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The low FODMAP diet in the management of irritable bowel syndrome: an evidence-based review of FODMAP restriction, reintroduction and personalisation in clinical practice

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Short title: Implementing the low FODMAP diet

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Abstract

Dietary restriction of fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAPs) is effective in the management of functional gastrointestinal symptoms that occur in irritable bowel syndrome (IBS). Numerous reviews have been published regarding the evidence for their restriction in the low FODMAP diet, however few reviews discuss the implementation of the low FODMAP diet in practice. The aim of this review is to provide practical guidance on patient assessment and the implementation and monitoring of the low FODMAP diet. Broadly speaking, the low FODMAP diet consists of three stages: FODMAP restriction; FODMAP reintroduction; and FODMAP personalisation and these can be covered in at least two dietetic appointments. The first appointment focuses on confirmation of diagnosis, comprehensive symptom and dietary assessment, detailed description of FODMAPs and their association with symptom induction, followed by counselling regarding FODMAP restriction. Dietary counselling should be tailored to individual needs and appropriate resources provided. At the second appointment, symptoms and diet are re-assessed and, if restriction has successfully reduced IBS symptoms, education is provided on FODMAP reintroduction to identify foods triggering symptoms. Following this, the patient can follow FODMAP personalisation whereby a less restrictive diet is consumed that excludes their personal FODMAP triggers and enables a more diverse dietary intake. This review provides evidence and practice guidance to assist in delivering high quality clinical service in relation to the low FODMAP diet.

1.0 Introduction

Irritable bowel syndrome (IBS) is a debilitating functional gastrointestinal disorder characterised by abdominal pain associated with a change in bowel habit and features of disordered defaecation. The global prevalence of IBS is 11.2% and it is more common in women and people under 50 years of age ⁽¹⁾. It is associated with decreased quality of life ⁽²⁾ and lower self-rated health compared with other functional gastrointestinal disorders or chronic conditions such as asthma and rheumatoid arthritis ⁽³⁾. Thus, there is increased use of healthcare ⁽⁴⁾, significant interference with daily activities and increased absenteeism from work ^(5,6) compared to those without IBS.

The pathophysiology of IBS involves a complex interaction between visceral hypersensitivity, dysmotility, dysbiosis of the gastrointestinal microbiota, alterations in the brain-gut axis and psychosocial factors ⁽⁷⁾. The management of IBS involves a range of approaches including lifestyle, psychological and pharmacological ⁽⁸⁾. However, pharmacological treatments generally only target one symptom of this multi-symptom syndrome and a technical review reported high levels of evidence for only one of nine pharmacological treatments for IBS ⁽⁸⁾. Consequently, dietary modification is increasingly used to manage symptoms of IBS.

Dietary triggers are reported to be central to symptom generation in 50-84% of patients with IBS ^(2,9,10) and for many years dietary management focussed on altering specific dietary components (e.g. dietary fibre, lactose) ^(11,12). More recently, dietary restriction of fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAPs) have been investigated in the management of functional gut symptoms in IBS.

The mechanisms and efficacy of the low FODMAP diet have been reviewed in depth elsewhere ⁽¹³⁾. There have also been at least five systematic reviews of the low FODMAP diet broadly reporting improvements in abdominal pain, bloating and in some integrated symptom scores ^(14–18), However, some of these systematic reviews have included uncontrolled and before-and-after trials ^(16–18). To date there are at

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least 10 randomised controlled controls or randomised comparative trials of the low FODMAP diet, most of which demonstrate its efficacy compared with control, resulting in a clinical response in 50-80% of IBS patients ⁽¹³⁾. These have varied from highly controlled feeding trials ^(19,20) to studies of the provision of dietary counselling by an experienced dietitian ^(21,22). However, a systematic review of the quality of randomised controlled trials of the low FODMAP diet identified limitations in their design, including high risk of bias for blinding of participants and outcome measurement, selection of control groups and objective evaluation of data ⁽²³⁾. However, it is also recognised that ensuring participant blinding and identifying appropriate controls can be very challenging in dietary intervention trials ⁽²⁴⁾.

In view of the effectiveness demonstrated in these studies, the low FODMAP diet is now included in National Institute for Health and Clinical Excellence (NICE) guidelines for IBS management in primary care in the United Kingdom (UK) ⁽²⁵⁾ and as 'second line' intervention by the British Dietetic Association guidelines ⁽²⁶⁾. It is recommended that general 'healthy eating for IBS' advice (so-called 'first line' advice) be attempted prior to the low FODMAP diet, as two randomised comparative trials have shown this to be as effective as the low FODMAP diet for some symptom outcomes and is likely to be both easier to advise and easier to follow ^(27,28).

The publication of research and guidelines recommending the use of the low FODMAP diet as second line advice has increased demand for dietitian-led low FODMAP services and a greater understanding of the low FODMAP diet is required among dietitians, gastroenterologists and general practitioners. However, given the large number of previously published trials, systematic reviews and guidelines in this area, extensive discussion of the mechanisms and evidence for the low FODMAP diet is beyond the scope of this review. However, few reviews actually describe this complex dietary intervention and how it is implemented in clinical practice. Therefore, the aim of this review is to provide practical guidance on assessment, implementation and monitoring of the low FODMAP diet and other practical aspects important for high quality clinical service delivery.

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The low FODMAP diet can be covered in at least two appointments with a dietitian who is trained in this area. The first appointment includes confirmation of IBS diagnosis and comprehensive nutritional assessment, including baseline symptom and dietary assessment. Therefore, prior to discussing the approach to implementing the low FODMAP diet, this review will first discuss the importance of taking a full and detailed assessment by a trained dietitian.

2.0 Assessment and monitoring of dietary interventions in IBS

Comprehensive assessment is central to all successful dietary management, and the basis for monitoring the effectiveness of the intervention. Assessment methods should be detailed, valid, relevant to patients and, where feasible, should mirror the outcome measures that are used in the research studies that underpin the dietary intervention in question.

Anthropometry and biochemistry are important in IBS, for example anthropometric measurements should include weight, weight history, height, body mass index, whilst biochemical assessment may include tests to exclude other diagnoses (online supporting material, **OSM1**) and biochemical markers of nutritional status, where relevant. However, the clinical and dietary assessment of the patient with IBS are often the most demanding and are discussed below.

2.1 Clinical assessment: diagnosis

There is currently no diagnostic biomarker for IBS and symptoms overlap with other organic gastrointestinal and gynaecological conditions and as a result, IBS is often a diagnosis of exclusion of organic disease. This can understandably be perceived as unsatisfactory for some patients who are experiencing debilitating symptoms and therefore a positive diagnosis should be emphasised ⁽²⁵⁾. Routine examinations and investigations should be undertaken by the referring clinician (gastroenterologist, general practitioner, family doctor) according to local guidelines to exclude organic causes of disease (e.g. inflammatory bowel disease, gastrointestinal cancer, coeliac disease). Tests for coeliac disease should be performed whilst following a glutencontaining diet for at least six weeks. In addition, the doctor and dietitian should

enquire about previous use and effectiveness of a gluten-free diet, in particular where there is suspicion of non-coeliac gluten sensitivity, for example in those with other manifestations (e.g. fatigue, 'foggy mind') ⁽²⁹⁾. Suggestions for examinations and investigations based upon guidelines in the UK are summarised in online supporting material (**OSM1**). These also suggest that extensive additional tests (e.g. colonoscopy, abdominal ultrasound) are unnecessary unless other organic pathology is suspected and needs to be excluded ^(8,25,30).

The recently revised Rome IV criteria should be used by the referring clinician (gastroenterologist, general practitioner, family doctor) and confirmed by the dietitian to identify the type of functional bowel disorder (e.g. IBS, functional bloating, functional diarrhoea) ⁽³¹⁾. For IBS to be diagnosed, the Rome IV criteria require the presence of recurrent abdominal pain (on average at least 1 day per week in the last 3 months) associated with two or more of; (i) pain related to defecation; (ii) associated with a change in frequency of stool; or (iii) associated with a change in frequency of stool; or (iii) associated with a change in form (appearance) of stool (**Box 1**) ⁽³¹⁾. In addition, the IBS subtype should be recorded which may be useful in both tailoring dietary counselling to specific symptoms and enabling dietitians to evaluate the effectiveness of the low FODMAP diet in different IBS sub-groups. The Rome IV classifications are IBS with constipation (IBS-C), IBS with diarrhoea (IBS-D), IBS with mixed symptoms (IBS-M) and IBS un-subtyped (IBS-U), with the process of classification displayed in **Box 1**.

Although clinic experience suggests that the low FODMAP diet may well be effective in managing functional bowel disorders other than IBS (i.e. functional bloating, functional diarrhoea), the research evidence to date relates predominantly to its role in managing functional gut symptoms in IBS.

2.2 Clinical assessment: past medical history and family history

Information pertaining to past medical history and family history should be recorded in line with standard dietetic practice. Assessment of lifestyle factors such as employment, stress, social history and physical activity is important in order to determine their association with symptoms. Current and previous use of IBS medication (e.g. antispasmodics, laxatives, antimotility agents, tricyclics and selective serotonin re-uptake inhibitors) and other treatments (cognitive behavioural therapy, hypnosis) and their effectiveness in managing symptoms is important to record in line with standard dietetic practice and may be important for decisions about future treatment options should dietary intervention be ineffective.

It is important to ask regarding known allergies and intolerances (especially food) ⁽²⁶⁾, whether food intolerance tests have been undertaken, whether clinically relevant (e.g. lactose breath test) or not (e.g. allergen-specific IgG, kinesiology). For example, commercially available food intolerance tests are not valid markers of food intolerance but are often used by patients to inappropriately guide dietary exclusion. Such tests have been reviewed elsewhere and patient re-education regarding appropriate food exclusion may be required ⁽³²⁾.

2.3 Clinical assessment: gastrointestinal symptoms, stool output and quality of life

Objective clinical markers of symptom severity do not exist. Therefore, it is imperative to use valid and practical symptom-assessment tools to measure baseline symptoms and to monitor response to dietary intervention. Symptoms should be assessed in terms of their onset, duration, frequency, severity, pattern and impact on daily life. A variety of other assessment tools are available for use in IBS (**Table 1**).

Global symptom severity questions are dichotomous response questions that are easy to administer and interpret ⁽³⁵⁾. A range of examples are used in dietary intervention trials in IBS including *'were your symptoms adequately controlled in this phase?*⁽⁴⁸⁾ or *'over the last seven days, have you had satisfactory relief of your gut symptoms?*⁽²¹⁾. A global symptom severity question is recommended as an outcome measures in IBS treatment trials ^(34,37,49) but may not be sensitive enough to measure the presence or change in impact of mild symptoms or minor changes in symptoms ⁽⁵⁰⁾. Therefore, in addition to using global symptom severity questions, individual symptoms should also be measured.

An example of a tool to measure the frequency and severity of gastrointestinal symptoms is the Gastrointestinal Symptom Rating Scale (GSRS). The GSRS consists of 15 questions with a 4-point Likert scale response set (absent, mild, moderate, severe), thus measuring the presence/absence (and if measured daily, the frequency) and severity of symptoms. The symptoms contained on the original GSRS are abdominal pain, heartburn, acid regurgitation, sucking sensations in the epigastrum, nausea and vomiting, borborygmus (abdominal rumbling), abdominal distension (bloating), eructation (belching), flatulence, decreased and increased stool frequency, loose or hard stools, stool urgency and incomplete evacuation, although the terminology used have been updated through wider use. The GSRS has been validated in IBS ^(21,51). The GSRS has been modified specifically for use in IBS, termed the GSRS-IBS which includes 13 items and a 7-point Likert scale response describing issues with symptoms including abdominal pain, diarrhoea, constipation and bloating ⁽³⁸⁾.

Several other tools result in a score to measure the severity of global IBS symptoms and as such are termed integrated symptom severity scores. The IBS Severity Scoring System (IBS-SSS) ⁽⁴⁰⁾ is an integrated symptom severity score that includes questions relating to pain severity, days of pain, abdominal distension, satisfaction with bowel habit and quality of life. It is comprised of four 100 mm visual analogue scale questions and a question regarding stool frequency, totalling a maximum score of 500 (higher score equates to greater symptoms). A reduction of at least 50 points or a reduction of 50% in the total score have been used to indicate a 'minimally clinically important difference' ⁽⁴⁰⁾ indicative of a clinical response ⁽⁵²⁾. The IBS-SSS has been recommended by some as a primary outcome measurement in drug trials ⁽³⁴⁾ and dietary trials ^(34,41). Other integrated symptom severity scores for IBS are available, including the Functional Bowel Disorder Severity Index and IBS Symptom Questionnaire ⁽³⁵⁾, however the most commonly used remains the IBS-SSS ⁽³⁵⁾.

Alteration in bowel habit is a diagnostic feature of IBS; hence stool frequency and consistency should always be measured. Stool frequency varies widely in the general population, however, abnormal stool frequency is sometimes considered to be less

than 3 times a week or more than 3 times a day ⁽⁵³⁾. Stool frequency may be recorded retrospectively using subjective Likert scales (e.g. less than once a week, 1-3 times per week, etc). Both stool frequency and consistency can be recorded in clinical practice either retrospectively or prospectively using objective, albeit proxy, stool charts. The Bristol Stool Form Scale is a validated measure of stool consistency that incorporates seven verbal and pictorial descriptors of stool form (Type 1-2 hard, Types 3-5 normal, Types 6-7 loose) ⁽⁴³⁾. It can be used to assess stool consistency at the initial and follow-up appointment and is also the recommended approach to subtyping in IBS (**Box 1**) ⁽³¹⁾. Although the Bristol Stool Form Scale is validated, there can be inaccuracies in assigning stools to their correct stool types, and this has been shown to be the case particularly at diagnostic boundaries, for example between hard and normal stools (i.e. differentiating Types 5 and 6) ⁽⁴³⁾. Other stool charts are available, for example the King's Stool Chart ⁽⁵⁴⁾, but are not validated in IBS.

Quality of life measures the impact of IBS on patients' lives, making it an important patient-reported outcome measure as well as important for health economic analysis and commissioning of health services.

The most widely-used tools are the Short Form 36 Health Survey (SF-36), which is a generic questionnaire (i.e. not specific to IBS), and the IBS Quality of Life (IBS-QOL) questionnaire, which is specific to the impact of IBS ⁽⁴⁵⁾. The latter includes domains on bodily pain, energy/fatigue and social functioning which are important in patients with IBS ⁽⁵⁵⁾. Some evaluations of the low FODMAP diet have investigated its effect on quality of life ⁽⁵⁶⁾, although few have done so in randomised controlled trials.

2.4 Dietary assessment

Several methods are used in the dietary assessment of patients with IBS and a combination of qualitative and semi-quantitative approaches should be adopted.

Qualitative questions that elucidate food knowledge, food preferences, food access/availability, food cost, eating pattern, food group consumption and cooking methods should be determined (as in all dietetic consultations), together with

identifying foods perceived to induce symptoms, current dietary restrictions and use of nutritional supplements, probiotics and prebiotics and complementary and alternative medicines.

In terms of quantitative dietary assessment, some methods are very intensive and largely reserved for the research setting (e.g. duplicate diets, weighed intake), however, in clinical practice, the method of choice should enable an efficient but accurate assessment of current nutrient and FODMAP intake. Examples of techniques include a food diary, 24-hour recall or diet history, whilst a food frequency questionnaire that includes FODMAP intake has also been validated for assessment of individual FODMAP intake ⁽⁵⁷⁾.

3.0 Low FODMAP diet: implementing the intervention

Research evidence and clinical expertise was used to develop an overview of the process of implementing a low FODMAP diet in clinical practice (**Figure 1**) ^(13,25,58–61). The low FODMAP diet refers to three important and distinct stages that occur across two to three clinical appointments: FODMAP restriction (initial appointment); FODMAP reintroduction (short-term follow up appointment); and FODMAP personalisation (long-term follow-up).

In brief, the initial appointment can consist of a detailed assessment, explanation of the effects of FODMAPs followed by tailored dietary counselling regarding FODMAP restriction. At the second appointment, symptoms and diet are re-assessed and, if restriction has successfully reduced IBS symptoms, dietary counselling regarding FODMAP reintroduction should be undertaken to enable patients to identify specific FODMAP triggers and the doses that induce their symptoms. Finally, in the long term, which may or may not require a formal follow-up appointment, FODMAP personalisation occurs whereby a less restrictive diet is consumed that excludes FODMAPs that induce symptoms but enables a more diverse dietary intake.

4.0 FODMAP restriction (initial appointment)

Once a comprehensive clinical and dietary assessment has been conducted, as described earlier, and a clinical decision to intervene with a low FODMAP diet has been made, the first stage of the dietary intervention is FODMAP restriction. Most clinical trials investigate only the initial FODMAP restriction stage, but it is important for doctors, dietitians and patients to appreciate that this is not a "diet for life" but instead an approach to dramatically reduce FODMAP intake below the level at which they induce functional gut symptoms followed by a staged reintroduction and personalisation process (**Figure 1**). It is important that the dietitian emphasises these points at this initial appointment.

Patients should receive an explanation regarding the principles of why FODMAPs can induce gastrointestinal symptoms ^(59,61). Verbal explanation alongside pictorial representation of the mechanisms of FODMAPs in the GI tract can be used to describe their effects.

Briefly, studies using ileostomy models or MRI have shown that high FODMAP diets or high doses of specific FODMAPs (e.g. fructose, mannitol) result in increased luminal water in the small intestine ^(62–64). Furthermore, studies using breath testing or MRI have shown that high FODMAP diets or high doses of specific FODMAPs (e.g. oligosaccharides) increase colonic gas production as a result of fermentation by the microbiota ^(20,63). FODMAPs in such high doses have been shown to induce functional gut symptoms, such as pain, bloating and diarrhoea, which are believed to be the result of the increases in small intestinal water and colonic gas. However, not all people with IBS develop symptoms during FODMAP challenge and it is hypothesised that these symptoms occur only in those with visceral hypersensitivity, although lower pain thresholds and higher somatisation may also be involved ⁽⁶⁵⁾. It is likely that there is a threshold at which increased colonic gas provokes symptoms and that this varies between patients and depends on factors such as the severity of visceral hypersensitivity, gastrointestinal motility, dietary constituents and stress, as well as differences in the type and dose of FODMAP consumed ^(13,20,63,65).

4.1 FODMAPs in the diet

Patients should be counselled regarding the food sources of each FODMAP and how these can be excluded from the diet, whilst avoiding a reduction in dietary quality. A brief, but far from exhaustive, list of examples of dietary sources of FODMAPs and review of their digestion and absorption is provided in **Table 2**.

Oligosaccharides include fructans (major sources include wheat, onion and garlic) and α -galacto-oligosaccharides (major sources include beans and pulses). All humans lack enzymes that hydrolyse these oligosaccharides, thus they are not digested or absorbed and on arrival in the colon are readily fermented by the colonic microbiota, in some cases producing gas ⁽⁶¹⁾.

Lactose is a disaccharide found in milk and milk products. The enzyme lactase is required for hydrolysis allowing subsequent jejunal absorption of the constituent monosaccharides (galactose and glucose). There is an age specific genetic down-regulation of lactase expression dependent on ethnicity ⁽⁶⁶⁾. In those without sufficient lactase activity, lactose maldigestion can result in its fermentation by the colonic microbiota, leading to symptoms of bloating and flatulence in some susceptible individuals ^(66,67).

Fructose is a monosaccharide that is incompletely absorbed in some people, and which results in increased small intestinal water ⁽⁶³⁾. In contrast, consumption of glucose in conjunction with fructose enables glucose-fructose co-transport through the GLUT2 transporter, thus reducing the impact on small intestinal water ⁽⁶³⁾. Where fructose is present in high concentrations (e.g. large volumes of fruit juice) or in excess of glucose (e.g. foods such as mango, fig, honey), this can lead to high levels of small intestinal fructose, increasing small intestinal water and in susceptible individuals can lead to functional gut symptoms ⁽⁶⁵⁾. Therefore, in practice foods with high levels of fructose, or where fructose is present in excess of glucose, are excluded. Recent research has shown that artificial co-administration of glucose with fructose (e.g. adding glucose to fructose containing foods and drinks) does not reduce IBS symptoms and therefore should not be recommended to patients ⁽⁶⁸⁾.

Polyols, which include sorbitol (e.g. apple, pear), mannitol (e.g. mushroom, cauliflower) and xylitol (e.g. artificial sweetener in some sugar-free chewing gums and sweets) are passively absorbed along the small intestine depending on the molecular size, intestinal pore size, transit time and presence of gastrointestinal disease ⁽⁶¹⁾. There is evidence that very high doses of mannitol increases small intestinal water ⁽⁶⁴⁾, and therefore polyols are also restricted during this initial stage of the low FODMAP diet.

4.2 Resources to enhance dietary adherence

Most of the randomised controlled trials showing clinical benefit of the low FODMAP diet were executed with dietary counselling provided by a dietitian trained in this approach ⁽⁶⁹⁾. The provision of comprehensive counselling and suitable educational resources are thought to be positively associated with dietary adherence ^(41,51,60,70,71). Appropriate resources could cover the effects of FODMAPs in the GI tract, food sources of FODMAPs, appropriate low FODMAP alternatives and practical information such as food labelling, eating out, recipe adaptation and low FODMAP meal ideas. The resources that are available include written diet sheets, smart phone applications and cook books, as well as patient-led websites. Some online resources provide only brief lists of suitable and unsuitable foods that are insufficient to achieve adequate FODMAP restriction. Furthermore, it is important that any supportive information is supplementary to detailed dietary counselling from a dietitian, rather than the sole method of dietary education ⁽⁶⁹⁾.

Data on the FODMAP composition of foods are increasing and should be used as the basis to guide dietitians regarding which foods should be restricted in this initial stage of the low FODMAP diet ^(72–77). Numerous diet sheets and smart phone applications are available from a wide variety of sources, many of which incorporate up-to-date lists of suitable and unsuitable foods based upon FODMAP composition data. Mobile health technologies are increasingly used in dietetic practice ⁽⁷⁸⁾. However, such data are predominantly limited to unprocessed food commodities, thus maintaining the need for patients to carefully read and interpret ingredient labels on pre-prepared food products. Dietitians should offer support and teaching regarding reading ingredient labels, whilst in some countries smartphone

applications are available that scan ingredient labels for FODMAP-containing foods to assist people with IBS to categorise foods as being suitable or unsuitable. In addition, some foods have logos that certify when food products have been analysed and confirmed to be low FODMAP.

Some nuances of FODMAP restriction should be explained to patients. For example, the fructan content of wheat is relatively low, but because it is eaten in large quantities (e.g. as bread or pasta) it contributes the largest amount of fructans to the diet ⁽⁷⁹⁾ and therefore foods containing wheat as a major ingredient should be excluded. However, foods containing wheat as a minor ingredient, and therefore contain only very small amounts of fructans (e.g. sauces with wheat starch thickener), do not need to be excluded ⁽⁶⁰⁾, and this should be explained in order to prevent unnecessary food restriction. In contrast, some ingredients are completely avoided, for example onion ingredients (e.g. dried onion, onion powder), as these are concentrated sources of fructans ^(74,75).

Common reported barriers to adherence to the low FODMAP diet may include the increased cost of suitable alternative dietary products (e.g. wheat-free breads and cereals) ⁽⁸⁰⁾, perceptions regarding low palatability of some specialist food products ⁽⁵¹⁾ and limited options for eating outside of the home ^(60,70). Therefore it is important that the dietitian addresses these potential challenges during dietary counselling, including discussing shopping, suitable alternatives, palatability, cooking and recipe modification during restriction stage of the low FODMAP diet.

4.3 Duration of FODMAP restriction

Randomised controlled trials of strict FODMAP restriction have lasted for up to six weeks ⁽¹³⁾, but have been shown to alter the gastrointestinal microbiota and may affect nutritional adequacy ^(21,81). Thus, only 4 weeks is recommended for clinical practice as this provides sufficient time for the majority of patients to achieve symptom improvement ⁽⁵⁹⁾. However, clinical capacity, availability of dietetic expertise and patient choice may extend the duration, often increasing the FODMAP restriction stage up to 12 weeks ⁽⁸²⁾.

4.4 Personal application

Where possible, dietary counselling should be tailored to the individual and there are occasions where lactose and/or fructose do not need to be restricted where there is clinical suspicion that these do not induce symptoms. Breath tests for lactose, fructose or polyol malabsorption have previously been recommended, however they are no longer indicated. False positives and false negatives are common and there is poor correlation between malabsorption and intolerance ^(51,77). Furthermore, they only measure colonic fermentation products and do not account for the effect of FODMAPs on small intestinal water ^(62–64).

There may be cases where strict FODMAP restriction is inappropriate (e.g. patient's ability to understand and comply, significant existing dietary restrictions). In such circumstances, dietitians may use their clinical judgement to implement a partial FODMAP restriction (i.e. restriction of only major FODMAP sources), although as yet there are no quality research studies to support such partial FODMAP restriction.

At the end of the first appointment during which FODMAP restriction has been counselled, a summary of what has been discussed should be provided to enhance the learning experience. Importantly, dietitians should explain the need for patients to spend time reviewing the information provided and to plan how to incorporate FODMAP restriction into their dietary lifestyle, including planning shopping, day-today adherence and food-related social activities.

Generally, 45-60 minutes is required for a new one-to-one appointment to educate patients on FODMAP restriction ^(21,51,59,60,71) and this can present challenges for dietetic services that may be restricted on appointment duration. For such services, this is an opportunity to develop alternative delivery methods that enable greater capacity e.g. group education ⁽⁸²⁾ or a series of shorter appointments.

5.0 FODMAP reintroduction (short-term follow-up)

The aim of FODMAP reintroduction is for individuals to identify which FODMAPs they can consume without exacerbating their IBS symptoms. FODMAP reintroduction involves staged, dosed, FODMAP challenges to assess tolerance with the aim of improving dietary variety and nutritional adequacy in the long term. Despite the importance of this stage of the low FODMAP diet, there is surprisingly little research to inform dietetic practice in this area and currently no randomised controlled trials. Therefore, what follows is a review of the limited research literature integrated with a description of best practice followed in our centre.

It is good practice to follow-up all patients who have received dietary counselling for FODMAP restriction in order to prevent them from continuing FODMAP restriction for the long term. This is thought to be important as a small number of studies have reported that FODMAP restriction impacts both the gastrointestinal microbiota ^(21,81) and nutrient intake ⁽²¹⁾, although there is limited understanding of their long term consequences on health nor the effect of FODMAP reintroduction on these. A shorter second appointment with a dietitian of approximately 20-30 minutes in duration, between 4-12 weeks after the initial appointment, is the most widely used approach to begin the FODMAP reintroduction process ^(51,82).

At this appointment, it is important to assess anthropometry and in particular body weight, as small amounts of weight loss have been reported during the FODMAP restriction stage ⁽²¹⁾. Clinical assessment should review changes in IBS-medication as well as symptoms, stool output and quality of life using the same validated tools used at baseline, as described earlier. Assessing the impact of FODMAP restriction on symptom frequency and severity will help to determine the success of the dietary intervention, direct the focus of the dietary assessment and allow the dietitian to undertake either continued restriction or initiate FODMAP reintroduction. Dietary assessment should assess adherence to the low FODMAP diet and assessment of nutritional adequacy should be both qualitative and semi-quantitative and targeted nutrients shown to be at risk during the low FODMAP diet (i.e. fibre, calcium, iron) ⁽²¹⁾. Dietary adherence can be measured using a Likert or visual analogue scale targeting FODMAP-containing foods, although validated scales specifically measuring adherence to the low FODMAP diet are not yet available. Following low FODMAP diet counselling from a dietitian, 64-77% of patients report high adherence rates ^(51,70,71). At this appointment it is also important to explore the acceptability of the

low FODMAP diet in terms of cost, availability of suitable foods and impact on social activities.

If symptoms have improved sufficiently for the patient, advice on FODMAP reintroduction should be provided. Clinical experience suggests there is variability in tolerance to different FODMAPs, as well as between individuals and within the same individual over time, and this should be explained during the follow-up appointment.

The FODMAP reintroduction process involves maintaining strict FODMAP restriction whilst undergoing food challenges whereby a food high in one FODMAP is tested over 3 days at increasing doses (**Figure 1**). An individual challenge with a food high in only one FODMAP (e.g. mango) is used to identify individual tolerance to that whole group of FODMAPs (i.e. fructose). The exception is fructans, where variations in molecular structure result in variations in fermentation and gas generation ⁽⁸³⁾, and therefore rather than one food being used as a challenge to represent all fructancontaining foods, several foods are used (i.e. bread, onion, garlic). The foods used in the challenges are selected to ensure all types of FODMAPs are tested. However, there is limited research on the optimal number and order of foods to reintroduce and in practice these are selected based upon the clinical picture and dietary preferences. Suggested examples include bread, onions, garlic (fructans), lentils (GOS), milk (lactose), mango (fructose), apricot (sorbitol) and mushrooms (mannitol), together with foods containing combinations of FODMAPs ⁽⁸⁴⁾.

Prior to each subsequent food challenge, symptoms should be minimal, and this can be achieved with a washout period of strict FODMAP restriction for three days ^(59,85). The washout period prevents cumulative effects of previous challenges carrying over and impacting on symptoms during the next challenge, although if no symptoms occurred during the previous challenge, patients can choose to move straight to the next food challenge. Patients are encouraged to continue the series of individual food challenges with as many high FODMAP foods as appropriate to increase dietary variety and avoid unnecessary food restriction. If there is no impact of a food challenge on symptoms, then that food can be considered suitable to include in the patient's diet, but only once all the food challenges have been completed. If there is a substantial increase in symptoms during the 3-days of the challenge period, then the patient ceases the challenge. If symptoms are exacerbated, the patient will either be able to determine whether the food group should be avoided completely (for example, where severe symptoms occur on day 1), or whether small portions might be tolerated occasionally (for example, where mild symptoms only occur on day 3).

Much of the research on patients' sensitivity to individual FODMAPs investigates those given in the pure form as supplemental drinks, rather than in foods or meals. Symptom induction to both supplemental drinks and foods is likely to be susceptible to a high nocebo effect. However, the wide variation in impact of individual FODMAPs on IBS symptoms is also likely to be affected by the total FODMAP load consumed at one meal, other food components within the meal (e.g. fat, fibre), gastrointestinal transit time, visceral hypersensitivity and the gastrointestinal microbiota ^(13,65). In addition, lifestyle and stress are important contributors to symptoms in IBS in general and likely contribute to the variation in symptom exacerbation experienced within the same individual over time. Reassurance that high FODMAP foods are unlikely to have negative effects beyond symptom induction may be important to discuss at the follow up visit, especially if avoidance of FODMAP-containing food negatively affects the patient's QOL.

6.0 FODMAP personalisation (long term self-management)

The aim of FODMAP personalisation is to increase dietary variety and improve nutritional adequacy whilst maintaining IBS symptom control. Most patients who have undertaken the reintroduction stage can adopt long-term self-management without a third appointment, however, in some cases, a third dietetic appointment may be needed to confirm nutritional adequacy and to clarify any concerns.

FODMAP personalisation involves constructing a 'modified-FODMAP diet' whereby restriction is continued but those FODMAPs / foods that did not induce symptoms

during the reintroduction stage are now included in the diet. This is described as the FODMAP personalisation stage as the quantities and types of FODMAPs able to be consumed vary depending upon individual tolerance to FODMAPs identified during the reintroduction stage. As near a diet to 'normal' should be encouraged during FODMAP personalisation, with a strong focus on patients following a healthy diet, achieving national dietary guidelines for macronutrients and micronutrients (including fibre) and importantly being able to choose a diverse diet that is enjoyable and does not restrict psychosocial aspects of the patient's life (e.g. eating out, socialising).

One study reported that 57% of patients experienced adequate symptom relief following such a 'modified FODMAP diet' after 6-18 months, including a sustained benefit in 70% of patients who reported adequate relief during initial FODMAP restriction ⁽⁸⁶⁾. Another study reported satisfaction with symptoms in 72.1% of responders at a mean of 15.7 months follow-up ⁽⁵¹⁾. However, these studies lacked control groups, had high attrition rates, and only reported data in those who completed follow-up appointments and questionnaires, common difficulties in long term follow-up studies of dietary interventions ⁽²⁴⁾.

7.0 Specific considerations

7.1 Inadequate symptom response

Research indicates that approximately 50-80% of patients with IBS experience symptom relief following FODMAP restriction, meaning that 20-50% do not ⁽¹³⁾. Detailed, valid and repeated symptom assessment will identify which patients and which symptoms do not respond. Some patients may not respond due to poor adherence, which can be assessed at short-term follow-up. If adherence is suboptimal, and the patient wishes to re-attempt strict FODMAP restriction then addressing barriers to adherence and further follow-up should be provided. However, for patients who adhered strictly and yet did not experience symptom relief, then the low FODMAP diet has failed and should be ceased ⁽⁸⁷⁾, at which point FODMAPs should be introduced back into the diet, with assessment of response to detect whether gastrointestinal symptoms worsen. In those having a small (albeit

insufficient) response to FODMAP restriction, return to a normal diet should be done gradually to prevent abrupt worsening of symptoms.

Where FODMAP restriction has failed to resolve symptoms, other dietary approaches can be attempted. Probiotics supplementation has been shown to be effective in some patients with IBS, with nine systematic reviews published thus far. However, response to probiotics varies greatly and can depend upon the strain used and symptoms experienced ⁽⁸⁸⁾. A review and guidelines have recently been published indicating which probiotic strains and doses have been shown to be efficacious for which symptom ^(26,89). In addition, supplemental dietary fibre, in particular ispaghula/psyllium, may provide overall IBS symptom relief ⁽¹¹⁾.

Psychological factors and stress are known contributors to IBS symptoms and may have a greater impact on symptoms than diet in some patients ⁽⁹⁰⁾. Thus, further dietary intervention may not be indicated and referral back to the referring clinician is advised. Non-dietary treatment options for IBS include cognitive behavioural therapy and hypnotherapy ^(91,92).

Research is underway to identify markers that predict response to FODMAP restriction. Two studies have reported numerous bacterial groups that were different at baseline in those who subsequently experienced a clinical response to the low FODMAP diet ^(93,94), and a recent study has identified faecal volatile organic compounds profiles that predicted response to the low FODMAP diet with 100% accuracy ⁽⁹⁵⁾. These approaches must be tested in external validation populations and further approaches that utilise readily accessible information to predict response are required.

Finally, another potential explanation for the lack of response to FODMAP restriction may be that symptoms are, at least in part, the result of non-coeliac gluten sensitivity ⁽²⁹⁾. Thus, in patients where there is clinical suspicion of gluten sensitivity, preliminary research suggests that a gluten-free diet may be trialled with some success ⁽⁹⁶⁾, although intensive dietary education is required as adherence may be poorer in the absence of a confirmed diagnosis of coeliac disease ⁽⁹⁷⁾.

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7.2 Nutritional adequacy

Patients with IBS have similar dietary intakes compared with the general population and in general they meet dietary recommendations ^(98,99). However, some studies report avoidance of entire food groups and/or specific food types in people with IBS ^(2,9,10).

Few studies have investigated the effect of the low FODMAP diet on nutritional adequacy in the short or long term, and these have been reviewed previously ^(13,100). One study showed that compared with habitual diet FODMAP restriction (following in-depth counselling from a dietitian) resulted in broadly similar micronutrient intakes, except for lower calcium intakes ⁽²¹⁾. Meanwhile another study showed that IBS patients who received no dietary counselling self-restricted their diet more than those who had been given detailed counselling and also had significantly lower calcium intakes, although the advice in the latter group was provided two years previously ⁽¹⁰¹⁾. Factors that may impair calcium intake during FODMAP restriction include: excessive restriction of dairy sources even when lactose does not exacerbate symptoms (e.g. small amounts of milk, yoghurt and cheese can be consumed whilst keeping lactose intakes low); and inadequate substitution of dairy sources of calcium with fortified substitutes (e.g. non-dairy alternative milk products based on soya, oat, rice and nuts).

The low FODMAP diet significantly alters carbohydrate sources, (e.g. cereals and grains, fruit and vegetables). The low FODMAP diet has been shown to reduce fibre intakes in one study ⁽¹⁰²⁾, but not in another ⁽²¹⁾. Patients should be advised to follow national recommendations for fruit and vegetable intake, unless other medical issues contraindicate this, and expert dietetic advice should be provided regarding selection of high-fibre, low-FODMAP fruit and vegetable, grains and cereals.

7.3 Constipation

The low FODMAP diet reduces small intestinal water (62) and some have expressed concern about exacerbation of constipation in patients with IBS ⁽¹⁰³⁾. Despite this, there is some limited evidence that a low FODMAP diet may actually be effective for IBS-constipation ^(51,82). Patients may find improvement in constipation during

FODMAP personalisation. Meta-analyses have shown that some fibre supplements are effective in managing constipation specifically ⁽¹⁰⁴⁾ and IBS in general ⁽¹¹⁾. Ensuring appropriate fibre sources or fibre supplementation with rice or oat bran or linseeds may therefore be appropriate ^(26,105). Finally, meta-analyses have shown that some probiotic strains are effective in managing constipation specifically ⁽¹⁰⁶⁾ and IBS symptoms in general ⁽¹⁰⁷⁾ and therefore dietitians and gastroenterologists should use guidelines to recommend specific probiotic strains to manage specific symptoms such as constipation ^(26,89,108).

7.4 Changes to the gastrointestinal microbiota

The low FODMAP diet affects the gastrointestinal microbiota ^(21,81,93). Some FODMAPs (e.g. inulin-type fructans and GOS) are prebiotics, which are defined as a 'substrate that is selectively utilized by host microorganisms conferring a health benefit' ⁽¹⁰⁹⁾. Supplements of fructans and GOS increase the numbers of bifidobacteria and some studies also show increases in other major groups such as *Faecalibacterium prausnitzii* ^(110,111). Thus, FODMAP restriction naturally reduces prebiotic intake that is presumed, at least in part, to be responsible for the impact on the gastrointestinal microbiota. A low FODMAP diet has been shown to reduce luminal bifidobacteria (21,81,94), F. prausnitzii (81) and reduce overall bacterial abundance ⁽⁸¹⁾. The significance of these alterations in microbiota are unclear as these studies only report short-term effects during FODMAP restriction and it is not known if these effects persist following FODMAP reintroduction and FODMAP personalisation in the long-term, whether they are related to symptom improvement nor whether these reductions lead to any detrimental effects on colonic health. Reintroduction of FODMAPs to tolerance may attenuate some of these alterations in the gut microbiota. Meanwhile a large randomised controlled trial demonstrated that probiotic co-administration was able to partially prevent some of the changes to the microbiota occurring during the low FODMAP diet ⁽²²⁾. Further studies of FODMAP restriction combined with probiotic or prebiotic supplementation are warranted.

7.5 Delivering an effective dietetic service

There is an increasing demand for using the low FODMAP diet for IBS symptom management, however there is only evidence of clinical effectiveness with dietitianled education ⁽⁶⁹⁾. The diet is a relatively new intervention and there is a limited supply of dietitians with appropriate expertise. Therefore, patients and clinicians have sought alternative educational methods such as online and written literature. However, these delivery methods have not been rigorously investigated and could lead to incomplete FODMAP restriction (and therefore lack of efficacy) or over-restrictive dietary intake (and therefore nutritional inadequacy). Alternative approaches towards dietetic-led delivery of low FODMAP dietary counselling are therefore required.

Dietitian-led low FODMAP group education has recently been evaluated in a nonrandomised study investigating clinical outcomes and economic cost compared with one-to-one dietetic education. Group education was shown to be as clinically effective as one-to-one education, and was inevitably less expensive ⁽⁸²⁾. However, this study is limited by the lack of randomisation to the group *versus* one-to-one interventions ⁽⁸²⁾. Alternatively, web-based symptom measurement alongside dietitian-led low FODMAP counselling has been tested and shown to improve symptoms compared to probiotics or no intervention ⁽¹¹²⁾. It is likely that web-based interventions may be acceptable in the IBS population ⁽¹¹³⁾.

High quality research is urgently needed to determine the safety, effectiveness and cost for using alternative educational methods for administration of the low FODMAP diet.

8.0 Conclusion

The low FODMAP diet, delivered through dietitian-led dietary counselling, is effective in the management of functional gastrointestinal symptoms in IBS. It includes three important and distinct stages: FODMAP restriction; FODMAP reintroduction; and FODMAP personalisation and it is important that people with IBS do not follow a lifelong restriction. This review provides details of how to administer

the diet and the aspects of patient care that need to be considered at each stage of the dietetic process. There are still many unanswered questions regarding the longterm effects of a low FODMAP diet and educational methods that may be useful to achieve symptom control, thus further high quality research should focus on these areas.

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Box 1 Rome IV diagnostic criteria for irritable bowel syndrome and the approach

the subtyping IBS.

Rome IV Diagnostic Criteria for Irritable Bowel Syndrome

Recurrent abdominal pain, on average, at least 1 day per week in the last three months, associated with two or more of the following criteria:

- 1. Related to defecation
- 2. Associated with a change in frequency of stool
- 3. Associated with a change in form (appearance) of stool

These criteria must be fulfilled for the last three months with symptom onset at least six months before diagnosis.

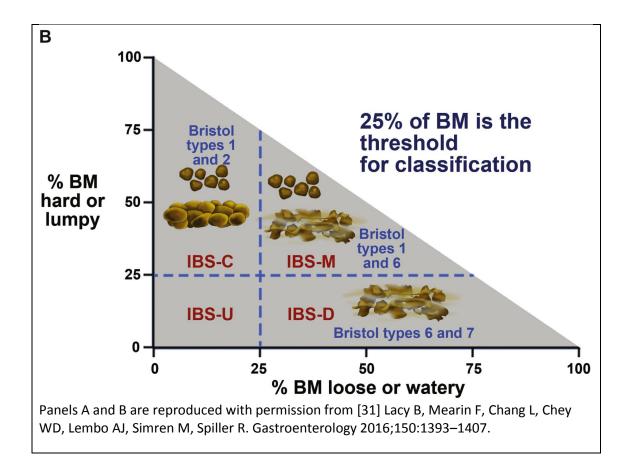
Rome IV Diagnostic Criteria for IBS Subtypes

IBS subtype should be classified for all patients. For epidemiology or clinical practice, this can be based upon retrospective estimate of the frequency of different stool types using the Bristol Stool Form Scale (BSFS). However, for clinical trials, subtyping should be based upon 14 days of stool diary reports (Panel A).

| A | | |
|--------|---------|--|
| Type 1 | | Separate hard lumps, like nuts (hard to pass) |
| Type 2 | | Sausage-shaped but lumpy |
| Type 3 | | Like a sausage but with cracks on the surface |
| Type 4 | \sim | Like a sausage or snake, smooth and soft |
| Type 5 | | Soft blobs with clear-cut edges |
| Type 6 | For the | Fluffy pieces with ragged edges, a mushy stool |
| Type 7 | | Watery, no solid pieces, entirely liquid |

During assessment of IBS subtype, patients should not be receiving medication to treat bowel habit abnormalities (i.e. should occur off laxatives and antidiarrheal agents). IBS subtyping is more accurate when patients have at least 4 days of abnormal bowel habits per month and subtyping should be based on days where abnormal bowel habits occurred. The criteria for the different subtypes are described in the table below and in Panel B.

| | Hard or lumpy stools (BSFS 1 or 2) | Loose or watery stools (BSFS 6 or 7) |
|--------------------------|---------------------------------------|---|
| IBS constipation (IBS-C) | >25% of stools | <25% of stools |
| IBS diarrhoea (IBS-D) | <25% of stools | >25% of stools |
| IBS mixed (IBS-M) | >25% of stools | >25% of stools |
| IBS unclassified (IBS-U) | <25% of stools | <25% of stools |



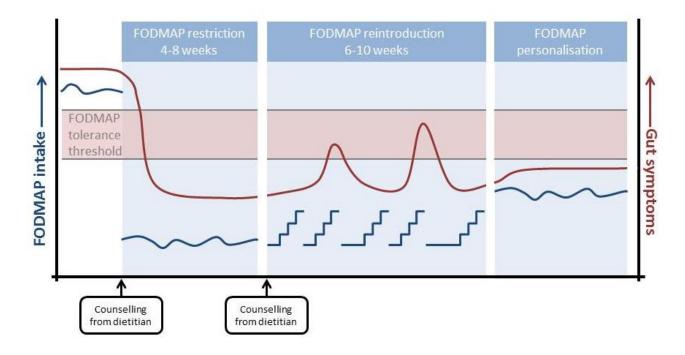


Figure 1. FODMAP intake and symptoms during the three stages of the low FODMAP diet

Prior to dietary counselling from a dietitian, FODMAP intake in the habitual diet varies from day to day but is above the FODMAP tolerance threshold for that patient who therefore experiences functional gut symptoms. (i) During FODMAP restriction, total FODMAP intake is dramatically reduced to below the tolerance threshold and symptoms respond in 50-80% of patients. (ii) During FODMAP reintroduction, whilst continuing with FODMAP restriction, FODMAP-containing foods are used as challenges. Challenge foods are consumed in increasing amounts over a 3-day period whilst monitoring symptoms, with each 3-day period separated by at least 1 day depending upon symptom provocation. (iii) During FODMAP personalisation, FODMAP-containing foods that were successfully challenged can be reintroduced into the diet over the long term in order to increase dietary variety, whilst keeping the type and total amount of FODMAP intake below the tolerance threshold for that patient in order to limit functional gut symptoms.

Table 1: Selection of assessment tools to measure gastrointestinal symptoms, stool form and quality of life in IBS

| Tool | Description | Validation and uses |
|--|---|--|
| Global symptom question ⁽³³⁾ | Single question with dichotomous (yes/no) response to measures global symptoms (e.g. "Did you have adequate relief of your IBS symptoms?") | Validated to evaluate relief from pain/discomfort ⁽³³⁾ . Used as primary endpoint in clinical trials ⁽³⁴⁾ and assessment of global symptomatology ⁽³⁵⁾ . However, complex series of symptoms must be operationalised into a single question and response. |
| Gastrointestinal Symptom Rating Scale (GSRS) ⁽³⁶⁾ | 15-item symptom questionnaire with a 4-point or 7-point Likert scale for symptom severity | Validated in IBS ⁽³⁶⁾ and used in clinical outcome trials ⁽³⁷⁾ and in low FODMAP dietary trials ⁽²¹⁾ . |
| Gastrointestinal Symptom Rating Scale for IBS (GSRS- IBS) ⁽³⁸⁾ | 13-item symptom questionnaire using a 7 point Likert scale for symptom severity | GSRS-IBS expanded on the previous GSRS to include symptoms characteristic of IBS (pain, diarrhoea, constipation, bloating, satiety). Validated for use in clinical trials of IBS in one study ⁽³³⁾ |
| Visual Analogue Scale for IBS (VAS-IBS) ⁽³⁹⁾ | 9-item symptom questionnaire measuring the response of IBS symptoms to treatment. Scores are calculated for each item by measuring responses on a 100 mm VAS anchored with 0 (very severe discomfort) and 100 (no discomfort at all) | Not fully validated. Evaluated in female patients with IBS, for use in research and clinical practice ⁽³⁹⁾ |
| IBS Severity Scoring System (IBS-SSS) ⁽⁴⁰⁾ | Two-part questionnaire with first part consisting of 5 items regarding symptom severity. Each item generates a maximum score of 100 using VAS, leading to a total score of 500. Scores indicate IBS symptom severity i.e. mild (75-175), moderate (175-300) and severe (>300). A reduction of 50 points or of 50% have been used to indicate a minimally clinically important difference in symptoms. | Validated in IBS ⁽⁴⁰⁾ and used as a primary outcome measure in drug trials ⁽³⁴⁾ and dietary trials ^(34,41) . |

| Bristol Stool Form Scale ⁽⁴²⁾ | 7-point scale with written and pictorial | Validated as a measure of whole gut transit time. Used in | |
|---|--|---|--|
| Scale | descriptors of stool form. Types 1-2 considered | clinical and research settings to measure stool form ⁽⁴²⁾ . | |
| | hard, Types 3-5 considered 'normal', Types 6-7 | Widely used in IBS research studies and generally valid | |
| | considered loose/liquid. | against gold standards ⁽⁴³⁾ | |
| 36-Item Short-Form | 36-item health-related quality of life | Validated in clinical practice and research ⁽⁴⁵⁾ . Generic | |
| Health Survey (SF-36) | questionnaire using a multi item scale that | measure often used in combination with a disease-specific | |
| (44) | measures eight health concepts each scored from | measure of quality of life. | |
| | 0 (poor health) to 100 (optimal health) | | |
| IBS Quality of Life | 34-item IBS-specific quality of life questionnaire | Validated in female patients with moderate to severe IBS | |
| questionnaire (IBS- QOL) ⁽⁴⁶⁾ | using a 5 point Likert scale. | ⁽⁴⁷⁾ . Preferred tool for establishing changes in IBS-specific quality of life ⁽³⁵⁾ | |

Table 2 Categories of FODMAPs, examples of their major sources and their digestion and absorption

| Categories of FODMAPs | Examples of major sources | Digestion and absorption process |
|---|--|--|
| Oligosaccharides | | |
| Fructans (oligofructose, inulin, fructo- oligosaccharides (FOS)) | Wheat, rye, onion, garlic, artichoke, low fat dairy products | Humans lack enzymes to hydrolyse oligosaccharides so are no absorbed |
| Galacto-oligosaccharides (GOS) (Raffinose, Stachyose) | Pulses, legumes, some nuts | |
| Disaccharide | | |
| Lactose | Milk and milk products | The enzyme lactase is required for hydrolysis and absorption in the small intestine. Lactase expression decreases over time following weaning depending on ethnicity |
| Monosaccharide | | |
| Fructose | Mango, fig, honey, fructose corn syrup, sweetener in dairy products, jam | |
| Polyols | | |
| Sorbitol | Stoned fruit, apple | Passive absorption along the length of the small intestine |
| Mannitol | Cauliflower, mushroom | depending on molecular size, intestinal pore size, small |
| Lactitol, xylitol, erythritol, maltitol Sugar free gum | | intestinal transit time and presence of gastrointestina disease |

This table provides only examples of major sources of different FODMAPs. It is not a comprehensive list and is insufficient to form the basis of FODMAP restriction.