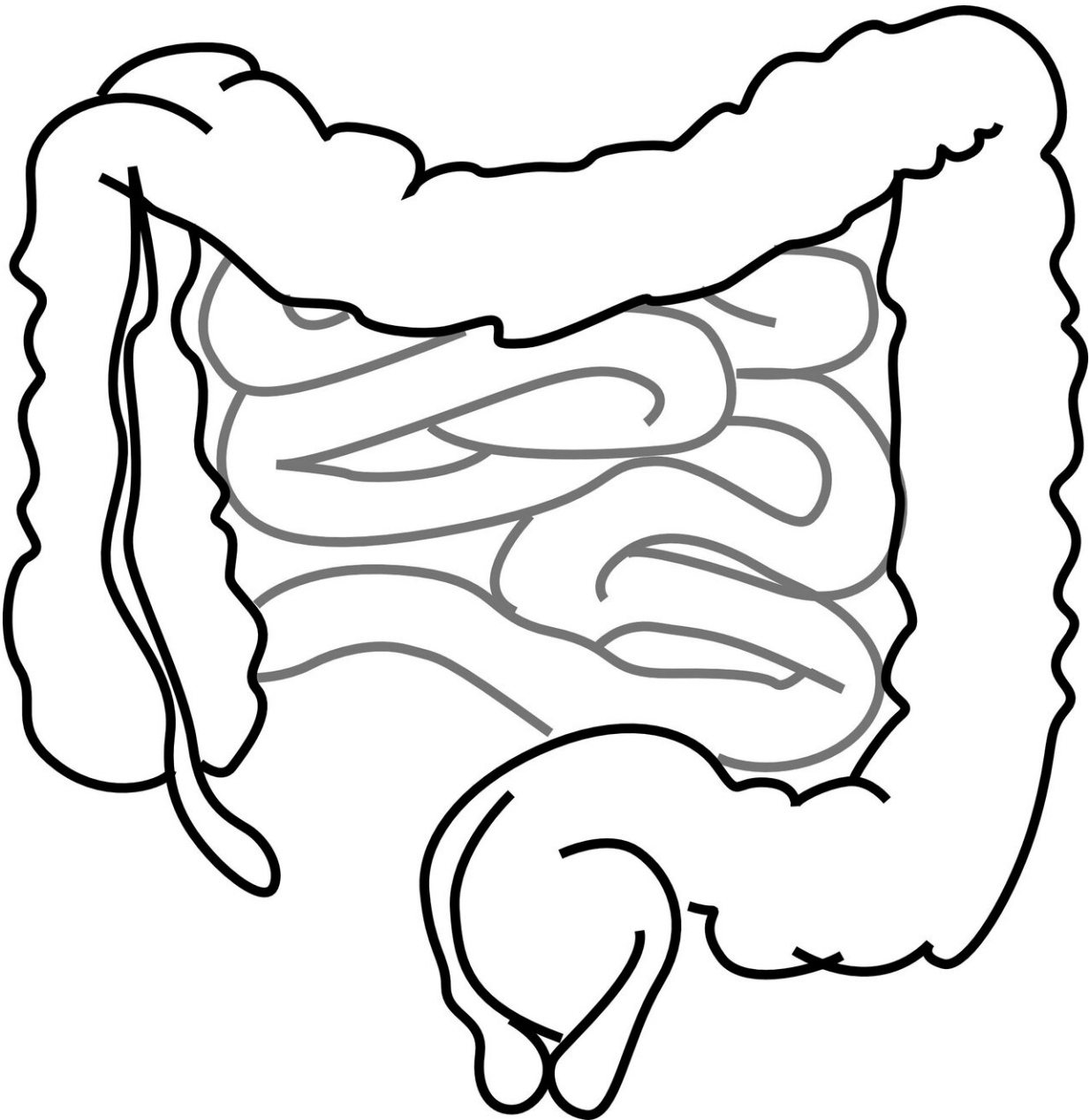


Open-label placebo offers new treatment for disorders of gut-brain interaction in children

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Pain-predominant disorders of gut-brain interaction (DGBIs) in children—such as functional abdominal pain (FAP) and irritable bowel syndrome (IBS)—can lead to disabling symptoms, poor quality of life and high use of health care resources. Studies suggest that an open-label placebo (OLP) approach—in which patients are aware that they are receiving a placebo—can benefit adults, but little is known about this in children. A group of investigators led by Boston Children's Samuel Nurko, MD, MPH conducted the first OLP study in pediatrics in a multicenter randomized crossover trial published today in *JAMA Pediatrics*.

The study looked at 30 children between the ages of 8 and 18 who were diagnosed with IBS or FAP. The [patients](#) tracked their pain for seven days leading up to the study. They were then randomized to either a control or OLP group, with a crossover after three weeks.

Researchers explained the basic concept of a placebo and that they have been beneficial in some previous studies. Patients took 1.5 ml of an inert liquid placebo twice a day; this syrup mimicked the appearance of other medications used in pediatric care. All of the patients were given access to hyoscyamine for use as a rescue medication and kept symptom diaries throughout the study.

Nurko and his colleagues found that patients' mean pain scores were significantly lower during the OLP treatment than during the control period; they also took nearly twice as many tablets of hyoscyamine during the control period than during the OLP period, and there were no side effects.

"A significant placebo effect has been observed in double-blind clinical studies in children with DGBIs. It's widely believed that concealment or deception is required to elicit a placebo response, but our study shows that the open administration of a [placebo](#) treatment—i.e. non-concealed and without deception—is effective," said Nurko. "The exact nature of the response is still not known, but my hope is to be able to understand the process so we'll be able to harness it and use in routine clinical care."

The results of this first-of-its-kind study in [pediatric patients](#) with DGBIs show promise as a future non-pharmacologic therapy of these difficult-to-treat conditions.

More information: Samuel Nurko et al, Effect of Open-label Placebo on Children and Adolescents With Functional Abdominal Pain or Irritable Bowel Syndrome, *JAMA Pediatrics* (2022). [DOI: 10.1001/jamapediatrics.2021.5750](#)

Provided by Children's Hospital Boston

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