> |                  |                 |
|---|------------------|-----------------|
|   | Strictly follows | Does not follow |

|              | n   | %   | n  | %   |
|--------------|-----|-----|----|-----|
| Not at all   | 88  | 11% | 9  | 32% |
| Slightly     | 199 | 25% | 7  | 25% |
| Moderately   | 192 | 24% | 2  | 7%  |
| Quite a bit  | 155 | 20% | 6  | 21% |
| A great deal | 152 | 19% | 4  | 14% |
| Total n      | 786 |     | 28 |     |

chi-square \*\*13.746

\*\*p=0.008

| <i>Question: I feel afraid to eat out because my food may be contaminated</i> |                  |     |                 |     |
|---|------------------|-----|-----------------|-----|
|   | Strictly follows |     | Does not follow |     |
|   | n                | %   | n               | %   |
| Not at all  | 31               | 4%  | 6               | 21% |
| Slightly  | 165              | 21% | 6               | 21% |
| Moderately  | 193              | 25% | 8               | 29% |
| Quite a bit   | 164              | 21% | 6               | 21% |
| A great deal  | 228              | 29% | 2               | 7%  |
| Total n   | 781              |     | 28              |     |

chi-square \*\*\*22.805

\*\*\*p=0.000

Table 3. Comparison of strictly following a gluten-free diet and not strictly following a gluten-free diet on quality of life

Finally, the researcher compared age groups and the effect of age on the quality of life. However, since the participants were allowed to write in their age instead of selecting from a drop down option, a number of them chose not to put in their age at all and a few entered in an invalid age such as 141 years or 2 years. The researcher categorized the valid responses into 18-25 years old, 26-36 years old, 36-45 years old, 46-55 years old, and 56 years or more. Using Chi-square, the responses to four questions were statistically significant and showed that age can affect the quality of life of individuals with celiac disease. The responses to those questions are listed below in table 4.

| The Effect of Age on Quality of Life of Individuals With Celiac Disease |           |     |           |     |           |     |           |     |           |     |
|---|-----------|-----|-----------|-----|-----------|-----|-----------|-----|-----------|-----|
| <i>Question: I feel worried that I will suffer from this disease</i>    |           |     |           |     |           |     |           |     |           |     |
|   | 18-25     |     | 26-35     |     | 36-45     |     | 46-55     |     | 56+ years |     |
|   | years old |     | years old |     | years old |     | years old |     | old       |     |
|   | n         | %   | n         | %   | n         | %   | n         | %   | n         | %   |
| Not at all  | 8         | 8%  | 24        | 14% | 21        | 10% | 20        | 11% | 26        | 17% |
| Slightly  | 20        | 20% | 53        | 30% | 62        | 31% | 57        | 30% | 49        | 32% |
| Moderately  | 38        | 38% | 57        | 32% | 59        | 29% | 53        | 28% | 46        | 30% |
| Quite a bit   | 23        | 23% | 27        | 15% | 42        | 21% | 35        | 19% | 23        | 15% |
| A great deal  | 10        | 10% | 15        | 9%  | 17        | 8%  | 22        | 12% | 11        | 7%  |

|         |    |  |     |  |     |  |     |  |     |  |
|---------|----|--|-----|--|-----|--|-----|--|-----|--|
| Total n | 99 |  | 176 |  | 201 |  | 187 |  | 155 |  |
|---------|----|--|-----|--|-----|--|-----|--|-----|--|

chi-square \*304.505

\*p=0.044

| <i>Question: I feel like I am limited in eating meals with coworkers</i> |                    |     |                    |     |                    |     |                    |     |                  |     |
|--|--------------------|-----|--------------------|-----|--------------------|-----|--------------------|-----|------------------|-----|
|  | 18-25<br>years old |     | 26-35<br>years old |     | 36-45<br>years old |     | 46-55<br>years old |     | 56+ years<br>old |     |
|  | n                  | %   | n                  | %   | n                  | %   | n                  | %   | n                | %   |
| Not at all   | 1                  | 1%  | 7                  | 4%  | 8                  | 4%  | 9                  | 5%  | 13               | 8%  |
| Slightly   | 11                 | 11% | 17                 | 10% | 29                 | 14% | 22                 | 12% | 34               | 22% |
| Moderately   | 20                 | 20% | 31                 | 18% | 28                 | 14% | 39                 | 22% | 32               | 21% |
| Quite a bit  | 32                 | 31% | 55                 | 31% | 66                 | 33% | 34                 | 19% | 39               | 25% |
| A great deal   | 38                 | 37% | 66                 | 38% | 70                 | 35% | 73                 | 41% | 38               | 24% |
| Total n  | 102                |     | 176                |     | 201                |     | 177                |     | 156              |     |

chi-square \*\*338.542

\*\*p=0.001

| <i>Question: I feel afraid to eat out because my food may be contaminated</i> |                    |     |                    |     |                    |     |                    |     |                  |    |
|---|--------------------|-----|--------------------|-----|--------------------|-----|--------------------|-----|------------------|----|
|   | 18-25<br>years old |     | 26-35<br>years old |     | 36-45<br>years old |     | 46-55<br>years old |     | 56+ years<br>old |    |
|   | n                  | %   | n                  | %   | n                  | %   | n                  | %   | n                | %  |
| Not at all  | 2                  | 2%  | 4                  | 2%  | 9                  | 5%  | 8                  | 5%  | 14               | 9% |
| Slightly  | 16                 | 16% | 40                 | 23% | 36                 | 18% | 39                 | 22% | 40               | 9% |

|              |     |     |     |     |     |     |     |     |     |     |
|--------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Moderately   | 28  | 28% | 37  | 21% | 44  | 22% | 45  | 26% | 43  | 28% |
| Quite a bit  | 17  | 17% | 31  | 18% | 53  | 27% | 40  | 23% | 30  | 20% |
| A great deal | 37  | 37% | 61  | 35% | 58  | 29% | 44  | 25% | 26  | 17% |
| Total n      | 100 |     | 173 |     | 200 |     | 176 |     | 153 |     |

chi-square \*\*345.210

\*\*p=0.001

| <i>Question: I feel concerned that my long-term health will be affected</i> |           |     |           |     |           |     |           |     |           |     |
|---|-----------|-----|-----------|-----|-----------|-----|-----------|-----|-----------|-----|
|   | 18-25     |     | 26-35     |     | 36-45     |     | 46-55     |     | 56+ years |     |
|   | years old |     | years old |     | years old |     | years old |     | old       |     |
|   | n         | %   | n         | %   | n         | %   | n         | %   | n         | %   |
| Not at all  | 5         | 5%  | 14        | 8%  | 12        | 6%  | 5         | 3%  | 24        | 16% |
| Slightly  | 23        | 23% | 38        | 22% | 46        | 23% | 48        | 28% | 40        | 26% |
| Moderately  | 23        | 23% | 43        | 25% | 69        | 35% | 55        | 32% | 35        | 23% |
| Quite a bit   | 29        | 29% | 49        | 28% | 47        | 24% | 48        | 28% | 31        | 20% |
| A great deal  | 20        | 20% | 30        | 17% | 23        | 12% | 18        | 10% | 23        | 15% |
| Total n   | 100       |     | 174       |     | 197       |     | 174       |     | 153       |     |

chi-square \*\*\*366.603

\*\*\*p=0.000

Table 4. Comparison of age on quality of life

#### **Gluten-free Fad Diet Perceptions**

The participants then answered nine questions that the primary researcher developed. These questions were rated on the Likert scale similar to the CD-QOL, but answered with either: strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree. The first question stated: "I find myself defending my need to eat gluten-free when out in public." Of 803 responses, 26 (3%) participants responded "strongly disagree", 64 (8%) participants responded "disagree", 99 (12%) participants responded "neither agree nor disagree", 347 (43%) participants responded "agree", and 267 (33%) participants responded "strongly agree." The next question asked the participants to rate the phrase: "I believe that people, outside of my family and friends, understand the severity of celiac disease." Of 812 responses, 445 (55%) participants responded "strongly disagree", 290 (36%) participants responded "disagree", 40 (5%) participants responded "neither agree nor disagree", 25 (3%) participants responded "agree", and 12 (1%) participants responded "strongly agree." The next question stated: "The attention that the gluten-free diet receives in the media, due to other people eating gluten-free outside of medical advice, is helpful for celiac disease. Of 803 responses, 285 (35%) participants responded "strongly disagree", 247 (31%) participants responded "disagree", 155 (19%) participants responded "neither agree nor disagree", 101 (13%) participants responded "agree", and 15 (2%) participants responded "strongly agree."

Next the survey asked the participants to rate the phrase: "The term "gluten intolerance" is appropriate for celiac disease. Of 810 responses, 504 (62%) participants responded "strongly disagree", 187 (23%) participants responded "disagree", 64 (8%)

participants responded “neither agree nor disagree”, 48 (6%) participants responded “agree”, and 7 (1%) participants responded “strongly agree.” The survey then asked: “People, outside of my family and friends, understand that cross-contamination of gluten can make me sick. A total of 806 participants responded with 459 (57%) participants responded “strongly disagree”, 252 (31%) participants responded “disagree”, 48 (5%) participants responded “neither agree nor disagree”, 36 (4%) participants responded “agree”, and 11 (1%) participants responded “strongly agree.” Next, the survey asked the participants to respond to the phrase: “I feel safe ordering off gluten-free menus at most restaurants. Of 807 responses, 163 (20%) participants responded “strongly disagree”, 297 (37%) participants responded “disagree”, 180 (22%) participants responded “neither agree nor disagree”, 159 (20%) participants responded “agree”, and 8 (1%) participants responded “strongly agree.”

Then, the survey asked the participants “I think restaurant personnel take celiac disease seriously.” Of 807 responses, 216 (27%) participants responded “strongly disagree”, 335 (42%) participants responded “disagree”, 178 (22%) participants responded “neither agree nor disagree”, 71 (9%) participants responded “agree”, and 7 (1%) participants responded “strongly agree.” The survey then asked the participants to rate the phrase: “I am satisfied with the current dietary treatment for celiac disease.” Of 803 responses, 122 (15%) participants responded “strongly disagree”, 232 (29%) participants responded “disagree”, 224 (28%) participants responded “neither agree nor disagree”, 182 (23%) participants responded “agree”, and 43 (5%) participants responded

“strongly agree.” Finally, the survey asked the participants to rate the phrase: “I believe celiac disease is represented honestly in the media.” Of 799 responses, 317 (40%) participants responded “strongly disagree”, 276 (35%) participants responded “disagree”, 155 (19%) participants responded “neither agree nor disagree”, 50 (6%) participants responded “agree”, and 1 (0%) participants responded “strongly agree.”

The researcher compared responses by participants based on time since diagnosis, comparing those diagnosed under three months prior to the survey, three months to one year prior to the survey, one year to five years prior to the survey, six years to ten years prior to the survey, 11 to 15 years prior to the survey, 16 to 20 years prior to the survey, and 21 years or more prior to the survey. Using Chi-square, 2 of the 9 questions were statistically significant for time since diagnosis having an effect on the perception of the gluten-free fad diet. The results from these questions are listed below in table 5.

| The Effect of Time Since Diagnosis on the Perception of the Gluten-free Fad Diet in Individuals With Celiac Disease |           |                |              |               |                |                |           |
|---|-----------|----------------|--------------|---------------|----------------|----------------|-----------|
| <i>Question: I feel safe ordering off gluten-free menus at most restaurants</i>                                     |           |                |              |               |                |                |           |
|   | <3 months | 3 mo to 1 year | 1 to 5 years | 6 to 10 years | 11 to 15 years | 16 to 20 years | 21 years  |
|   | n (%)     | n (%)          | n (%)        | n (%)         | n (%)          | n (%)          | n (%)     |
| Strongly Disagree   | 7 (53.8)  | 18 (22.2)      | 75 (19.6)    | 32 (16.5)     | 17 (20)        | 2 (6.3)        | 12 (23.1) |
| Disagree  | 3         | 27             | 145          | 68 (35.1)     | 30             | 10             | 14        |

|           |         |          |           |           |         |          |         |
|-----------|---------|----------|-----------|-----------|---------|----------|---------|
|           | (23.1)  | (33.3)   | (37.9)    |           | (35.3)  | (31.3)   | (26.9)  |
| Neither   |         |          |           |           |         |          |         |
| Agree nor | 2       | 21       |           |           | 16      |          |         |
| Disagree  | (15.4)  | (25.9)   | 81 (21.1) | 40 (20.6) | (18.8)  | 7 (21.9) | 13 (25) |
| Agree     | 1 (7.7) | 9 (11.1) | 65 (17)   | 46 (23.7) | (22.4)  | (31.3)   | (17.3)  |
| Strongly  |         |          |           |           |         |          |         |
| Agree     | 0       | 0        | 4 (1)     | 1 (0.5)   | 1 (1.2) | 2 (6.3)  | 0       |
| Total n   | 13      | 75       | 370       | 187       | 85      | 31       | 48      |

chi-square \*37.070

\*p=0.043

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

| <i>Question: The attention that the gluten-free diet receives in the media, due to other people eating gluten-free outside of medical advice is helpful for celiac disease</i> |           |                |              |               |                |                |          |
|--|-----------|----------------|--------------|---------------|----------------|----------------|----------|
|  | <3 months | 3 mo to 1 year | 1 to 5 years | 6 to 10 years | 11 to 15 years | 16 to 20 years | 21 years |
|  | n (%)     | n (%)          | n (%)        | n (%)         | n (%)          | n (%)          | n (%)    |
| Strongly   | 4         | 33             | 139          |               | 30             |                | 16       |
| Disagree   | (30.8)    | (40.7)         | (36.3)       | 55 (28.4)     | (35.3)         | 8 (25)         | (30.8)   |
| Disagree   | 5         | 18             | 108          | 74 (38.1)     | 20             | 10             | 12       |
|  | (38.6)    | (22.2)         | (28.2)       |               | (23.5)         | (31.3)         | (23.1)   |

|           |         |         |           |           |         |          |        |
|-----------|---------|---------|-----------|-----------|---------|----------|--------|
| Neither   |         |         |           |           |         |          |        |
| Agree nor | 3       |         |           |           | 13      |          | 14     |
| Disagree  | (23.1)  | 13 (16) | 80 (20.9) | 29 (14.9) | (15.3)  | 3 (9.4)  | (26.9) |
|           |         |         |           |           | 15      |          | 6      |
| Agree     | 1 (7.7) | 7 (8.6) | 40 (10.4) | 25 (12.9) | (17.6)  | 7 (21.9) | (11.5) |
| Strongly  |         |         |           |           |         |          |        |
| Agree     | 0       | 2 (2.5) | 3 (0.8)   | 2 (1)     | 5 (5.9) | 3 (9.4)  | 0      |
| Total n   | 13      | 73      | 370       | 185       | 83      | 31       | 48     |

chi-square \*\*48.679

\*\*p=0.002

Note: Number in parenthesis represents the percentage of the number of individuals responding for each group

Table 5. Comparison of length of time on the gluten-free diet on perception of the effects of the gluten free diet

Next, the researcher used Chi-square to analyze the effect of gluten-free diet adherence on fad diet perception but there was no statistical significance in the responses. Finally, the researcher used Chi-square to compare age groups and the effect of age on the perception of the gluten-free fad diet. Again, since the participants were allowed to free write in their age, a number of them chose not to put in their age at all and a few entered in an invalid age such as 141 years or 2 years. The researcher categorized the valid responses into 18-25 years old, 26-36 years old, 36-45 years old, 46-55 years old,

and 56 years or more. The responses to two questions were statistically significant. The responses to those questions are listed below in table 6.

| The Effect of Age on the Perception of the Gluten-free Fad Diet in Individuals With Celiac Disease                  |                    |     |                    |     |                    |     |                    |     |                  |     |
|---|--------------------|-----|--------------------|-----|--------------------|-----|--------------------|-----|------------------|-----|
| <i>Question: I believe that people, outside of my family and friends, understand the severity of celiac disease</i> |                    |     |                    |     |                    |     |                    |     |                  |     |
|   | 18-25<br>years old |     | 26-35<br>years old |     | 36-45<br>years old |     | 46-55<br>years old |     | 56+ years<br>old |     |
|   | n                  | %   | n                  | %   | n                  | %   | n                  | %   | n                | %   |
| Strongly Disagree   | 55                 | 55% | 97                 | 56% | 107                | 54% | 99                 | 57% | 84               | 55% |
| Disagree  | 38                 | 38% | 57                 | 33% | 73                 | 37% | 65                 | 37% | 50               | 32% |
| Neither Agree nor Disagree  | 4                  | 4%  | 10                 | 6%  | 10                 | 5%  | 6                  | 3%  | 10               | 6%  |
| Agree   | 3                  | 3%  | 7                  | 4%  | 5                  | 3%  | 4                  | 2%  | 5                | 3%  |
| Strongly Agree  | 0                  | 0%  | 3                  | 2%  | 3                  | 2%  | 1                  | 1%  | 5                | 3%  |
| Total n   | 100                |     | 174                |     | 198                |     | 175                |     | 154              |     |

chi-square \*\*325.506

\*\*p=0.006

| <i>Question: People, outside of my family and friends, understand that cross-contamination can make me sick</i> |       |       |       |       |           |
|---|-------|-------|-------|-------|-----------|
|   | 18-25 | 26-35 | 36-45 | 46-55 | 56+ years |
|   |       |       |       |       |           |

|                            | years old |     | years old |     | years old |     | years old |     | old |     |
|----------------------------|-----------|-----|-----------|-----|-----------|-----|-----------|-----|-----|-----|
|                            | n         | %   | n         | %   | n         | %   | n         | %   | n   | %   |
| Strongly Disagree          | 59        | 60% | 97        | 56% | 119       | 60% | 99        | 57% | 79  | 52% |
| Disagree                   | 26        | 26% | 52        | 30% | 60        | 30% | 57        | 33% | 53  | 35% |
| Neither Agree nor Disagree | 13        | 13% | 10        | 6%  | 6         | 3%  | 8         | 5%  | 10  | 7%  |
| Agree                      | 1         | 1%  | 10        | 6%  | 12        | 6%  | 7         | 4%  | 5   | 3%  |
| Strongly Agree             | 0         | 0%  | 3         | 2%  | 1         | 1%  | 3         | 2%  | 4   | 3%  |
| Total n                    | 99        |     | 172       |     | 198       |     | 174       |     | 151 |     |

chi-square \*\*\*367.428

\*\*\*p=0.000

Table 6. Comparison of age on perception of gluten-free fad diet trend

### Qualitative Analysis of Free Answer Question

The final portion of the survey consisted of one free-response answer question that asked the participants to respond in no more than five sentences: “How does other people following the gluten-free diet, outside of medical direction for celiac disease, irritable bowel syndrome, non-celiac gluten sensitivity, or wheat allergy, affect your life”? A total of 719 participants chose to answer this question.

Many of the responses had multiple themes in one answer, which highlighted the complexity of the problem. For example, one participant responded: “I have found that people following the diet outside medical reasons causes others to view my diet as

optional as well and therefore take it less seriously, often leading to a risk of exposure, either directly or by cross-contamination, as well as constant insensitive comments from people outside of my family.” This response was tallied under the themes: “Celiac disease is not taken seriously because people don't understand the severity of the disease”, “Other people think I am following a fad or that eating gluten-free is optional for me”, and “I feel judged or stigmatized by others because people make fun of the diet.” Another response, “On the one hand, it creates more gluten-free options available. On the other hand, people don't take my disease as seriously because they think I am a fad dieter, which is scary for my personal health”, was tallied under “Celiac disease is not taken seriously because people don't understand the severity of the disease” and “Other people think I am following a fad or that eating gluten-free is optional for me.” One respondent wrote: “In some ways, it has created a stigma that those who have those conditions do not need to actually avoid gluten. However, it has also increased the gluten-free options.” This response was coded under “I feel judged or stigmatized by others because people make fun of the diet” as well as “There is an increase of better quality gluten-free products that are more clearly labeled.” Listed below in table 7 is the total tally of the themes.

| <i>Negative Theme</i>   | Total | %   |
|---|-------|-----|
| Celiac disease is not taken seriously because people don't understand the severity of the disease | 331   | 46% |
| Gluten-free products are more expensive   | 9     | 1%  |

|  |     |     |
|--|-----|-----|
| It is irritating or upsetting that other people are eating gluten-free   | 33  | 5%  |
| I feel less safe eating out and feel the need to defend myself in public because restaurants do not understand | 171 | 24% |
| Other people think I am following a fad or that eating gluten-free is optional for me                          | 197 | 27% |
| I feel judged or stigmatized by others because people make fun of the diet                                     | 80  | 11% |
| There are more cross-contamination issues because there is a public misperception of true gluten-free          | 165 | 23% |
| <i>Positive Theme</i>  |     |     |
| It is beneficial because there is improved awareness about celiac disease                                      | 53  | 7%  |
| There is an increase of better quality gluten-free products that are more clearly labeled                      | 175 | 24% |
| It makes it easier to eat out because there are more options at restaurants                                    | 40  | 6%  |
| Gluten-free food is more affordable  | 12  | 2%  |
| <i>Neutral Theme</i>   |     |     |
| It does not affect me  | 36  | 5%  |

Table 7. Major themes of the perception of the gluten-free fad diet and the effects on quality of life

## **Discussion**

### **CD-QOL**

When the researcher analyzed the responses to the CD-QOL portion of the survey, it became apparent that having celiac disease negatively affects quality of life. In about half of the CD-QOL questions, more respondents felt “a great deal” affected than “not at all” affected by the disease. In general, the respondents felt “moderately” affected.

The areas that respondents felt the most affected by were in feeling limited by the disease, feeling concerned that the disease will cause other health problems, feeling socially stigmatized, feeling limited in eating meals with coworkers, feeling like they are not able to have special foods like birthday cake and pizza, feeling like there are not enough choices for treatment, finding it difficult to travel, feeling afraid to eat out because of food may be contaminated, feeling worried about family members having celiac disease, and feeling concerned that their long-term health will be affected. Many of the areas of quality of life that were the most affected were related to the need to follow the gluten-free diet such as not being able to have special foods, not being able to travel, being afraid of food being contaminated, or not being able to eat meals with coworkers. This shows that the gluten-free diet itself is responsible for a reduction in the quality of life. Furthermore, this may implicate that when the diet is ridiculed or people do not take it seriously, it can have negative effects on the quality of life of individuals with celiac disease.

The areas that the respondents felt the least affected by were in feeling worried that they would suffer from the disease, feeling worried about the increased risk of cancer from the disease, feeling like the diet is sufficient treatment, feeling depressed because of the disease, feeling frightened by the disease, feeling like they do not know enough about the disease, feeling overwhelmed about having the disease, having trouble socializing because of the disease, and feeling like they cannot live a normal life because of the disease. This shows that while the disease itself can still cause a reduction in the quality of life of individuals with celiac disease, the areas that are most affected are related to having to follow the gluten-free diet.

When the researcher compared length of time from diagnosis to quality of life, a trend emerged. Those who had been diagnosed more recently experienced a greater reduction in quality of life than those who had been living with the disease for a longer period of time. For example, those who had been diagnosed under three months prior to the survey felt the most limited by the disease, with 46.2% of the thirteen respondents stating that they felt limited by the disease “a great deal” or “quite a bit.” However, those who were diagnosed later did not feel as limited by the disease. The trend continued when the respondents rated the phrase “I feel worried that I will suffer from this disease.” Those who had been diagnosed under three months prior to the survey felt more worried that they would suffer from the disease than those who had been diagnosed longer with 38.5% of the thirteen respondents feeling “a great deal” or “quite a bit” worried. This trend continued for most of the survey with those diagnosed under three months prior to

the survey feeling the most concerned that the disease will cause other health problems, feeling worried about an increased risk of cancer, feeling socially stigmatized, feeling unable to have special foods, feeling like they do not know enough about the disease, finding it difficult to travel, feeling afraid to eat out because food may be contaminated, feeling worried about the increased risk of other family members having celiac disease, and feeling concerned that their long-term health will be affected. This may imply that a shorter length of time since diagnosis has a negative affect on quality of life. Better education at time of diagnosis may help to improve the quality of life of individuals recently diagnosed with celiac disease, although further research is needed.

When the researcher compared adherence to the gluten-free diet, those who did not strictly follow the gluten-free diet had a better quality of life compared to those who did strictly follow the diet. This further indicates that the gluten-free diet itself affects quality of life, implying that if the diet is not taken as seriously by others or is being ridiculed or thought of as a fad, quality of life can be negatively affected. Referring to table three, there were four questions that were statistically significant for the gluten-free diet having an effect on quality of life. The group that did not strictly follow the gluten-free diet had more respondents (14%) who were “not at all” concerned about other health problems compared to participants who strictly followed the gluten-free diet (4%). However, 24% of those who did not strictly follow the gluten-free diet were concerned “a great deal” about other health problems. Participants who strictly followed the gluten-free diet felt that they knew enough about the disease. When asked to rate the phrase “I feel

like I don't know enough about the disease", 81% of those who strictly follow the gluten-free diet stated "not at all" or "slightly." Fewer participants in the group that did not strictly follow the gluten-free diet, however, felt that they knew enough about the disease with 58% stating "not at all" or "slightly. This could show that a knowledge deficit about the disease can lead to lower rates of adherence further highlighting the need for better education at time of diagnosis.

Participants who did not strictly follow the diet found it easier to take long trips and were less afraid to eat out because of contamination. When asked if they found it difficult to take long trips, 32% of the group that did not strictly follow the diet stated "not at all" while only 11% of the group that did strictly follow the diet stated "not at all." Also, when asked if they felt afraid to eat out because their food may be contaminated, 21% of the group that did not strictly follow the diet stated "not at all" and only 7% stated "a great deal", while 4% of the group that strictly followed the diet stated "not at all" and 29% stated "a great deal." These findings indicate that those who do not strictly adhere to the diet are less worried about traveling or eating out compared to those who strictly follow the diet. By eliminating the worry about cross-contamination or accidental gluten ingestion, a complementary pharmacological treatment could improve quality of life by allowing individuals with celiac disease to not strictly follow the gluten-free diet when dining out or traveling. This could help to normalize the way individuals with celiac disease experience those events and minimize the worry and stress that they feel, thus increasing their quality of life.

Age also appeared to have an effect on quality of life; the older a person who has celiac disease is, the less the disease impacts quality of life. This could be because there are greater health issues that develop later in life that make having celiac disease become less significant, although more research is needed. For example, the oldest group was less concerned about their long-term health being affected by celiac disease with 16% reporting that they were “not at all” concerned, while 5% of the 18-25 year-olds, 8% of the 26-35 year-olds, 6% of the 36-45 year-olds, and 3% of the 46-55 year-olds felt “not at all” concerned. Additionally, 37% of the group of 18-25 year-olds felt that they were “a great deal” limited in eating meals with coworkers, while 38% of 26-35 year-olds, 35% of 36-45 year-olds, 41% of 46-55 year-olds felt the same, yet only 24% of the 56 and older group felt “a great deal” limited in eating meals with coworkers. This age group likely has the most number of retirees, thus making them less worried about eating with coworkers. One effect noted in this study was that the older individuals with celiac disease were, the less they felt afraid to eat out because of contamination. In the group of 18-25 year-olds, 37% felt “a great deal” afraid to eat out, while 35% of the 26-35 year-olds, 29% of the 36-45 year-olds, 25% of the 46-55 year-olds, and only 17% of the 55 and older group felt “a great deal” afraid. This could be due to people eating out less often when they age and therefore being less affected as they get older.

### **Gluten-free Fad Diet Survey**

The next portion of the survey included nine questions designed to reflect the respondent’s opinion about the gluten-free fad diet that were rated on the Likert scale.

The respondents overwhelmingly felt that they found themselves defending the need to eat gluten-free when out in public and they did not believe that people other than their family and friends understood the severity of celiac disease. The respondents also felt that the attention that the gluten-free diet receives in the media due to other people eating gluten-free outside of medical advice was not helpful for celiac disease, and that the term “gluten intolerance” was not appropriate for celiac disease. Additionally, respondents felt that people other than family and friends did not understand that cross-contamination of gluten could make them sick, that they did not feel safe ordering off gluten-free menus at most restaurants, and that restaurant personnel did not take celiac disease seriously. Lastly, the respondents did not feel satisfied with the current dietary treatment for celiac disease and they did not feel that celiac disease is represented honestly in the media.

These responses may show that the gluten-free fad diet is negatively affecting quality of life by causing individuals with celiac disease to feel that they need to defend their treatment to distance themselves from fad dieters. Furthermore, the gluten-free fad diet may cause other people to not take celiac disease seriously, which may in turn lead to more cross-contamination issues if restaurant personnel feel that celiac disease is not a serious condition. This effect was shown in the CD-QOL portion where individuals responded that they felt afraid to eat out because their food may be contaminated and that they felt socially stigmatized by having the disease. Additionally, using the term “gluten intolerance” to refer to celiac disease may be causing the general public to have a misconception about what celiac disease is, possibly leading to them thinking it is similar

to a lactose intolerance rather than the serious autoimmune disease that it is, which may be why these individuals felt that celiac disease is not represented honestly in the media.

When the researcher compared the responses of various age groups, the group that disagreed the most with the phrase “I believe that people, outside my family and friends, understand the severity of celiac disease” was the 46-55 year-olds with 94% stating that they “strongly disagree” or “disagree.” Furthermore, the age groups that disagreed the most with the statement “People, outside of my family and friends, understand that cross-contamination can make me sick” were the 36-45 year-olds and the 46-55 year-olds. Additionally, when broken down by period of time since diagnosis, the group that had been diagnosed less than three months prior to the survey felt the least safe ordering off gluten-free menus at most restaurants while the group that had been diagnosed 16-20 years prior to the survey felt most safe ordering off gluten-free menus at most restaurants. This shows that individuals who have more recently been diagnosed with celiac disease feel more anxiety about eating out, possibly due to the gluten-free diet being so new to them. Lastly, the group that was diagnosed three months to a year prior to the survey felt the most strongly that the attention that the gluten-free diet receives in the media, due to other people eating gluten-free, was not helpful for celiac disease. The group that was diagnosed 16 to 20 years prior to the survey did not feel as strongly. This could happen because individuals who are diagnosed more recently spend more time researching their condition and thus read more articles about it. Additionally, this could occur because the group that had been diagnosed longer ago felt that the attention that the diet receives is

better for celiac disease because more people are aware of the condition now than they were when that group was diagnosed.

### **Free Answer Question**

Overall, almost half (46%) of the responses included the theme: celiac disease is not taken seriously because people do not understand the severity. As one respondent stated, “people don't understand the severity of celiac vs. people just eating gluten-free for choice.” Another respondent wrote, “means that I'm not taken seriously as people see all gluten-free diets as a choice rather than a necessity.” Yet another respondent noted, “they make people take my autoimmune disease less seriously, like it's (sic) a joke. They discredit a medical condition which often has terrible ramifications.” These findings reveal that people following the gluten-free diet, outside of medical advice for treating celiac disease, IBS, or a wheat allergy, negatively affect individuals with celiac disease by causing them to feel that their disease is not taken seriously.

Nearly a quarter (24%) of the responses included the theme: there is an increase of better quality gluten-free products that are more clearly labeled. As one respondent wrote, “with gluten-free becoming a fad in recent years I have found it much easier to purchase gluten-free food”, showing that it is easier to find manufactured products because the fad diet has created a bigger gluten-free product market. Interestingly, the same number (24%) of the responses indicated that they felt less safe eating out and felt the need to defend themselves in public because restaurants do not understand the gluten-free diet for individuals with celiac disease. One respondent highlighted this effect by

stating that “I have to explain the disease and it's (sic) effects everywhere I go.” This shows that while the gluten-free fad diet has made it easier to eat at home, it has also made it harder to eat out at restaurants. The fad diet appears to be fueling the product market by creating an opportunity for food manufacturers to profit from the trend. However, the fad diet also creates confusion among restaurant staff that sees more individuals requesting gluten-free food but not needing the same level of attention to avoidance of cross-contamination.

Over a quarter (27%) of the respondents also included the theme: other people think I am following a fad or that eating gluten-free is optional for me. For example, one respondent stated, “people tend to see gluten-free as a fad, or health choice and not a medical necessity. Cross contamination seems to have no meaning because they don't think it's really an issue.” Another respondent wrote, “people don't take it seriously, and frequently insist that it is in my head, that I could "get used to it" if I just "ate a little.” They think I am a hypochondriac and just jumped onto this because it is trendy. Both my kids have biopsy dx (sic) celiac as well, and frequently we get cross contaminated if we try to eat out, and people roll their eyes when we bring our own food or question a waiter because they think we just like the attention. It is humiliating, so we hardly socialize.” These responses show that the gluten-free fad diet negatively affects individuals with celiac disease by making them feel like other people group them together with the fad dieters. As one respondent wrote, “I do feel like there's an eye-roll inducing stigma around eating gluten-free now, where you get lumped in with fad dieters, which is

unfortunate.” Since the fad diet is now coming under scrutiny and being ridiculed on mainstream media as well as social media, this can cause anxiety for individuals with celiac disease since the diet remains their only treatment.

Furthermore, 23% of the respondents felt that “There are more cross-contamination issues because there is a public misperception of true gluten-free.” This highlights the need for more awareness about celiac disease and the dietary treatment. The trend correlated with the responses from the CD-QOL, with 49% of the respondents stating that they felt a great deal or quite a bit afraid to eat out because their food may be contaminated. Worry about cross-contamination issues can lead to anxiety in social situations or avoidance of social events as indicated by the previous respondent who stated that “we hardly socialize”, thus causing a decrease in quality of life.

Several respondents noted how individuals who follow the gluten-free fad diet are able to pick and choose from menu items with and without gluten, which can lead to confusion amongst restaurant personnel. For example, one respondent stated, “it’s hard to explain to people how I cannot have even a little bit of gluten when someone else is saying they can” Another participant stated, “it makes people less careful with those of us who are eating a gf (sic) diet for celiac disease. I have seen people ask for a gluten-free meal, then eat bread that was brought for others at the table.” Yet another respondent wrote, “individuals who eat gluten-free without direction from a medical professional can cause problems by some people not taking it seriously. The type of people I’m referring to are the people who order pasta at a restaurant with gluten-free pasta and a side order of

breadsticks and garlic bread. People like that can make it dangerous for diagnosed celiacs (sic) like myself to eat out at restaurants and can often result in the stereotypes associated in the media of people who are gluten-free.” This discrepancy can be difficult for restaurant staff to understand and frustrating for food preparers when the majority of individuals who eat gluten-free do not have celiac disease.

Many respondents recalled being ridiculed for following a gluten-free diet. As one respondent wrote, “most people think the gluten-free diet is a joke. At most restaurants when I ask for the GF menu I get a look and people roll their eyes.” Another respondent stated, “I have been called an ‘entitled hippie, among other things, and told to get over it ‘for one meal’ (or day or week...) and asked to stop causing problems for everyone because of a ‘made up fake disease that only impacts rich white people.’ ” Yet another respondent recalled, “a gluten-free lifestyle has become the butt of jokes. I have heard a number of hurtful comments when I inquired about gluten-free menu options.” This can show that while the backlash against the gluten-free fat diet permeates through mainstream and social media, individuals with celiac disease have been caught in the crosshairs of the public eye and face ridicule and negativity for following the only treatment available for their disease.

Overall, there were 986 comments that were deemed negative, while only 280 comments were deemed positive, and 36 comments were deemed neutral. This shows that the gluten-free fad diet is overwhelmingly having a negative affect on individuals with celiac disease. The biggest negative effect is that individuals with celiac disease feel that

their disease is not taken seriously and that other people do not understand the severity of the disease. Additionally, individuals with celiac disease feel that restaurants do not understand the difference between someone who chooses to eat gluten-free and someone with celiac disease who needs to avoid cross contamination out of medical necessity. Since individuals with celiac disease put their health in the hands of restaurant personnel or friends and loved ones who prepare food for them, it can be dangerous to their well being if the food preparers do not take their disease and the dietary treatment seriously.

### **Limitations**

The biggest limitation in this study was the gluten-free fad diet perception portion of the survey. The responses by participants were not evenly distributed, indicating that the questions could have been biased or that that the researcher was able to ask questions that other individuals living with celiac disease can relate to. The results of the portion of the survey that was mean to test the perception of the gluten-free fad diet were inconsistent with the results of the CD-QOL portion of the survey, indicating construct-validity bias. Further research would be beneficial to determine the validity of the questions that were developed by the primary researcher. In the future, the questions could be given to a focus group of individuals with celiac disease and then tested by a larger group without the CD-QOL and free answer portion to lessen the potential bias in these questions and to increase the validity of the responses. Testing these questions in a focus group with a representative sample of individuals with celiac disease could have decreased the bias further. However, using the validated CD-QOL helped to show how

some of the responses to the gluten-free fad diet survey corresponded to quality of life and thus added validity to the study as a whole.

Although this study had a large sample size, one limitation was participant recruitment. Since participants were recruited through email and Facebook and the survey was taken online, it excluded those with celiac disease that did not regularly use a computer or did not frequently check their email or use Facebook. One way to make the study more robust would have been to recruit through an additional national celiac support group. Additionally, this study only included American adults with biopsy-confirmed celiac disease, and thus may not be representative of adults with celiac disease in other countries, the pediatric celiac disease population, or those diagnosed by blood work or dietary exclusion under medical supervision.

### **Future Direction**

This study highlights the need for a complimentary pharmacological treatment in addition to the gluten-free diet to help ease the treatment burden of the gluten-free diet. If a pharmacological agent existed, it could allow individuals with celiac disease to consume small amounts of gluten, which could greatly increase their quality of life by making them feel less worried about cross-contamination. This could make dining out or eating food that other people prepare for them much easier for this group of people, thus allowing them to experience social situations without living in fear of cross-contamination or feeling socially stigmatized. Once a pharmacological agent is available,

further research could assess the quality of life of individuals who take the medication verses the quality of life of those who do not take the medication.

Additionally, this study shows the need for better education for restaurant personnel about a strict gluten-free diet for individuals with celiac disease verses those who choose to eat gluten-free for other reasons. Adding a section about food allergies and celiac disease to the Food Handler's Safety Card class, a required course taken by restaurant personnel in California, could help to improve awareness and cause less confusion in that state. The course already covers topics such as food borne illness and hygiene, so a section on food allergies and celiac disease could flow easily with the content already provided. Nationwide advocacy, through groups such as Beyond Celiac (Formerly the National Foundation for Celiac Awareness), The Gluten Intolerance Group, and Celiac Support Association, could help similar programs to be required in other states. Future studies could focus on the efficacy of these programs, specifically on whether quality of life is improved by these individuals feeling less afraid to eat out because of contamination, and perhaps lead to policy change at the national level.

Furthermore, this study highlights a need for educating the general public about celiac disease and the gluten-free diet. As this study shows, many people with celiac disease feel like their disease is not taken seriously and that other people ridicule their condition and the treatment of their disease. By teaming with celebrities who have celiac disease or a family member with celiac disease, celiac advocacy groups could help to counter some of the misinformation about the condition by putting a public face on the

condition. Individuals with celiac disease and the medical practitioners who treat them need to have a strong public presence in the mainstream media and social media to counter the misinformation and ridicule that the gluten-free diet receives. The founder of Beyond Celiac, Alice Bast, already works at the national level writing opinion pieces for publications such as the Huffington Post and appears on talk shows such as the Doctors. By continuing this outreach with other well-known public figures such as Jon Stewart or Elizabeth Hasselbeck, celiac advocacy groups can work to bring accurate information about the disease and what it is like to live with the condition while following the gluten-free diet to the public.

### **Conclusion**

This study showed that having celiac disease and its treatment, the gluten-free diet, negatively affects the quality of life of individuals with the disease. A recent diagnosis with the disease, under three months ago, most negatively affects quality of life, showing the need for better education and resources at time of diagnosis. Age of the individual with celiac disease has an effect on quality of life, with the younger adult population with the disease feeling the most affected, especially in social areas such as eating meals with coworkers. Furthermore, this study revealed that having to follow the gluten-free diet negatively affects quality of life of individuals with celiac disease. This study also showed that individuals with celiac disease feel that the term “gluten intolerance” is not appropriate for their disease, that they feel the need to defend themselves when out in public, and that restaurants do not take their diet seriously.

When individuals with celiac disease are allowed to share their personal experiences of how other people who follow the gluten-free diet affect their lives, they feel that it causes people to not take their disease seriously. Furthermore, individuals with celiac disease report being ridiculed in public and feeling socially stigmatized for having the disease and needing to strictly follow the gluten-free diet. While the gluten-free fad diet has made it easier for individuals with celiac disease to manage their diet at home because more gluten-free products are readily available, the fad diet has also made it more difficult for individuals with celiac disease to dine out because of the confusion it has created about what is truly gluten-free.

Ultimately, this study highlights the need for additional treatment options that can lessen the treatment burden for this population and help to normalize social events. Additionally, the findings from this study show the need for better education at time of diagnosis to help improve the quality of life of newly diagnosed individuals with celiac disease. Further education of the general population and restaurant personnel can help this population navigate social events and dining out without feeling worried about cross-contamination or being ridiculed.

## References

- Alaedini, A. & Green, P. (2005). Narrative review: Celiac disease: Understanding a complex autoimmune disorder. *Annals of Internal Medicine*, *142*(4), 289-98. doi:10.7326/0003-4819-142-4-200502150-00011
- Aziz, I., Karajeh, M. A., Zilkha, J., Tubman, E., Fowles, C., & Sanders, D. (2014). Change in awareness of gluten-related disorders among chefs and the general public in the UK: A 10-year follow-up study. *European Journal of Gastroenterology & Hepatology*, *26*(11), 1228-1233. doi: 10.1097/MEG.000000000000166
- Bast, A. (2016, February 25). Stop making light of the gluten-free diet (Web log post). Retrieved from [http://www.huffingtonpost.com/alice-bast/stop-making-light-of-the-gluten-free-diet\\_b\\_9293064.html](http://www.huffingtonpost.com/alice-bast/stop-making-light-of-the-gluten-free-diet_b_9293064.html)
- Biesiekierski, J., Muir, J., Gibson, P. (2013). Is gluten a cause of gastrointestinal symptoms in people without celiac disease?. *Current Allergy and Asthma Reports*, *13*(6), 631-638. doi:10.1007/s11882-013-0386-4
- Biesiekierski, J., Newnham, E., Irving, P., Barrett, J., Haines, M., & Doecke, J. (2011). Gluten causes gastrointestinal symptoms in subjects without celiac disease: A double-blind randomized placebo-controlled trial. *American Journal of Gastroenterology*, *106*(3), 508-514. doi:10.1038/ajg.2010.487
- Biesiekierski, J., Peters, S., Newnham, E., Rosella, O., Muir, J., & Gibson, P. (2013). No

effects of gluten in patients with self-reported non-celiac gluten sensitivity after dietary reduction of fermentable, poorly absorbed, short-chain carbohydrates.

*Gastroenterology*, 145(2), 320-328. doi:10.1053/j.gastro.2013.04.051

Black, J.L. & Orfila. (2011). Impact of coeliac disease on dietary habits and quality of life. *Journal of Human Nutrition and Dietetics*, 24, 582-587. Doi:10.1111/j.1365-277X.2011.01170.x

Catassi, C., Fabiani, E., Giuseppe, I., D'Agate, C., Francavilla, R., Biagi, F., ... Fasano, A. (2007). A prospective, double-blind, placebo-controlled trial to establish a safe gluten threshold for patients with celiac disease. *The American Journal of Clinical Nutrition*, 85, 160-166.

Ciacci, C. & Zingone, F. (2015). The perceived social burden in celiac disease. *Diseases*, 3, 102-110. doi:10.3390/diseases3020102

Davis, W. (2014). *Wheat belly: Lose the wheat, lose the weight, and find your path back to health*. San Francisco, California, United States of America: Rodale Books.

Derr, L. (2006). When food is poison: The history, consequences, and limitations of the food allergen labeling and consumer protection act of 2004. *Food and Drug Law Journal*, 61(1), 65-165

Dorn, S. D., Hernandez, L., Minayas, M. T., Morris, C. B., Hu, Y., Leserman, J., ...Drossman, D. A. (2009). The development and validation of a new coeliac disease quality of life survey (CD-QOL). *Alimentary Pharmacology and Therapeutics*, 31, 666-675. doi: 10.1111/j.1365-2036.2009.04220.x

- Dowd, A. J., Tamminen, K. A., Jung, M. E., Case, S., McEwan, D., & Beauchamp, M. R. (2013). Motives for adherence to a gluten-free diet: A qualitative investigation involving adults with coeliac disease. *Journal of Human Nutrition and Dietetics*, 27, 542-549. doi: 10.1111/jhn.12203
- Fasano, A. & Catassi, C. (2012). Celiac disease. *The New England Journal of Medicine*, 367, 2419-2426. doi: 10.1056/NEJMcp1113994
- Fell, J. (January, 14, 2015). Gluten-free craze is boon and bane for those with celiac disease. *NPR*. Retrieved from <http://www.npr.org/sections/thesalt/2015/01/14/375709527/gluten-free-craze-is-boon-and-bane-for-those-with-celiac-disease>
- Friedman, L. (2014). Jimmy Kimmel asks gluten-free people what gluten is – and hilariously, they have no idea. *Business Insider*. Retrieved from <http://www.businessinsider.com/jimmy-kimmel-asks-what-is-gluten-video-2014-5>
- Gaesser, G. & Angadi, S. (2012). Gluten-free diet: Imprudent dietary advice for the general population?. *Journal of the Academy of Nutrition and Dietetics*. 112(9). 1330-1333. doi: 10.1016/j.jand.2012.06.009
- Golley, S., Corsini, N., Topping, D., Morell, M., & Mohr, P. (2014). Motivations for avoiding wheat consumption in Australia: Results from a population survey. *Public Health Nutrition*. 18(3). 490-499. doi: 10.1017/S1368980014000652
- Gluten Intolerance Group. (2017). Getting started on a gluten-free diet. Retrieved from

<https://www.gluten.org/resources/getting-started/getting-started-gluten-free-diet/>

- Green, P.H.R. & Cellier, C. (2007). Celiac Disease. *The New England Journal of Medicine*, 357, 1731-1743. doi: 10.1056/NEJMra071600
- Gujral, N., Freeman, H., & Thomson, A. (2012). Celiac disease: Prevalence, diagnosis, pathogenesis, and treatment. *World Journal of Gastroenterology*, 18(42), 6036-6059. doi: 10.3748/wgj.v18.i42.6036
- Haines, M. L., Anderson, R. P., & Gibson, P. R. (2008). Systematic review: The evidence base for long-term management of coeliac disease. *Alimentary Pharmacology and Therapeutics*, 28, 1042-1066. doi: 10.1111/j.1356-2036.2008.03820.x
- Hall, N. J., Rubin, G., & Charnock, A. (2009). Systematic review: Adherence to a gluten-free diet in adult patients with coeliac disease. *Alimentary Pharmacology and Therapeutics*, 30, 315-330. doi: 10.1111/j.1356-2036.2009.04053.x
- Kav, T. & Sivri, B. (2012). Is enteroscopy necessary for diagnosis of celiac disease?. *World Journal of Gastroenterology*, 18(31), 4095-4101. doi:10.3748/wjg.v18.i31.4095
- Kelly, C.P., Green, P.H.R., Murray, J.A., DiMariano, A., Colatrella, A., Leffler, D.A., ...Fedorak, R.N. (2012). Larazotide acetate in patients with coeliac disease undergoing a gluten challenge: A randomized placebo-controlled study. *Alimentary Pharmacology and Therapeutics*, 37, 252-262. doi: 10.1111/apt.12147

- Kremer, W. (2015, July). The great gluten-free diet fad. *BBC News*. Retrieved from <http://www.bbc.com/news/magazine-33486177>
- Lahdeaho, M., Kaukinen, K., Laurila, K., Voutikka, P., Koivurova, O., Karja-Lahdensuu, T., ... Maki, M. (2014). Glutenase ALV003 attenuates gluten-induced mucosal injury in patients with celiac disease. *Journal of Gastroenterology*, *146*, 1649-1658. doi: 10.1053/j.gastro.2014.02.031
- Lee, A. R., Ng, D. L., Diamond, B., Ciaccio, E. J., & Green, P. H. R. (2012). Living with coeliac disease: Survey results from the USA. *Journal of Human Nutrition and Dietetics*, *25*, 233-238. doi: 10.1111/j.1365-277X.2012.01236.x.
- McCarthy, E. (2014). Backlash has begun against gluten-free dieters. *The Washington Post*. Retrieved from [https://www.washingtonpost.com/lifestyle/style/backlash-has-begun-against-gluten-free-dieters/2014/07/06/61953aba-f7be-11e3-a3a5-42be35962a52\\_story.html](https://www.washingtonpost.com/lifestyle/style/backlash-has-begun-against-gluten-free-dieters/2014/07/06/61953aba-f7be-11e3-a3a5-42be35962a52_story.html)
- McCarville, J.L, Nisemblat, Y., Galipeau, H.J., Jury, J., Tabakman, R., Cohen, A., ... Verdu, E. F. (2014). BL-7010 demonstrates specific binding to gliadin and reduces gluten-associated pathology in a chronic mouse model of gliadin sensitivity. *Plos One*, *9(11)*, e109972. doi: 10.1371/journal.pone.0109972
- Mdhagen, G. & Hallert, C. (2003). High rate of gastrointestinal symptoms in celiac patients living on a gluten-free diet: Controlled study. *The American Journal of Gastroenterology*, *98(9)*, 2023-2026. doi: 10.1016/S0002-9270(03)00543-4
- Mintel. (2015, December 4). Half of Americans think gluten-free diets are a fad while

25% eat gluten-free foods. (Press release). Retrieved from <http://www.mintel.com/press-centre/food-and-drink/half-of-americans-think-gluten-free-diets-are-a-fad-while-25-eat-gluten-free-foods>

Paarlahti, P., Kurppa, K., Ukkola, A., Collin, P., Huhtala, H., Maki, M., Kaukinen, K. (2013). Predictors of persistent symptoms and reduced quality of life in treated coeliac disease patients: A large cross-sectional study. *BMC Gastroenterology*, *13*(75), 1-8. doi:10.1186/1471-230X-13-75

Piccalo, G. (August 1, 2010). The New Star Diet Craze. *The Daily Beast*. Retrieved from <http://www.thedailybeast.com/articles/2010/08/01/gluten-free-eating-the-new-celebrity-diet-trend.html>

Pietzak, M. (2012). Celiac disease, wheat allergy, and gluten sensitivity: When gluten free is not a fad. *Journal of Parental and Enteral Nutrition*, *36*(1), 68s-75s. doi:10.1177/01486-7111426276

Painter, K. (2008, August 18). Gluten-free diets gaining in popularity. *USA Today*. Retrieved from [http://usatoday30.usatoday.com/news/health/painter/2008-08-17-gluten\\_N.htm](http://usatoday30.usatoday.com/news/health/painter/2008-08-17-gluten_N.htm)

Perlmutter, D. (2013). Grain brain: The surprising truth about wheat, carbs, and sugar—your brain's silent killers. New York City, New York, United States of America: Little, Brown and Company.

Plugis, N.M. & Khosla, C. (2015). Therapeutic approaches for celiac disease. *Best*

*Practice and Research Clinical Gastroenterology*, 29(3), 503-521. doi:

10.1016/j.bpg.2015.04.005

Rampertab, S. D., Pooran, N., Brar, P., Singh, P., Green, P. H. R. (2006). Trends in the presentation of celiac disease. *The American Journal of Medicine*, 119, 355.e9-355.e14. doi: 10.1016/j.amjmed.2005.08.044

Reilly, N.R. & Green, P.H.R. (2012). Epidemiology and clinical presentations of celiac disease. *Seminars in Immunopathology*, 34(4), 473-478. doi:10.1007/s00281-012-0311-2

Rostom, A., Murray, J., Kagnoff, M. (2006). American gastroenterological association (AGA) institute technical review on the diagnosis and management of celiac disease. *Gastroenterology*, 131(6), 1981-2002. doi:10.1053/j.gastro.2006.10.004

Sainsbury, K. & Mullan, B. (2011). Measuring beliefs about gluten-free diet adherence in adult coeliac disease using the theory of planned behavior. *Appetite*, 56, 476-483. Doi:10.1016/j.appet.2011.01.026

Sainsbury, K., Mullan, B., & Sharpe, L. (2013). Reduced quality of life in coeliac disease is more strongly associated with depression than gastrointestinal symptoms. *Journal of Psychosomatic Research*, 75, 135-141. doi:10.1015.j.jpsychores.2013.05.011

Shah, S., Akbari, M., Vanga, R., Kelly, C. P., Hansen, J., Theethira, T., ... Leffler, D. A.

- (2014). Patient perception of treatment burden is high in celiac disease compared to other common conditions. *American Journal of Gastroenterology*, 109(9), 1304-1311. doi: 10.1038/ajg.2014.29
- Smith, M. & Goodfellow, L. (2011). The relationship between quality of life and coping strategies of adults with celiac disease adhering to a gluten-free diet. *Gastroenterology Nursing*, 34(6), 460-468. doi: 10.1097/SGA.0b013e318237d201
- Swerdloff, A. (2015, July 28). The gluten-free backlash has begun on social media. *Munchies, NP*. Retrieved from <http://munchies.vice.com/articles/the-gluten-free-backlash-has-begun-on-social-media>
- Swidey, N. (2015, October 27). How we made gluten into a monster. *The Boston Globe*. Retrieved from <https://www.bostonglobe.com/magazine/2015/10/27/how-made-gluten-into-monster/GYIZbgqfWtBmLOE88yr5EO/story.html>
- Theofilou, P. (2013). Quality of life: Definition and measurement. *Europe's Journal of Psychology*, 9(1), 150-162. doi: 10.5964/ejop.v9i1.337
- Tonutti, E. & Bizzaro, N. (2014). Diagnosis and classification of celiac disease and gluten sensitivity. *Autoimmunity Reviews*, 13(4-5), 472-476. doi:10.1016/j.autrev.2014.01.043
- Ulluwishewa, D., Anderson, R.C., McNabb, W., Moughan, P.J., Wells, J.M., & Roy,

N.C. (2011). Regulation of tight junction permeability by intestinal bacteria and dietary components. *The Journal of Nutrition*, 141, 769-776. doi: 10.3945/jn.110.135657

US FDA announces new standards for 'gluten-free' labeling. (2013). *Progressive Digital Media Food News*.

Welstead, L. (2015). The gluten-free diet in the 3<sup>rd</sup> millennium: Rules, risks, and opportunities. *Diseases*, 3(3), 136-149. doi: 10.3390/diseases3030136

Zarkadas, M., Dubois, S., MacIsaac, K., Cantin, I., Rashid, M., Roberts, K., ... & Pulido, O. (2012). Living with coeliac disease and a gluten-free diet: A Canadian perspective. *Journal of Human Nutrition and Dietetics*, 26, 10-23. doi:10.1111/j.1365-277X.2012.01288.x

## Appendix A

### Implied Consent Form

The effects of the gluten free fad diet on adults with celiac disease  
Tiffany Epperson, RD

#### Implied Consent to Participate in Research

Data collected from this confidential survey will be used for completion of a Master's degree in Family and Consumer Science at San Francisco State University. The information gathered will be used to understand how other people following the gluten free diet outside of medical supervision affects the quality of life of individuals with celiac disease.

The survey questions are related to the participant's quality of life and their perceptions about the gluten free fad diet.

You have been invited to participate because you are an American adult over the age of 18 who has biopsy-confirmed celiac disease and has been following a strict gluten free diet for a minimum of three months.

You must be 18 years of age or older to participate. There are no risks or benefits to you in participating in this survey. You may choose to participate or not. You may answer only the questions you feel comfortable answering, and you may stop at any time. If you do not wish to participate, you may simply exit the survey by closing your browser window, with no penalty to yourself. If you do participate, **completion of the survey indicates your consent to the above conditions. Your decision whether or not to participate in this research will have no influence on your present or future status at San Francisco State University.**

**Please do not put your name on this form.** The survey should take approximately 15 minutes to complete. Any questions or concerns should be directed to the principal investigator, Tiffany Epperson, RD, at [epperson@mail.sfsu.edu](mailto:epperson@mail.sfsu.edu) or the research advisor, Professor Gretchen George, PhD RD, at [gjgeorge@sfsu.edu](mailto:gjgeorge@sfsu.edu).

## Appendix B

### Online Survey

10/28/2015

Qualtrics Survey Software

#### CD-QOL and GF fad diet perception survey

Data collected from this confidential survey will be used for completion of a master's degree in Family and Consumer Science at San Francisco State University. The information gathered will be used to understand how other people following the gluten free diet outside of medical supervision affects the quality of life of individuals with celiac disease.

You have been invited to participate because you are an American adult over the age of 18 who has biopsy-confirmed celiac disease and has been following a strict gluten free diet for a minimum of three months.

You must be 18 years of age or older to participate. There are no risks or benefits to you in participating in this survey. You may choose to participate or not. You may answer only the questions you feel comfortable answering, and you may stop at any time. If you do not wish to participate, you may simply return the blank survey, with no penalty to yourself. If you do participate, **completion and return of the survey indicates your consent to the above conditions. Your decision whether or not to participate in this research will have no influence on your present or future status at San Francisco State University.**

**Please do not put your name on this form.** The survey should take approximately 15 minutes to complete. Any questions or concerns should be directed to the principal investigator, Tiffany Epperson, RD, at [epperson@mail.sfsu.edu](mailto:epperson@mail.sfsu.edu) or the research advisor, Professor Gretchen George, PhD RD, at [ggeorge@mail.sfsu.edu](mailto:ggeorge@mail.sfsu.edu).

If you would like to continue with this survey, please select from the answers below:

*I am over the age of 18*

*I am under the age of 18*

Have you been diagnosed with celiac disease by a medical doctor?

Yes

No

How were you diagnosed with celiac disease?

Intestinal biopsy

Intestinal biopsy with positive blood tests

Positive blood tests

Elimination of gluten from diet

What is your gender?

Male

Female

Prefer not to answer

10/28/2015

Qualtrics Survey Software

Do you follow a strict gluten free diet, meaning you intentionally eliminate all sources of dietary gluten from your diet even avoiding cross-contamination, to treat your celiac disease?

Yes

No

*When were you diagnosed with celiac disease?*

Under 3 months ago

3 months to 1 year ago

1 to 5 years ago

6 to 10 years ago

11 to 15 years ago

16 to 20 years ago

21 years ago or more

What is your age?

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 fill in the box that best describes your feelings.

I feel limited by this disease.

Not at all

Slightly

Moderately

Quite a bit

A great deal

I feel worried that I will suffer from this disease.

Not at all

Slightly

Moderately

Quite a bit

A great deal

10/28/2015

Qualtrics Survey Software

I feel concerned that this disease will cause other health problems.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel worried about my increased risk of cancer from the disease.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel socially stigmatized for having this disease.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel like I am limited in eating meals with coworkers.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel like I am not able to have special foods like birthday cake and pizza.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

10/28/2015

Qualtrics Survey Software

I feel that the diet is sufficient treatment for my disease.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel that there are not enough choices for treatment.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel depressed because of my disease.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel frightened by having this disease.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel like I don't know enough about the disease.

- Not at all
- Slightly
- Moderately
- Quite a bit

10/28/2015

Qualtrics Survey Software

A great deal

I feel overwhelmed about having the disease.

Not at all

Slightly

Moderately

Quite a bit

A great deal

I have trouble socializing because of my disease.

Not at all

Slightly

Moderately

Quite a bit

A great deal

I find it difficult to travel or take long trips because of my disease.

Not at all

Slightly

Moderately

Quite a bit

A great deal

I feel like I cannot live a normal life because of my disease.

Not at all

Slightly

Moderately

Quite a bit

A great deal

I feel afraid to eat out because my food may be contaminated.

Not at all

Slightly

Moderately

10/28/2015

Qualtrics Survey Software

- Quite a bit
- A great deal

I feel worried about the increased risk of one of my family members having celiac disease.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel like I think about food all the time.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

I feel concerned that my long-term health will be affected.

- Not at all
- Slightly
- Moderately
- Quite a bit
- A great deal

Please think about your experience of living with celiac disease, and look at the statements below. Each statement has five possible responses. For each statement, please fill in the box that best describes your feelings.

I believe that people, outside of my family and friends, understand the severity of celiac disease.

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

10/28/2015

Qualtrics Survey Software

The term "gluten intolerance" is appropriate for celiac disease.

- » Strongly Disagree
- » Disagree
- » Neither Agree nor Disagree
- » Agree
- » Strongly Agree

People, outside of my family and friends, understand that cross-contamination of gluten can make me sick.

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

I feel safe ordering off gluten free menus at most restaurants.

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

I think restaurant personnel take celiac disease seriously.

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

I am satisfied with the current dietary treatment for celiac disease.

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

10/28/2015

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I believe celiac disease is represented honestly in the media.

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

I find myself defending my need to eat gluten free when out in public.

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

The attention that the gluten free diet receives in the media, due to other people eating gluten free outside of medical advice is helpful for celiac disease.

- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

Please answer the following question in the space provided below in five sentences or less.

*How does other people following the gluten free diet, outside of medical direction for celiac disease, irritable bowel syndrome, non-celiac gluten sensitivity, or wheat allergy, affect your life?*

## Appendix C

### Recruitment Script

Recruitment script to be included in the disseminating email:

Do you have biopsy-confirmed celiac disease? If so, please participate in a short survey about how other people following the gluten free diet outside of medical supervision affects the quality of life of individuals with celiac disease. Tiffany Epperson, a Registered Dietitian who has celiac disease, is conducting a research study through San Francisco State University and would like your help in participating in an anonymous survey. The survey should only take about 15 minutes to complete and you can take it at your convenience. Your opinion matters! Please click on the link below to participate.

## Appendix D

### CD-QOL License Agreement

#### LICENSE AGREEMENT

This Agreement, effective as of the Effective Date defined below, is made by and between Licensee (identified below) and The Rome Foundation, Inc., a Virginia not-for-profit corporation with offices in Raleigh, North Carolina, U.S.A. ("Licensor").

WHEREAS Licensor owns and controls the exclusive worldwide rights and copyright in and to the Licensed Work(s) (defined below); and

WHEREAS Licensee seeks the right to use the Licensed Work(s) for the Permissible Use for the Term and in the Territory (all defined below).

NOW THEREFORE, in consideration of the mutual promises set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

#### DEFINITIONS

|                  |   |
|------------------|---|
| Licensee         | <p>Tiffany Epperson RD<br/>San Francisco State University</p> <p>Entity type:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> For-profit pharmaceutical company or clinical research organization (CRO)</li> <li><input type="checkbox"/> For-profit medical education provider or marketing agency</li> <li><input type="checkbox"/> Not-for-profit medical education provider</li> <li><input type="checkbox"/> Not-for-profit professional organization or association</li> <li><input type="checkbox"/> Universities, colleges, institutes of higher learning</li> <li><input type="checkbox"/> Government agency</li> <li><input checked="" type="checkbox"/> <b>Individual investigator or academician</b></li> <li><input type="checkbox"/> Clinician in private practice</li> </ul> |
| Effective Date   | <b>October 1, 2015</b>  |
| Licensed Work(s) | <ul style="list-style-type: none"> <li><input type="checkbox"/> <i>Rome III: The Functional Gastrointestinal Disorders, Third Ed.</i></li> <li><input type="checkbox"/> <i>Rome IV: The Functional Gastrointestinal Disorders, Fourth Ed.</i></li> <li><input type="checkbox"/> <i>Understanding the Irritable Gut</i> (Thompson WG, 2008)</li> <li><input type="checkbox"/> <i>Rome III Diagnostic Criteria for Functional Gastrointestinal Disorders</i></li> </ul>   |

|                   |  |
|-------------------|--|
|                   | <input type="checkbox"/> <i>Rome III Diagnostic Questionnaire for the Adult Functional GI Disorders and Scoring Algorithm (including any and all individual modules)</i><br><input type="checkbox"/> <i>Rome III Psychosocial Alarm Questionnaire for the Functional GI Disorders (including any and all individual modules)</i><br><input type="checkbox"/> <i>Rome III Diagnostic Questionnaire for the Pediatric Functional GI Disorders – for infants and toddlers (including any and all individual modules)</i><br><input type="checkbox"/> <i>Computer-based Learning Program for Functional GI Disorders</i><br><input type="checkbox"/> <i>Clinical Diagnostic Algorithms (including any and all individual algorithms)</i><br><input type="checkbox"/> <i>Bristol Stool Form Scale</i><br><input checked="" type="checkbox"/> <i>Other CD-QOI.</i> |
| Exempt Entity     | <p>Is Licensee any of the following:</p> <input type="checkbox"/> Rome Foundation pharmaceutical sponsor<br><input checked="" type="checkbox"/> <b>Individual investigator</b><br><input type="checkbox"/> Clinician in private practice who will use the Licensed Works solely for clinical purposes, and not for research or educational services  |
| Permissible Media | <p><input checked="" type="checkbox"/> <b>All forms of media now known or hereinafter devised</b></p> <p>If not all forms of media, then select one of the following:</p> <input type="checkbox"/> Print only<br><input type="checkbox"/> Digital/Electronic only  |
| Territory         | <input type="checkbox"/> Worldwide<br><p>If not worldwide, then select the appropriate region(s):</p> <input checked="" type="checkbox"/> <b>United States</b><br><input type="checkbox"/> Canada<br><input type="checkbox"/> Latin America<br><input type="checkbox"/> European Community<br><input type="checkbox"/> Australia and New Zealand<br><input type="checkbox"/> South America<br><input type="checkbox"/> Africa<br><input type="checkbox"/> Middle East<br><input type="checkbox"/> Other  |

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| <p>Permissible Use</p>   | <p><input checked="" type="checkbox"/> <b>Research, including but not limited to clinical trials, epidemiological surveys and studies, and clinical/physiologic studies, namely to study the perceived effect of the gluten free diet on the quality of life of American adults with biopsy-confirmed CD.</b></p> <p><input type="checkbox"/> Educational services, including but not limited to symposia, seminars, training programs, and curricula, namely:<br/>_____<br/>(identify the specific educational use by title and date)</p> <p><input type="checkbox"/> Clinical purposes.</p> |

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1. Grant of License. Subject to the terms and conditions of the Agreement, Licensor grants to Licensee a personal, nontransferable and nonexclusive right to use each of the Licensed Work(s), solely for the Permissible Use in the Permissible Media for the Term and in the Territory (the "License"). Such License includes the right to reproduce the Licensed Work(s), display the Licensed Work(s) publicly, and prepare derivative works based upon the Licensed Work(s) solely in connection with the Permissible Use. All rights not expressly granted to Licensee herein are hereby reserved by Licensor.

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4. Credit to Licensor. Licensor shall receive appropriate credit for the Licensed Work(s) in any work in which the Licensed Work(s) appear or are otherwise used. Licensee shall have the right to use Licensor's name, "The Rome Foundation", in connection with Licensee's use of the Licensed Work(s).

5. Payment of License Fees/Translation Fees. Licensee shall pay to Licensor the applicable License Fee and/or Translation Fee for use of the Licensed Work(s). The License Fee and/or Translation Fee shall be due payable to Licensor at the address in Section 11 upon invoice by Licensor.

6. Ownership Acknowledgment. Licensee acknowledges and confirms that all copyrights in and to the Licensed Work(s), in whatever media, version or form, shall belong exclusively, irrevocably and throughout the world to Licensor, and Licensee agrees that it will not attack or challenge such ownership rights in any manner whatsoever.

7. Assignment. Any assignment by Licensee of its rights under this Agreement shall be subject to the prior written consent of Licensor, which shall not be unreasonably withheld but which may require additional license fees to be paid to Licensor as a precondition to any such consent. Licensor shall have the right to sell or transfer its right to receive the License Fee under the Agreement to any party at any time. This Agreement shall be binding upon and inure to the benefit of Licensee and Licensor and their respective successors and assigns.

8. Representations and Warranties/Indemnification.

a. Representations and Warranties. Licensor hereby represents that it possesses the right, power, and authority to execute, perform, and deliver its obligations under this Agreement, and that the Licensed Work(s) are original and do not infringe the intellectual property rights of any third party, or otherwise violate or infringe any rights whatsoever of any third party, including without limitation any rights of privacy or publicity.

b. Indemnification. Licensor shall indemnify and hold harmless Licensee, its affiliates, subsidiaries, licensees, and assigns, and their respective officers and employees, from and against any and all claims, charges, costs, causes of action, judgments, or liabilities (including, without limitation, attorneys' fees) that may arise as the result of or in connection with a breach or alleged breach by Licensor of its representations, warranties, or obligations hereunder. Licensee shall indemnify and hold harmless Licensor, its affiliates, subsidiaries, licensees, and assigns, and their respective officers and employees, from and against any and all claims, charges, costs, causes of action, judgments, or liabilities (including, without limitation, attorneys' fees) that may arise as the result of or in connection

with (i) a breach or alleged breach by Licensee of its representations, warranties, or obligations hereunder, (ii) an unauthorized use of the Licensed Work(s) or (iii) any derivative work created by Licensee except to the extent the third party claim asserts rights in the Licensed Work(s).

9. Term and Termination.

- a. Term. The License granted herein shall be for the Initial Term herein defined. Licensee shall have the option to renew this Agreement, including the License granted herein, upon the same terms stated herein, including the License Fee, for an additional period equal to the duration of the Initial Term (the "Renewal Term"; together with the Initial Term, the "Term") by providing written notice to Licensor of its intention to renew the Agreement no less than one month prior to the end of the Initial Term.
- b. Termination. In the event that Licensee fails in a material manner to fulfill any of the terms and conditions of this Agreement, Licensor shall have the right, upon written notice to Licensee detailing the claimed breach(es), to terminate this Agreement, such notice being effective thirty (30) days after having been given and if such breach has not (in the sole discretion of Licensor) been fully cured during such thirty (30) day period. If the event that this Agreement is terminated pursuant to this Section 9(b) and due to Licensee's uncured material breach of this Agreement, the License Fee shall not be refunded in full or in part.
- c. Effect of Termination. Upon the expiration or termination of this Agreement, all of the rights of Licensee under this Agreement shall terminate and Licensee shall immediately discontinue all use of the Licensed Work(s). Termination of this Agreement pursuant to the terms and conditions hereof shall be without prejudice to the terminating party's other rights and remedies at law or in equity.

10. Protection of Licensed Work(s). Each Party shall promptly notify the other of any actual or threatened infringement of the Licensed Work(s). Licensor shall have the first right to institute legal proceedings at its own expense against such actual or threatened infringement, but if Licensor should decide not to pursue legal proceedings, it shall duly notify Licensee, which shall then have the right to institute such proceedings at Licensee's own expense. Regardless of which Party brings suit, Licensor and Licensee shall cooperate with one another in the event such proceedings against third party infringers are brought.

11. Notices. All notices and other communications required or permitted under this Agreement shall be made as follows:

If to Licensor:

The Rome Foundation, Inc.  
P.O. Box 6524  
Raleigh, North Carolina 27628  
U.S.A.

Facsimile: 919-900-7646

If to Licensee, at the address written above.

All notices or other communications shall be made by express overnight mail or courier service, or via facsimile so long as confirmation of receipt is obtained and a copy is placed in regular mail for delivery by the U.S. Postal Service the same day facsimile transmission occurs and confirmation is received. Either Party may change its address for service of notices and other communications by providing written notice of such change of address pursuant to the terms of this Section 11.

12. Disclaimers and Limitations of Liability. THE LICENSED WORK(S) AND ALL INFORMATION, CONTENT, AND MATERIALS INCLUDED IN THE LICENSED WORK(S) AND ALL INFORMATION, CONTENT, AND MATERIALS INCLUDED IN THE LICENSED WORK(S) ARE PROVIDED BY LICENSOR ON AN "AS IS" BASIS. LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, AS TO THE COMPLETENESS, ACCURACY, TIMELINESS, OR RELIABILITY OF THE INFORMATION, CONTENT OR MATERIALS INCLUDED IN OR OTHERWISE MADE AVAILABLE IN THE LICENSED WORK(S). LICENSOR IS NOT RESPONSIBLE OR LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, CONSEQUENTIAL OR OTHER DAMAGES, COSTS, EXPENSES, LEGAL FEES, OR LOSSES (INCLUDING WITHOUT LIMITATION LOST PROFITS, LOST INCOME, OR LOST OPPORTUNITY COSTS) OF ANY KIND IN CONNECTION WITH THE LICENSED WORK(S) AND/OR ANY USE OF THE INFORMATION CONTAINED WITHIN THE LICENSED WORK(S), OR INFORMATION MADE AVAILABLE THROUGH OR REFERENCED BY THE LICENSED WORK(S), AND/OR DAMAGES THAT RESULT FROM THE USE OF THE LICENSED WORK(S). IN NO EVENT SHALL THE TOTAL LIABILITY OF LICENSOR TO LICENSEE, FOR ANY AND ALL DAMAGES, LOSSES, AND CAUSES OF ACTION RESULTING FROM USE OF THE LICENSED WORKS, PURSUANT TO THE LICENSES GRANTED HERE, WHETHER IN CONTRACT, TORT OR OTHERWISE, EXCEED THE LICENSEE FEE PAID FOR THE LICENSED WORK(S). LICENSOR PROVIDES THE LICENSED WORK(S) AS A RESOURCE OF GENERAL INFORMATION. LICENSEE ACCEPTS THAT INFORMATION CONTAINED IN THE LICENSED WORK(S) IS SUBJECT TO CHANGE WITHOUT NOTICE. THE LICENSED WORK(S) DO NOT PROVIDE, NOR ARE THEY MEANT TO PROVIDE SPECIFIC MEDICAL OPINIONS OR DIAGNOSES REGARDING YOUR OR ANOTHER PERSON'S CONDITION, NOR DO THE LICENSED WORK(S) REPLACE THE MEDICAL OPINIONS OR DIAGNOSES THAT MAY BE PROVIDED BY A MEDICAL PROFESSIONAL.

13. Dispute Resolution. This Agreement shall be interpreted and construed in accordance with the laws of the State of North Carolina, U.S.A. All claims, actions, proceedings and disputes arising out of this agreement shall be commenced exclusively in Raleigh, North Carolina, U.S.A., and all parties consent to personal jurisdiction in Raleigh, North Carolina, U.S.A.

- A. Good Faith Negotiation. The Parties agree that, before resorting to any formal dispute resolution process concerning any dispute arising from or in any way relating to this Agreement (a "Dispute"), they will first attempt to engage in good faith negotiations in an effort to find a solution that serves their respective and mutual interests, including their continuing business/professional relationship. Party-principals agree to participate directly in the negotiations. Unless otherwise agreed in writing, the Parties shall have five (5) business days from the date the questioning party gives Notice (defined below) of the particular issue to begin these negotiations and 15 business days from the Notice date to complete these negotiations concerning the Dispute.
- b. Mediation. If the negotiations do not take place within the time provided in Section 13(A) above, or if the negotiations do not conclude with a mutually agreed upon solution within that time frame (or its agreed upon extension), the Parties agree to mediate any Dispute. The parties agree to participate in at least four hours of mediation in accordance with the mediation procedures of JAMS International, and to try in good faith to settle the dispute by mediation before resorting to other dispute resolution procedures. The parties agree to share equally in the costs of the mediation. The mediation shall be administered by a local JAMS office to be designated by JAMS headquarters. The Parties agree to have the principals participate in the mediation process, including being present throughout the mediation session(s). The Parties shall have thirty (30) calendar days within which to commence the first mediation session following the conclusion of the good faith negotiations to resolve the dispute. The Parties agree that any mediated settlement agreement may be converted to an arbitration award or judgment (or both) and enforced according to the governing rules of civil procedure, Sections 304, 207 or 9 of the Federal Arbitration Act, the New York Convention, the Panama Convention, and other available enforcement mechanisms including multilateral treaties, bilateral Friendship, Commerce and Navigation treaties and traditional principles of comity among nations. The Parties further confirm their motivating purpose in selecting mediation is to find a solution that serves their respective and mutual interests, including their continuing business/professional relationship.
- c. Arbitration. If mediation does not take place within the time provided in Section 13(B) above, or if mediation does not conclude with a mediated settlement agreement, the Parties agree that the Dispute shall be settled and determined by arbitration in New York City before a panel of three (3) arbitrators pursuant to the International Arbitration Rules offered by the American Arbitration Association in conjunction with the International Center for Dispute Resolution. The parties agree to impose a time limit of six (6) months on any such arbitration proceeding, as measured from the date of the first claimant's first filing. The parties agree that the arbitrators shall have the power to award forms of relief including but not limited to damages, injunctive relief, preliminary injunctive relief, temporary restraining orders, and reasonable attorneys' fees and expenses to any party in such arbitration. Anything to the contrary herein notwithstanding, a temporary

restraining order or injunction may be obtained by Licensor or Licensee from a court of appropriate jurisdiction pending the determination of any controversy pursuant to this arbitration provision.

14. Miscellaneous.

- a. This Agreement contains the entire agreement and understanding between the parties. There are no covenants, representations, or warranties not herein expressly set forth. This Agreement may not be changed, modified or amended except by the written agreement of the parties.
- b. A waiver of any right under this Agreement is only effective if it is in writing and it applies only to the circumstances for which it is given. No failure or delay by Licensor or Licensee in exercising any right or remedy under this Agreement or by law, or in requiring strict observance or performance of any provision of this Agreement, shall constitute a waiver of that (or any other) right or remedy, nor preclude or restrict its further exercise. No single or partial exercise of such right or remedy shall preclude or restrict the further exercise of that (or any other) right or remedy.
- c. This Agreement shall not be construed as creating an agency, partnership, joint venture, or any other form of association, and the parties shall at all times be and remain independent contractors. Except as expressly agreed by the parties in writing, neither party shall have any right or authority, express or implied, to assume or create any obligation of any kind, or to make any representation or warranty, on behalf of the other party or to bind the other party in any respect.
- d. Should there be any conflict between any provision of this Agreement and any present or future law (statutory or common law), contrary to which the Parties have no legal or enforceable right to contract, the provision of this Agreement affected shall be curtailed and limited only to the extent necessary to bring it within legal and enforceable requirements, and the other provisions of this Agreement shall not be affected but shall remain in full force and effect.
- e. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same document. The Agreement may be transmitted by electronic means in PDF format, and reproductions of signatures by electronic means in PDF format, or by facsimile, will be treated as binding as if original.
- f. The Parties warrant that the individual whose signature appears below has been duly authorized to sign this Agreement and to bind each Party thereto.

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

LICENSEE

LICENSOR

The Rome Foundation, Inc.

By:  RD

By: W. N. Hilliard, Jr.

Name: TIFFANY EPPERSON

Name: W.N. Hilliard, Jr.

Title: REGISTERED DIETITIAN

Title: Executive Director