

## **Probiotics no help to young kids with stomach virus**

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Children with stomach viruses increasingly are given probiotics to ease symptoms of vomiting and diarrhea. But a major U.S. study led by Washington University School of Medicine in St. Louis shows that a commonly used probiotic is not effective in improving symptoms in young patients with gastroenteritis.

The findings are published Nov. 22 in The New England Journal of



## Medicine.

While rarely fatal in the United States, gastroenteritis—frequently yet erroneously called "stomach flu"—accounts for 1.7 million pediatric emergency room visits and more than 70,000 hospitalizations each year.

The study, involving nearly 1,000 <u>children</u> ages 3 months to 4 years, provides evidence against the popular and costly use of probiotics—live microorganisms believed to restore the balance of intestinal bacteria and boost the immune system.

"Probiotics have become an increasingly popular way to treat children experiencing acute gastroenteritis," said the study's lead author, David Schnadower, MD, who conducted the research as a Washington University professor of pediatrics and a physician at St. Louis Children's Hospital. "Some smaller studies have indicated that probiotics may help, however, such studies had a number of limitations. We sought to provide independent and conclusive evidence for or against <u>probiotic</u> use in infants and toddlers with acute gastroenteritis."

The researchers evaluated a common probiotic known as Lactobacillus rhamnosus GG, or LGG, which is sold over the counter as Culturelle. Certain versions of the probiotic are intended for babies and children.

A similar study in Canada, also published in the same issue of The *New England Journal of Medicine* and co-authored by Schnadower, evaluated effectiveness of a different probiotic—Lacidofil—in children with gastroenteritis. The findings of that study, led by the University of Calgary Cumming School of Medicine in Alberta, mirrored those in the U.S. study.

"The results of the U.S. and Canadian studies were not ambiguous," added the U.S. study's co-author, Phillip I. Tarr, MD, Washington



University's Melvin E. Carnahan Professor of Pediatrics and director of the Pediatric Division of Gastroenterology, Hepatology and Nutrition. "Probiotics had no effect on the children. Parents are better off saving their money and using it to buy more fresh fruits and vegetables for their children."

There are no treatments for pediatric acute gastroenteritis other than giving children fluids to prevent dehydration and, sometimes, medication to relieve nausea. The lack of options has prompted some physicians and parents to give ill children probiotics.

Probiotics generally are considered safe. However, the Food and Drug Administration (FDA) does not regulate dietary supplements such as probiotics as stringently as it does prescription and over-the-counter drugs. "Also, manufacturers of probiotics generally can claim that these microorganisms have positive health benefits without rigorous evidence to support their use," Schnadower said.

Consumers worldwide spend billions of dollars each year on probiotic enriched foods, as well as over-the-counter supplements in pill and powder form. The researchers cited statistics showing that the global market for probiotics is predicted to expand in the United States from \$37 billion in 2015 to \$64 billion in 2023.

"Because of the popularity of probiotics, it was important to make sure their use is worth the cost," said Schnadower, who is now the senior academic director of the Division of Emergency Medicine at Cincinnati Children's Hospital Medical Center. "In this instance, probiotics added no measurable benefit, and, therefore, they are not worth the added cost."

The U.S. study involved 971 children treated between July 2014 and June 2017 in the emergency departments at St. Louis Children's and nine



other geographically diverse U.S. academic medical centers. Participants were eligible if they had come to the emergency room with symptoms of gastroenteritis: watery stools, vomiting, diarrhea or other signs of acute intestinal infection. They also had to have not have taken probiotics in the preceding two weeks.

Half of the children in the study were randomly assigned to receive the probiotic LGG twice daily for five days, while the others took a similarly looking and tasting placebo. Otherwise, the children received standard clinical care.

Neither the researchers nor the parents knew which children had received the probiotics.

Regardless of whether the children took a placebo or probiotic, their symptoms and recovery were nearly identical. The data showed that diarrhea in both groups of kids lasted about two days and the kids missed an average of two days of day care.

"We tested many different scenarios—infants compared with toddlers, whether the patient had taken antibiotics, whether the gastroenteritis was caused by virus or bacteria, and how long the diarrhea had been going on before the treatment was given. We also had the probiotic independently tested for purity and strength. Every time, we reached the same conclusion," Schnadower said. "LGG did not help."

**More information:** Stephen B. Freedman et al, Multicenter Trial of a Combination Probiotic for Children with Gastroenteritis, *New England Journal of Medicine* (2018). DOI: 10.1056/NEJMoa1802597, <u>dx.doi.org/10.1056/NEJMoa1802597</u>



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