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Evaluation of Health-Related Quality of Life in Patients Treated with Synbiotics: a Prospective Observational Study

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ABSTRACT

Objectives: *Abdominal bloating and gastrointestinal discomfort are common complaints that significantly impair patients' health-related quality of life (HRQoL). Probiotic and synbiotic formulations have been proposed as supportive therapies for improving gastrointestinal symptoms and patient-reported outcomes, yet real-world data on their impact on HRQoL remain limited. Our objective was to evaluate changes in physical and mental components of HRQoL in adult patients treated with a synbiotic formulation containing* Saccharomyces boulardii *SB01,* Lactobacillus bulgaricus *LB42,* Lactobacillus rhamnosus *LRa05 and fructooligosaccharides (FOS) in routine clinical practice.*

Materials and methods: *This prospective monocentric observational study included 50 adult patients treated with a synbiotic formulation containing* Saccharomyces boulardii *SB01,* Lactobacillus bulgaricus *LB42,* Lactobacillus rhamnosus *LRa05 and FOS for 15 days. Health-related quality of life was assessed using the 12-item Short Form Health Survey (SF-12) at baseline and at 30-day follow-up. Changes in SF-12 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores were analyzed using Wilcoxon signed-rank tests. Clinically meaningful improvement was defined using the minimal clinically important difference (MCID). Effect sizes were calculated and correlations between changes in PCS and MCS were assessed using Spearman's rho.*

Results: *The PCS scores improved significantly from baseline to follow-up (mean change +4.42, p-value= 0.003). Clinically meaningful improvement in physical HRQoL was observed in 46% of participants. In contrast, MCS scores declined significantly over the same period (mean change −9.17, p-value < 0.001) and no participants achieved MCID for mental HRQoL. Changes in physical and mental HRQoL were not significantly correlated (p-value = 0.112).*

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Conclusions: *In routine clinical practice, treatment with the studied synbiotic formulation was associated with a statistically significant and clinically meaningful improvement in physical HRQoL, while mental HRQoL showed a significant decline over the short-term follow-up. These findings highlight divergent trajectories of physical and mental health outcomes and underscore the importance of multidimensional HRQoL assessment in patients with gastrointestinal disorders.*

Keywords: quality of life, *Saccharomyces boulardii*, *Lactobacillus*, irritable bowel syndrome, bloating.

INTRODUCTION

Abdominal bloating and related gastrointestinal discomfort are among the most frequently reported symptoms in patients, often associated with alterations in the gut microbiota and impaired gut function. These symptoms may significantly affect daily functioning and health-related quality of life (HRQoL), even in the absence of overt structural gastrointestinal disease. As a result, there is growing interest in therapeutic strategies aimed not only at symptom control, but also at improving patient-reported outcomes (1).

Probiotics and synbiotics have been proposed as effective interventions for modulating the gut microbiota and alleviating gastrointestinal symptoms, including bloating, abdominal pain and irregular bowel habits. Their potential role in functional gastrointestinal disorders has been widely investigated, with several meta-analyses and clinical trials suggesting beneficial effects on gastrointestinal symptoms and HRQoL. However, reported outcomes vary considerably depending on the specific strains used, dosage, formulation and patient population (2-6).

Saccharomyces boulardii, a non-pathogenic yeast strain, has been extensively studied for its therapeutic potential in gastrointestinal disorders. Evidence from randomized controlled trials and systematic reviews support the role of *S. boulardii* supplementation in reducing the incidence of antibiotic-associated diarrhea and improving symptom severity and quality of life in patients with irritable bowel syndrome (IBS). Nevertheless, the magnitude and consistency of these effects remain dependent on clinical context and study design (7, 8).

Lactobacillus species such as *Lactobacillus rhamnosus* and *Lactobacillus bulgaricus* have also been investigated for their role in supporting intestinal homeostasis, modulating immune responses and influencing gut–brain interactions. While several studies suggest that *Lactobacillus*-containing formulations may improve gastrointestinal symptoms and overall well-being, findings regarding sustained effects on HRQoL remain heterogeneous (9).

Health-related quality of is an important outcome in the evaluation of therapeutic interventions for functional gastrointestinal disorders, encompassing both physical and mental health. Validated instruments such as the 12-item Short Form Health Survey (SF-12) enable standardized assessment of HRQoL and have been widely used in clinical research to quantify changes attributable to pharmacological, nutritional and microbiota-targeted interventions (2, 10).

Despite growing evidence from controlled clinical trials, real-world observational data examining the impact of synbiotic combinations containing *S. boulardii* and *Lactobacillus* strains on HRQoL in routine clinical practice remain limited. Therefore, the present prospective observational study aimed to evaluate changes in SF-12 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from baseline to 30 days in adult patients treated with a defined synbiotic formulation under standard care conditions. ❑

MATERIALS AND METHODS

Study design and patients

This was a prospective monocentric observational study conducted in routine clinical practice at the Gastroenterology Outpatient Unit of Fundeni Clinical Institute, Bucharest, Romania, from November 2025 to January 2026.

Adult patients (≥18 years) diagnosed with irritable bowel syndrome, functional dyspepsia, functional abdominal bloating, or functional diarrhea who received a defined synbiotic formulation under standard care conditions were eligible for inclusion. All selected subjects received the formulation at a dose of two tablets *per* day

for 15 consecutive days, as prescribed by their treating physician according to routine clinical practice.

Inclusion criteria comprised individuals aged 18 or older with an indication for treatment, their ability to comprehend and complete the SF-12 questionnaire and patient's willingness to participate in the study.

Exclusion criteria included concurrent participation in another clinical study, known allergy to any of the product's ingredients, pregnancy or lactation, current or previous neoplasia or cytotoxic drugs, history of alcohol and drug abuse, psychiatric disorders and unwillingness to take part in the study.

Patients were evaluated at two time points: 1) baseline visit (Day 0) – collection of demographic data and medical history, completion of the SF-12 questionnaire and initiation of treatment; and 2) follow-up visit (Day 30 ± 3 days) – completion of the SF-12 questionnaire, assessment of treatment compliance and adverse events report.

Data were recorded on anonymized case report forms.

The primary outcome was the change in SF-12 PCS score from baseline to Day 30. Secondary outcomes included the change in SF-12 MCS score, proportion of patients achieving a clinically meaningful improvement, defined as a minimal clinically important difference (MCID) of 3–5 points, tolerability and incidence of reported adverse events.

A total sample size of 50 patients was planned. Assuming a standard deviation of 10 points for SF-12 PCS and MCS scores, this sample size provides 80% power to detect a mean difference of approximately four points at a two-sided significance level of 0.05, corresponding to a clinically meaningful change.

Statistical analysis

Data analysis was performed using statistical software SPSS (20.0 version from IBM Corporation, Armonk, NY, USA). Descriptive statistics were used to summarize baseline characteristics and outcome measures. Continuous variables were expressed as mean ± standard deviation (SD) or median with minimum and maximum values, as appropriate, while categorical variables were presented as frequencies and percentages.

Paired comparisons between baseline and follow-up SF-12 scores were performed using the paired Student's t-test or the Wilcoxon signed-rank test, depending on data distribution. Effect sizes were calculated where appropriate. Correlations between changes in physical and mental health scores were assessed using Spearman's rank-order correlation coefficient. A two-sided p-value < 0.05 was considered statistically significant.

Ethical considerations

The present study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Fundeni Clinical Institute (November 14th 2025, approval number 48888). All participants provided written informed consent prior to inclusion. Data confidentiality and patient privacy were ensured in compliance with the General Data Protection Regulation (GDPR). ❑

RESULTS

A total of 50 adult patients were included in the statistical analysis. Of these, 33 participants (66%) were females and 17 (34%) males. Patients' age ranged from 20 to 73 years, with a median age of 50.5 years.

Regarding lifestyle characteristics, the smoking status was evenly distributed, with 13 participants (26%) reporting active smoking and 37 (74%) no smoking. Occasional alcohol consumption was reported by 22 participants (44%), while 28 subjects (56%) declared no alcohol use. Most participants reported no known allergies (66%). Among those with allergies, pollen (14%) and dust (12%) allergies were the most frequently reported, followed by food (6%) and drug allergies (2%).

Descriptive statistics for SF-12 PCS (PCS-12) and MCS-12 scores at baseline (Day 0) and follow-up (Day 30) are presented in Table 1.

The PCS-12 score was 48.20 [standard deviation (SD) = 7.59] at baseline mean (M) and it increased to 52.62 (SD = 4.99) at follow-up. In contrast, the mean MCS-12 score decreased from 40.54 (SD = 13.93) at baseline to 31.37 (SD = 5.54) at follow-up.

Difference score analyses indicated a mean improvement in physical health (M = 4.42, SD = 6.21), while mental health scores showed a mean decline over time (M = −9.17, SD = 10.54).

Variable	Time point	Mean	Standard deviation	Minimum	Maximum
PCS-12	Baseline	48.20	7.59	34.33	59.05
PCS-12	Follow-up	52.62	4.99	38.90	58.08
MCS-12	Baseline	40.54	13.93	27.29	62.25
MCS-12	Follow-up	31.37	5.54	27.29	46.96

PCS: Physical Component Summary; MCS: Mental Component Summary

TABLE 1. Descriptive statistics for physical and mental health scores at baseline and follow-up

Variable	Negative ranks (n)	Positive ranks (n)	Ties (n)	Z	p	Effect size (r)
PCS-12	24	24	2	-2.99	0.003	0.42
MCS-12	48	2	0	-6.34	< 0.001	0.90

PCS: Physical Component Summary; MCS: Mental Component Summary

TABLE 2. Wilcoxon signed-rank test results for changes in physical and mental health

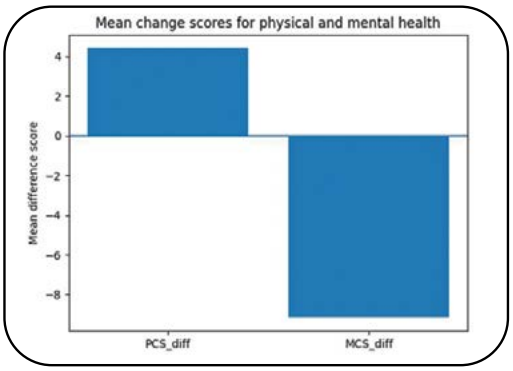

FIGURE 1. Mean change score for physical and menthal health

Clinically meaningful improvement in physical health, defined by attainment of the MCID, was observed in 23 participants (46%). The remaining 27 ones (54%) did not reach the MCID threshold for PCS-12. In contrast, no participant achieved a clinically meaningful improvement in mental health. All subjects were classified as not reaching the MCID threshold for MCS-12.

Wilcoxon signed-rank test revealed a statistically significant improvement in PCS-12 scores from baseline to follow-up ($p = 0.003$). Among participants, 24 showed an increase in PCS-12 scores, 24 a decrease and two subjects exhibited no change. Importantly, the mean rank of positive differences (36.46) exceeded that of negative differences (12.54), indicating a general tendency toward improved physical health.

Wilcoxon signed-rank test also demonstrated a highly significant decline in MCS-12 scores between baseline and follow-up ($p < 0.001$). The majority of participants ($n = 48$) experienced a reduction in MCS-12 scores, while only two subjects showed an increase. The mean rank of negative differences (26.50) was substantially higher than that of positive differences (1.50), indicating a pronounced deterioration in mental health. Results of the Wilcoxon signed-rank tests are summarized in Table 2.

To explore the relationship between changes in physical and mental health, a Spearman rank-order correlation was conducted between PCS and MCS difference scores. The analysis revealed a weak negative correlation that did not reach statistical significance ($p = 0.112$), indicating that improvements in physical health were not significantly associated with changes in mental health within the study period. Figure 1 illustrates the contrasting patterns of change in physical and mental health across the study period. ❑

DISCUSSION

The present prospective observational study evaluated changes in HRQoL in adult patients treated with a synbiotic formulation containing *Saccharomyces boulardii* SB01, *Lactobacillus bulgaricus* LB42, *Lactobacillus rhamnosus* LRa05 and fructooligosaccharides (FOS) under routine clinical practice conditions. The main findings indicate a statistically significant and clinically meaningful improvement in the physical component of HRQoL, accompanied by a medium-to-large effect size, alongside a significant decline in the mental component of HRQoL over a 30-day period.

The observed improvement in SF-12 PCS scores is consistent with existing evidence suggesting that probiotic and synbiotic interventions can positively influence physical aspects of quality of life in patients with gastrointestinal disorders. Several meta-analysis indicate that probiotics may reduce gastrointestinal symptom burden and improve patient-reported outcomes, particularly in functional gastrointestinal disorders such as irritable bowel syndrome and functional bloating (1, 2, 11-13). Improvements in abdominal discomfort, bowel regularity and gastrointestinal tolerance are likely to translate into better physical functioning and daily activity performance, as reflected in higher PCS scores.

Specifically, *Saccharomyces boulardii* has been shown to have beneficial effects through

multiple mechanisms, including modulation of intestinal barrier integrity, regulation of inflammatory responses and stabilization of gut microbiota composition. Randomized controlled trials have demonstrated that *S. boulardii* supplementation can improve quality of life outcomes in patients with irritable bowel syndrome compared with placebo, particularly in physical health domains (3). Similarly, systematic reviews have reported reductions in symptom severity and improved global well-being among patients receiving *S. boulardii* formulations (4). The magnitude of PCS improvement observed in the present study, as well as the proportion of patients achieving a minimal clinically important difference, are similar to these previously reported findings, despite differences in study design and patient populations (14-16).

Lactobacillus strains, including *L. rhamnosus* and *L. bulgaricus*, have also been involved in supporting gastrointestinal homeostasis and enhancing gut–immune interactions. Reviews of probiotic interventions suggest that *Lactobacillus* containing formulations may improve gastrointestinal symptoms and physical well-being, although effects on overall HRQoL remain heterogeneous (5). The combined use of multiple probiotic strains together with prebiotic components such as FOS may enhance microbial diversity and functional resilience of the gut ecosystem, potentially contributing to the observed physical health benefits in this real-world cohort.

In contrast to the improvement observed in physical HRQoL, mental health-related quality of life, as assessed by the SF-12 MCS, showed a significant and pronounced decline. This finding diverges from some reports in the literature suggesting modest improvements or neutral effects of probiotic supplementation on mental well-being and psychological symptoms (2, 5). However, existing evidence regarding mental health outcomes remains inconsistent, with several studies reporting limited or no effects of probiotic interventions on anxiety, mood or psychological quality of life, particularly over short follow-up periods (17-19).

The decline in MCS scores observed in the present study may reflect the multifactorial nature of mental health, which is influenced by psychological stress, social context, comorbid conditions and external life events that are not directly targeted by microbiota-modulating interventions. Furthermore, observational real-world studies lack the ability to control for such confounding factors, which may exert a stronger influence on mental HRQoL than gastrointestinal symptom improvement alone. Notably, no participants achieved a clinically meaningful improvement in MCS scores, and changes in physical and mental health were not significantly correlated, suggesting that improvements in physical functioning do not necessarily improve mental well-being.

These findings are similar to previous observations that physical and mental components of HRQoL may follow distinct trajectories in patients with gastrointestinal disorders (2). While symptom relief may improve physical functioning, mental health outcomes may require longer treatment durations, targeted psychological interventions or integrated care approaches addressing stress, anxiety and coping mechanisms. The effect size observed for the decline in MCS underscores the importance of systematically monitoring mental health outcomes in clinical practice, even when physical symptoms appear to improve.

Overall, the present study demonstrates that synbiotic treatment may offer clinically relevant improvements in physical HRQoL, while mental health outcomes may remain unchanged or even worsen over short-term follow-up. These findings highlight the importance of multidimensional HRQoL assessment and support the need for comprehensive management strategies that address both physical and psychological dimensions of gastrointestinal disorders.

Several limitations of the present study should be acknowledged. Firstly, the observational design without a control or placebo group limits the ability to establish causal relationships between synbiotic treatment and observed changes in HRQoL. Placebo effects and regression to the mean cannot be excluded. The relatively small sample size and single-center setting may also limit the extension of the findings to broader patient populations. Although the sample size was sufficient to detect clinically meaningful changes in PCS scores, the study may have been underpowered to detect smaller effects or subgroup differences, particularly for mental health outcomes. The follow-up period was limited to 30 days, which may not be sufficient for longer-term effects of synbiotic treatment, particularly in mental health-related quality of life. Changes in psychological well-being may require longer intervention dura-

tions or sustained symptom improvement. Finally, mental health outcomes may have been influenced by unmeasured psychosocial factors, such as stress, anxiety or external life events, which were not systematically assessed in the study. ❑

CONCLUSIONS

In this prospective observational study, treatment with a synbiotic formulation containing *Saccharomyces boulardii*, *Lactobacillus bulgaricus*, *Lactobacillus rhamnosus* and FOS was associated with a statistically significant and clinically meaningful improvement in physical health-related quality of life over a 30-day period. Nearly half of the participants achieved a minimal clinically important improvement in physical functioning, supporting the potential clinical utility of this synbiotic combination in patients with gastrointestinal complaints.

In contrast, mental health-related quality of life demonstrated a significant decline, highlighting a divergence between physical and mental health trajectories and underscoring the complexity of HRQoL outcomes in this patient population. Changes in physical and mental health were not significantly correlated, suggesting that improvements in gastrointestinal symptoms and physical functioning alone may be insufficient to positively influence mental well-being.

These findings emphasize the importance of multidimensional HRQoL assessment in clinical practice and suggest that future studies should explore combined or longer-term interventions targeting both physical and psychological domains. Controlled studies with larger sample sizes and extended follow-up periods are warranted to further clarify the role of synbiotic therapy in improving overall quality of life in patients with functional gastrointestinal disorders. ❑

Conflicts of interest: none declared.
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