CLINICAL TRIAL

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Digestive Enzyme Formulation Intervention For Managing Irritable Bowel Syndrome Symptoms Recurrence In Responders To The Mediterranean Diet-Adjusted Low Fodmaps Diet: A Single-Arm Clinical Trial

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Introduction:

The low-FODMAPs diet has proven benefits for symptom management and quality of life improvement in patients with irritable bowel syndrome (IBS). Recently, a tasteless, add-on to any food dietary formulation of digestive enzymes specifically designed to target the most common FODMAPs, e.g., fructan, galacto-oligosaccharides, and lactose, claims similar efficacy in symptom management (1,2).

Aims & Methods:

In this single-center, single-arm clinical trial, we aimed to assess the effectiveness of this formulation administered over four weeks in managing the recurrence of IBS symptoms among patients who had previously responded to a Mediterranean version of the low-FODMAPs diet (3). We enrolled responders who had either completed our clinical trial intervention with a Mediterranean diet-adjusted low-FODMAPs diet (4) or were in our clinical practice. We instructed participants to sprinkle the contents of one sachet formulation onto every meal before they began eating and to avoid polyol-rich foods (e.g., stone fruits, cauliflower, mushrooms, some artificial sweeteners). To reduce the placebo effect, the sachets were not labelled and were completely transparent. We determined the study sample size (n=40) based on the primary study outcome, namely symptomatic improvement measured by IBS-SSS decrease, post-intervention. Secondary outcomes included: response rate (drop of >50 points of the IBS-SSS); reduction of symptoms burden using the IBS-GSRS tool; quality of life measured by IBS-QoL and SF-12 questionnaires, and adherence measured by the number of sachets consumed divided by the number of sachets each patient should have used intheir daily meals. ClinicalTrials.gov NCT06749613.

Results:

From January 2025 to March 2026, 34 (30 from the clinical trial, 4 from the clinical practice) patients (79.4% females, 42±12 yrs) were recruited, with an IBS-SSS score at enrolment of 271±75. 30 patients completed the study, and 4 were withdrawn due to the lack of efficacy. At the end of the intervention, patients showed significant improvement in symptom severity (IBS-SSS: -93 ± 111; 95%CI= -135, -51; PP analysis). Responders' rates were 73.3% and 64.7% in the PP and ITT analyses, respectively. Significantly higher SF-12 Physical scale and IBS-QoL scores, as well as significantly lower GSRS score, were measured at the end of the intervention (Table 1). Adherence rate was 82.8%, and no patient discontinued the intervention due to an adverse event.

TABLE 1. SECONDARY ENDPOINTS, PP ANALYSIS

Score, mean (sd)	Baseline	Follow-up	Difference	95%CI	p-value
IBS-GSRS	3.84 (1.02)	2.79 (1.11)	-1.05 (1.31)	-1.54, -0.56	<0.001
SF-12 Physical	42.41 (10.04)	47.51 (8.65)	5.11 (11.56)	0.79, 9.42	0.022
SF-12 Mental	41.39 (11.1)	44.34 (12.07)	2.95 (10.15)	-0.84, 6.74	0.122
IBS-OoL total	58.43 (23.91)	68.11 (23.08)	9.68 (16.55)	3.5. 15.9	0.003

Conclusion:

Recurring IBS symptoms in patients who previously benefited from the Mediterranean diet-adjusted low-FODMAPs diet can be successfully managed with a four-week enzyme supplementation targeting the fermentation of fructans, inulin, lactose, and galacto-oligosaccharides.

References:

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