

CLINICAL SUMMARY

Evaluation of Nutritional Support with *Lactobacillus acidophilus* NCFM® and *Bifidobacterium lactis* BI-07 in Patients with Irritable Bowel Syndrome (IBS): Summary of Clinical Experience

Introduction

IBS is a common gastrointestinal (GI) disorder affecting approximately 10%-20% of the general population. It is characterized by a group of symptoms in which abdominal pain/cramping is related to changes in bowel patterns, such as frequent bowel movements, loose stools, diarrhea, or constipation. Other associated complaints include abdominal bloating, excess passage of gas, and sensation of incomplete evacuation.

Considered a functional disorder, IBS is a diagnosis of exclusion and there is currently no effective conventional drug treatment. There is some evidence to suggest that intestinal microflora is altered in patients with IBS compared to individuals with normal bowel function.¹ Therefore, researchers and clinicians alike have evaluated the effectiveness of supplementation of beneficial microflora, or probiotics. The following retrospective clinical analysis and case studies were designed to evaluate the effectiveness of nutritional programs that incorporate probiotics in the forms of strain-identified *L. acidophilus* NCFM and *B. lactis* BI-07 in patients with IBS.

Published Research Conducted by Faber et al.

Clinical Study

In a retrospective clinical analysis, 26 consecutive patients with IBS were evaluated.¹ The patients received *L. acidophilus* NCFM, *B. lactis* BI-07, and globulin protein concentrate with fructooligosaccharides (FOS), along with individualized care. After 4 weeks, the patients' questionnaire scores suggested significant improvements in IBS symptoms and quality of life (Figures 1 and 2).

33% Improvement in IBS Quality of Life Score

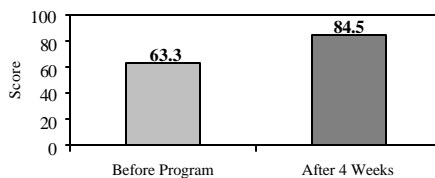


Figure 1. After 4 weeks, the average score on the IBS Quality of Life Questionnaire* increased from 63.3 to 84.5 ($p < .001$), suggesting significant improvements in well-being.

51% Improvement in IBS Symptom Frequency Index Score

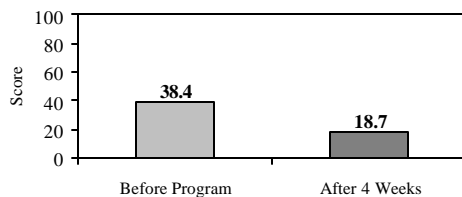


Figure 2. The patients' average score on the IBS Symptom Frequency Index Score** decreased from 38.4 to 18.7 after 4 weeks, suggesting significant improvements in IBS symptoms.

Case Studies Conducted at the Functional Medicine Research CenterSM (FMRC)

Case Study #1

A 41-year-old female presented with a history of IBS, with typical symptoms of abdominal pain, severe constipation, and a bowel movement every 3 to 7 days.² She was instructed to begin dairy-free *L. acidophilus* NCFM and *B. lactis* BI-07 combination, 2 capsules twice daily, along with a glutamine/licorice combination formula, an antispasmodic botanical blend, and the elimination of dairy and wheat. Over the course of 17 weeks, the patient's questionnaire scores suggested substantial improvements in general physical symptoms and specific symptoms associated with IBS (Figures 3 and 4).

85% Decrease in MSQ Score

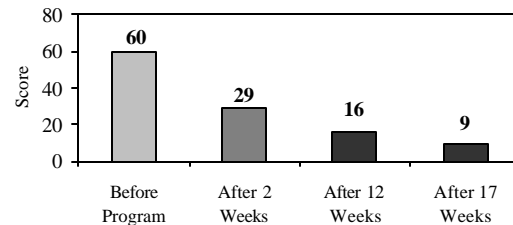


Figure 3. After 17 weeks, the patient's MSQ[†] score decreased from 60 to 9. This result suggests a substantial improvement in general well-being.

69% Decrease in IBS Bothersome Symptoms Questionnaire Score

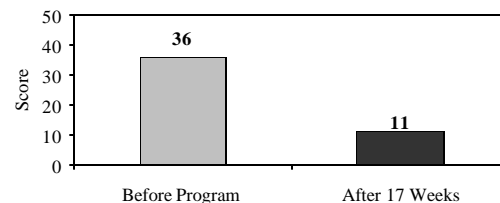


Figure 4. The patient's score on the IBS Bothersome Symptom Questionnaire** score dropped from 36 to 11, suggesting a notable decrease in IBS symptoms.

Case Study #2

A 26-year-old female presented with long-term digestive problems, beginning in her teens, and had recently been diagnosed with microscopic colitis and IBS by colonoscopy.³ Laboratory results indicated possible cryptosporidium and presence of candidiasis. She was counseled to begin a dairy-free probiotic supplement (*L. acidophilus* NCFM and *B. lactis* BI-07), 2 capsules twice daily, in combination with a medical food for inflammation and an elimination diet. After 16 weeks, the patient's serum candida IgA notably decreased (Figure 5), and her stool cryptosporidium antigen test was negative.

Reduction in Candida Antibodies

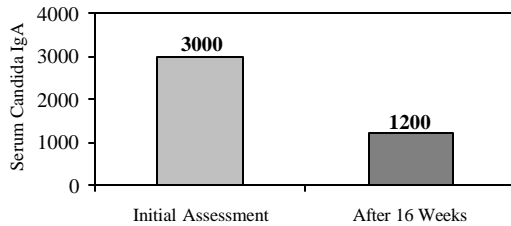


Figure 5. After 16 weeks, the patient's serum candida IgA decreased from 3000 ELISA units to within reference range at 1200 (reference range: 800-2000 ELISA units).

Case Study #3

A 23-year-old female presented with a 2-year history of IBS with abdominal pain, constipation, and occasional bloating.⁴ Stool analysis, physical examination, and initial assessment with questionnaires confirmed her diagnosis. She was immediately instructed to begin a modified elimination diet, a fiber supplement, and ground flaxseeds. After 2 weeks, she was counseled to start food reintroduction and a dairy-free *L. acidophilus* NCFM and *B. lactis* BI-07 combination supplement, 2 capsules three times daily. After 14 weeks, a stool analysis indicated increased recovery of the gut microflora lactobacilli and bifidobacteria, and the patient reported resolution of IBS symptoms. Results of questionnaires suggested considerable improvements in general physical symptoms and frequency of symptoms associated with IBS (Figures 6 and 7).

89% Decrease in MSQ Score

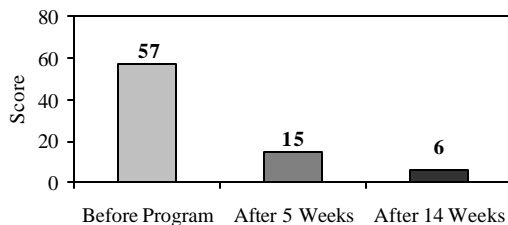


Figure 6. After 14 weeks, the patient's MSQ[†] score decreased from 57 to 6, suggesting a substantial improvement in general well-being.

56% Decrease in IBS Symptoms Frequency Questionnaire Score

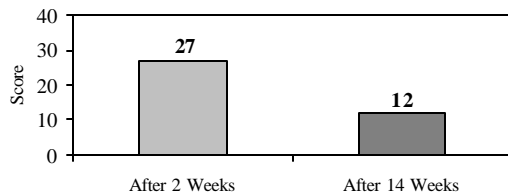


Figure 7. After 14 weeks, the patient's score on the IBS Symptoms Frequency Questionnaire** decreased from 27 to 12, indicating a notable improvement in IBS symptoms.

Conclusion

A healthy gut physiology is framed by the interactions between microflora and GI tissues that influence nutrient absorption, toxin excretion, and bowel patterns. Research suggests that intestinal microflora may be altered in patients with IBS, a condition characterized by abnormal bowel patterns such as frequent diarrhea or constipation. The results of these clinical observations suggest that a targeted nutritional support program incorporating probiotics—particularly in the forms of strain-identified *L. acidophilus* NCFM and *B. Lactis* BI-07—may help to restore a healthy GI microflora balance and relieve a wide range of bothersome symptoms in patients with IBS.

References

1. Faber SM: Irritable bowel syndrome and reinoculation with probiotics. *Am J Gastroenterol* 2002;97:A211.
2. Case Study: A Case Study Evaluating the Effects of Targeted Nutritional Support, including *Lactobacillus acidophilus* NCFM[®] and *Bifidobacterium lactis* BI-07, in a Patient with Irritable Bowel Syndrome (IBS). Metagenics, Inc; 037IBS504.
3. Case Study: A Case Study Evaluating the Effects of a Nutritional Support Program, Incorporating *Lactobacillus acidophilus* NCFM[®] and *Bifidobacterium lactis* BI-07, in a Patient with Irritable Bowel Syndrome (IBS). Metagenics, Inc; 039IBS504.
4. Case Study: A Case Study Designed to Evaluate the Effects of a Targeted Nutritional Approach, incorporating *Lactobacillus acidophilus* NCFM[®] and *Bifidobacterium lactis* BI-07, in a Patient with Irritable Bowel Syndrome (IBS). Metagenics, Inc; 068IBS1004.

Note

Case Studies Conducted at the FMRC

The information provided in each of these case studies describes the results of one patient under the care of a licensed healthcare practitioner and may not be a typical response. The case studies were conducted at the Functional Medicine Research Center (FMRC), the clinical research arm of Metagenics, Inc. Dan Lukacz, ND, is the Medical Director of the FMRC. Financial support was provided by Metagenics, Inc.

Questionnaires for Evaluation

*The IBS-QOL is a self-administered clinical tool for the evaluation of quality of life of individuals with IBS and includes questions related to symptoms, functional status, perceived quality of life, and social disability. A higher score indicates better quality of life, while a lower score indicates a poorer quality of life. The IBS-QOL can be administered with the IBS Symptom Frequency Questionnaire to assess the severity of IBS symptomatology.

** The IBS Symptoms Frequency and Bothersome Symptoms Questionnaires are condition-specific questionnaires that range in score from 0 to 78. Higher scores indicated more frequent or more bothersome symptoms; while lower scores indicate fewer symptoms or less bothersome symptoms: scores <20 mean infrequent or no symptoms; scores > 40 mean symptoms are often or always present.

†The Medical Symptoms Questionnaire (MSQ) is a clinical tool for the evaluation of general physical symptoms. Total scores above 75 are generally associated with substantial symptomatology and disability; scores below 30 generally indicate few or low-intensity symptoms.