

Health & Nutrition Sciences

Can Live and Active Cultures Benefit Healthy Adults?

Live and active culture *Bacillus coagulans* Unique IS2 Improves Stool Characteristics in Healthy Individuals

According to the International Scientific Association for Probiotics and Prebiotics (ISAPP), “live and active cultures” are often found in fermented foods, but do not have defined microbial content and lack studies documenting health effects, therefore, falling short of the criteria to be called “probiotics.”

While certain bacterial strains have been shown to improve gut health in people with digestive disorders, scientific evidence to support probiotic benefits in generally healthy adults is still emerging.

More research is needed to establish specific health benefits², such as:



Disease prevention



Reduced antibiotic use



Alleviating Traveler's Diarrhea

Background: *B. coagulans* Unique IS2 Improving Gut Health

B. coagulans Unique IS2 has been shown to improve gut health in people with constipation, irritable bowel syndrome, and diarrhea in multiple studies.³⁻⁷ This is promising, as over **60 million Americans and 20 million Canadians alone suffer from digestive disorders each year.**^{8,9} Even outside of diagnosed digestive conditions, generally healthy people also live with digestive health issues, like poor stool quality, irregular bowel movements, and gut symptoms, like bloating, pain, and gas.¹⁰

But can *B. coagulans* Unique IS2 also improve gut symptoms in generally healthy individuals?

To answer this question, PepsiCo scientists conducted a study to explore Unique IS2's potential to improve gut health in generally healthy adults.¹¹



Study Design

Generally healthy adults with infrequent bowel movements (3 to <7 per week) took **1 capsule of *B. coagulans* Unique IS2 per day (2 billion CFU/capsule)** or a placebo capsule for 4 weeks.

Participants completed:

Daily bowel movement diaries on the frequency and consistency (hardest to softest) of their bowel movements.¹²

The Gastrointestinal Quality of Life Index, a 36-item questionnaire that measures gut symptoms.¹³

Health & Nutrition Sciences

Results



BM frequency significantly improved in participants taking Unique IS2, however, this was **not statistically different from the change observed in participants taking placebo**



No significant difference for incidence of watery stools



After 4 weeks, **the stool consistency score significantly improved** in those who took Unique IS2 compared to their baseline



No significant difference in gut microbiota composition



At weeks 1 and 4, those taking Unique IS2 had a **decreased incidence** of hard stools compared to placebo



B. coagulans Unique IS2 was **well-tolerated and safe** over 4 weeks

Key Takeaways



B. coagulans Unique IS2 **significantly decreased the incidence of hard stools** compared to placebo



Healthy individuals looking to improve gut symptoms they should focus on an **overall healthy diet**



More research is needed to establish the probiotic potential of live and active cultures in generally healthy people

References

- Hill C, Guarner F, Reid G, et al. Expert consensus document. The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. *Nat Rev Gastroenterol Hepatol*. 2014;11(8):506–514. doi:10.1038/nrgastro.2014.66
- Merenstein DJ, Tancredi DJ, Karl JP, et al. Is There Evidence to Support Probiotic Use for Healthy People?. *Adv Nutr*. 2024;15(8):100265. doi:10.1016/j.advnut.2024.100265
- Madempudi RS, Ahire JJ, Neelamraju J, Tripathi A, Nanal S. Randomized clinical trial: The effect of probiotic *Bacillus coagulans* Unique IS2 vs. placebo on the symptoms management of irritable bowel syndrome in adults. *Sci Rep*. 2019;9(1):12210. Published 2019 Aug 21. doi:10.1038/s41598-019-48554-x
- Madempudi RS, Neelamraju J, Ahire JJ, Gupta SK, Shukla VK. *Bacillus coagulans* Unique IS2 in constipation: A double-blind, placebo-controlled study. *Probiotics Antimicrob Proteins*. 2020;12(2):335–342. doi:10.1007/s12602-019-09542-9
- Sudha MR, Bhonagiri S. Efficacy of *Bacillus coagulans* strain unique IS-2 in the treatment of patients with acute diarrhea. *Int J Probiotics Prebiotics*. 2012;7(1):33–37.
- Sudha MR, Jayanthi N, Aasin M, Dhanashri RD, Anirudh T. Efficacy of *Bacillus coagulans* Unique IS2 in treatment of irritable bowel syndrome in children: A double blind, randomised placebo controlled study. *Benef Microbes*. 2018;9(4):563–572. doi:10.3920/BM2017.0129
- Venkataraman R, Shenoy R, Ahire JJ, Neelamraju J, Madempudi RS. Effect of *Bacillus coagulans* Unique IS2 with Lactulose on functional constipation in adults: A double-blind placebo controlled study. *Probiotics Antimicrob Proteins*. 2023;15(2):379–386. doi:10.1007/s12602-021-09855-8
- National Institutes of Health. Opportunities and challenges in digestive diseases research: Recommendations of the National Commission on Digestive Diseases. U.S. Department of Health and Human Services, National Institutes of Health. 2009. <https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/opportunities-challenges-digestive-diseases-research-recommendations-national-commission>
- Canadian Digestive Health Foundation. Digestive Conditions. 2018. <https://cdhf.ca/en/digestive-conditions/>
- Almaro CV, Ballal ML, Chey WD, Nordstrom C, Khanna D, Spiegel BMR. Burden of gastrointestinal symptoms in the United States: Results of a nationally representative survey of over 71,000 Americans. *Am J Gastroenterol*. 2018;113(11):1701–1710. doi:10.1038/s41395-018-0256-8
- LeMoire A, Replogle R, Shinn L, et al. *Bacillus coagulans* Unique IS2 improves stool characteristics in healthy adults with infrequent bowel movements: a randomized, double-blind, placebo-controlled trial. *Benef Microbes*. Published online June 1, 2025. doi:10.1163/18762891-bja00072
- Lewis SJ, Heaton KW. Stool form scale as a useful guide to intestinal transit time. *Scand J Gastroenterol*. 1997;32(9):920–924. doi:10.3109/00365529709011203
- Eypasch E, Williams JI, Wood-Dauphinee S, et al. Gastrointestinal Quality of Life Index: Development, validation and application of a new instrument. *Br J Surg*. 1995;82(2):216–222. doi:10.1002/bjs.1800820229