

# Systematic review: dietary fibre and FODMAP-restricted diet in the management of constipation and irritable bowel syndrome

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## SUMMARY

### Background

Dietary fibre supplements have been advocated for the management of chronic constipation (CC) and irritable bowel syndrome (IBS). Recently, a fermentable oligosaccharide, disaccharide, monosaccharide and polyol (FODMAP) restricted diet has been recommended for IBS.

### Aim

To systematically examine recent evidence for dietary interventions with fibre in CC and IBS and FODMAP-restricted diet in IBS, and provide recommendations.

### Methods

We searched PUBMED, MEDLINE, OVID and COCHRANE databases from 2004 to 2014. Published studies in adults with CC and IBS and constipation-predominant IBS (IBS-C) that compared fibre with placebo/alternative and FODMAP-restricted diet with alternative were included.

### Results

Of 550 potentially eligible clinical trials on fibre, 11 studies were found and of 23 potentially eligible studies on FODMAPs, six were found. A meta-analysis was not performed due to heterogeneity and methodological quality. Fibre was beneficial in 5/7 studies in CC and 3/3 studies in IBS-C. FODMAP-restricted diet improved overall IBS symptoms in 4/4 and IBS-C symptoms in 1/3 studies and three studies did not meet inclusion criteria. There were significant disparities in subject selection, interventions and outcome assessments in both fibre and FODMAPs studies.

### Conclusions

Fibre supplementation is beneficial in mild to moderate CC and IBS-C, although larger, more rigorous and long-term RCTs are needed (Fair evidence–Level II, Grade B). Although the FODMAP-restricted diet may be effective in short-term management of selected patients with IBS (Fair evidence–Level II, Grade C) and IBS-C (Poor evidence–Level III, Grade C), more rigorous trials are needed to establish long-term efficacy and safety, particularly on colonic health and microbiome.

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## INTRODUCTION

Chronic Constipation (CC) is defined by multiple bowel symptoms that include difficult or infrequent passage of stool, hardness of stool or a feeling of incomplete evaluation.<sup>1, 2</sup> It is a common problem that affects approximately 20% of the world's population, with a higher prevalence in women and the elderly.<sup>3</sup> Regional estimates include from 4.1% to 22.4% in Europe,<sup>4–8</sup> from 12% to 27.2% in North America,<sup>3, 9</sup> from 14.2% to 25.6% in Central and South America<sup>10–12</sup> and from 2.6% to 24.8% in Asia.<sup>10, 13–17</sup> Irritable bowel syndrome (IBS) is defined by abdominal pain or discomfort that is associated with altered bowel habit over a period of at least 3 months.<sup>18</sup> Epidemiologic trends globally give an IBS prevalence of 6.5% to 34.2%.<sup>19–22</sup> In North America, the prevalence is 10–15% with the constipation predominant IBS subgroup (IBS-C) accounting for approximately 5%.<sup>23</sup>

Although perceived to be a benign condition, CC can result in chronic illness with potentially serious complications (faecal impaction, incontinence, bowel perforation, bleeding, haemorrhoids and anal fissure), and is associated with impaired quality of life and significant healthcare burden.<sup>24, 25</sup> The course of illness in IBS is characterised by recurring symptoms, impaired quality of life, increased health care costs and reduced work productivity.<sup>26–30</sup> The impact of these entities on patients' lives, and their burden on the healthcare system is enormous. In Johanson *et al.*'s analysis of health statistics from the USA, England and Wales, the occurrence of constipation increased with advancing age, with an exponential increase in prevalence after the age of 65.<sup>31</sup>

A recent Dutch study by Dik *et al.*, showed the mean total CC-related direct medical costs per patient in the first year after diagnosis were €310 ± 845, €367 ± 882 in persistent disease, €292 ± 808 in episodic disease and €263 ± 613 in nonrecurrent disease.<sup>32</sup> The estimated US annual direct medical costs related to constipation alone are estimated to include approximately \$1.6 billion in out-patient costs and \$852 million in in-patient costs,<sup>33, 34</sup> and comprises at least 2.5 million ambulatory care physician visits every year.<sup>35</sup> A recent study on the economic impact of IBS found annual international estimates of direct medical costs per patient of US \$742–\$7547, UK £90–£316, France €567–€862, Canada \$259, Germany €791, Norway €262 and Iran \$92, with the cost of absenteeism and presenteeism between £400 and £900 per patient annually.<sup>36</sup>

Traditionally, individuals with CC and IBS-C are advised to increase dietary fibre intake to alleviate symp-

toms, but data from randomised controlled trials (RCTs) regarding the benefit of this approach is limited. Also, recent attention has focused on the restriction of a group of fermentable carbohydrates, termed FODMAPs (Fermentable oligosaccharides, disaccharides, monosaccharides and polyols), which include fructo-oligosaccharides (FOS), galacto-oligosaccharides (GOS), disaccharides (e.g. lactose), monosaccharides (e.g. fructose) and polyols (e.g. sorbitol), primarily in the management of IBS-C. Its rationale is that there are several individuals who either malabsorb, or are sensitive to FODMAPs, and if these foods are ingested they may result in symptoms such as bloating, diarrhoea, gas, constipation or abdominal pain that are often interpreted as IBS. FODMAPs, when malabsorbed, are highly osmotic substances that can cause an influx of water into the colon and result in diarrhoea, or through fermentation by colonic bacteria can lead to excess gas production. In individuals with visceral hypersensitivity, intestinal distension triggered by gas or fluids may either exacerbate or induce abdominal symptoms. A reduction in consumption of FODMAPs would in theory, reduce fluid transit in the gut and improve symptoms.<sup>37</sup> However, because many patients on this diet have decreased fibre intake, it may also cause constipation.<sup>38</sup>

Fibre is effective in the management of CC, but bloating, distension, flatulence and cramping may limit the use of insoluble fibre, especially if increases in fibre intake are not gradual. In our previous 2005 systematic review, we found methylcellulose, bran and calcium polycarbophil had poor levels of evidence to support a recommendation for or against the use of these therapies in the management of CC, and no new studies have been published on these compounds. Psyllium was found to have a fair level of evidence, with moderate levels of evidence to support its use in the management of CC.<sup>39</sup> In IBS, insoluble fibre may exacerbate symptoms and provide minimal relief, but soluble fibre, such as psyllium, can be effective.<sup>40, 41</sup> Although food intake commonly precipitates symptoms of IBS, data from RCTs are limited regarding dietary manipulation and restriction, such as the FODMAP-restricted diet. A recent systematic review by Ford *et al.* was published regarding the management of IBS and chronic idiopathic constipation.<sup>41</sup> In this systematic review, our aim is to examine the recent (last 10 years) evidence for fibre supplementation and for a FODMAP-restricted diet in the management of CC and IBS-C, and discuss their role in current management strategies for these disorders. The time period

(2004–2014) was chosen because previous reviews in CC have addressed the role of fibre<sup>29, 39, 42</sup> and newer diagnostic criteria have been established for CC and IBS-C that have been widely adopted in clinical trials, including the use of more rigorous outcome measures such as complete spontaneous bowel movements (CSBMs). Finally, the FODMAP-restricted diet has only been introduced during this time period.

## METHODS

A search of the medical literature was conducted using PUBMED, MEDLINE, OVID and the COCHRANE databases to identify studies examining the efficacy of fibre in patients with IBS and constipation, using the following search terms: fiber, fibre, fibres, vegetable fiber, vegetable fibre, plant fiber, plant fibre, constipation, difficulty defecating, constipated, IBS, irritable bowel syndrome. In our previous 2005 systematic review, we evaluated traditional medical therapies, including fibre, in CC,<sup>39</sup> therefore our current search was limited to studies dating from January 2004 to September 2014. For inclusion, studies had to compare fibre with placebo, alternative fibre agent, or no therapy and report dichotomous data assessing response to therapy, continuous data examining the effect of therapy on either mean number of stools per week, or continuous data examining the effect of therapy on mean symptom scores. The minimum age was 16 years of age with a minimum duration of therapy of at least 1 week. Studies had to be published in full manuscript form. Studies were then classified into three categories including CC (if subtype was not identified), IBS and dyssynergic defecation (DD).

A search of the medical literature was also conducted using PUBMED, MEDLINE, OVID and the COCHRANE databases to identify studies examining the efficacy of a FODMAP-restricted diet in patients with IBS and constipation, using the following search terms: FODMAP, FODMAPs, constipation, difficulty defecating, constipated, IBS and irritable bowel syndrome. Because the FODMAP-restricted diet is a relatively new intervention, all studies in the past 10 years were included. For inclusion, studies had to involve subjects with IBS and had to investigate the efficacy of a FODMAP-restricted diet intervention. Because these studies are still highly heterogeneous, no additional criteria were used. The minimum age of participants was 16 years with a minimum duration of therapy of at least 2 days. Due to the expected paucity of studies, we intentionally liberalised the inclusion of shorter duration and nonrandomised studies for the purposes of our review. Studies had to be published in full manuscript

form. An additional search for 'FODMAPs and Constipation' was also conducted, but this did not retrieve any additional results.

Treatment recommendations were based on the grading system recommended by the US Preventive Services Task Force.<sup>43</sup> The levels of evidence according to this system include Good evidence (Level 1) with consistent results from well-designed, well-conducted studies; Fair evidence (Level II) with results that show benefit, but strength limited by the number, quality, or consistency of the individual studies; and Poor evidence (Level III) with insufficient results because of limited number or power of studies, flaws in their design or conduct. The classification of recommendations based on this system include Grade A with good evidence to support use of the modality, Grade B with moderate evidence to support use of the modality, Grade C with poor evidence to support a recommendation for or against the use of the modality, Grade D with moderate evidence against the use of the modality and Grade E with good evidence to support a recommendation against the use of the modality.

## DATA EXTRACTION

Data were extracted onto a spreadsheet, including the criteria used to define response to therapy, number in the fibre intervention group and control group, and treatment effect in each group. Dose and duration of therapy, subtype of constipation, primary outcome measure used to define response to therapy, level of blinding and proportion of female patients was also assessed. Methodology scores on a five point scale were assigned with a score of 1 or 2 given for randomisation (two for appropriate randomisation technique and concealed allocation explicitly stated or described, 1 for a study simply described as 'randomised'); scores of 0–2 were given for blinding (two when both subjects and investigators were blinded to the treatment by use of identical placebo or other technique, 1 when the study was described as 'double-blind,' and 0 when the study was not double-blind); a score of 0 or 1 was given for frequency of withdrawals (one when the number of withdrawals and reason for withdrawals were stated and 0 when no statement was made pertaining to withdrawals).

## RESULTS

### Fibre supplements and CC and IBS

The search strategy for fibre identified 1951 citations and 550 clinical trials, of which 46 were potentially eligible

for this systematic review (Figure 1). From this pool, a total of 11 studies were eligible for inclusion. A meta-analysis was not performed due to methodological quality and heterogeneity of the studies identified. Seven studies were identified dealing with fibre. One of these studies compared dried plums vs. psyllium. Four studies were identified dealing with fibre and IBS-C. One study examined fibre in DD, and one compared a high-fibre diet vs. psyllium.

**FODMAPS and IBS**

The search strategy for FODMAPs identified 355 citations, and 23 citations were potentially eligible for this systematic review (Figure 1). Eleven were excluded because they did not use human subjects, five were excluded because they were not clinical trials, one was excluded because it only used healthy subjects, and one was excluded because it did not involve a FODMAP-restricted diet intervention.

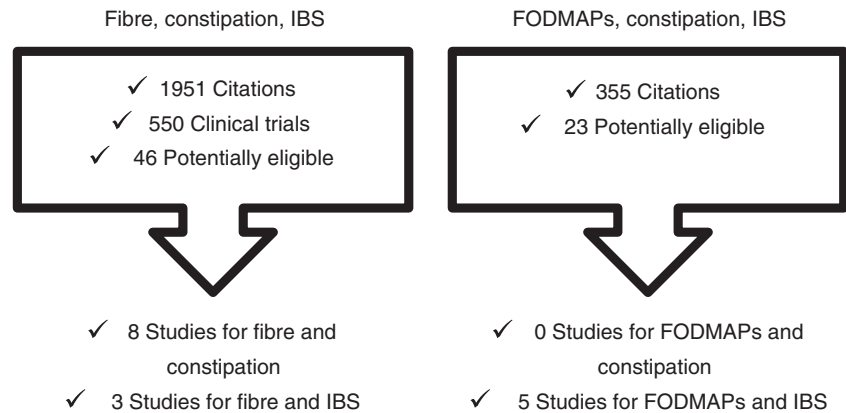
**FIBRE IN CHRONIC CONSTIPATION (TABLE 1)**

In 2006, Hongisto *et al.* conducted a randomised controlled trial (RCT) with a two-by-two factorial design in Finland, in patients with self-reported constipation.<sup>44</sup> Fifty-nine patients (100% female) with a mean age of 41 years (range 18–57 years) were recruited, and were entered into a 3 week dietary intervention that was followed by a 3 week follow-up period. The patients were entered into one of the following interventions: (i) rye bread+ *Lactobacillus rhamnosus* strain GG (LGG) yoghurt, (ii) rye bread, (iii) LGG yoghurt and (iv) control. Minimum consumption was 8 × 40 g fibre-rich rye bread, 8 × 24 g low-fibre toast, 2 × 150 g LGG yoghurt, respectively. The intervention group with rye bread + LGG yoghurt had a mean of 1.5 stools per day compared with 0.9 in the control group ( $P = 0.001$ ). The

authors also found that rye bread shortened total intestinal transit time (mean difference,  $-0.7$ ; CI (95),  $-1.1$  to  $-0.2$ ;  $P = 0.007$ ), softened faeces ( $-0.3$ ; CI (95),  $-0.4$  to  $-0.2$ ;  $P < 0.001$ ) and made defecation easier ( $-0.4$ ; CI (95),  $-0.5$  to  $-0.2$ ;  $P < 0.001$ ). There were increased gastrointestinal symptoms (1.6; CI (95), 0.7–2.4;  $P < 0.001$ ) compared with the low fibre toast consumed in the LGG and control groups, however, there were fewer symptoms in the rye bread + LGG group compared with the rye bread group ( $-1.3$ ; CI (95),  $-2.4$  to  $-0.2$ ;  $P = 0.027$ ), suggesting simultaneous consumption of LGG yoghurt relieves the adverse gastrointestinal effects associated with increased intake of fibre.

In 2007, a RCT in patients with self-reported constipation enrolled 43 subjects (74% female), with a mean age of 76 years (range 61–92 years).<sup>45</sup> They participated in an 8 week cross-over trial, with a 2-week baseline period and 2, 3-week dietary intervention periods, with a 2-week wash-out period between the interventions. The fibre intervention was 260 g/day test yoghurt containing GOS (12 g/day), prunes (12 g/day) and linseed (6 g/day) vs. a control yoghurt. They found that the defecation frequency was 5.7 times/week during the baseline period, and during the intervention, defecation frequency was higher during intervention vs. the control period (8.0 vs 7.1 times/week,  $P = 0.011$ ). Also during the intervention period, defecation was easier (on the scale 0–3, 1.3 vs. 1.5,  $P = 0.010$ ), and there was a tendency towards softer stools (on the scale 0–3, 2.1 vs. 2.2,  $P = 0.059$ ) compared with the control yoghurt period.

In 2008, another RCT of CC patients (Rome II criteria) enrolled 32 subjects (88% female) with an average age of  $47 \pm 15$  years, of whom 15 were randomised to the fibre intervention and 17 to placebo.<sup>46</sup> The fibre intervention was composed of inulin and digestion-resistant maltodextrin enriched semi-skimmed milk (20 g of



**Figure 1 | Schematic diagram describing our search strategy and studies included for this systematic review.**

fibre/day) vs. semi-skimmed milk alone during a 20-day-treatment period. They found in the fibre intervention group, the proportion with straining during defecation (35.7% vs. 78.6%,  $P < 0.0001$ ), sensation of incomplete evacuation ( $P < 0.001$ ), sensation of obstruction ( $P < 0.001$ ) and the days between bowel movements were all significantly lower.

In 2010, Sturtzel *et al.* conducted a controlled, parallel intervention trial in a geriatric hospital in Austria, in patients with CC requiring laxative therapy.<sup>47</sup> Thirty frail patients with multiple chronic diseases aged 57–98 years were recruited (% female not reported), and 15 each were randomised to fibre intervention or no therapy for 12 weeks. The fibre intervention was 5.2 g/day oat-bran mixed into the daily common meals. The fibre group intervention was well-tolerated and laxative use decreased by 59% ( $P < 0.001$ ), while it increased by 8% in the control group ( $P > 0.05$ ). Also in the control group, plasma B12 decreased faster ( $P < 0.05$ ). In both groups, B6 and folate status remained unchanged. Plasma homocysteine decreased in both groups ( $P < 0.05$ ).

In 2012, Linetzky Waitzberg *et al.* conducted a RCT in Brazil, in patients with CC, with less than three stools per week.<sup>48</sup> Sixty patients (100% female, age 18–65 years) were recruited, and 28 received fibre intervention and 32 placebo, during a 3 week treatment period. The fibre intervention was 15 g/day of inulin and partially hydrolysed guar gum (IPHGG) (fibre group) vs. maltodextrin (placebo group). They found an increased frequency of weekly bowel movements ( $5.95 \pm 2.50$  intervention group vs.  $6.70 \pm 3.83$  control group,  $P = 3.27$ ), and increased patient satisfaction in both groups, with no significant difference (40.9% intervention group vs. 41.7% control group,  $P = 0.372$ ). The authors assessed changes in faecal microbiota as well as short-chain fatty acids in both groups, and found that total *Clostridium* species significantly decreased in the fibre group ( $P = 0.046$ ) and increased in the placebo group ( $P = 0.047$ ), while there were no changes in faecal short-chain fatty acid profile. It is possible that the use of maltodextrin as the placebo may have affected the placebo group's clinical response.

In 2011, Pucciani *et al.* conducted a single-blind RCT in Italy, in patients with obstructed defecation.<sup>49</sup> Forty-five patients (100% female) with a mean age of 55.2 years, were recruited and 21 were randomised into Group 1, a high-fibre diet arm, and 24 were randomised

into Group 2, a psyllium arm. The high-fibre diet intervention consisted of approximately 30 g fibre per day (dietary fibre type not specified) vs. the psyllium intervention of 3.6 g twice daily. After a preliminary clinical evaluation, including the obstructed defecation syndrome (ODS) score, all patients underwent defecography and anorectal manometry as well as rehabilitative treatment according to the 'multimodal rehabilitative programme' for obstructed defecation. The mean length of the rehabilitation cycle was  $4.46 \pm 2.2$  months for Group 1 patients and  $3.78 \pm 1.4$  months for Group 2 patients ( $P = 0.14$ ). The number of bowel movements per week did not differ significantly between Group 1,  $6.43 \pm 3.45$ , vs. Group 2,  $7.10 \pm 5.08$  ( $P = \text{N.S.}$ ), and both groups had a significantly better Bristol stool form scale (BSFS) score and ODS scores. The authors found that the Group 2 women who underwent volumetric rehabilitation (11 patients) had significantly lower post-rehabilitative conscious rectal sensitivity threshold values than pre-rehabilitative values ( $P < 0.002$ ).

In 2011, Attaluri *et al.* conducted a single-blind, randomised cross-over study in the USA, in patients with CC meeting Rome III criteria.<sup>50</sup> Forty patients (93% female) with a mean age of 38 years, were recruited and were randomised in a cross-over fashion to two 3 week treatment periods, each with a 1 week wash-out period. The fibre interventions included dried plums (50 g b.d., fibre = 6 g/day) or psyllium (11 g b.d., fibre = 6 g/day). The authors found that the primary outcome measure, the number of CSBMs per week with dried plums was significantly greater than that with psyllium ( $3.6 \pm 0.4$  vs.  $2.9 \pm 0.3$ ,  $P = 0.001$ ). Stool consistency scores also improved significantly ( $P < 0.05$ ) with dried plums when compared with psyllium. Straining and global constipation symptoms did not differ significantly between treatments. They concluded that dried plums are safe, palatable and more effective than psyllium for the treatment of mild-to-moderate constipation, and should be considered as a first line therapy.

## FIBRE AND IRRITABLE BOWEL SYNDROME (TABLE 2)

In 2005, Rees *et al.* conducted a longitudinal, prospective, randomised, placebo-controlled trial in England, in patients with IBS-C meeting Rome I criteria.<sup>51</sup> Patients were included if stool frequency was reported to be less than once per day or was of variable frequency, if their stools were once or twice a day and 'hard', 'pellety' or 'variable' in form, or if straining to defecate was

**Table 1 | Randomised controlled trials of fibre in the treatment of CC**

Study and clinical setting	CC criteria	Methodology	Methodology Score*	Active intervention/fibre dose/duration	No. in fibre arm	Treatment effect in fibre arm	No. in control arm	Treatment effect in control arm	In favor of fibre/significance
Hongisto <i>et al.</i> <sup>44</sup> , secondary care out-patient† setting (Finland)	Self-reported	Randomised, two-by-two factorial design	1/0/0 = 1	Four diet groups: (i) rye bread + <i>Lactobacillus rhamnosus</i> GG (LGG) yoghurt, (ii) rye bread, (iii) LGG yoghurt and (iv) control/fibre dose = 39.36 g (rye bread) (mostly insoluble) /3 week intervention	15	1.3 mean stools/day	14	0.9 mean stools/day	Yes, <i>P</i> = 0.001
Sairanen <i>et al.</i> <sup>45</sup> , secondary care out-patient† setting/nursing home (Finland)	Self-reported	Randomised, double-blind, cross-over	2/2/0 = 4	260 g/day of either control yoghurt or test yoghurt containing Galactooligosaccharide (GOS) (12 g/day), prunes (12 g/day) and linseed (6 g/day)/fibre dose = 2.34 g (mixed soluble/insoluble) /2 week dietary intervention	43	8 bowel movements/week	43	7.1 bowel movements/week	Yes, <i>P</i> = 0.011
López Román <i>et al.</i> <sup>46</sup> , secondary care out-patient† Setting (Spain)	Rome II	Prospective, randomised, double-blind	1/1/0 = 2	Treatment Group A received fibre enriched semi-skimmed milk (20 g of fibre/day composed of inulin and maltodextrin); Control Group B received semi-skimmed milk/fibre dose = 20 g (soluble)/20 days	15	35.7% straining at defecation	17	78.6% straining at defecation	Yes, <i>P</i> < 0.0001
Sturtzel <i>et al.</i> <sup>47</sup> , secondary care† geriatric hospital (Austria)	CC requiring laxative use	Controlled, parallel intervention	1/0/0 = 1	5.2 g/day oat-bran mixed into the daily common meals vs. control/fibre dose = 0.78 g (soluble)/12 weeks	15	59% discontinued laxative use	15	8% increased laxative use	Yes, <i>P</i> < 0.001
Linetsky Waitzberg <i>et al.</i> <sup>48</sup> , health workers, secondary care out-patient† setting (Brazil)	< 3 bowel movements/week	Randomised, double-blind, placebo controlled	1/2/0 = 3	Inulin and partially hydrolysed guar gum (IPHG)/fibre dose = N.A. (soluble) /3 weeks	28	5.95 ± 2.50 bowel movements/week	32	6.70 ± 3.83 bowel movements/week	No, <i>P</i> = N.S.
Pucciani <i>et al.</i> <sup>49</sup> , secondary care out-patient setting (Italy)	Rome III	Single-blind, randomised trial	2/0/0 = 2	High-fibre diet (approximately 30 g fibre per day, type not specified)/fibre dose = 30 g (total/day) vs. Psyllium 7.2 g/fibre dose = 1.96 g (not specified) /4 months	High-fibre diet, 21	6.43 ± 3.45 bowel movements/week	Psyllium, 24	7.10 ± 5.08 bowel movements/week	Yes‡, <i>P</i> = N.S.
Attaluri <i>et al.</i> <sup>50</sup> , secondary care out-patient† setting (USA)	Rome III	Single-blind, randomised cross-over study	2/0/1 = 3	Dried plums (50 g b.d., fibre = 6 g/day) or psyllium (11 g b.d., fibre = 6 g/day)/fibre dose = 6 g (soluble/insoluble) / 3 weeks	Dried Plums, 40 (cross-over)	3.6 ± 0.4 CSBMs/week	Psyllium, 40 (cross-over)	2.9 ± 0.3 CSBMs/week	Yes, <i>P</i> = 0.001

CSBMs, complete spontaneous bowel movements; N.A., not available; N.S., not significant.

\* See text. Randomisation/Blinding/Statement on Withdrawals = Total.

† Presumed if not stated as primary or tertiary.

‡ Improved bowel symptoms in both the high fibre and psyllium groups.

common. Twenty-eight patients (86% female) with a mean age of 36 years (range 20–69 years) were recruited, and 14 each were randomised to a fibre intervention or placebo. The fibre intervention was 10–20 g/day of coarse wheat bran supplement to their normal diet vs. a low fibre placebo for 8–12 weeks. All stools were collected for a 7-day baseline period, to allow assessment of whole gut transit time using radio-opaque markers (hours), frequency of defecation (number/day), faecal wet weight (g/24 h) and faecal form (scale 1–8; 1 = watery, 8 = pellety). After 8–12 weeks of intervention, reassessment of these parameters was done. They found that the fibre intervention group had an increase in faecal wet weight (g/24 h) of  $28 \pm 25$  g compared with the placebo group, which demonstrated a mean decrease of  $10 \pm 41$  g ( $P < 0.02$ ). Other bowel function measurements and recorded symptoms did not differ significantly.

In 2011, Choi *et al.* conducted a RCT in South Korea, in patients with IBS meeting Rome III criteria, who were

subtyped into IBS-C, IBS-D (diarrhoea predominant) and IBS-M (mixed).<sup>52</sup> A total of 142 patients (75% female with a mean age of 33.9 years) were recruited, and 70 were randomised to the fibre intervention for 4 weeks. The fibre intervention was 150 mL of probiotic fermented milk with 3.15 g fibre powder using sea tangle extract, radish extract and glasswort extract, which are mostly soluble fibres, vs. 150 mL probiotic fermented milk alone. Changes in Visual Analog Scale (VAS) scores were measured for abdominal pain or discomfort, abdominal distention or bloating, urgency, straining, feeling of incomplete evacuation and improvement in overall IBS symptoms, in addition to flatulence/week, frequency/week, defecation duration and BSFS for stool consistency. For the overall IBS group, all parameters improved in both groups except for flatulence, defecation frequency, stool consistency and feeling of incomplete evacuation. Straining improved more in the fibre group. Similar trends were seen for the other IBS subtypes, however, in the IBS-C group defecation frequency was

**Table 2 | Randomised controlled trials of fibre in the treatment of IBS**

Study and clinical setting	IBS criteria	Methodology	Methodology Score*	Active intervention and Dose/Duration	No. in fibre arm	Treatment effect in Fibre Arm	No. in control arm	Treatment effect in control arm	In favor of fibre/significance
Rees <i>et al.</i> <sup>51</sup> ; secondary care out-patient† setting (England)	Rome I, IBS-C	Longitudinal, prospective, randomised, placebo-controlled trial	1/0/1 = 2	10–20 g/day of coarse wheat bran vs. low fibre placebo/fibre dose = 4.3–8.6 g (mostly insoluble)/8–12 weeks	14	Increased mean stool wet weight 28 ± 25 g/24 h	14	Decreased mean stool wet weight 10 ± 41 g/24 h	Yes, <i>P</i> < 0.02
Choi <i>et al.</i> <sup>52</sup> ; secondary care out-patient† setting (South Korea)	Rome III, IBS subtyped into IBS-C, IBS-D, IBS-M	Randomised, double-blind, controlled trial	1/2/1 = 4	150 mL of probiotic fermented milk with 3.15 g fibre powder using sea tangle, radish and glasswort extract vs. 150 mL probiotic fermented milk alone. Fibre dose = N.A. (mostly soluble)/4 weeks	70	IBS-C, BMs/week Δ3.97, Abd. Pain VAS Δ-1.72, Abd. Pain/week Δ-2.72, Abd. Distention VAS Δ-2.96, Flatulence/day Δ0.06, BM duration Δ-8 min, Urgency VAS Δ-0.31, Straining VAS Δ-5.47, BSFS Δ1.56, Incomplete Evacuation Δ-2.96	71	IBS-C, BMs/week Δ0.53, Abd. Pain VAS Δ-1.58, Abd. Pain Frequency/week Δ-1.69, Abd. Distention VAS Δ-2.36, Flatulence/day Δ-0.39, BM duration Δ-2.06 min, Urgency VAS Δ-2.08, Straining VAS Δ-1.81, BSFS Δ1.17, Incomplete Evacuation Δ-2.36	Yes, <i>P</i> < 0.014 (for BM frequency, all other parameters not significantly different between fibre and control)
Min <i>et al.</i> <sup>53</sup> ; secondary care out-patient† setting (South Korea)	Rome III, IBS subtyped into IBS-C, IBS-D, IBS-M	Randomised, double-blind, controlled trial	2/2/0=2	Twice daily Composite yoghurt with acacia dietary fibre, high-dose <i>B. lactis</i> vs. Control product/Fibre Dose = N.A. (soluble)/8 weeks	19	Overall IBS improvement VAS 64.2 ± 17.0; IBS-C VAS 72.4 ± 18.4; IBS-D VAS NS. Improvement in overall BM satisfaction 2716; IBS-C NS; IBS-D 32.9; IBS-M NS	22	Overall IBS improvement VAS 50.4 ± 20.5; IBS-C VAS 50.0 ± 21.8; IBS-D VAS NS. Improvement in overall BM satisfaction 15.51; IBS-C NS; IBS-D 7.81; IBS-M NS	Yes (Overall IBS symptoms, overall BM satisfaction; IBS-C, overall IBS symptoms; IBS-D overall BM satisfaction) <i>P</i> < 0.001
Cockerell <i>et al.</i> <sup>54</sup> ; Primary/secondary care out-patient setting (England)	Rome III, IBS subtyped into IBS-C, IBS-D, IBS-M, IBS-U	Open-randomised controlled trial	2/0/1 = 3	Two tablespoons of whole or ground linseeds per day vs. no linseeds/fibre dose = 5.6 g (whole), 3.8 g (ground) (both soluble and insoluble)/4 weeks	26	Per protocol analysis showed reduction in IBS symptom severity score Whole linseeds 84/ Ground linseeds 64.3, (100 mm VAS across five components‡)	13	Per protocol analysis showed 41.7 reduction in IBS symptom severity score (100 mm VAS across five components‡)	Yes (Per protocol analysis), <i>P</i> = 0.017 (whole)/ <i>P</i> = 0.006 (ground) (ITT analysis negative)

N.A., Not available; VAS, Visual Analog Scale; BM, bowel movement; N.S., not significant.

\* See text. Randomisation/Blinding/Statement on Withdrawals = Total.

† Presumed if not stated as primary or tertiary.

‡ Pain, number of days in pain, bloating severity, satisfaction with bowel habit and the degree to which IBS symptoms have interfered with quality of life.

significantly improved in the fibre group ( $\Delta 3.97$  BMs/week, *P* = 0.007), and was not significantly improved in the control ( $\Delta 0.53$  BMs/week, *P* = 0.53). Based on their results the probiotic fermented milk improved numerous parameters in IBS, with an additive benefit of increased stool frequency conferred by fibre supplementation in the IBS-C group.

In 2012, Min *et al.* conducted a RCT in South Korea, in patients with IBS meeting Rome III criteria.<sup>53</sup> One hundred and thirty patients (70% female) with a mean age of 35.8 years were recruited, and 65 each were randomised to the fibre intervention or placebo for 8 weeks. The fibre intervention was twice daily composite yoghurt with acacia dietary fibre, high-dose *B. lactis* vs. a control product. The subgroup of IBS-C had a total of 19 patients in the treatment group and 22 in the control arm. In IBS-C, improvement in overall IBS symptoms was significantly higher in the test group than in the control group ( $72.4 \pm 18.4$  vs.  $50.0 \pm 21.8$ , *P* < 0.001). The bowel habit satisfaction did not differ between the test and control groups, and while defecation frequency and feeling of incomplete

evacuation did differ between the groups, it improved in both groups.

In 2012, Cockerell *et al.* conducted an open randomised controlled trial in England, in patients with IBS meeting Rome III criteria.<sup>54</sup> Forty patients (53% female) were recruited, aged 18–70 years, and 13 each were randomised to two separate treatment arms, and 13 were randomised to no therapy. The fibre interventions included two tablespoons twice daily of whole linseeds and two tablespoons twice daily of ground linseeds vs. no therapy. Thirty-one subjects completed the study. The primary outcome measure was a reduction in symptom severity score from the baseline week to week 4. The authors found in a per protocol analysis that subjects in the intervention groups reported a significant improvement in composite symptom severity scores from baseline to week 4 in whole linseeds vs. control [299.7 (94) vs. 215.7 (147); *P* = 0.017] and ground linseeds vs. control (310.6 (140) vs. 246.3 (154); *P* = 0.006). However, no significant difference was found in the number of subjects who improved between any of the groups in the intention-to-treat

analysis [whole linseeds  $n = 8/14$  (57%); ground linseeds  $n = 10/13$  (77%); controls  $n = 5/13$  (39%);  $P = 0.140$ ].

### FODMAP-RESTRICTED DIET IN IRRITABLE BOWEL SYNDROME (TABLE 3)

In 2010, a study by Ong *et al.* took 15 healthy subjects and 15 subjects with IBS (87% female, median age 41 years, Rome III criteria) and performed a single-blind cross-over study to investigate the FODMAP-restricted diet in Australia. Of the 15 IBS subjects, 4 had IBS-D, 7 had IBS C, 2 had IBS-M and 2 patients had untyped IBS (IBS-U).<sup>55</sup> Patients were excluded if they had self-reported lactose intolerance, if they had other significant comorbidities or if they had taken antibiotics or probiotics 8 weeks prior the study. Participants were placed on a FODMAP-restricted diet (9 g/day) or a high FODMAP diet (50 g/day) for 2 days each with a 7 day wash-out period between diets. Diets were matched for total energy, starch, protein, fat and resistant starch and fibre. All food was provided to the subjects. Breath samples were collected and participants also filled out GI symptom questionnaires. Hydrogen levels were higher for both groups when on the FODMAP-restricted diet, and patients with IBS produced significantly more hydrogen than healthy controls while on the high FODMAP diet ( $P = 0.025$  for the FODMAP-restricted diet,  $P = 0.039$  for the high FODMAP diet). For IBS patients, all symptoms were significantly lower while on the FODMAP-restricted diet, including abdominal pain ( $P = 0.006$ ), bloating ( $P = 0.002$ ), passage of gas ( $P = 0.002$ ), nausea ( $P = 0.01$ ), heart burn ( $P = 0.025$ ) and lethargy ( $P = 0.012$ ). The passage of gas was also significantly lower in healthy subjects while they were on the FODMAP-restricted diet ( $P = 0.007$ ). Otherwise, symptoms were unchanged for healthy individuals while on the different diets.

In 2011, Staudacher *et al.* performed a retrospective observational trial in the UK to compare the effectiveness of the NICE dietary guidelines (which include either increasing fibre, decreasing fibre and use of probiotics or various exclusion diets, which were not detailed in the analysis) to that of the FODMAP-restricted diet.<sup>38</sup> In this study, 82 patients with IBS according to NICE guidelines (Rome criteria not used) were included and 71% of subjects were female. The average age of these patients was 38.1 years. Forty-three patients received information on the FODMAP-restricted diet while the other 39 received information on the NICE guidelines. There were no significant differences between groups.

Information was gathered at follow-up visits with a dietician 2–6 months after the initial visit. Significantly fewer patients in the FODMAP-restricted diet group had bloating, abdominal pain, gas, nausea, low energy levels or dissatisfaction with their symptom control. There were no differences in the number of those with diarrhoea or constipation when compared with those who received the NICE dietary guidelines ( $P$  values given above). After the magnitude of symptom improvement was assessed, the FODMAP-restricted diet group was found to have decreased levels of bloating ( $P = 0.026$ ), abdominal pain ( $P = 0.014$ ), gas ( $P = 0.01$ ), diarrhoea ( $P = 0.017$ ), constipation ( $P = 0.007$ ) and their composite score ( $P = 0.002$ ), but not for nausea ( $P = 0.155$ ) or energy levels ( $P = 0.235$ ). There were no differences between groups with regard to ease of following the diet (70% of FODMAP-restricted diet group, 85% of NICE group,  $P = 0.112$ ) or ease of understanding the written information (100% of the FODMAP-restricted diet group, 94% of NICE group,  $P = 0.116$ ). Based on a subgroup of the FODMAP-restricted diet group, 64% of patients reported following the diet strictly, and another 30% said that they followed the diet at least some of the time. Overall, this study suggests that the FODMAP-restricted diet may improve duration of symptoms, but specific IBS subtype analysis was not performed, duration of follow-up and outcome assessment was variable.

In 2013, de Roest *et al.* performed a prospective observational trial examining the FODMAP-restricted diet in New Zealand.<sup>56</sup> All patients received glucose, lactose and fructose breath tests, and patients with conditions other than IBS were excluded. IBS subtype was not specified. Each patient saw a dietician for FODMAP-restricted diet education for 1 h initially, and again for 30 min after 6 weeks. Adequate calcium and fibre intake was ensured. Of 192 patients who received dietary intervention, only 90 (46.9%) completed follow-up questionnaires. Average follow-up time was 15.7 months and 84.4% of respondents were females. Females were more likely to reply to the questionnaire. Otherwise, there were no significant differences between those who replied and those who did not. Average age of participants was 47 years. Abdominal pain ( $P = 0.000$ ), bloating ( $P = 0.000$ ), constipation ( $P = 0.003$ ), diarrhoea ( $P = 0.000$ ), nausea ( $P = 0.000$ ), gas ( $P = 0.000$ ), loose bowel movements ( $P = 0.000$ ), hard stools ( $P = 0.001$ ), urgent need for bowel movement ( $P = 0.000$ ), feeling of incomplete evacuation ( $P = 0.000$ ), straining during a bowel movement ( $P = 0.000$ ), feeling full shortly after starting a meal ( $P = 0.001$ ), visible swelling of the abdomen ( $P = 0.000$ )



**Table 3 |** Trials examining the FODMAP-restricted diet in IBS

Study and clinical setting	IBS criteria	Methodology	Methodology Score*	Active intervention / duration	No. in FODMAP-restricted Arm	Treatment effect in FRD Arm	No. in control arm	Treatment effect in control arm	In Favor of FODMAP-restriction/significance
Ong <i>et al.</i> <sup>55</sup> , secondary care out-patient† setting (Australia)	Rome III, IBS subtyped in to IBS-D, IBS-C, IBS-M and IBS-U	Randomised single-blind cross-over study	2/0/0 = 2	FRD (9 g)/high (50 g) FODMAP/ 2 days per diet	15	Median composite score of 2/9 (range 0–7) on Likert scale for abdominal pain, bloating and wind	15	Median composite score of 6/9 (range 2–9) on Likert scale for abdominal pain, bloating and wind	Yes, $P = 0.002$ (No subtype analysis done)
Staudacher <i>et al.</i> <sup>38</sup> , primary/secondary care out-patient setting (UK)	NICE Guidelines, IBS subtype not reported	Non-randomised retrospective observational	0/0/0 = 0	FRD/NICE dietary guidelines (fibre, probiotics, exclusion diets) /2–6 months	43	% symptom improvement: bloating in 82%, abdominal pain 85%, gas 85%, diarrhoea 83%, constipation 67%, nausea 67%, increased energy levels 63%, composite score 86%, % satisfied with BM 76%	39	% symptom improvement: bloating 49%, abdominal pain 61%, gas in 50%, diarrhoea 62%, constipation 45%, nausea 29%, increased energy levels 37%, Composite score 49%, % satisfied with BM 54%	Yes, all symptoms improved, $P < 0.05$ , except constipation and diarrhoea
de Roest <i>et al.</i> <sup>56</sup> , secondary care out-patient† setting (New Zealand)	Not specified	Non-randomised prospective observational	0/0/1 = 1	FRD instruction from a dietitian. No control group used./Mean total 15.7 months	90	GI symptom score (7 point Likert) at baseline/6 weeks showed improvement in abdominal pain, bloating, constipation, flatulence, diarrhoea, nausea, passing gas, loose BMs, urgency for BMs, incomplete emptying, >3 BMs/day, straining, abd. pain relieved by BM, fulling full shortly after meal, visible abdominal swelling, indigestion all significantly improved, $P < 0.05$	NA	NA	Yes, all symptoms improved, $P < 0.05$ , except feeling full long after meals, burping and passage of mucus
Biesiekierski <i>et al.</i> <sup>57</sup> , primary/secondary care out-patient setting (Australia)	Rome III, IBS subtype not reported	Non-randomised prospective trial with additional study components	0/1/0 = 3 (Not randomised for FODMAP)	FRD/baseline/ 2 weeks	37	On VAS, overall symptoms, abdominal pain, bloating, satisfaction with stool consistency, wind and tiredness improved from the second week of the FRD run-in period compared with baseline, $P < 0.0001$ , but not nausea ( $P = 0.149$ ).	NA	NA	Yes, all symptoms improved, $P < 0.001$ , except changes in nausea not significant, $P = 0.149$
Halmos <i>et al.</i> <sup>58</sup> , secondary care out-patient† setting (Australia)	Rome III, IBS subtyped in to IBS-D, IBS-C, IBS-M and IBS-U	Randomised controlled single-blind cross-over	2/0/1 = 3	FRD (3.05 g/day)/ Control diet = average of 23.7 g FODMAP per day/ 21 days per diet	30	All IBS VAS, bloating 24.2, abdominal pain 22.5, dissatisfaction with stool consistency 25.9, composite score 73.1; similar for IBS-D and C	30	On VAS, bloating 45.1, abdominal pain 43.8, dissatisfaction with stool consistency 47.8, Composite score 137; similar for IBS-D and C	Yes, overall IBS, $P < 0.001$ ; similar for IBS-D and C
Pedersen <i>et al.</i> <sup>59</sup> , out-patient, secondary care out-patient† setting (Denmark)	Rome III, IBS subtyped in to IBS-D, IBS-C, IBS-A	Randomised, unblinded controlled trial	2/0/1 = 3	FRD vs. LGG vs. ND/6 weeks	42	All IBS reduction in IBS-SSS 133 ± 122; IBS-D total IBS-SSS 153 ± 136; IBS-C total IBS-SSS 200 ± 62; IBS-A 241 ± 111; change in IBS-QOL 8 ± 18	40 ND arm	All IBS reduction in IBS-SSS 68 ± 107; IBS-D total IBS-SSS 257 ± 118; IBS-C total IBS-SSS 277 ± 135; IBS-A 322 ± 62; change in IBS-QOL 0.1 ± 15	Yes for All IBS with IBS-SSS, $P < 0.001$ , IBS-D, $p < 0.01$ , IBS-A, $P = 0.01$ ; IBS-C subtype not significant, $P < 0.14$ . Change in IBS-QOL not significant in all IBS, $P = 0.13$ .

FRD, FODMAPs-restricted diet; LGG, *Lactobacillus rhamnosus*; ND, normal Danish/Western diet; BM, bowel movement; VAS, Visual Analog Scale; IBS-SSS, IBS severity score system; IBS-QOL, IBS quality of life. NA, not applicable

\* See text. Randomisation/Blinding/Statement on Withdrawals = Total.

† Presumed if not stated as primary or tertiary.

and indigestion ( $P = 0.015$ ) were all significantly improved at follow-up. Patients found to have fructose intolerance were significantly more likely to notice improvements in bloating ( $P = 0.000$ ), abdominal pain ( $P = 0.002$ ), gas ( $P = 0.000$ ), diarrhoea ( $P = 0.029$ ) and constipation ( $P = 0.032$ ) compared with those without fructose intolerance. In addition, 75.6% of patients said that they remained adherent to the diet, and adherence was found to be strongly correlated with symptom improvement, and 72% were satisfied with their symptoms at follow-up. Also, 90% found the written materials easy to understand, and 76% found that the breath tests made the diet easier to understand. Furthermore, 60% of patients found the diet easy to follow, 65% of patients could easily find suitable products and 43% found the diet easy to incorporate in daily life.

In 2013, Biesiekierski *et al.* completed a complex clinical trial in Australia with FODMAP restriction and gluten free diet followed by a randomised, double-blind cross-over trial of 16 g gluten per day, 16 g whey protein per day or 14 g whey protein + 2 g gluten per day, for 1 week, with a 2 week wash-out period and cross-over to the next group, to investigate if the symptoms of IBS are related to gluten intake rather than FODMAPs.<sup>57</sup> The study included 37 patients (84% female, ages 24–61) with non-coeliac gluten sensitivity and IBS (Rome III criteria), and 43% had IBS-D, 35% had IBS-C, and 22% had IBS-M or IBS-U. After a baseline period where patients recorded their usual diet and symptoms, all participants were placed on gluten free, FODMAP-restricted diet for 2 weeks. All main meals were supplied to the participants. Symptoms were assessed using a 100 mm VAS scale.

During this period, abdominal pain, bloating, satisfaction with stool consistency, gas and fatigue all significantly improved ( $P < 0.0001$ ). Nausea was not significantly improved ( $P = 0.149$ ), and 22% of patients noted an improvement in overall symptoms of 20 mm or more from baseline. After this portion of the study, patients continued on the FODMAP-restricted, gluten free diet (still receiving all main meals). Overall symptoms and pain increased significantly during the second portion of the study regardless of diet type. Bloating and fatigue worsened for the low gluten and whey protein diets, and 6 patients (16%) noted an increase in symptoms of 20 mm or more while on the high gluten trial. The worsening of symptoms across dietary arms was thought to be due to stress put on the patients due to the need for frequent clinic visits, rather than due to diet differences – though this clearly needs additional investigation. There were no significant differences on symptoms for any diet group.

In 2014, Halmos *et al.* completed a randomised, controlled, single-blind cross-over study in Australia. Healthy subjects were also included as a control group.<sup>58</sup> The study included 30 IBS patients (Rome III criteria, 10 with IBS-D, 13 with IBS-C, 5 with IBS-M and 2 with IBS-U), 70% of which were female and with a mean age of 41 years. Participants were randomised to receive either a high or low FODMAP diet for 21 days. Three meals and three snacks per day were provided to help ensure dietary compliance. Symptoms were allowed to return to baseline before the participant tried the next diet. Psyllium and hi-maize were added to the FODMAP-restricted meals to match the four diets for fibre and resistant starch. Patients also collected stool samples for 5 days at the end of each diet period so that faecal consistency, frequency and weight could be analysed. Overall mean symptom severity for the IBS subjects was found to be a mean of 36 mm on the 100 mm VAS at baseline, with a mean of 44.9 mm while on the high FODMAP (typical Australian diet) and a mean of 22.8 mm while on the FODMAP-restricted diet ( $P < 0.001$ ). Improvement of 10 mm or more from the baseline VAS score was seen in 70% of patients with FODMAP restriction. Differences in individual symptom scores are detailed above. For healthy controls, baseline VAS scores were 17.0 mm. No significant changes were seen between diets. There was reduced stool frequency and lower King's Stool Chart score for those with IBS-D while on the FODMAP-restricted diet, but no other differences were observed.

More recently in 2014, Pedersen *et al.* performed a randomised, unblinded controlled trial on the effect of a Low FODMAP diet (LFD), *Lactobacillus rhamnosus* GG

(LGG), and a normal Danish/Western diet (ND) in patients with IBS (Rome III).<sup>59</sup> This included 123 patients (73% female, mean age 37 years) randomised to LFD (42), LGG (41) and ND (40) for 6 weeks of the treatment diet. Patients were required to complete a weekly survey on IBS severity score system (IBS-SSS) and IBS quality of life (IBS-QOL). In addition, patients were further subtyped into IBS-C, IBS-D and IBS-A (IBS with alternating diarrhoea and constipation). Patients in the LFD group were instructed on the FODMAP-restricted diet with specialised dietician and nutritionist education, though their FODMAP intake was not quantified. A statistically significant decrease in the IBS-SSS scores was found for the overall IBS group on the LFD, with a mean reduction of  $133 \pm 122$  compared with the ND group,  $34 \pm 122$  ( $P < 0.01$ ). The LGG also had a lesser but significant reduction of  $68 \pm 107$ . Change in IBS-QOL were not found to be significant for any of the groups, and for the LFD was  $8 \pm 18$  ( $P = 0.13$ ). When the results were analysed by subtype, however, the results were found to be significant for the IBS-D and IBS-A subtypes, but they were not significant for the IBS-C subtype in either the LFD or LGG treatment groups (LFD  $P = 0.14$ , LGG  $P = 0.74$ ).

## DISCUSSION

CC and IBS-C are heterogeneous GI disorders with complex pathophysiology that continues to evolve. At least two subtypes of CC have been recognised, notably slow-transit constipation, where the propulsion of stool is significantly slower than normal, and DD, where the act of stooling is uncoordinated or dyssynergic – both conditions lead to prolonged stool retention and/or difficulty with evacuation.<sup>2, 60</sup> Many other patients with CC, which includes a majority of these patients, may have either milder versions of these mechanisms or are in the early stages of their development, probably stemming from deficiencies in their diet, altered intestinal microbiota or other mechanisms. Likewise, IBS-C is characterised by abdominal pain and irregular bowel habits, and is associated with visceral hypersensitivity, altered gut-brain-gut interactions, an altered intestinal microbiome, food intolerances and sometimes with alterations in intestinal transit and pelvic floor function.<sup>61–63</sup> Consequently, it is naïve to assume that any one form of drug treatment or dietary manipulation will provide relief to all comers with these heterogeneous conditions. However, changes in diet can contribute to the pathophysiology of these conditions. Identifying dietary factors and providing an appropriate diet with either natural fibre or fibre supplements and/or

identifying potential food ingredients that may trigger bowel symptoms such as fructose, lactose, fructans or sorbitol and their selective elimination or a holistic elimination diet such as the FODMAP-restricted diet may afford symptom relief and restore normal bowel function.

Dietary fibre is comprised of complex carbohydrate polymers that are poorly digested in the small bowel and are therefore delivered almost unchanged into the colon, where they may either bulk stool by drawing fluid into stool residues or undergo partial bacterial fermentation to produce short-chain fatty acids, hydrogen, methane, carbon dioxide and water.<sup>64</sup> Fibre can either be consumed regularly as part of routine food such as in the form of vegetables and fruits or can be taken as supplements in the form of bran or psyllium or synthetic compounds such as methylcellulose. They are often classified as soluble or insoluble fibre depending on their interaction with water, and further classified into highly, intermediate, minimally or nonfermentable fibre.<sup>40</sup> There are some fibre supplements such as Suprafiber that have a mix of soluble and insoluble fibre.<sup>50</sup> Most fibre studies have used psyllium, also known as ispaghula, which is derived from the seeds of the plant *Plantago ovata*, which is hygroscopic and mucilaginous. The husk of psyllium seed is indigestible and is a long-chain carbohydrate, and therefore a good source of soluble fibre and is intermediately fermentable. It is important to take adequate water with these products. In contrast, inulin, guar gum and FOSs are short-chain carbohydrates that are both soluble and highly fermentable sources of fibre; methylcellulose is a chemical compound, an insoluble fibre derived from cellulose.<sup>40</sup> Fibre accelerates colonic transit time, increases biomass and induces changes in colonic pH and intestinal microbiome and may have effects on permeability and inflammation.<sup>65, 66</sup> Although it is recommended that adults consume 20–35 g of dietary fibre per day, Americans may only consume 10–18 g of fibre per day.<sup>67, 68</sup>

Our previous 2005 review of fibre supplementation in CC found fair evidence (Level II) with a Grade B recommendation in support of the use of fibre supplementation, particularly for psyllium fibre.<sup>69–71</sup> Also, poor evidence (Level III) was found to support a recommendation for or against the use of other fibre agents (Grade C), such as calcium polycarboxylate, bran and methylcellulose. It was clear that more well-designed trials with well-defined outcome measures were needed. In addition, based on guidance from the US Food and Drug Administration (FDA) in 2012 regarding primary endpoints for IBS trials, more concrete responder definitions that include specific terminology such as SBMs and CSBMs

have been introduced. CSBM is a validated measure now routinely used in drug trials and approved by the European Medicines Agency (EMA) and US FDA as a valid measure for assessing constipation.<sup>72</sup>

Regrettably, the studies of fibre supplements in CC over the past 10 years have continued to use variable amounts of fibre from different sources, with calculated fibre doses ranging from 1 g to 40 g/day, have poor standardisation of the fibre content in the interventions and lack the use of standard terminology, such as SBMs and CSBMs (Table 1). Only 1/7 studies (Pucciani *et al.*) actually quantified the total daily fibre intake, although the type of fibre was not specified. These studies were all done in small numbers of subjects with study arms as low as 15 and up to 43, and for a short duration, from 3 to 12 weeks. The types of supplemented fibre included guar gum, inulin, psyllium, fibre-enriched milk, rye bread, wheat, yoghurt with acacia fibre, coarse wheat bran, whole or ground linseeds (also known as flaxseed) and dried plums. Given the heterogeneity of these studies, the small numbers of subjects and the short duration of follow-up for a chronic condition such as CC, there clearly remains a need for better designed, larger sample size studies, with clearly defined and meaningful outcome measures that assess constipation symptoms such as CSBMs and stool frequency. Furthermore, only one study in our review, by Attaluri *et al.*,<sup>50</sup> used the change in number of CSBMs as the primary outcome measure. This study used a cross-over design and found prunes (dried plums) to be superior to psyllium. None of the other fibre studies used the CSBM measure, making assessments across studies difficult. In fact, the majority of studies used less rigorous measures such as straining effort or reduction in laxative use, often considered secondary outcome measures in current clinical studies. Therefore, these studies were not robust enough to provide good evidence (Table 1). Furthermore, parallel design was rare in these studies. For a condition such as CC, it is important that these studies are conducted for at least 3 months, and follow-up information obtained for at least 6–12 months to assess long-term outcome. None of these studies met these measures. Our assessment showed that the evidence for quality of studies in CC was fair (Level II), with a recommendation of moderate evidence in support of the use of fibre supplementation (Grade B). Notably, a recent study presented in abstract form compared psyllium with Suprafiber in a larger sample of patients, and assessed CSBM/week and showed that both the mixed soluble/insoluble Suprafiber

and the soluble fibre psyllium improved the number of CSBMs/week (primary outcome measure) and improved stool consistency, straining effort and other secondary outcome measures.<sup>73</sup>

A recent American College of Gastroenterology monograph on CC felt that the quality of evidence for fibre was low, but gave a strong recommendation, because fibre increases stool frequency.<sup>41</sup> Likewise, they felt that fibre provided overall symptom relief in IBS, but gave psyllium a weak recommendation and felt the quality of evidence was moderate. For bran, the recommendation was also weak with a moderate quality of evidence (Table 2). A previous study by Ford *et al.* gave psyllium a small but statistically significant benefit in the treatment of IBS, although a Cochrane review did not give IBS a favourable recommendation, because the Ford review did not use an intention-to-treat analysis in their model.<sup>74, 75</sup> The studies of fibre in the treatment of IBS are limited (Table 2). The fibre supplements studied included bran, acacia dietary fibre and linseeds. There was also heterogeneity in the scales of measurement for IBS symptom improvement. More uniform symptom scales are necessary in addition to use of measures such as CSBMs noted for CC. Despite these limitations, studies demonstrated significant improvements in both stool weight and reduction in overall symptom scores. On the basis of these studies, we assessed the evidence to be fair (Level II), with moderate evidence to support the use of fibre supplementation in IBS-C (Grade B).

In the few published trials of the FODMAP-restricted diet in IBS, the duration has typically been 2–3 weeks. However, in studies of patients with IBS and dietary interventions, it is important that these studies are conducted for at least 3 months, and follow-up evaluation for at least 6–12 months to assess long-term outcome. Although none of these studies met these measures, a FODMAP-restricted diet was shown to be more effective than dietary guidelines in IBS.<sup>38</sup> Though patients found to be sensitive to FODMAPs often observe symptom improvement within the first week of trying the FODMAP-restricted diet, there is a clear increase in efficacy over the first 6 weeks, so it is recommended that patients who may benefit from the diet attempt strict adherence for at least 6–8 weeks, although clinicians may usually recommend a 4 week trial. If the diet has shown little efficacy after 8 weeks of elimination, the diet may be discontinued. FODMAPs have an additive effect on symptoms in patients with IBS,<sup>76, 77</sup> so total FODMAP

intake is important. However, some people may be more sensitive to some groups of FODMAPs than others. A study by Böhn *et al.* that examined self-reported dietary intolerances in IBS found that 70% of surveyed patients reported sensitivity to foods high in FODMAPs, 49% reported sensitivity to dairy products (high in lactose), 36% were sensitive to beans (galactans) and 23% were sensitive to plums (fructose + polyols).<sup>78</sup>

More studies are needed to determine nutritional adequacy, because patients on the FODMAP-restricted diet were found to have altered starch, total sugar, carbohydrate and calcium intake. Fibre intake is often a concern for these patients. Recent studies show that the FODMAP-restricted diet reduces total bacterial count, increases faecal pH and alters intestinal microbiome composition and may cause impaired colonic health.<sup>79</sup> There is also the potential for developing nutritional deficiency, especially in unsupervised settings.<sup>80</sup> It is unknown if the change in prebiotic intake in the FODMAP-restricted diet has negative effects on the intestinal microbiome or if associated changes in gut microenvironment could affect health. It appears that it is safe to follow the diet as long as necessary, with the assistance of a dietician.<sup>38</sup> Hence, it is important to emphasise that patients receiving this dietary restriction should be monitored for long-term effects on health, and more data are needed regarding benefits vs. harm. Interestingly, a recent Italian study showed that IBS patients experience considerable benefit from restricting FODMAPs in the diet,<sup>81</sup> and gluten avoidance in addition to a FODMAP-restricted diet does not confer additional benefit.

The role of FODMAP-restricted diet in the management of IBS shows promise, but needs to be better defined.<sup>41</sup> The key principle for its success appears to be dietary education. While effective in the short term, there are practical barriers with education and compliance, and its long-term safety or efficacy is not yet proven. On the basis of these studies, we assessed that the quality of evidence is fair (Level II), with poor evidence to support a recommendation for or against the FODMAP-restricted diet in the management of IBS (Grade C).

## CONCLUSION

In conclusion, our review shows that dietary interventions with natural fibre or fibre supplements can be useful for the management of patients with CC and IBS-C (Level II Evidence, Grade B), and likewise FODMAP-

restricted diet can be helpful in patients with IBS, although more evidence is needed (Level II Evidence, Grade C). Not all patients are likely to benefit with these interventions because these are heterogeneous disorders with multiple pathophysiological mechanisms causing the illness. For example, a FODMAP-restricted diet may be more useful in IBS-D and IBS-M rather than IBS-C. We feel that a careful selection of CC and IBS-C patients through detailed dietary enquiry and surveys, and/or breath tests for fructose, lactose or fructan intolerance may identify patients who are more likely to respond to these dietary interventions. Also, nutrition counselling through a dedicated dietician is a key towards success of this management approach.

### AUTHORSHIP

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*Author contributions:* Dr S. Rao provided the overall concept and framework for the manuscript including identifying clinical trials and evidence for grading them and cowrote the manuscript along with coauthors and proofed and finalised the article. Dr S. Yu researched and identified appropriate articles and participated in

writing, referencing and preparation of the manuscript and tables and all data relating to the role of fibre in constipation and IBS. Ms. A. Fedewa researched and identified appropriate articles and participated in writing, referencing and preparation of the manuscript and tables relating to the role of FODMAPs and IBS and constipation. All three authors reviewed all tables and abstracted data together and arrived at consensus regarding the grade of evidence and recommendations.

All authors approved the final version of the manuscript.

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