# FODMAPs, but not gluten, elicit modest symptoms of irritable bowel syndrome: a double-blind, placebocontrolled, randomized three-way crossover trial

# Background/introduction/summary

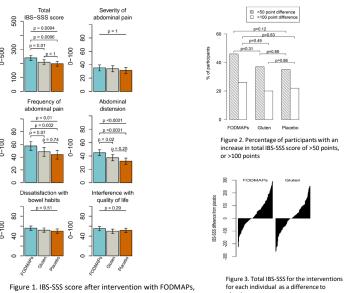
Irritable bowel syndrome (IBS) is a chronic common functional bowel disorder<sup>1</sup>. Symptoms have been associated with foods, such as FODMAPs (easily fermentable dietary fiber containing Fermentable Oligosaccharides, Disaccharides, Monosaccharides, and Polyols) and gluten. Previous studies suffer from a suboptimal study design due to small sample size and for being unblinded or single-blinded. Furthermore, studies have focused on the elimination of FODMAPs from the diet, not as a provocation<sup>2</sup>.

Therefore, the aim of this study was to investigate the effects of week-long intervention with FODMAPs, gluten or non-fermentable placebo on the IBS symptom severity score (IBS-SSS) in a double-blind, randomized, placebo-controlled cross-over study design.

#### Materials and Methods Medium to severe IBS n=110 Women and men Daily doses (1.5 times a daily intake) Fructose Lactose 15.2 Galacto-oligosaccharides 1.5 FODMAPs: 50 gram Fructo-oligosaccharides 7.0 4.5 Gluten: 17.3 gram Sorbitol Mannitol 1.8 Gluten FODMAPs Metabolomics Anthropometric Clinical

#### Results

In subjects with moderate to severe IBS (n=103), FODMAPs caused higher total IBS-SSS (mean [SE] 240 [9]) than placebo (208 [9]; p=0.00056) or gluten (198 [9]; p=0.013), but with no difference between gluten and placebo (p=1.0) (Figure 1). In order for clinical significance a change of 50 points is needed, the difference between FODMAPs and placebo was 42 points. Proportion of participants increasing with 50 or 100 points did not differ between the interventions (Figure 2). Also, there were large interindividual differences in response to the interventions (Figure 3).



gluten, or placebo. Higher scores indicate more severe symptoms

Nordin et al (2021) AJCN doi: 10.1093/ajcn/ngab337

#### Conclusions

FODMAPs, but not gluten, caused modest gastrointestinal symptoms in people with IBS, compared to placebo. There was a considerable interindividual variability in response to the interventions which warrants further detailed studies to identify underlying causes and enable prediction of responses.

Ongoing work in this project is to study the effect of the interventions on the metabolome and the gut microbiota in order to gain mechanistic insights. In addition, the possibility to predict outcome in relation to the interventions is under investigation.

#### Reference

<sup>1</sup> .Functional Gastrointestinal Disorders: History, Pathophysiology, Clinical Features, and Rome IV. *Gastroenterology* 2016;150:1262–1279

<sup>2</sup> Dionne et al. A Systematic Review and Meta-Analysis Evaluating the Efficacy of a Gluten-Free Diet and a Low FODMAPs Diet in Treating Symptoms of Irritable Bowel Syndrome. Am J Gastroenterology 2018;11(9):1290-1300

## Acknowledgements

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