

# **Irritable bowel syndrome patients obtain robust, enduring relief from home-based treatment program**

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The research describes an IBS treatment developed by Jeffrey Lackner, PsyD, with colleagues at New York University and Northwestern University. The treatment consists of a form of cognitive behavioral therapy (CBT) that teaches practical skills for controlling gastrointestinal symptoms. Credit: Douglas Levere/University at Buffalo

In the largest federally funded non-drug clinical trial for irritable bowel syndrome (IBS), patients with the most severe and persistent symptoms achieved robust and sustained relief by learning to control symptoms with minimal clinician contact. Led by University at Buffalo researchers in collaboration with colleagues at New York University and Northwestern University, the study was published online before print in *Gastroenterology*.

The research is a product of 20 years of funding from the National Institute of Diabetes, Digestive and Kidney Diseases of the National Institutes of Health, and one of the largest, behavioral medicine trials not including a drug arm. It reflects a longtime partnership between researchers at UB and NYU, who pooled their respective expertise and talents to develop and test a novel [treatment](#) strategy.

Of 436 patients recruited at UB and Northwestern, 61 percent reported symptom improvement two weeks after home-based behavioral treatment ended compared to 55 percent in clinic-based treatment and 43 percent who received patient education. The treatment benefit also persisted for as long as six months after treatment ended.

"This is a novel, game-changing treatment approach for a public health problem that has real personal and economic costs, and for which there

are few medical treatments for the full range of symptoms," said Jeffrey Lackner, PsyD, lead author, professor in the Department of Medicine in the Jacobs School of Medicine and Biomedical Sciences at UB and director of its Behavioral Medicine Clinic. He is affiliated with UB's Clinical and Translational Science Institute.

## **Women are disproportionately affected**

IBS is a persistent and difficult-to-treat condition that is one of the most common diseases that gastroenterologists and primary care physicians treat. It's characterized by chronic abdominal pain, diarrhea and/or constipation. Medical and dietary treatment have a disappointing track record of relief for many patients.

Afflicting between 10 and 15 percent of adults worldwide, most of whom are female, the condition creates a public health burden that causes pain, isolation and frustration, all of which impair quality of life. Beyond the personal toll, Lackner said, the economic burden of IBS in the U.S. is estimated at \$28 billion annually.

"These findings will be welcomed by many women and men," he continued, "who have unfortunately been stigmatized, marginalized and too often treated as 'head cases' merely because no definitive cause for their symptoms is identified through routine medical testing."

This treatment will help address a major barrier to quality health care faced by those living in rural areas, Lackner added, because now these patients will have access to a state-of-the-art treatment once only available in metropolitan areas.

According to NYU Silver School of Social Work Professor James Jaccard, PhD, a key investigator on this research program since its inception in 2000, "The creative development of this symptom-

management approach for IBS can affect millions of people, primarily women, who suffer from this often stigmatized and poorly understood condition. By integrating perspectives from medicine and the social sciences, it illustrates the power of team-oriented and multidisciplinary approaches to reducing health care disparities in vulnerable populations."

While IBS affects mostly women, Lackner said this study is noteworthy because 20 percent of the patients were male, many of whom are themselves reluctant to seek help. "These men are more likely to reach out for help if they can access treatment that is brief and home-based," he said.

## **Brain-gut connections**

The treatment consists of a form of [cognitive behavioral therapy](#) (CBT) that teaches practical skills for controlling gastrointestinal symptoms, either during 10 clinic visits, or four clinic sessions in conjunction with self-study materials developed by Lackner in a previous NIH grant. Both CBT treatments focused on information on brain-gut interactions, self-monitoring of symptoms, triggers and consequences, worry control, muscle relaxation and flexible problem-solving.

"The treatment is based on cutting-edge research that shows that brain-gut connection is a two-way street," Lackner explained. "Our research shows that patients can learn ways to recalibrate these brain-gut interactions in a way that brings them significant symptom improvement that has eluded them through medical treatments."

## **Physicians and patients agree on improvement**

Lackner added that the study's strength is underscored by the fact that both patients and the gastroenterologists, who evaluated patients and



were unaware of which treatment patients were assigned, reported similar rates of symptom improvement as patients.

"One measure of the strength of clinical-trial findings is when two data sources report similar data about an endpoint," he explained. "In our study, there was striking similarity between the treatment response reported by patients and 'blind' assessors. This pattern of agreement from patients and physicians shows that we see very real, substantial and enduring improvement in GI symptoms immediately after treatment ends and many months later."

## **'Mind-based intervention'**

The research holds special interest for Emeran Mayer, MD, PhD, professor in the David Geffen School of Medicine at UCLA and executive director of the G. Oppenheimer Center for Neurobiology of Stress and Resilience, an internationally known expert on the interactions between the digestive and nervous systems and women's health.

"This study clearly established the clinical value of a mind-based intervention for IBS," said Mayer. "The success of this research shows that this should be offered to patients not as a last resort but as a safe and effective first or second-line therapy. It's very different from the pharmaceutical model where you are searching for magic-bullet medications. With current medications, you cannot treat the whole patient. The medications can improve their bowel habits, but it's not a complete treatment for the patient with IBS."

Lackner oversaw the training of clinicians who work with Mayer at UCLA on the UB program. The two have been building on this work with a groundbreaking study of how the microbiome of IBS [patients](#) influences their response to cognitive behavioral therapy. The collaborative work is jointly funded by a \$2.3 million NIH grant to

UCLA, the lead institution, and UB. Results from that study are forthcoming.

Provided by University at Buffalo

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