

# First clinical trial finds probiotic treatment with dead bacteria is better than placebo at alleviating symptoms of IBS

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Probiotic bacteria that have been killed by heat can significantly improve symptoms of irritable bowel syndrome (IBS) compared to placebo, and

are not associated with any safety risk, according to a new 12-week, randomised, double-blind, placebo-controlled clinical trial with 443 patients published in *The Lancet Gastroenterology & Hepatology* journal.

Although they do not know the exact way this potential treatment works, the researchers suggest that these dead bacterial cells are able to stick to cells lining the stomach in the same way that live probiotics do. This may help to strengthen the gut's barrier against harmful bacteria and toxins, which otherwise may contribute to the symptoms of IBS. They also observed a strong [placebo](#) effect, which is common in IBS studies, but the [probiotic](#) treatment was still significantly better than placebo.

Previous trials with probiotics to alleviate IBS symptoms have focused on live bacterial strains, with a few having a significant clinical effect, including *Bifidobacterium bifidum* MIMBb75. This bacterium is particularly good at sticking to cells in the gut wall, which could explain its effects. The use of live probiotics is considered safe, but they have a limited shelf life. Some bacteria die in storage, so it is not known how many are still alive when people take them. On rare occasions, live probiotics have also been reported to cause severe infections, particularly in people with severe illnesses or compromised immune systems. Non-viable probiotics could therefore be an even safer alternative, with the added advantage of a longer shelf life, even in countries with warm climates.

"To our knowledge, no other dead bacterial strain has been found to significantly improve IBS and its symptoms, but the probiotic we used in this first clinical trial appears to reach or even surpass the effects of the live form," says Professor Peter Layer from University of Hamburg Teaching Hospital, Germany, who led the research.

Symptoms of IBS include recurrent episodes of abdominal pain, flatulence, a swollen stomach, feeling uncomfortably bloated, pain while

defecating, diarrhoea, and constipation. The symptoms can harm patients' quality of life, and according to previous studies, the effect on quality of life can be even worse in people with chronic diseases. The causes of IBS are not fully known, but the internal lining of the gut is thought to be more permeable in patients with symptoms.

All patients in the new study experienced chronic abdominal pain or discomfort on at least three days in the past three months, with symptoms having started at least six months previously (in accordance with Rome III diagnostic criteria). In addition, the researchers only included patients who experienced abdominal pain on at least two days in the two weeks prior to the start of the study.

They randomly assigned 443 patients to take either two capsules of heat-inactivated *Bifidobacterium bifidum* MIMBb75, or two placebo capsules, twice daily, for eight weeks. They measured whether abdominal pain improved by at least 30% over eight weeks of treatment, from when they took the first capsule of treatment, and whether all IBS symptoms were significantly relieved at least 50% of the time while the capsules were being taken.

Out of 221 patients who received the probiotic, 74 (34%) experienced an improvement in abdominal pain by at least 30% and a significant alleviation of IBS symptoms at least 50% of the time, compared to 43 (19%) of the 222 patients who received the placebo. This translates to 1.7 times greater treatment success in the probiotic group.

There was no difference in side effects between the groups, and none of the side effects were severe. The most common side effect reported was abdominal pain, which was reported by less than 1% of patients in both groups. 200 (91%) of patients rated the tolerability of treatment as good or very good, compared to 191 (86%) in the placebo group.

The authors highlight the considerable placebo response as a potential limitation of the study, with 19% of patients recording an improvement in symptoms according to the study criteria. However, they point out that a strong placebo response is common in controlled IBS trials. For example, in some studies, over 40% of patients have reported an improvement in IBS symptoms when receiving only a placebo.

"Our results show for the first time that dead or alive, it's possible to preserve the beneficial effects of some [probiotic bacteria](#)," says co-author Dr. Viola Andresen, also from University of Hamburg teaching hospital. "They could be just as effective as live probiotics, as well as even safer, with the added commercial benefit of a longer shelf life."

Writing in a linked Comment, lead author Nicholas Talley (who was not involved in the study) from the University of Newcastle, Australia, says: "A previous, smaller randomised controlled trial reported that viable *B bifidum* modestly improved IBS symptoms compared with placebo. Andresen and colleagues' trial reported a similar benefit of non-viable *B bifidum* to that observed with viable organisms in terms of effect size. A strength of the study was that all IBS subtypes were included in the analysis, and the inactivated bacterial therapy appeared to benefit the different subgroups."

**More information:** Viola Andresen et al, Heat-inactivated *Bifidobacterium bifidum* MIMBb75 (SYN-HI-001) in the treatment of irritable bowel syndrome: a multicentre, randomised, double-blind, placebo-controlled clinical trial, *The Lancet Gastroenterology & Hepatology* (2020). [DOI: 10.1016/S2468-1253\(20\)30056-X](https://doi.org/10.1016/S2468-1253(20)30056-X)

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