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## Impact of a diet low in fermentable carbohydrates on gastrointestinal symptoms, stool output and faecal pH in patients with irritable bowel syndrome: a randomised controlled trial

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Fermentable carbohydrates have been proposed as triggers for gastrointestinal (GI) symptoms in irritable bowel syndrome (IBS). A diet low in Fermentable Oligo, Di-, Monosaccharides and Polyols (FODMAPs) has been shown to improve IBS symptoms in retrospective studies in both Australia<sup>(1)</sup> and the UK<sup>(2)</sup>. Furthermore, in patients who improve on a low FODMAP diet, their symptoms return when challenged with FODMAPs<sup>(3)</sup>. The aim of this randomised controlled trial was to investigate the effectiveness of a low FODMAP diet in managing symptoms of IBS.

Adult patients with IBS (with bloating and/or diarrhoea) were recruited from gastroenterology outpatient clinics. Exclusion criteria included those with other GI disorders (e.g. IBD), previous GI surgery and use of antibiotics, probiotics or prebiotics in the previous 4 weeks. Patients were randomised to a low FODMAP diet (intervention) or their habitual diet (control) for 4 weeks. The incidence and severity of GI symptoms were measured using the Gastrointestinal Symptom Rating Scale<sup>(4)</sup> and the global symptom question. Stool frequency and consistency were recorded using a validated stool diary (Bristol Stool Chart). A stool sample was also collected to measure faecal pH using a pH meter and electrode. All outcome measures were recorded at baseline and follow-up. Continuous data were compared using an independent samples t-test and categorical data were compared using the chi squared test. The study was approved by an NHS Research Ethics Committee and assigned a clinical trials registration number (ISRCTN 62040425).

Of the 41 patients randomised, 6 withdrew (5 protocol violations, 1 lost to follow up). There was no difference in demographic characteristics, symptoms, stool frequency, stool consistency or faecal pH between groups at baseline. In the intention-to-treat analysis, more patients in the low FODMAP group experienced improvements in bloating (14/19, 74% vs 7/22, 32%  $P = 0.007$ ), borborygmi (13/19, 68% vs 8/22, 36%;  $P = 0.041$ ), urgency (10/19, 53% vs 5/22, 23%;  $P = 0.047$ ) and overall symptoms (15/19, 79% vs 8/22, 36%;  $P = 0.006$ ) compared with controls. Importantly, more patients reported adequate control of symptoms on the global symptom question in the low FODMAP group (13/19, 68%) compared with the control group (5/22, 23%) ( $P = 0.003$ ). In the per protocol analysis, there was a lower incidence (3.6 vs 5.9 days;  $P = 0.007$ ) and severity score (0.8 vs 1.5;  $P = 0.013$ ) for bloating, and a lower incidence (5.1 vs 6.8 days;  $P = 0.003$ ) and severity score (1.1 vs 1.7;  $P = 0.003$ ) for overall symptoms in the FODMAP group compared with controls, respectively. There were no significant differences in the incidence or severity of patient-reported diarrhoea between groups. However, patients in the low FODMAP group had a lower stool frequency (9.3 vs 14.2 stools week,  $P = 0.025$ ) and a trend towards greater proportion of stools with normal consistency (33% vs 16%;  $P = 0.059$ ) compared with controls. There were no differences in faecal pH between the low FODMAP group ( $6.48 \pm 0.56$ ) and the control group ( $6.55 \pm 0.65$ ) ( $P = 0.732$ ).

This is the first randomised controlled trial investigating the effect of a low FODMAP diet in patients with IBS, demonstrating improvements in a range of symptoms and normalisation of stool output. The mechanisms through which these effects are mediated are suggested to be a reduction in luminal gas production and small intestinal water volume. Despite these benefits, there were no deleterious effects of the low FODMAP diet on faecal pH. Further work is required to assess safety aspects including the effect on the microbiota and the nutritional adequacy of the diet.

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