RESEARCH PROTOCOL

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<th>Date</th>
<th>3/1/17</th>
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<tbody>
<tr>
<td>Title</td>
<td>Impact of diet on functional gastrointestinal symptoms; a national population based survey</td>
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Purpose of Study:
- To delineate the role of diet in functional gastrointestinal (GI) symptoms.
- To determine the prevalence of functional GI disorders in the general population.
  - **Primary Aim:** To describe common triggers for food-related GI symptoms.
  - **Secondary Aims:** To assess prevalence of self-reported functional GI disorders and awareness of dietary modification programs for GI symptoms.

Hypothesis or Research Question
- We hypothesize that functional GI symptoms are very common, and may not be associated with formal diagnoses.
- We further hypothesize that certain foods may be triggers for symptoms, and that food ‘sensitivity’ is common in the population.
- Finally, we hypothesize that the majority of people are aware of gluten-free eating but are less aware of other dietary treatments for GI symptoms.

Background

Hippocrates said “Let food be thy medicine, and medicine be thy food”\(^1\). This quote rings true today, more than ever before. Functional GI disorders, involving symptoms such as gas/bloating, diarrhea, constipation and abdominal pain, are estimated to impact between 35 and 45 million Americans, an overwhelming 15-20% of the population. These symptoms are responsible for upwards of 20 billion dollars in healthcare costs and extensive loss of quality of life for sufferers\(^2,3\). Moreover, many patients suffer in silence, with 67% of subjects waiting more than a year before treatment, and 11% waiting over 10 years\(^4\). Irritable bowel syndrome or IBS is the most prevalent functional GI disorder\(^5\), and several recent studies support the idea that dietary modifications may be key to alleviating this condition\(^6-16\).

Food sensitivities and reported intolerance to lactose, gluten, wheat, and carbohydrates are increasing globally. While the mechanism is unclear, restriction of particular foods or food groups may alleviate functional GI symptoms. Indeed, both gluten-free and low-FODMAP diets
have been shown to reduce symptoms in affected patients, and not exclusively in those with celiac disease or lactose intolerance\textsuperscript{16,17}.

The low-FODMAP diet was initially described in 2006, and to date, dozens of well-designed studies have confirmed its benefit for IBS\textsuperscript{11,13-15,18-27}. FODMAP is an acronym standing for Fermentable, Oligo, Di, and Mono-saccharides and Polyols. These short-chain carbohydrates are poorly digested and can lead to symptoms of gas, bloating, diarrhea and constipation. Other disorders showing benefit from FODMAP restriction include inflammatory bowel disorders (Crohn’s disease and colitis), gastroparesis, diverticulitis, post-gastric resection and small intestinal bacterial overgrowth (SIBO)\textsuperscript{9,12,28-32}. Benefit from this eating plan has surpassed touted success of medications commonly prescribed for IBS, without the side effects and high cost\textsuperscript{1}.

Thus, the purpose of this study is to document GI symptoms among the US population, as well as to ascertain awareness and utilization of dietary treatments that exist. Similar research has been conducted on small samples sizes in the United Kingdom\textsuperscript{17} but is lacking in the US. This information is important in identifying knowledge gaps and will aid both physicians and dietitians to educate their patients about these programs. Furthermore it is important for health care providers to understand the a priori knowledge and utilization of dietary modifications amongst sufferers of functional GI disorders.

Research Plan

- **Study Design**
  - This cross-sectional survey study will be administered through a secure online server at SurveyMonkey\textsuperscript{®}.

- **Participants**
  - The survey will be administered to men and women between the ages of 18 and 80.
  - Subjects will be recruited via email.
  - A cover email will explain how to access the survey and that participation is voluntary.
  - Email addresses will be obtained through SurveyMonkey\textsuperscript{®}.
  - The investigators will not have access to the email addresses or the subject contact information.
  - Exclusion Criteria:
    - Visual impairment.
    - Inability to read.
    - Inability to understand English.
    - Inability to use a computer to respond to questions.

- **Data Collection**
  - The survey consists of questions regarding GI symptoms\textsuperscript{33}, strategies for managing symptoms, foods that may trigger symptoms, and awareness of dietary plans for GI symptoms.
  - Demographic information will also be obtained.
• The survey instrument is attached.

• **Intervention or experimental aspect of the study**
  • There is no intervention.

• **Statistical Analysis**
  • Demographic data will be described using frequency (percentage) for categorical variables and mean (standard deviation) or median (interquartile range) for continuous variables.
  • Categorical data will be analyzed using Pearson’s chi-square or Fisher’s exact test; continuous data will be analyzed using Student’s t-test.
    o A goal of greater than 500 subjects is sought. Sufficient emails will be obtained from SurveyMonkey® to accomplish this sample size.

**Ethical Considerations**
• **Informed consent**
  • By completing the survey, providers will be giving their consent to participate. No separate informed consent will be administered.

• **Privacy information**
  • The surveys are completely confidential. No identifying information will be obtained.

**Cost/Budget**
• Approximately $3500 for the use of the email addresses.

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<th>Estimated Period of Time to Complete Study</th>
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<td>When will study begin?</td>
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<td>Protocol Development Completed</td>
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<td>Admin Review Time</td>
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<td>IRB Approval</td>
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<td>Data collection</td>
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<td>Data analysis</td>
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<td>Presentation development (if applicable)</td>
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<td>Manuscript Development (if applicable)</td>
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<td>Journal submission process (if applicable)</td>
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References