The Efficacy of a Diet Low in Fermentable Sugars in the Reduction of Symptoms for Patients with Irritable Bowel Syndrome

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Recommended Citation
Steigleder, Odessa, "The Efficacy of a Diet Low in Fermentable Sugars in the Reduction of Symptoms for Patients with Irritable Bowel Syndrome" (2013). School of Physician Assistant Studies. 456.
https://commons.pacificu.edu/pa/456
The Efficacy of a Diet Low in Fermentable Sugars in the Reduction of Symptoms for Patients with Irritable Bowel Syndrome

Abstract

Background: Irritable bowel syndrome (IBS) is a common disorder, affecting 7-10% of the worldwide population. It consists of abdominal pain and altered bowel habits present for at least three months. Poorly absorbed, short-chain carbohydrates are grouped based on chain length and result in the acronym FODMAP: fermentable oligo-, di-, mono-, and polyols. These FODMAPs pass through the small bowel unabsorbed and may be affecting symptoms in those with IBS. Does a diet low in fermentable sugars improve symptoms for patients with IBS?

Method: An exhaustive literature search was conducted using Medline, CINAHL, and Google Scholar with use of keywords “FODMAP diet” and “irritable bowel syndrome.” Further review of bibliographies was completed for any other relevant resources. Articles were then assessed for quality using Grading of Recommendations, Assessment, Development, and Evaluation (GRADE).

Results: After reviewing for relevancy, three articles met inclusion criteria. These articles included three randomized control trials. A double-blinded, randomized, placebo-controlled trial with 26 participants demonstrated reduction in symptom severity with a diet low in FODMAPs. A randomized control trial with 41 participants successfully established a reduced symptom profile in patients with IBS when adhering to a diet low in FODMAPs. Lastly, a randomized, single-blinded control trial recruited both healthy patients and those with IBS to demonstrate the success of a low FODMAP diet.

Conclusion: A diet low in fermentable sugars has demonstrated reduction of symptoms in patients with irritable bowel syndrome. Primary care providers as well as GI specialists can educate their patients with IBS on the diet and encourage them to adhere with little worry of cost or harm to the population. Although the studies have limitations and further, stronger research is needed, the benefits of this lifestyle intervention seem to outweigh the risks to the patient.

Degree Type
Capstone Project

Degree Name
Master of Science in Physician Assistant Studies

Keywords
Irritable bowel syndrome, FODMAP diet

Subject Categories
Medicine and Health Sciences

This capstone project is available at CommonKnowledge: https://commons.pacificu.edu/pa/456
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The Efficacy of a Diet Low in Fermentable Sugars in the Reduction of Symptoms for Patients with Irritable Bowel Syndrome

Odessa Steigleder

A Clinical Graduate Project Submitted to the Faculty of the School of Physician Assistant Studies
Pacific University
Hillsboro, OR
For the Masters of Science Degree

Faculty Advisor: Dr. Mark Pedemonte
Clinical Graduate Project Coordinator: Annjanette Sommers, PA-C, MS
Biography

Odessa Steigleder has lived in Portland, Oregon since childhood. She received her Bachelor of Science degree from Oregon State University in Corvallis, Oregon in 2007 with a major in Exercise and Sports Science. She is happily married and plans to stay in the Portland area following graduation to be near family and friends.
Abstract

**Background:** Irritable bowel syndrome (IBS) is a common disorder, affecting 7-10% of the worldwide population. It consists of abdominal pain and altered bowel habits present for at least three months. Poorly absorbed, short-chain carbohydrates are grouped based on chain length and result in the acronym FODMAP: fermentable oligo-, di-, mono-, and polyols. These FODMAPs pass through the small bowel unabsorbed and may be affecting symptoms in those with IBS. Does a diet low in fermentable sugars improve symptoms for patients with IBS?

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**Conclusion:** A diet low in fermentable sugars has demonstrated reduction of symptoms in patients with irritable bowel syndrome. Primary care providers as well as GI specialists can educate their patients with IBS on the diet and encourage them to adhere with little worry of cost or harm to the population. Although the studies have limitations and further, stronger research is needed, the benefits of this lifestyle intervention seem to outweigh the risks to the patient.

**Keywords:** Irritable bowel syndrome, FODMAP diet
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Note: Results given are the median, interquartile range, and maximum and minimum

List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>FODMAP</td>
<td>Fermentable oligo-, di-, mono-, and polyols</td>
</tr>
<tr>
<td>IBS</td>
<td>Irritable Bowel Syndrome</td>
</tr>
<tr>
<td>GI</td>
<td>Gastrointestinal</td>
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</table>
The Efficacy of a Diet Low in Fermentable Sugars in the Reduction of Symptoms for Patients with Irritable Bowel Syndrome

BACKGROUND

Irritable bowel syndrome (IBS) is a common disorder, affecting 7-10% of the worldwide population. It consists of abdominal pain and altered bowel habits present for at least three months. 1 Three components help to define the disease, and these are gut reactivity in response to luminal stimuli or distention that results in symptoms of diarrhea or constipation, increased sensitivity of the gut with increased visceral perception and pain, and altered regulation of the brain-gut communication possibly influenced by stress.2 The condition can be present as diarrhea, constipation, or alternating in predominance, where as the diarrhea and alternating types being the more commonly seen.1 Those with this condition often have worsening symptoms of abdominal pain and bloating following meals, leading many patients to assume a food allergy as the culprit. Specific diagnostic tests are lacking for the condition and patients are therefore diagnosed by exclusion of other disease entities and the application of symptom-based criteria. The diagnostic criteria most commonly utilized are that of the Rome Criteria. 3 This defines IBS as recurrent abdominal pain or discomfort at least 3 days per month in the last 3 months associated with two or more of the following: improvement with defecation, onset associated with change in frequency of stool, and onset associated with a change in form of stool.4

IBS is 1.5 times more likely in women. It is one of the most commonly seen conditions by both primary care providers as well as gastrointestinal (GI) specialists and
therefore causes large healthcare expenses. This population is known to have more frequent doctor visits, more workdays missed with a resulting lower work productivity, and consume more medications as well as overall direct costs than those without the diagnosis.¹

Current treatment options include eliminating known dietary triggers such as lactose or caffeine, use of medications that target the dominant symptom, cognitive behavioral therapy, and anti-depressants. IBS seems to be inadequately managed in the clinical setting, however, and this is potentially due to conventional treatment methods suboptimally controlling symptoms.⁵

Carbohydrates or sugars are common ingredients within daily diets across the world. These dietary substances are large polysaccharides or disaccharides that must undergo digestion to then become absorbable monosaccharides. Active transport occurs within the small intestine to absorb these end products. One’s diet can influence the efficiency of this process and the carbohydrate load that then reaches the colon unabsorbed. These carbohydrates undergo fermentation by colonic bacteria and theories exist stating this process is important in the symptoms of bloating, abdominal distention, and changes in bowel habits.⁶ Poorly absorbed, short-chain carbohydrates are grouped based on chain length and result in the acronym FODMAP: fermentable oligo-, di-, mono-, and polyols.⁷ These FODMAPs pass through the small bowel unabsorbed and may be affecting symptoms in those with IBS.⁶ Foods high in FODMAPs are not necessarily the cause of the condition but in the presence of IBS, they may bring on the symptoms of bloating, abdominal pain, and motility changes.⁷ Common foods found to
be rich sources of FODMAPs include wheat, rye, onions, garlic, artichokes, legumes, milk, honey, apples, pears, sugar-free gums/mints, mushrooms, and cauliflower. If this is the case, the use of a diet low in FODMAPs has the potential to reduce the symptom severity within this population. This review will address the research further.

**METHODS**

An exhaustive literature search was conducted using Medline, CINAHL, and Google Scholar with use of keywords “FODMAP diet” and “irritable bowel syndrome.” Further review of bibliographies was completed for any other relevant resources. Relevant randomized control trials with focused data on the efficacy of a diet low in fermentable sugars in patients with IBS were included. Articles were excluded if the study looked at patient populations with other bowel diagnoses such as Crohn or Celiac disease. Articles were then assessed for quality using Grading of Recommendations, Assessment, Development, and Evaluation (GRADE).

**RESULTS**

The initial systematic literature search resulted in 237 articles. After reviewing for relevancy, three articles met inclusion criteria. These articles included three randomized control trials. See Table 1.

**Shepherd et al**

This double-blinded, randomized, placebo-controlled trial, conducted in Australia, investigated the effect of fermentable sugars on symptom severity in patients with IBS. The trial involved 26 participants with IBS who were recruited from a
hospital-based dietetic practice. The median age of participants was 38 years old, four participants were male, and all were Caucasian except one patient of Chinese heritage. Participants had varied IBS symptoms with twelve diarrhea-predominant, five constipation-predominant, and eight alternating bowel habits. Twelve participants were being treated with symptom-based medications at recruitment and these were continued at a stable dose throughout the study. One participant was excluded due to withdrawal prior to treatment. Primary outcomes included patient symptoms, evaluated by a global symptom question of “Were your symptoms adequately controlled in this phase?” and symptom scoring based on a visual analogue scale assessing the severity of several symptoms.  

Inclusion criteria of the study was diagnosis of IBS based on the Rome II Criteria, positive fructose breath hydrogen testing following a 35-gram load of fructose, instruction in a low FODMAP diet at least three months prior to recruitment, and significant improvement of GI symptoms on this diet. Exclusion criteria included the diagnosis of Celiac Disease, Inflammatory Bowel Disease, or other co-morbidity. 

Patients were provided all food for the duration of the study. This was a diet low in FODMAPs for 22 weeks. The patients were tested with one of four test substances in a four-arm, crossover design. These substances were varying carbohydrates, given in the form of powder drinks, dosed three times a day with meals. Three of the substances were fermentable sugars (fructan, fructose, fructan/fructose mix), all providing separate control arms. The last substance contained glucose, which provided the treatment arm as this is not a fermentable sugar and represents a diet of low in FODMAPs. The drinks were provided in phases of low, medium, and high doses based on grams of sugar and were
similar in flavor and texture. A washout period of 10 days was implemented between test arms. Symptoms were evaluated by daily diary entries with primary end points being addressed. 

The proportion of patients who answered positively to the global symptom question at maximal testing dose was substantially larger in the treatment arm than that of the other control arms high in FODMAPs. IBS symptom severity assessed via the visual analogue scale also was significantly reduced within the treatment arm. This result was true across all symptoms evaluated. Lastly, it was seen that patients were able to maintain obedience to the low FODMAP diet as greater than 95% admitted to adherence. See Figure 1.

One limitation of this study, the authors noted, was that giving the test substances in liquid form may have a different physiologic response than carbohydrates provided within food. Also, participants were instructed to refrain from a diet high in FODMAPs for 3-36 months prior to this study. It is possible that this diet altered the colonic microbiota such that the patients then hyper-reacted to introduced fermentable sugars during the study. Lastly, the individuals selected for inclusion were patients with IBS who had shown improvement in symptoms while adhering to a low FODMAP diet prior to the study. This could introduce selection bias because the individuals being observed are then of a particular population that are known to respond well to the intervention.

Staudacher et al

This randomized control trial, conducted in England, looked at IBS symptom severity following adherence to either a low FODMAP diet or “normal” diet. They also addressed luminal microbiology via stool sampling as a surrogate outcome. The study
assessed 99 participants for eligibility based on a seven-day symptom severity screening. Of those assessed, 41 were selected and randomized to treatment or control groups. These participants were recruited from GI outpatient clinics and demographics were roughly equivalent in both groups. The median age was 35 years old and more than half were female.  

Inclusion criteria of the study involved participants 18-65 years old with the diagnosis of IBS based on Rome III Criteria. Participants were excluded if they had a history of other major GI conditions, had a previous GI resection or organ disorder, had constipation-predominant IBS, were pregnant or lactating, or had been using probiotics or bowel preparations within the previous 4 weeks. The primary end point of the study was luminal microbiology through stool sampling and the secondary end point was effect on symptom severity.  

After a seven day screening period in which symptom, stool, and diet evaluations were completed, education in and instruction to follow either a low FODMAP diet or to continue their normal diet was provided. Participants were therefore not blinded to their allocated treatment. They were then followed over a 4-week period. During the fourth and final week, they completed a daily symptom diary based on a symptom rating scale. The symptom scale was a 4-point system with a score of 0 indicating no symptoms and 3 indicating severe symptoms. They were also assessed using a global symptom question: “Were your symptoms adequately controlled over the previous week?” Similar stool screenings as done in the preliminary period were completed.  

At follow up, more participants within the treatment group of a low FODMAP diet reported symptom control based on the global symptom question as compared to the
control group. As well, more participants within the treatment group experienced a reduction in symptom severity scores for overall symptoms, abdominal pain, and bloating. Also, it was found that patients within the low FODMAP regimen were able to strongly adhere to this diet despite the new restrictions placed on the patients, indicating compliance has high potential in this population.\(^9\) See Table 2.

The authors of the study did admit to limitations. Although the two groups received equal contact time with study conductors, the control group was not provided with advice for symptoms and this could have led to a placebo affect within the intervention group. The authors admit this could have been avoided through blinding with providing all food and drink to participants. Secondly, the study witnessed reduced luminal bacteria after this 4-week trial within the low FODMAP group. Although this group observed decreased symptoms, whether or not the reduced luminal bacterium has detrimental long-term effects on colonic health is unknown and would need to be further studied.\(^9\)

**Ong et al**

This randomized, single-blinded control trial,\(^10\) conducted in Australia, assessed the efficacy of a diet low in fermentable sugars within a healthy patient population as well as with patients diagnosed with IBS. It was done in a crossover design in which 15 healthy individuals and 15 individuals with IBS were randomized and blinded to treatment or control groups. The IBS participants were recruited from the Functional Gut Disorder Clinic and the healthy participants were recruited from advertising at the local university. Although the two groups were similarly high in female participants, the
median ages were 23 years old within the healthy group and 41 years old within the IBS group.\textsuperscript{10}

The study followed inclusion and exclusion criteria for each patient population. For the healthy participants, they were included if they had no GI symptoms and believed themselves to be “healthy.” Participants were included within the IBS group if they fulfilled the diagnosis of IBS based on the Rome III criteria. All participants were 18 years or older. Participants were excluded if they had medically significant co-morbidities, were pregnant, had lactose intolerance, or had used probiotics or antibiotics within the preceding 8 weeks.\textsuperscript{10}

All participants consumed a high FODMAP, as well as, a low FODMAP diet for two-day periods with a seven-day washout period in between. To aid in blinding, these diet regimens were provided to all subjects. A seven-day baseline symptom questionnaire and food diary was completed prior to initiating treatment or control diets. Breath sample collection was also done. These evaluations were then repeated during both arms of the study.\textsuperscript{10}

Analysis of the data demonstrated that the healthy participants had a slightly improved symptom profile following the low FODMAP diet but this was shown to be statistically insignificant in most symptoms based on p values. This indicates that healthy participants are less affected by dietary changes. The participants with IBS had marked improvement of symptoms. This suggests that patients with IBS have a high likelihood of symptom improvement with a low FODMAP diet.\textsuperscript{10} See Table 3.
The authors do admit to a small sample size and suggest that larger cohorts of patients would need to be further studied to observe symptom profiles and effect of fermentable sugars.  

**DISCUSSION**

Providers that care for patients with IBS have utilized many treatment options over the years including several medications with potentially harmful side effects. These have often been unsuccessful as witnessed by statistics of healthcare usage by patients with IBS.  

This high utilization of healthcare without consistently positive outcomes may impede on overall satisfaction of the healthcare experience. Uncontrolled symptoms result in missed workdays and decreased productivity possibly resulting in a reduced quality of life. Practitioners continually search for the lowest harm, yet most effective intervention for their patients. This research suggests that educating patients with IBS on a diet low in fermentable sugars and encouraging their adherence may have meaningful results in their symptom severity, healthcare experience, and quality of life. All three studies demonstrated that a diet low in fermentable sugars effectively reduces symptoms in patients with irritable bowel syndrome. Although lifestyle changes can be difficult to adhere to, the witnessed participants in the Shepherd et al study have seemingly followed this diet. This gives validation for a clinician to provide education for patients who are capable of adhering to a lifestyle modification such as this during their office visits. They may also recruit informed dietitians for further assistance with patient education. Providers have the opportunity to utilize this intervention for those individuals who are not interested in or have not found relief with medication treatment. Overall, the
findings suggest that a diet low in FODMAPs to be a potentially well-tolerated, low harm intervention for patients with abdominal symptoms related to IBS.

Although these findings are promising, there are several limitations to the studies discussed. Overall, small sample sizes were observed. Future research will need to include larger populations to truly see efficacy and any potential weaknesses of the diet. Two of the studies utilized a crossover design. This structure introduces risk of bias as the participants are exposed to both treatment and control, possibly influencing their interpretation of symptoms on each diet. Although these crossover studies attempted to blind the participants to food profile, a crossover effect is still a possibility. Future studies should avoid the crossover design. As mentioned, blinding was attempted by two studies. The Staudacher et al study did not make an attempt to blind participants or data analysts. Not having sufficient concealment can cause a performance bias, altering the overall results. Although the Shepherd et al study made stronger efforts to blind by using powder drinks with similar taste profiles, the other studies made less of an effort with either single blinding or not blinding whatsoever. Future studies will need to utilize a double blinding method of introducing the treatment and control interventions to avoid bias.

**CONCLUSION**

A diet low in fermentable sugars has demonstrated reduction of symptoms in patients with Irritable Bowel Syndrome. Primary care providers as well as GI specialists can educate their patients with IBS in the diet and encourage them to adhere with little worry of cost or harm to the population. Although the studies have limitations, further,
stronger research is needed; the benefits of this lifestyle intervention seem to outweigh the risks to the patient.
References


Table 1 Characteristics of Reviewed Studies, GRADE profile

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Limitations</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Inconsistency</th>
<th>Publication bias likely</th>
<th>Quality</th>
<th>Importance</th>
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</thead>
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<tr>
<td>Shepherd et al(^8)</td>
<td>RCT</td>
<td>Serious limitation(^a)</td>
<td>No indirectness</td>
<td>Serious imprecision(^b)</td>
<td>No inconsistency</td>
<td>No</td>
<td>Low</td>
<td>Important</td>
</tr>
<tr>
<td>Staudacher et al(^9)</td>
<td>RCT</td>
<td>Serious limitation(^c)</td>
<td>Serious indirectness(^d)</td>
<td>Serious imprecision(^b)</td>
<td>No inconsistency</td>
<td>No</td>
<td>Very low</td>
<td>Important</td>
</tr>
<tr>
<td>Ong et al(^10)</td>
<td>RCT</td>
<td>Very serious limitation(^e)</td>
<td>No indirectness</td>
<td>Serious imprecision(^b)</td>
<td>No inconsistency</td>
<td>No</td>
<td>Very low</td>
<td>Important</td>
</tr>
</tbody>
</table>

\(^a\)Risk of selection bias due to Shepherd et al study selecting participants that positively respond to low FODMAP diet

\(^b\)Small sample size

\(^c\)Lack of blinding

\(^d\)Use of surrogate outcome as primary end point

\(^e\)Single blinding and crossover effect
Table 2 Staudacher et al<sup>a</sup> study: Symptom incidence and severity in patients with IBS following 4 weeks of treatment vs control diet<sup>a</sup>

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Control&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Treatment&lt;sup&gt;c&lt;/sup&gt;</th>
<th>P value</th>
<th>Control&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Treatment&lt;sup&gt;c&lt;/sup&gt;</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incidence&lt;sup&gt;d&lt;/sup&gt; (days/wk)</td>
<td>Severity Score&lt;sup&gt;e&lt;/sup&gt; (P value)</td>
<td></td>
<td>Incidence&lt;sup&gt;d&lt;/sup&gt; (days/wk)</td>
<td>Severity Score&lt;sup&gt;e&lt;/sup&gt; (P value)</td>
<td></td>
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<tr>
<td>Bloating</td>
<td>5.7 (4.9-6.4)</td>
<td>3.8 (3.0-4.6)</td>
<td>0.002</td>
<td>1.4 (1.2-1.6)</td>
<td>0.9 (0.6-1.1)</td>
<td>0.002</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>4.8 (4.1-5.5)</td>
<td>3.6 (2.8-4.4)</td>
<td>0.02</td>
<td>1.1 (0.9-1.4)</td>
<td>0.8 (0.5-1.1)</td>
<td>0.07</td>
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<tr>
<td>Flatulence</td>
<td>5.6 (4.6-6.5)</td>
<td>4.3 (3.3-5.3)</td>
<td>0.07</td>
<td>1.2 (1.0-1.5)</td>
<td>0.8 (0.5-1.1)</td>
<td>0.018</td>
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<tr>
<td>Flatulence</td>
<td>2.8 (1.9-3.7)</td>
<td>2.0 (1.0-3.0)</td>
<td>0.22</td>
<td>0.7 (0.4-0.9)</td>
<td>0.4 (0.2-0.6)</td>
<td>0.11</td>
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<td>Urgency</td>
<td>3.7 (2.7-4.7)</td>
<td>2.6 (1.5-3.7)</td>
<td>0.15</td>
<td>0.8 (0.6-1.1)</td>
<td>0.6 (0.3-0.8)</td>
<td>0.13</td>
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<tr>
<td>Diarrhea</td>
<td>2.2 (1.3-3.1)</td>
<td>1.4 (0.4-2.4)</td>
<td>0.24</td>
<td>0.4 (0.2-0.6)</td>
<td>0.3 (0.1-0.5)</td>
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<td>Constipation</td>
<td>1.0 (0.5-1.5)</td>
<td>0.8 (0.3-1.3)</td>
<td>0.56</td>
<td>0.2 (0.1-0.2)</td>
<td>0.1 (0.1-0.2)</td>
<td>0.69</td>
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<td>Incomplete evacuation</td>
<td>3.1 (2.1-4.1)</td>
<td>2.1 (1.0-3.2)</td>
<td>0.16</td>
<td>0.7 (0.4-0.9)</td>
<td>0.4 (0.2-0.7)</td>
<td>0.16</td>
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<td>Heartburn</td>
<td>0.5 (0.0-1.1)</td>
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<td>0.1 (0.0-0.2)</td>
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<td>Nausea</td>
<td>1.8 (0.9-2.7)</td>
<td>1.5 (0.5-2.5)</td>
<td>0.67</td>
<td>0.4 (0.2-0.6)</td>
<td>0.3 (0.1-0.5)</td>
<td>0.64</td>
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<tr>
<td>Tiredness</td>
<td>2.0 (1.1-3.9)</td>
<td>1.3 (0.6-2.6)</td>
<td>0.35</td>
<td>0.9 (0.7-1.1)</td>
<td>0.5 (0.3-0.7)</td>
<td>0.015</td>
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<tr>
<td>Overall</td>
<td>1.6 (1.3-1.9)</td>
<td>0.9 (0.8-1.1)</td>
<td>0.001</td>
<td>1.7 (1.4-1.9)</td>
<td>1.1 (0.8-1.3)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

<sup>a</sup> Values are estimated using a 95% CI; control n=19, treatment n=16  
<sup>b</sup> Patients who continued normal diet  
<sup>c</sup> Patients who received FODMAP diet advice  
<sup>d</sup> 95% CI for number of days per week that patients experienced a symptom  
<sup>e</sup> 95% CI for severity score using the 4-point symptom severity scale
Table 3: Ong et al\textsuperscript{10} study: Symptom scores of IBS and healthy patients during high and low FODMAP diet

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Group</th>
<th>Number of subjects with symptom score</th>
<th>P value</th>
<th>RR value</th>
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<tbody>
<tr>
<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>0 1 2 3</td>
<td>0 1 2 3</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>Healthy</td>
<td>10 5 - -</td>
<td>6 8 1 -</td>
<td>0.145</td>
</tr>
<tr>
<td></td>
<td>IBS</td>
<td>6 8 1 -</td>
<td>2 4 7 2</td>
<td>0.006</td>
</tr>
<tr>
<td>Abdominal bloating</td>
<td>Healthy</td>
<td>10 5 - -</td>
<td>8 7 - -</td>
<td>0.484</td>
</tr>
<tr>
<td></td>
<td>IBS</td>
<td>6 6 3 -</td>
<td>1 3 6 5</td>
<td>0.002</td>
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<tr>
<td>Excessive flatus</td>
<td>Healthy</td>
<td>9 5 1 -</td>
<td>1 6 5 3</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>IBS</td>
<td>6 7 1 1</td>
<td>2 7 6</td>
<td>0.002</td>
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<tr>
<td>Nausea</td>
<td>Healthy</td>
<td>13 3 - -</td>
<td>12 3 - -</td>
<td>0.773</td>
</tr>
<tr>
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<td>IBS</td>
<td>12 3 - -</td>
<td>7 5 2 1</td>
<td>0.010</td>
</tr>
<tr>
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<td>Healthy</td>
<td>13 3 - -</td>
<td>14 1 - -</td>
<td>0.424</td>
</tr>
<tr>
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<td>IBS</td>
<td>10 5 - -</td>
<td>6 6 2 1</td>
<td>0.025</td>
</tr>
<tr>
<td>Tiredness/lethargy</td>
<td>Healthy</td>
<td>11 4 - -</td>
<td>10 3 2 -</td>
<td>0.454</td>
</tr>
<tr>
<td></td>
<td>IBS</td>
<td>9 5 1 -</td>
<td>4 7 1 3</td>
<td>0.012</td>
</tr>
</tbody>
</table>
Figure 1  Scores as Reported on the 100-mm VAS for symptoms at the end of the phase of the maximal dose in the Shepherd et al study.\textsuperscript{8} 
Note: Results given are the median, interquartile range, and maximum and minimum scores.