Prebiotic or probiotic supplements to relieve gastrointestinal complaints in patients with constipation-predominant IBS: A 4-week randomized double-blinded placebo-controlled intervention trial

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Background

Irritable Bowel Syndrome (IBS) is a disease that affects many people. To date, no adequate treatment is available. This is partially due to the heterogeneity of the patients and the complicated pathophysiology in which not all mechanisms are understood. Dietary interventions are one promising route to relieve IBS-related complaints, such as constipation.

Objective

We explored the effects of a 4-week intervention with either a prebiotic acacia fiber or a probiotic *Bifidobacterium Lactis* supplement on stool frequency, stool consistency, stool mass, IBS symptoms and Quality of Life (QoL), in people with IBS with constipation-predominant complaints (IBS-C).

Methods

In total, 180 IBS-C patients were included in a randomized double-blinded placebo-controlled human intervention study. The study started with a 4-week observation period (week 1-4), followed by a 4-week intervention period (week 5-8) in which participants received either 10 grams Prebiotic acacia fiber (AF), 4 grams (2 x 10^{11} CFU/g) probiotic *Bifidobacterium Lactis* (BLa) or placebo (maltodextrin).

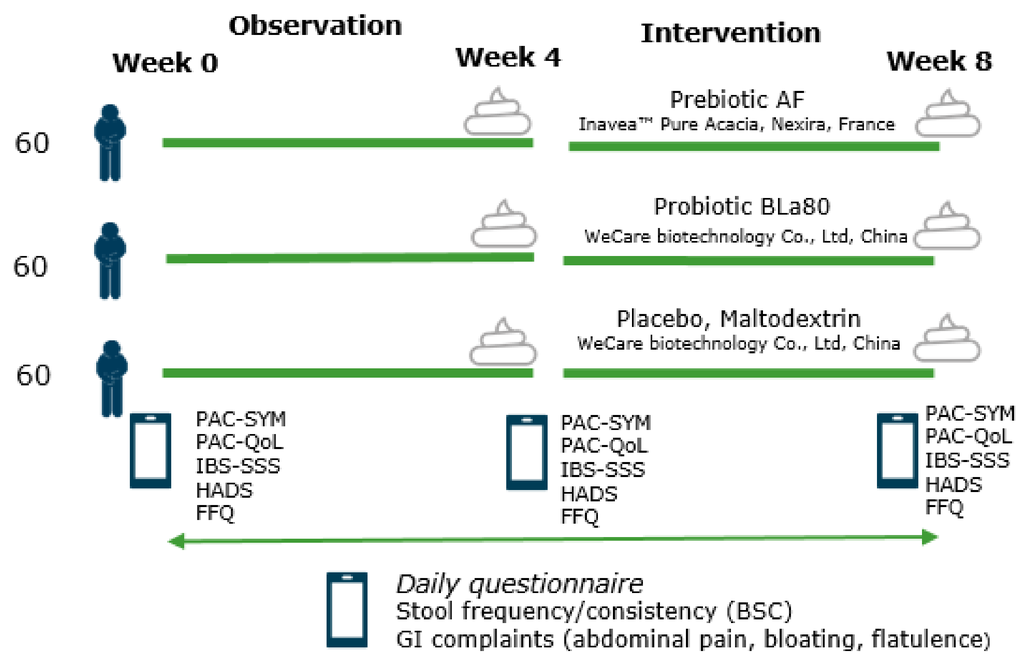

Figure 1. Schematic overview of study design.
At the start and at the end of both study periods, study participants completed several online questionnaires on their IBS-related complaints (IBS-SSS, PAC-SYM), their Quality of Life (PAC-QOL, HADS), and their habitual dietary intake (FFQ). Stool mass was measured in week 4 and week 8.

Results

- Prebiotic AF significantly improved stool frequency compared to placebo (Figure 3). For probiotic Bla a trend was found.
- Prebiotic AF showed an increase in stool frequency of +1.3 stools per week, exceeding the US FDA's threshold for a clinically meaningful change (>1 stool per week) (Figure 2)
- Probiotic BLa showed a significant decrease in symptom severity, as assessed with the IBS-SSS, compared to placebo (Figure 4)
- A trend was found for a higher responder rate (> -0.75-point change) for constipation-related complaints (PAC-SYM) in the Prebiotic AF group compared to placebo

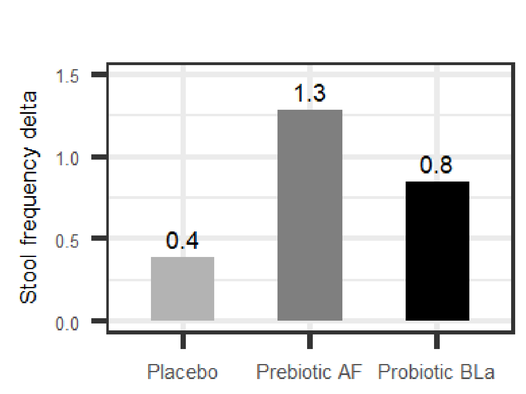

Figure 2. Change in stool frequency per week between intervention and observation period. Results show a significant increase for Prebiotic AF compared to placebo (P=0.02).

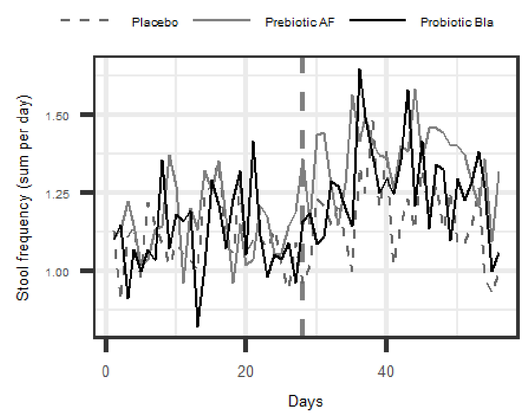

Figure 3. Daily variation in stool frequency. Prebiotic AF significantly increased stool frequency compared to placebo (P=0.047), for Probiotic BLa a trend towards increased stool frequency was found (P=0.06).

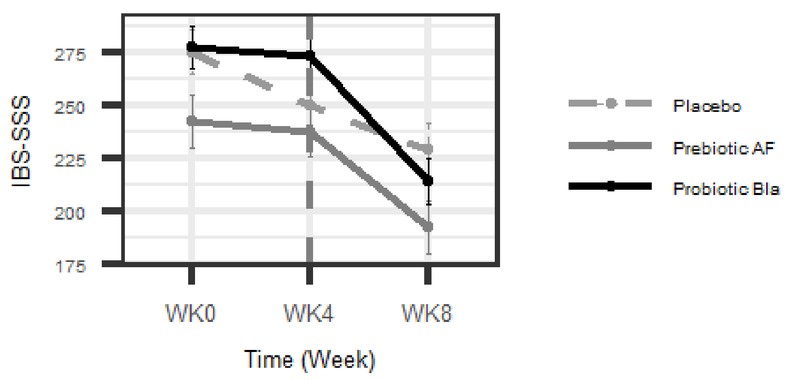

Figure 4. IBS symptom severity scores (IBS-SSS) before (WK0 and WK4) and after intervention (WK8). Probiotic BLa showed a significant decrease in symptom severity compared to placebo (P=0.02).

Conclusions

- Daily dietary supplementation with prebiotic and probiotic supplements may significantly relieve IBS-related complaints by increasing the stool frequency and decreasing symptom severity, respectively.
- These significant treatment effects were found despite the high intra-individual variability and strong placebo effects that are often found and reported in the IBS population

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