

FODMAP-Targeting Digestive Enzyme Blend for Management of Gastrointestinal Symptoms: A “Real-World” Pre-Post Intervention Cohort Study

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Alexander J Kaye¹, Sarah R Meyers², David Hachuel³, Jocelyn Wells³, Thomas Wallach^{3,4}, Savanna Thor¹

¹Division of Gastroenterology and Hepatology, SUNY Downstate Medical Center, Brooklyn, New York | ²Department of Psychiatry, Rutgers Robert Wood Johnson Medical School, Piscataway, New Jersey | ³Kiwi Biosciences, Cambridge, Massachusetts |

⁴Division of Pediatric Gastroenterology, SUNY Downstate Health Sciences University, Brooklyn, New York

Background and Aims

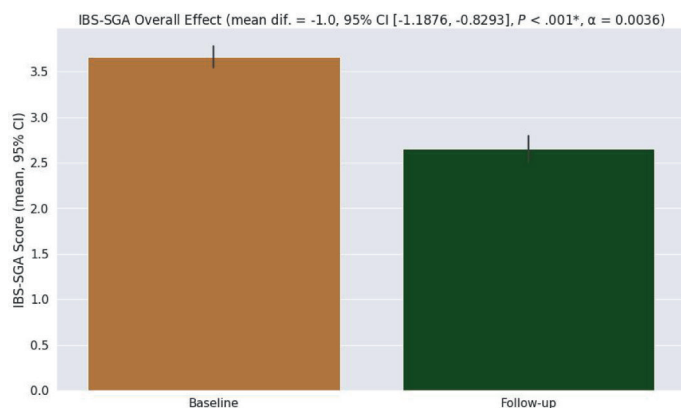
Irritable bowel syndrome (IBS) is a highly prevalent and morbid condition that causes tremendous symptom burden, impacts quality of life, and generates substantial healthcare costs. Current therapies are challenging to utilize and do not provide relief to many patients, creating a clear need for new innovation. In this study, we assess the efficacy of fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAP)-hydrolyzing digestive enzymes in controlling IBS symptoms.

DESIGN	INTERVENTION	ENDPOINTS												
<div> 1,075 online purchasers invited </div> <div> 118 adults analyzed </div> <div> IBS subtypes: <table> <tr> <td>IBS-D</td> <td><div></div></td> <td>40.7%</td> </tr> <tr> <td>IBS-M</td> <td><div></div></td> <td>29.7%</td> </tr> <tr> <td>IBS-C</td> <td><div></div></td> <td>18.6%</td> </tr> <tr> <td>IBS-U</td> <td><div></div></td> <td>7.6%</td> </tr> </table> </div> <div> Single-arm pre-post intervention study Outcome Measures: IBS-SGA, IBS-VAS, IBS-QoL </div>	IBS-D	<div></div>	40.7%	IBS-M	<div></div>	29.7%	IBS-C	<div></div>	18.6%	IBS-U	<div></div>	7.6%	<div> FODMAP-Targeting Digestive Enzyme Blend </div> <div> Fructan hydrolase → fructans Alpha-galactosidase → galactans/GOS Lactase → lactose </div> <div>  </div> <div> Administered directly to food during meals 4 weeks </div>	<div>  Overall IBS Symptoms </div> <div>  Specific Symptoms <ul style="list-style-type: none"> • Bloating • Diarrhea • Constipation </div> <div>  Mental Wellbeing </div> <div>  Food Avoidance Behaviors </div>
IBS-D	<div></div>	40.7%												
IBS-M	<div></div>	29.7%												
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Results:

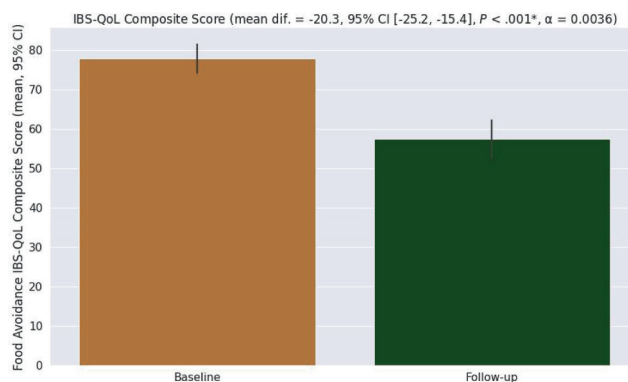
After 4 weeks using the FODMAP-targeting digestive enzyme blend, 78.0% (95% confidence interval [CI]: [69.7%, 84.5%]) reported improvements in bloating and flatulence, 75.0% (95% CI: [61.2%, 85.1%]) reported improvements in diarrhea (IBS-D only), 72.7% (95% CI: [51.9%, 86.9%]) reported improvements in constipation (IBS-C only), and 65.3% (95% CI: [56.3%, 73.2%]) reported improvements in abdominal pain. Significant improvements in overall IBS symptom severity were observed ($P < .01$). For specific IBS symptoms, the greatest improvements were seen in bloating and flatulence ($P < .01$) and abdominal pain ($P < .01$). Quality of life ($P < .01$), mental well-being ($P < .01$), and food avoidance behaviors ($P < .01$) all significantly improved as well.

IBS-SGA SCORES IMPROVED AT 4-WEEK FOLLOW-UP



IBS-SGA (Irritable Bowel Syndrome-Subject's Global Assessment) scores are shown for participants at baseline and 4-week follow-up. Scores are reported on a 5-point Likert scale ranging from 1 = 'Completely relieved' to 5 = 'Worse', with lower scores indicating greater perceived improvement in overall IBS symptoms. Data are presented as mean with 95% confidence intervals (CI).

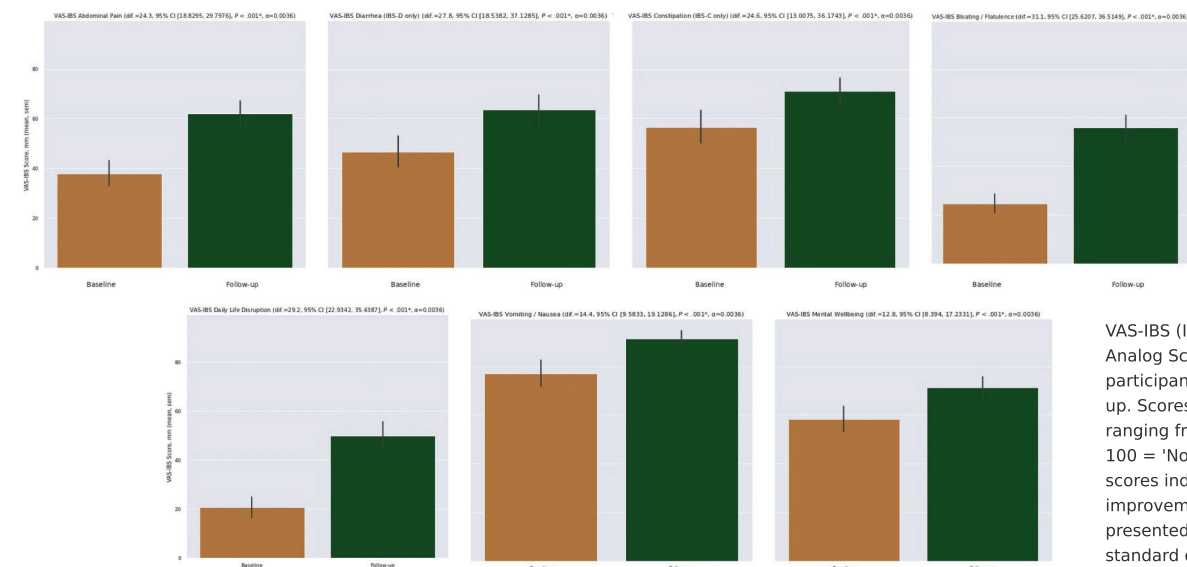
QUALITY OF LIFE, AS MEASURED BY THE IBS-QoL, IMPROVED, REPRESENTING REDUCED FOOD AVOIDANCE



Food avoidance IBS-QoL (Irritable Bowel Syndrome-Quality of Life) composite scores are shown for participants at baseline and 4-week follow-up. Individual questions are asked on a 5-point Likert scale ranging from 1 = 'Not at all' to 5 = 'A great deal'. Food avoidance IBS-QoL composite scores are reported on a 100-point scale with lower scores indicating better IBS specific quality of life related to food avoidance behaviors, specifically frustration with food options and increased need to watch the kind and amount of food eaten due to bowel problems. Data are presented as mean with 95% confidence intervals (CI).

Food avoidance IBS-QoL composite scores are calculated as: $\left(\frac{\text{The sum of the items} - \text{lowest possible score}}{\text{Possible raw score range}} \right) \times 100$

SPECIFIC DIGESTIVE SYMPTOMS, AS MEASURED BY THE VAS-IBS, IMPROVED AT CLINICALLY SIGNIFICANT LEVELS



VAS-IBS (Irritable Bowel Syndrome-Visual Analog Scale) scores are shown for participants at baseline and 4-week follow-up. Scores are reported on a 100-point scale ranging from 0 = 'Very severe discomfort' to 100 = 'No discomfort at all', with higher scores indicating greater perceived improvement in each IBS symptom. Data are presented as mean + standard deviation (SD).

Conclusion:

While further research is needed, this is a promising first report that enzymatic digestion may have the potential to decrease the burden of disorders of the gut-brain interaction, including IBS.