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TITLE PAGE

Title: Efficacy of *Saccharomyces cerevisiae* in Irritable Bowel Syndrome.

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Abbreviations:

IBS	irritable bowel syndrome
RCT	randomized controlled trial
SC	<i>Saccharomyces cerevisiae</i>

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Sirs;

We read with interest the randomized controlled trial (RCT) by Pineton de Chambrun et al.¹ Irritable bowel syndrome (IBS) is common, affecting between 10% and 20% of the community.² Although there is some evidence from RCTs for the efficacy of probiotics in the treatment of IBS,³ which organisms, species, and strains are beneficial remains unclear.⁴ More data are therefore welcome, and the authors should be commended for their study, in which they assessed the efficacy of *Saccharomyces cerevisiae* (SC) compared with placebo. However, we feel there are some issues with their study that need to be highlighted for the casual reader.

Firstly, the trial failed to demonstrate a statistically significant difference between SC and placebo in its primary endpoint, and in almost all of the secondary endpoints. However, the abstract only reports the dichotomous improvement in abdominal pain or discomfort, which was statistically significant but appears to be a post hoc analysis. Secondly, the authors stated that they conducted an intention-to-treat analysis. There were a total of 200 patients recruited into the study, 100 in each arm, yet the aforementioned dichotomous assessment to response was conducted in only 86 SC patients and 93 placebo patients. In this analysis, the authors demonstrated that 54 (62.8%) of 86 SC patients improved, compared with 44 (47.3%) of 93 placebo patients ($P = 0.04$). This is not a strict intention-to-treat analysis, and if one assumes that those who were lost to follow-up did not respond to therapy, then response rates are 54 of 100 SC patients, compared with 44 of 100 placebo patients, which is no longer statistically significant ($P = 0.17$).

While these data are encouraging, changes in individual symptom scores from baseline were similar in the placebo arm, reflecting the high placebo response rate in IBS,⁵ and highlighting the fact that, despite the authors conclusions that SC reduces abdominal pain and discomfort scores, it performed similarly to placebo in this RCT.

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