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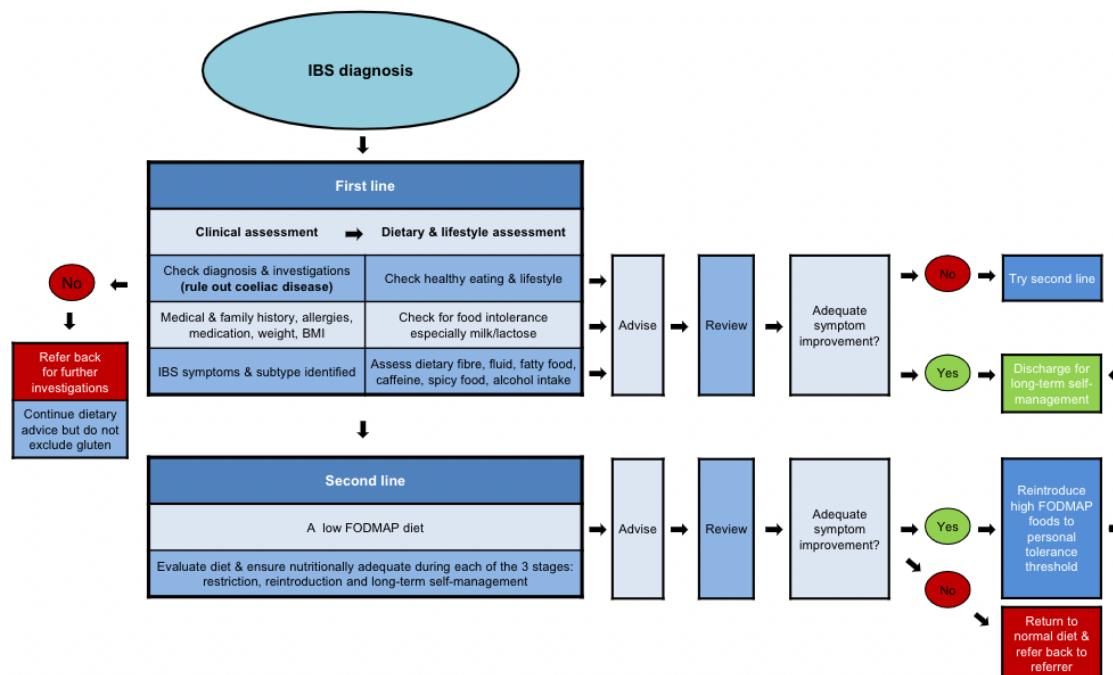
Rej A, Sanders DS, Shaw CC, et al. Efficacy and Acceptability of Dietary Therapies in Non-Constipated Irritable Bowel Syndrome: A Randomized Trial of Traditional Dietary Advice, the Low FODMAP Diet, and the Gluten-Free Diet. *Clinical Gastroenterology and Hepatology*. 2022;S1542-3565(22)00202-6.

## What We Know, Think We Know, or Are Starting to Know

It has been a while since we last [took a Deepdive](#) into the realm of Irritable Bowel Syndrome [IBS], for which diet is well-established as a primary trigger of symptoms <sup>(1)</sup>. Note the deliberate use of the word *trigger*, not *cause*; this reflects the fact that, based on current knowledge, IBS is classified as a functional gastrointestinal disorder, defined by the absence of diagnosed gastrointestinal disease such as Inflammatory Bowel Disease or Coeliac Disease <sup>(2)</sup>.

IBS is characterised by abdominal pain, distension, and alterations in bowel habits on a spectrum from diarrhoea to constipation, including a mix of both and periods with normal stools, which occur in the absence of biochemical, structural or metabolic abnormalities <sup>(2)</sup>. IBS is typically defined by whether the bowel habits are predominantly diarrhoea [IBS-D], constipation [IBS-C], mixed [IBS-M], or unspecified [IBS-U] <sup>(3)</sup>.

Given the characteristics of IBS, and the absence of identifiable abnormalities or disease, IBS is considered a disorder of the gut-brain axis <sup>(2)</sup>. With up to 9/10 individuals reporting that foods trigger symptoms of IBS <sup>(1)</sup>, diet has emerged as a first-line intervention in the management of IBS <sup>(3,4)</sup>. Most research has focused on general national healthy eating advice, and more specific exclusion diets such as the low FODMAP diet or gluten-free diet <sup>(3,4)</sup>. However, few studies have compared all three diets in an intervention.



**Figure** from <sup>(3)</sup> illustrating the pathways for dietary management of IBS following a diagnosis. Note that this is UK management, where the low FODMAP diet is the second line intervention; in the U.S., the low FODMAP diet is the first line intervention.

## **\*Geek Box: The Low FODMAP Diet**

*The acronym FODMAP stands for: Fermentable Oligosaccharides, Disaccharides, Monosaccharides, and Polyols, which are a group of carbohydrate compounds defined by the short-chain length. These compounds may require specific enzymes to digest that certain individuals may lack, and they also undergo fermentation in the colon, which may contribute to distension and bloating.*

*The Low FODMAP Diet [LFD] is an intervention for an individual with IBS and may be divided into three distinct phases. Phase 1 is 'Restriction', which requires strict adherence to the LFD for a period of 4-8 weeks, and during which the individual would be guided to maintain nutritional adequacy while replacing FODMAP foods with alternatives. If no symptom improvement occurs during the Restriction phase of the LFD, the diet is discontinued.*

*However, if the Restriction phase provides symptom relief, then the individual enters the Phase 2 'Reintroduction' period. This period is particularly important, because FODMAPs appear to exhibit a dose-dependent effect and the onset of symptoms often relates to the total dietary exposure of individual FODMAPs and their combinations.*

*For example, while an individual with IBS may be able to consume some milk in coffee, or have a single apple, if they ate a bowl of ice cream or if they had an apple with 2 slices of toast, this may trigger symptoms.*

*Therefore, the goal of the Reintroduction phase is the systematic use of food challenges with FODMAP foods, under the guidance of a nutrition professional, to test individual tolerance to different FODMAP foods and establish a personal threshold for tolerance, for example, 1 slice of bread or 200ml milk, within which the individual does not experience increased symptoms.*

*The aim of the Reintroduction phase is to transition to long-term individual management, where the patient is aware of their own personal tolerance levels to specific FODMAP foods. Thereafter, Phase 3 is 'Long-term Management', with the aim of helping the individual patient find a balance between symptom management and minimising dietary restrictions. This results in an individualised modified diet to the patients particular needs, the exact composition of which for FODMAP foods will differ from person to person*

## The Study

The study was pragmatic randomised trial in the United Kingdom comparing the three dietary approaches to IBS management:

- Traditional Dietary Advice [TDA]
- Low FODMAP Diet [LFD]
- Gluten Free Diet [GFD]

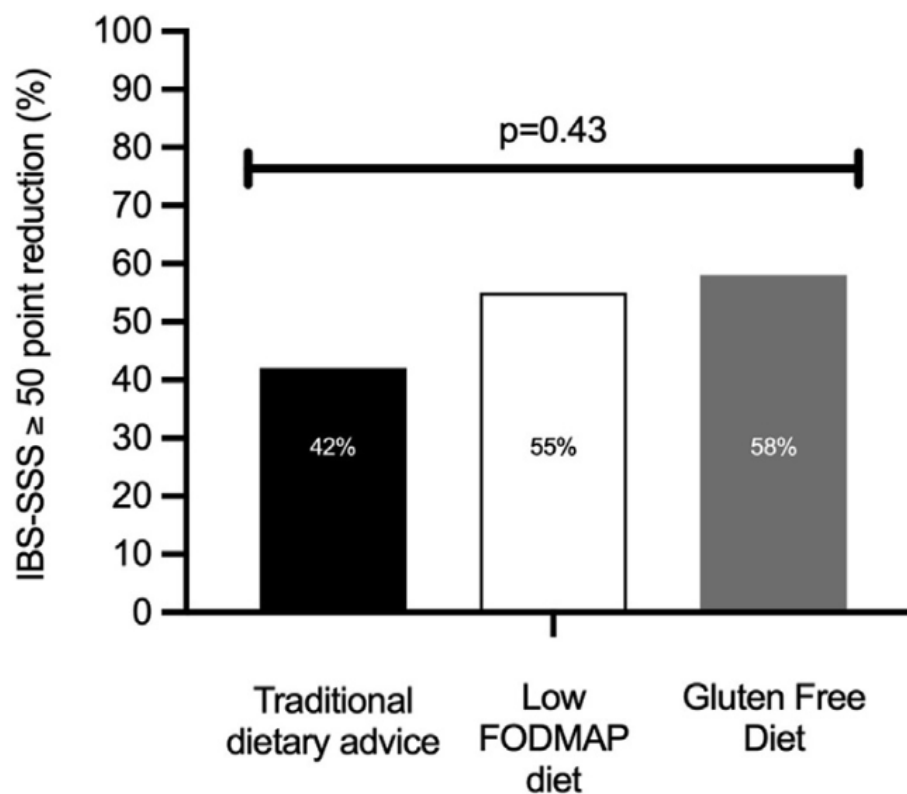
Participants were required to have an IBS Symptom Severity Score [IBS-SSS] of >75-points at baseline [75 to 175 = mild IBS; 175 to 300 = moderate IBS; 300 to 500 = severe], and to have a predominant IBS-D or IBS-M; participants with constipation-predominant [IBS-C] were excluded.

Participants were randomised to one of the three diets, following which participants received in-person consultation with specialist dietitians. Participants then proceeded to implement the diet in their own lives. The total duration of the trial was 4-weeks.

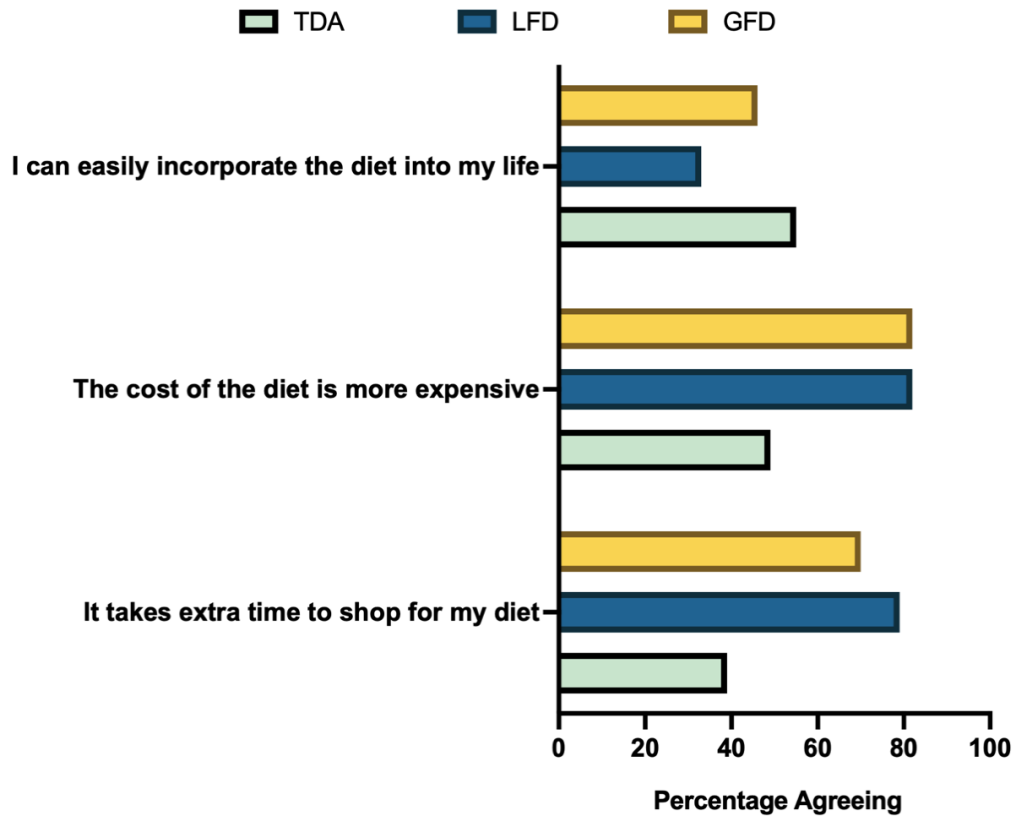
The primary outcome was number of clinical responders to each diet, defined as a >50-point reduction in IBS-SSS. Secondary outcomes included individual IBS-SSS components, quality-of-life and mood score changes, dietary changes, changes in the microbiota, and acceptability scores for each diet.

**Results:** 99 participants completed the study; 33 in each diet group. Participants were 37-years of age on average, 71% female, 88% White. In terms of IBS, 75% had IBS-D while 25% had IBS-M; average baseline IBS-SSS was 301-points, indicating severe IBS. According to the IBS-SSS the percentage of participants with mild, moderate, and severe IBS was 9%, 47%, and 45%, respectively.

- **Clinical Response to Diet:** The percentage of participants in each group achieving a >50-point reduction in IBS-SSS was 42% in the TDA, 55% in the LFD, and 58% in the GFD; the difference between groups was not statistically significant [see **figure**, below]. Of the IBS types, 54% with IBS-D and 44% with IBS-M achieved a clinical response, which was not statistically significant between groups. The type of diet did not affect the response rate according to IBS type.



- **Acceptability of Diets and Food-Related Quality of Life [QoL]:** There were significant differences between groups in food-related QoL, with more participants in the TDA group finding the diet less time-consuming to shop for, less expensive, and more easily incorporated into their life [see **figure**, below].



- **Other Secondary Outcomes:** There was no significant difference in energy, macronutrient, or micronutrient intakes between groups. The Diversity Index, a marker of microbial diversity in the colon, did not differ between diet groups. Total dietary FODMAP intake was significantly different, reduced from an average baseline level of ~25g/d to 7.6g in the LFD, 15.2g in the TDA, and 22.4g in the GFD, respectively.



## The Critical Breakdown

**Pros:** Randomisation method was appropriate [computer-generated; blocked in groups of 5 into each diet group]. Only two participants were recorded as dropouts, and balance was maintained across all diet groups through the study, which would be expected to minimise any bias in the data in favour of one group. Based on the power calculation of 31 participants required per arm, the trial had adequate statistical power to detect differences from the diets. Interestingly, the study had to respond to Covid-19 by moving the dietetic consultations online; there was no difference observed in participants achieving a clinical reduction in IBS-SSS between in-person or online consultations. As a pragmatic trial, the execution of the intervention reflects how it would be conducted in the real world.

**Cons:** Despite the authors noting that this is one of the largest dietary intervention trials in IBS to date, this says more about nutrition research than it is a strength of the study; the sample size is still small overall. This is important given the heterogeneity of IBS, so any given study is only really a reflection of the particular characteristics of the participants in that study. To the author's credit, they draw specific attention to this in their discussion; that to detect whether the 16% magnitude of difference observed between the GFD and TDA in this study were not a false positive would require a study with ~300 participants. Although the duration of the LFD in clinical practice is 4-6 weeks, and thus similar to the 4-week duration of this study, it is still a short duration of symptom improvement, and we can't extrapolate the findings to mean any such improvements would hold over the longer term.

## Key Characteristic

Conducting the QoL assessments of diet acceptability, in addition to the primary symptom-focused outcome, was an important aspect of this study's design given current UK management practice for IBS, in which general IBS healthy eating advice is the first line intervention [see the **figure** under **What We Know**, above] prior to the initiation of the LFD if no improvements in symptoms occur during the first line phase <sup>(3,4)</sup>.

While the percentage of participants achieving the clinical reduction of >50-points on the IBS-SSS was lowest in the TDA group, the diet still showed efficacy for this endpoint at 42%. Yet clearly in relation to the food related QoL outcomes, the TDA was easier, cheaper, and less time consuming. This clearly indicates a greater patient acceptability of the TDA over the more targeted, restrictive dietary interventions.

In [a previous Deepdive](#) of a meta-analysis comparing general IBS dietary advice to the LFD, the LFD was associated with significant reductions in symptoms of abdominal pain and bloating compared to general dietary advice. Findings like this have created an assumption that there is little benefit to the first line intervention, but it may depend on how well those general IBS healthy eating guidelines are implemented. In the present study, the TDA achieved a reduction in dietary FODMAPs of ~10g, which may be around a threshold suggested to result in benefits to symptoms <sup>(5)</sup>.

These are important findings, because if an individual may benefit from the diet without the additional time and effort involved in undertaking more restrictive diets, this is clearly preferable from the perspective both of clinical management and the individual patient. Moreover, it provides a degree of validation to the approach used in the UK, with general IBS healthy eating advice as the first line intervention, failing which the patient is guided to the more specific, but restrictive, LFD <sup>(3,4)</sup>.



## Interesting Finding

The percentage of participants achieving a clinical reduction of >50-points on the IBS-SSS was highest in the GFD, yet if we look at the change in actual FODMAP intake the GFD diet only altered from 27.4g/d at baseline to 22.4g/d after 4-weeks. This is interesting because in a previous intervention of IBS subjects, while FODMAP restriction improved symptoms, the reintroducing of gluten to their diet had no effect on symptoms once FODMAPs remained restricted <sup>(6)</sup>.

Studies like this have led to suggestions that the benefit to a GFD in individuals with IBS may not reflect the direct effects of gluten, but an indirect effect of lowering FODMAPs. However, the evidence overall is conflicting; there are several trials that suggest that gluten *per se* does not increase symptoms once FODMAPs are restricted, while most RCTs have shown a benefit to a GFD in IBS over 4-6 weeks <sup>(4)</sup>.

One of the indirect effects of a GFD in IBS may be through reductions in fructans, short-chain oligosaccharide carbohydrates found primarily in wheat and consumed through foods like bread; a recent double-blind RCT found that fructans triggered significantly more symptoms than gluten in patients with self-reported gluten intolerance <sup>(7)</sup>.

Thus, it could be that a GFD is beneficial in IBS because of concomitant reductions in fructans, other FODMAPs, and/or reductions in gluten itself. The lack of substantial reduction in total FODMAPs in the present study may point to fructans – fructo-oligosaccharides were the only significant change among individual FODMAPs in the GFD group – or gluten itself.

Either way, whether gluten is directly involved in triggering IBS symptoms remains unclear at this point, but the weight of evidence suggests that GFD does lead to short-term symptom improvement in individuals with IBS <sup>(4)</sup>.

## Relevance

The present study indicates that, when properly implemented, TDA may lead to meaningful improvements in IBS symptoms while being more patient-oriented and acceptable in everyday life.

The latter finding is arguably the most important of the present study given the diets all achieved improvements in symptoms, but the TDA diet did exhibit a 13% lower response rate compared to the LFD and 16% lower compared to the GFD. In the context of IBS management, these are trade-offs that require individual-level consideration.

It is important to highlight what TDA actually looks like; based on wider evidence for dietary triggers in IBS, this includes reductions in fatty and spicy food, alcohol, caffeine, and promoting of basic general healthy eating advice <sup>(3)</sup>. While meta-analyses appear to suggest that TDA is far less superior to the LFD, this may be due to poor implementation of the TDA <sup>(4)</sup>.

Other intervention trials comparing an LFD to general IBS healthy eating advice in Sweden <sup>(8)</sup>, or in the U.S. using UK-based modified National Institute for Health and Care Excellence [NICE] IBS guidelines <sup>(9)</sup> found similar efficacy to the TDA diet in the present study.

Ultimately, as the first trial to directly compare these dietary approaches, the present study has added to a “FODMAP-gentle” perspective on IBS management that aims for symptom improvement with the least restriction of FODMAPs, which appears to be the most time consuming and challenging to incorporate <sup>(4)</sup>. In this approach, the GFD may serve as a bridge between TDA and the full implementation of all three phases of the LFD <sup>(4)</sup>.

## Application to Practice

For a more thorough scientific explanation of the effects of gluten, [see this video](#). One of the positives to take from the present study is that there are several options available for dietary intervention in the management of IBS symptoms. While there may be some greater symptom improvement on more restrictive diets like the LFD and GFD, these differences are often of a small magnitude and we don't quite know how robust the observed differences are until larger studies are conducted.

To put this latter point into context for you, the 16% difference between the TDA and GFD amounted to a difference of 5 more participants achieving the 50-point IBS-SSS reduction in the GFD group. In a small study, that seems like a big difference; it could very well washout in a larger study.

From the perspective of patients who live with and manage their IBS on a day-to-day basis, the findings in relation to ease of incorporating a diet into their life, cost, and time saving, add important context to the consideration of what approach to take. There is little point in emphasising what 'best diet' may be for symptoms if an individual would be miserable: a lesson for any nutritional context.

Overall, these findings also stress the importance of proper implementation of the general IBS healthy eating advice; it may be that the first line approach is sufficient for an individual, with more patient acceptability, and this always warrants a shot before more restriction is advised.

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