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Personalized IBS Treatment: A Novel, IBS-Specific IgG-Guided Elimination Diet Effectively Reduces Abdominal Pain

Summary of the article published in Gastroenterology,
the flagship journal of the American Gastroenterological Association:

A Novel, IBS-Specific IgG ELISA-Based Elimination Diet in Irritable Bowel Syndrome: A Randomized, Sham-Controlled Trial

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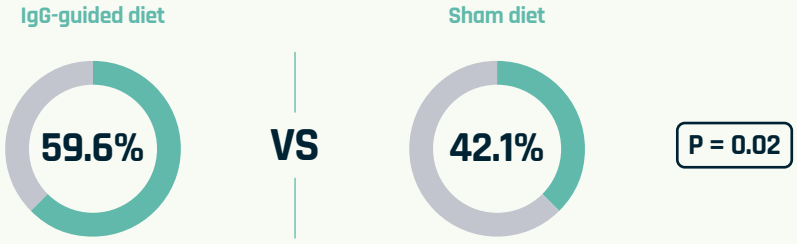
inFoods IBS
PRECISION MEDICINE FOR IBS

Key Findings

Significant Symptom Improvement

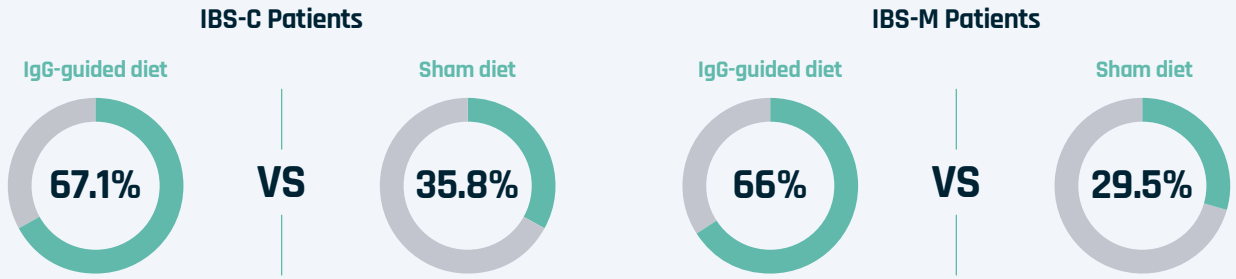
- More IBS patients on the IgG-guided elimination diet (inFoods® IBS) met the primary outcome:
  ≥ 30% reduction in abdominal pain (FDA-responder endpoint)



- A **numerically higher proportion** of IBS subjects on the IgG-guided diet met several global endpoints including improvement in IBS-GIS* and SGA#.

First Therapeutic Approach for IBS-M Patients

- IBS patients with constipation (IBS-C) or mixed symptoms (IBS-M; diarrhea, constipation) benefited most from the IgG-guided diet.



No Side Effects

- No adverse events attributed to the dietary intervention.

A personalized diet based on the inFoods® IBS Test is effective in reducing IBS symptoms.

*IBS-GIS: IBS Global Improvement Scale # Subject Global Assessment of Relief

The Authors' Voice

Expert Perspectives on the Power of Personalized Nutrition for IBS

Anthony Lembo, M.D.,

VICE CHAIR OF RESEARCH, CLEVELAND CLINIC'S DIGESTIVE DISEASE INSTITUTE

"Our diets are complex and identifying dietary triggers can be difficult. This IBS-specific IgG test can help patients who suffer from IBS identify specific dietary triggers."

William Chey, M.D.,

CHIEF OF GASTROENTEROLOGY & HEPATOLOGY, MICHIGAN MEDICINE

"This IBS-specific, IgG antibody test... could move us one step closer to a precision nutrition approach, in which providers can offer personalized dietary recommendations to each patient with IBS".

Prashant Singh, MBBS,

ASSISTANT PROFESSOR, DIVISION OF GASTROENTEROLOGY & HEPATOLOGY, MICHIGAN MEDICINE

"Because patients with IBS generally associate food as one of their main triggers for IBS symptoms, they're very interested in dietary therapies. Existing dietary therapies such as low-FODMAP are very complex and restrictive for patients."

Background and Aim

- **> 90% of IBS patients** avoid certain foods as they believe foods trigger their symptoms.
- **Dietary modifications** are commonly used to manage IBS symptoms.
- **Personalized approaches** to dietary therapies for IBS are an unmet need.

The clinical study compared the efficacy of an elimination diet based on the IBS-specific IgG assay (inFoods® IBS) against a sham elimination diet.

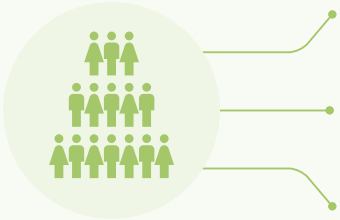
inFoods® IBS is an immunoassay-based Laboratory Developed Test (LDT) measuring elevated IgG antibodies to 18 food extracts in serum that may cause or trigger symptoms in IBS patients.

Largest Study on IgG Elimination Diet in IBS

Study Design

- **Study Sites:** Mayo Clinic Jacksonville & Scottsdale; Beth-Israel Deaconess Medical Center Boston (Harvard Medical School); Michigan Medicine; University of Texas Health Science Center, San Antonio; Houston Methodist Hospital; Cleveland Clinic Ohio
- **Study Design:** 8-week treatment, prospective, double-blinded, sham-controlled, randomized, multi-center
- **Treatment Arm:** Experimental Diet - Elimination of positive foods (elevated IgG level) from the diet
- **Placebo Arm:** Sham Diet - Elimination of negative foods from the diet, same number of foods removed as tested positive, same food group and similar consumption than positives

223 IBS Patients were included in the analysis



Baseline Characteristics

80 IBS-C — **43** Experimental Diet, **37** Sham Diet

74 IBS-D — **38** Experimental Diet, **36** Sham Diet

69 IBS-M — **37** Experimental Diet, **32** Sham Diet

	Experimental diet (n = 118)	Sham diet (n = 105)
Age, mean (SD)	39.5 (14.6)	40.7 (15.2)
Sex, n (%)		
Female	90 (76.3)	85 (81.0)
Male	28 (23.7)	20 (19.0)
No. of sensitivities to food, n (%)		
0	0	0
1–6	101 (85.6)	86 (81.9)
7 or more	17 (14.4)	19 (18.1)

Study Measures

- **Abdominal Pain Intensity (API) and Bloating:** 11-point Likert scale 0 to 10
- **Stool consistency** Bristol Stool Scale (BSS), number of bowel movements
- **IBS-SSS:** severity of abdominal pain, number of days with abdominal pain, severity of abdominal distension, dissatisfaction with bowel habits, interference with quality of life, 0 to 100 scale
- **IBS global improvement scale (IBS-GIS):** global improvement past 7 days, scale 1 to 7
- **IBS adequate relief scale (IBS-AR):** dichotomous question about symptoms (past week)
- **Subject Global Assessment of Relief (SGA):** relief of symptoms during past week, scale 1 to 5

Study Outcomes

Primary outcome:

Food and Drug Administration (FDA) responder definition of API:

- **30% reduction in mean daily abdominal pain score** from baseline for ≥ 2 of the last 4 weeks of the treatment period.
  - Clinically meaningful & matched rigor of registration trials of FDA-approved medications for IBS patients

Secondary outcomes / other analysis:

- Change from baseline in API, bloating, stool consistency, IBS-SSS, IBS-GIS, and SGA
- Subgroup analysis of 3 subtypes (IBS-C, IBS-D, IBS-M)
- Diet compliance