



Gut health

New Human Trial Shows Biotis™ GOS Impacts Stool Frequency and Gut Microbiota



Constipation is one of the most common digestive problems, and a major issue for 10-20% of the global population.^{1,2} When we talk about constipation, we mean less than 3 defecations per week, dry and hard stool or difficulty in defecating.³ Constipation is more common in women than in men and its prevalence rises with age.⁴ Symptoms may be acute (less than a week) or chronic (for at least three months) and have a significant impact on daily living and well-being.^{5,6}

Demand for (dietary) solutions to support digestive health complaints, such as constipation, isn't new. And, with 26% of consumers in 2020 unsatisfied with their digestive health,⁷ it's a trend that is here to stay. At FrieslandCampina Ingredients, we're responding by investing in the development and research of scientifically substantiated ingredients to help companies develop products that support the digestive comfort of adults.

This includes ingredients such as Biotis™ GOS which was the subject of exciting research on the impact of food on gut health. This well-controlled human trial showed the ability of Biotis™ GOS to increase stool frequency in the adult population with a low stool frequency.⁸

Want to know more? We've summarised the key findings of this study in this document!

But first, what is Biotis™ GOS?

Biotis™ GOS (galacto-oligosaccharides) is a dairy-derived prebiotic ingredient. GOS have been shown to influence the composition and activity of the human gut microbiota^{9,10,11} and improve defecation frequency in older adults.^{12,13}

What did the study aim to find out?

The intervention study was conducted by NIZO Food Research in close cooperation with FrieslandCampina Ingredients. It aimed to investigate whether the daily consumption of Biotis™ GOS influences stool characteristics and gut microbiota composition in the general adult population with constipation.

Who took part in the study?

132 healthy adults (94% female) aged 18-56 with self-reported constipation. Subjects were included in the study if they were healthy adults with a BMI between 18.5 and 28.0 kg/m², with self-reported constipation according to the Rome IV criteria with fewer than three bowel movements per week and one or more of the following criteria: for at least 25% of all defecations: straining, lumpy or hard stools, sensation of incomplete evacuation, a sensation of anorectal obstructions/blockage, or manual manoeuvres.

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What methods did the study use?

The study was designed as a double-blind randomised placebo-controlled clinical trial. Participants received either a daily dose of 5.5g of the prebiotic Biotis™ GOS, 11g of Biotis™ GOS, or a placebo (maltodextrin) for 21 days.

Participants were instructed not to make any changes to their lifestyle, but to maintain their physical activity and habitual food and fluid intake during and 14 days before the study. All participants were requested to stop using medications for their constipation and (non-pharmaceutical) drugs during the study.

Participants were asked to fill in a daily diary to use as input for the weekly questionnaire in which information was recorded about stool frequency, consistency, quality of life, compliance to the study protocol and also changes in daily habits such as physical activity and dietary patterns. Furthermore, at the start and after the intervention, stool samples were taken to study fecal microbiota.

The following methods were used to measure the impact of Biotis™ GOS:

- **Validated questionnaires:** Each week, participants completed the Constipation Scoring System, the Bristol Stool Chart, and the Patient Assessment of Constipation Symptoms questionnaire to assess the impact on stool frequency and consistency.
- **Microbiota analyses:** Participants were provided with stool-sampling kits to self-collect feces for gut microbiota sequencing analysis.

What were the results of the study?

Stool frequency

As can be seen in Figure 1, the study showed that 11g of Biotis™ GOS tends to increase stool frequency in adults with self-reported constipation. In reality, not all subjects had constipation (less than 3 stools per week) at the start of the study. In adults with a low stool frequency (≤ 3 stools per week), daily consumption of 11g of Biotis™ GOS significantly increased stool frequency. A subgroup analysis in which the participants were split based on younger adults and middle-aged adults showed that the effect on stool frequency was mainly present in the subjects aged 35 years or above.

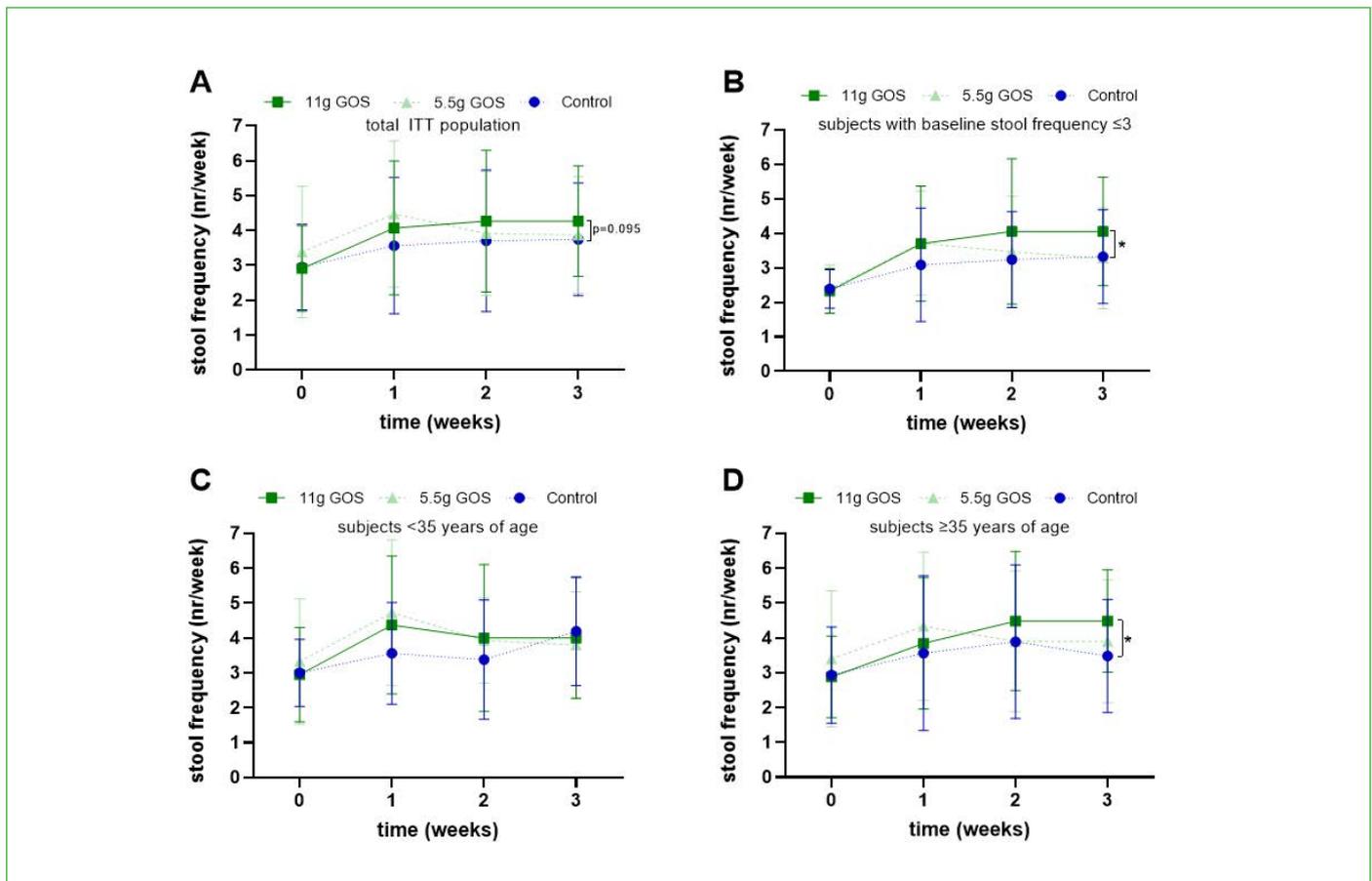


Figure 1: Stool frequency (adapted from Schoemaker et al. Nutrients. 2022 Jan 12;14(2):309)

Daily consumption of 11g of Biotis™ GOS resulted in a higher number of initial responders (increase in stool frequency, with at least 1 bowel movement, in the first week compared to baseline) and consistent responders (increase in stool frequency in first and last intervention week) compared to placebo.

As can be seen in Figure 2, Biotis™ GOS intake also impacted the gut microbiota composition, showing a clear dose-response effect on fecal beneficial *Bifidobacterium* levels. The presence of *Bifidobacteria* in the gut has been correlated to gut homeostasis and a decreased number of *Bifidobacterium* species has been associated with antibiotic-associated diarrhea, IBS and IBD.^{14,15} Another interesting finding of this study is the significant stimulating effect of 11g of Biotis™ GOS on fecal *Anaerostipes hadrus*. This species has been associated with gut health.^{16,17}

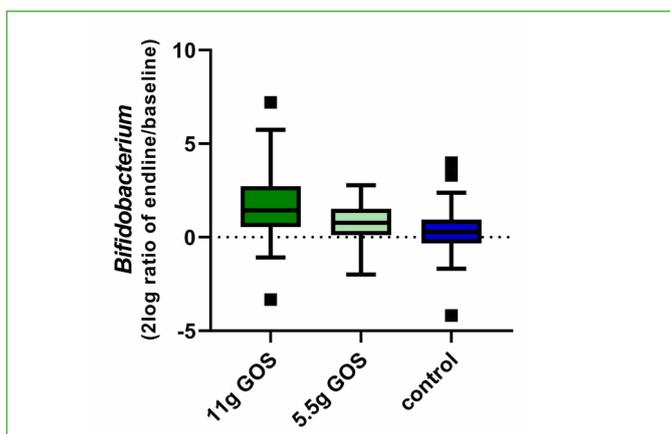


Figure 2: Bifidobacterium composition (%) (adapted from Schoemaker et al. Nutrients. 2022 Jan 12;14(2):309)

What do these findings mean for the nutrition and supplements industry?

Since the prevalence of gastro-intestinal (GI) discomfort is so widespread, and quality of life is strongly linked to a well-functioning GI tract, consumers are increasingly seeking natural, non-pharmaceutical solutions to support their gut health.

This study is very exciting because it is the first well-controlled human study that has used validated methods and has found a clinically relevant effect of GOS in the general adult population with low stool frequency. These results add to the growing scientific substantiation about Biotis™ GOS that's already available. Additionally, they suggest that a daily Biotis™ GOS supplement or fortified food and drink with Biotis™ GOS may be beneficial in instances of constipation.

You can read the full study [here](#) or find out more about the Biotis™ Gut Health Benefit Solutions range at www.biotis.com/gut-health



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