



**HIGHEST QUALITY –
SCIENTIFICALLY TESTED**

STUDY COLLECTION

Institut
AllergoSan



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SCIENTIFICALLY TESTED**

STUDY COLLECTION



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Positive Effects of a Multi-Species Probiotic on Antibiotic-Associated Diarrhoea and Intestinal Microbiota during Antibiotic Therapy

Koning *et al.*, American Journal of Gastroenterology; 2008



Abstract

Antibiotic-associated diarrhoea (AAD) is one of the most common side effects of taking antibiotics. It can occur both shortly after taking antibiotics and weeks later. The incidence of AAD ranges from 5% to 39% and is highly dependent on the definition of diarrhoea, the type of antibiotic, and the patient's condition. Most cases of AAD are due to the disruption of the gut microbiota, loss of colonisation resistance, the consequent overgrowth of potentially pathogenic germs, and changes in both the mucosal and systemic immune responses. Possible consequences range from longer hospitalisations and higher care costs to increased mortality. In this placebo-controlled, double-blind study, the effect of the specific pathogen-inhibiting multi-species probiotic OMNi-BiOTiC® 10 AAD (German trade name OMNi-BiOTiC® 10) on the occurrence of diarrhoea was investigated in 41 healthy volunteers who were given the antibiotic amoxicillin (500 mg, twice daily for 7 days).

Results

Taking the multi-species probiotic twice a day (5 g each dose, totalling 1×10^{10} CFU) from the first day of antibiotic treatment for two weeks resulted in significantly lower diarrhoea-associated intestinal motility compared to the placebo group (48% vs. 79%, $p < 0.05$). Similar positive effects were observed regarding stool consistency: in the probiotics group, only 21% of subjects experienced excessively soft stool consistency (≥ 5 on the Bristol Stool Scale) for at least 2 days, whereas in the placebo group, nearly twice as many subjects (42%) suffered from diarrhoea ($p < 0.05$).

Additionally, despite the one-week course of antibiotics, a significant increase in commensal *enterococci* and important anaerobes was detected in the probiotics group. In contrast, the number of *lactobacilli* in the placebo group was significantly reduced after the course of antibiotics. Notably, the PFGE (Pulsed Field Gel Electrophoresis) profile for typing the bacterial genome of 39 out of 40 *enterococcal* strains isolated from the stool of the probiotic group subjects was similar to that of the probiotic strain *Enterococcus faecium* W54, supplied orally via OMNi-BiOTiC® 10 AAD. This indicates a clear increase in microbial diversity in the probiotics group.

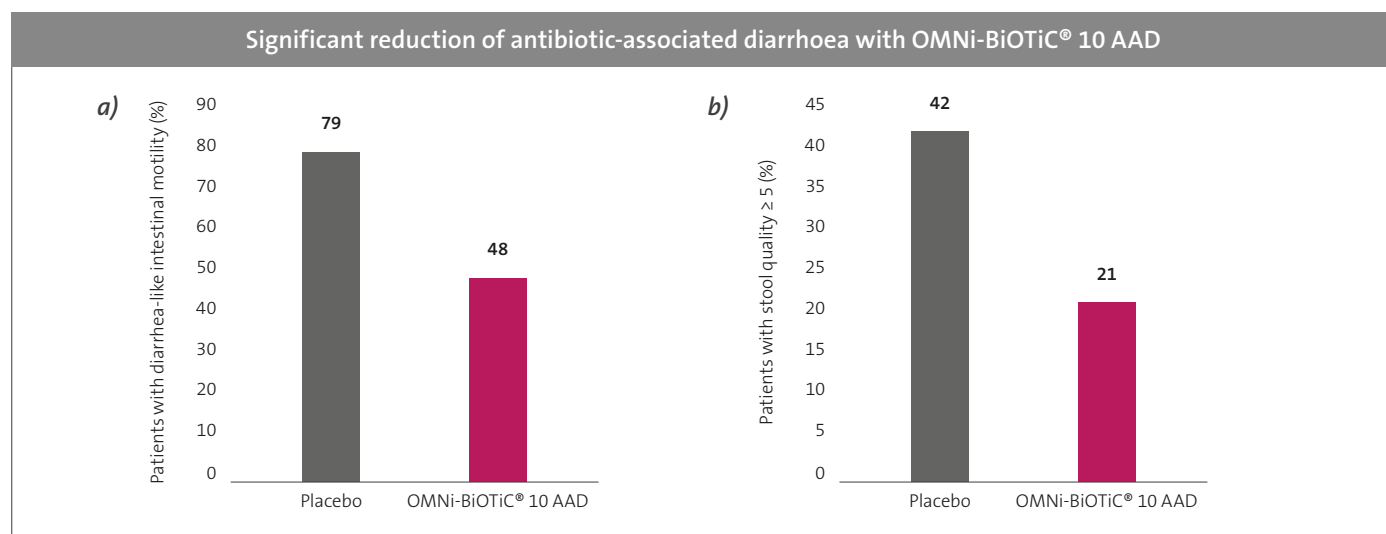


Figure: (a) During the observation period (two weeks), the probiotics group showed significantly lower diarrhoea-like intestinal motility ($p < 0.05$). (b) Significantly fewer subjects in the probiotics group showed diarrhoea (stool consistency ≥ 5 lt. Bristol Stool Scale for at least 2 days, $p < 0.05$).

Discussion and conclusion

This study clearly demonstrates that the timely use of the medically relevant probiotic OMNi-BiOTiC® 10 AAD from the first day of antibiotic treatment leads to significantly less diarrhoea. These findings indicate that specifically designed multi-species probiotics can prevent AAD by positively influencing the composition and function of

the gut microbiota, thereby restoring the integrity of the gut barrier. This preventative measure can help avoid serious complications, such as *Clostridium difficile* infections, and significantly reduce additional treatment costs.

Reduction of Antibiotic-Associated Diarrhoea by Using a Multi-Species Probiotic

Lang *et al.*, Journal für Gastroenterologische und Hepatologische Erkrankungen; 2009

Abstract

For the treatment of bacterial infections, patients are often prescribed antibiotics. However, even a single dose of antibiotics can damage the gut microbiome and trigger antibiotic-associated diarrhoea (AAD). Until 2008, AAD was frequently observed in the context of perioperative antibiotic prophylaxis at the General Surgery Department of the Neunkirchen Regional Hospital. This led to a dramatic increase in morbidity, and in some cases, mortality, prolonging hospital stays and significantly increasing treatment costs.

Positive modulation of the intestinal microbiome through the administration of specific probiotics from the first day of antibiotic treatment can restore the intestinal barrier and consequently reduce the incidence of AAD. In this study, the positive effect of the specifically pathogen-inhibiting multi-species probiotic OMNi-BiOTiC® 10 AAD (German trade name OMNi-BiOTiC® 10) was investigated in hospitalised patients of the surgical department (n = 199) who were treated with antibiotics.

Results

During the observation period of 6 months, the patients were treated with antibiotics for numerous infections (e.g. enteritis, colitis, diverticulitis, pneumonia, pancreatitis, appendicitis phlegmonosa and urinary tract infections). For the treatment of these infections, 24 different antibiotics were used in both mono- and combination therapy, covering all common antibiotic classes according to mechanism of action.

Despite the numerous different antibiotic substances used, only one out of 199 patients (= 0.5 %) developed AAD while taking OMNi-BiOTiC® 10 AAD (5×10^9 CFU, 2x daily) and not a single *Clostridium difficile* infection was detected. Compared to the general incidence rates of antibiotic-associated diarrhea (AAD) observed with different antibiotic classes, the use of OMNi-BiOTiC® 10 AAD resulted in a significantly reduced occurrence of AAD across all drug classes

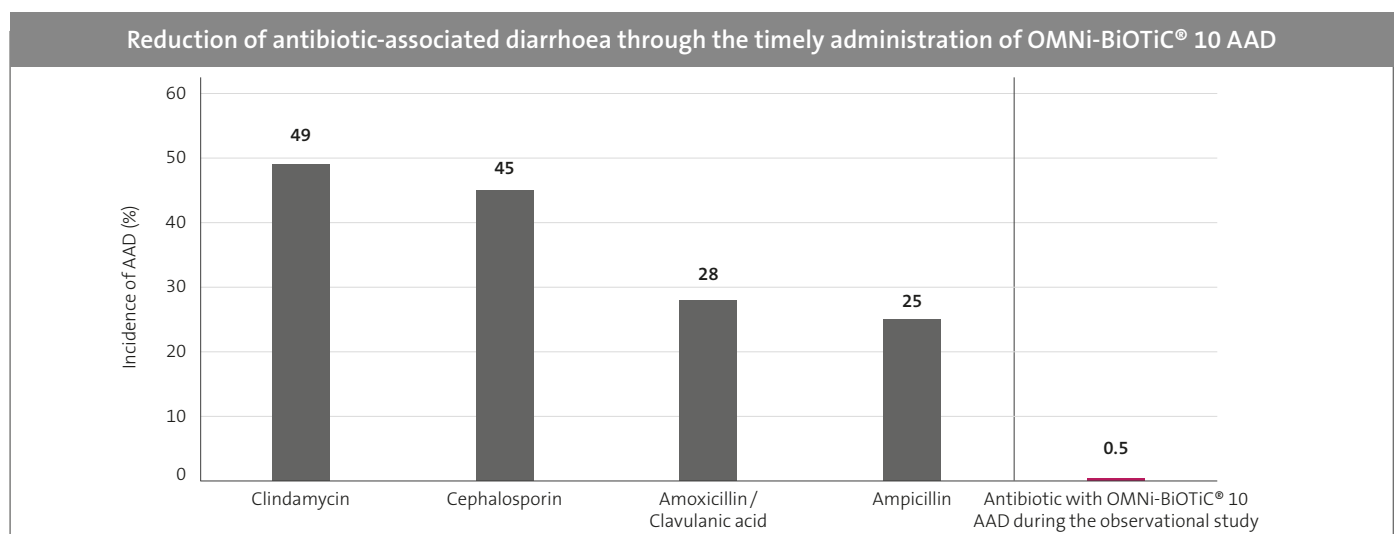


Figure: Significant reduction of AAD by OMNi-BiOTiC® 10 AAD to 0.5 % compared to the general incidence of AAD with antibiotic administration alone.

Discussion and conclusion

In summary, it is evident that despite the hospital environment and the associated increased bacterial exposure, taking OMNi-BiOTiC® 10 AAD from the first day of antibiotic treatment significantly reduces the incidence of AAD. As a result, serious complications such as *Clostridium difficile* infections can be prevented, the length of hos-

pital stay shortened, and substantially treatment costs significantly reduced. Furthermore, the use of this medically relevant probiotic enhances the overall quality of life for patients.

Successful Use of Probiotics in Antibiotic-Associated Diarrhoea in Care Homes

Van Wietmarschen *et al.*, BMC Gastroenterology; 2020

Abstract

Approximately 10% of residents in nursing homes for the elderly receive regular antibiotic treatments, typically for urinary tract infections, lower respiratory tract infections, and skin infections. The incidence of antibiotic-associated diarrhoea (AAD) caused by these treatments ranges from 2% to 25%, depending on the antibiotic used. Symptoms frequently develop shortly after the start of, or within a few weeks after, antibiotic therapy. Complications associated with AAD include dehydration, hospitalisation, increased nursing time, and additional hygiene measures. The objective of this study was to evaluate the positive effect of the medically relevant multi-species probiotic OMNi-BiOTiC® 10 AAD (German trade name: OMNi-BiOTiC® 10) on the incidence of antibiotic-associated diarrhoea among nursing home residents.

Results

Subjects took the probiotic (5 g, totalling 1×10^{10} CFU, twice daily) concomitantly with their antibiotic therapy and for an additional week after the end of the antibiotic course. Among the 93 patients, 167 antibiotic therapies were documented, with the multi-species probiotic OMNi-BiOTiC® 10 AAD being administered in 84 cases. The administration of this high-quality probiotic significantly reduced the incidence of AAD by approximately 50%, regardless of whether patients were taking amoxicillin or ciprofloxacin. Its inclusion to the patients' medication regimen facilitated its successful integration into day-to-day nursing home care. Furthermore, this probiotic was noted for its excellent tolerability.

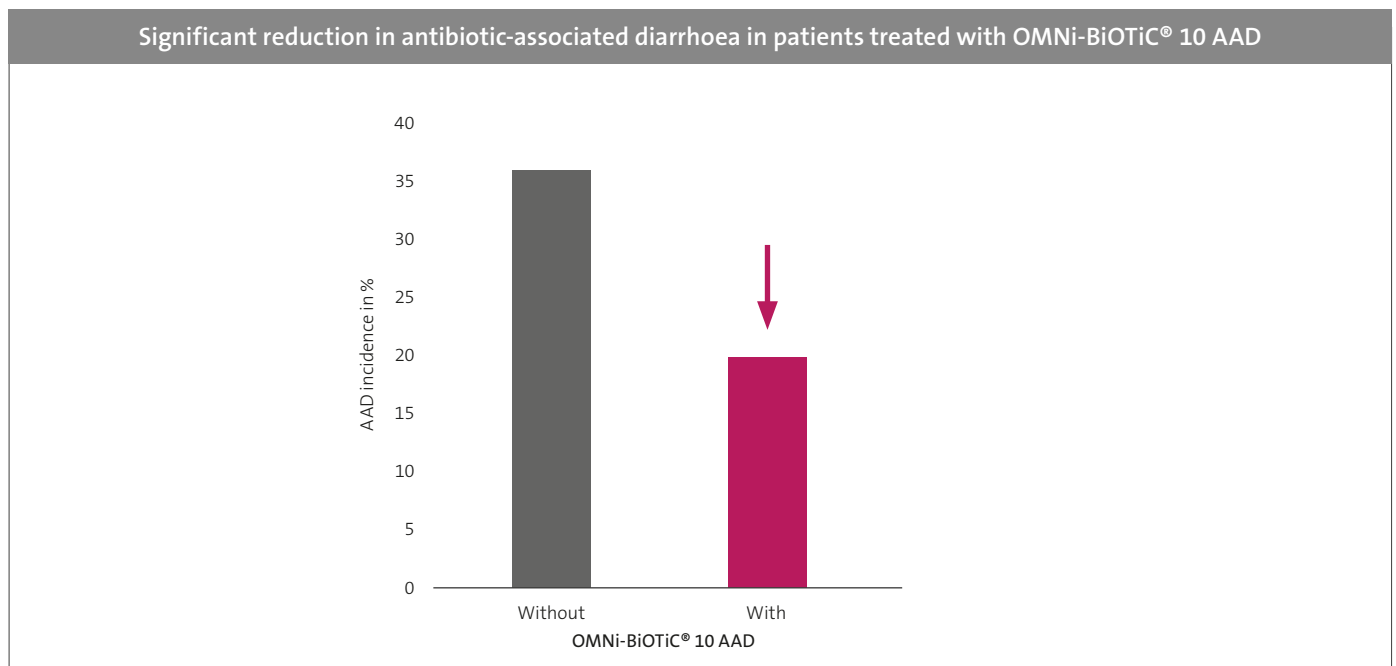


Figure: Marked reduction in the incidence of AAD among nursing home residents co-administered the multi-species probiotic.

Discussion and conclusion

This study has clearly demonstrated that the successful implementation of the OMNi-BiOTiC® 10 AAD multi-species probiotic in participating care homes reduced the incidence of antibiotic-associated diarrhoea among residents. Regardless of the primary underlying condition, this medically relevant probiotic prevented AAD in 50% of cases, thereby protecting patients from severe complications such as *Clostridioides difficile* infection. The reduction in AAD incidence helps save nursing time and costs and reduces the need for additional hy-

giene measures, which is of significant importance to the healthcare system. Preventing complications such as hospitalisations also results in substantial potential savings. The successful incorporation of this probiotic into patients' medication regimens allows nursing staff in these care homes to ensure its use during antibiotic therapy, enhancing the overall quality of care.

Use of a Multi-Species Probiotic in Internal Medicine Patients on Antibiotics to Prevent Antibiotic-Associated Diarrhoea



Gänzer *et al.*, Journal für gastroenterologische und neurologische Erkrankungen; 2022

Abstract

For the treatment of bacterial infections, patients are often prescribed antibiotics. However, even a single dose of an antibiotic can damage the gut microbiome and trigger antibiotic-associated diarrhoea (AAD). Positive modulation of the intestinal microbiome through the administration of specific probiotics from the first day of antibiotic treatment can restore the intestinal barrier and consequently reduce the incidence of AAD. In this study, the effect of the pathogen-inhibiting multi-species probiotic OMNi-BiOTiC® 10 AAD (German trade name OMNi-BiOTiC® 10) on the incidence of AAD was investigated in 202 internal medicine patients, particularly those aged 60 and over.

Results

Ninety-eight patients received the probiotic OMNi-BiOTiC® 10 AAD while taking antibiotics and for 7 days after the course of antibiotics; another 104 patients received only antibiotics. The results show that treatment with the multi-species probiotic leads to a significant 50% reduction in AAD ($p < 0.05$). In patients who were also taking proton pump inhibitors, the occurrence of diarrhea-like bowel movements was significantly reduced by 30% due to the use of OMNi-BiOTiC® 10 AAD.

Additionally, there were significantly fewer antibiotic-associated complaints and no *Clostridium difficile* infections in the probiotics group. Patients who received OMNi-BiOTiC® 10 AAD twice daily in addition to the respective antibiotic had shorter diarrhoea episodes on average compared to the control group. Notably, in the high-risk group of people over 90 years of age, not a single case of AAD occurred when the probiotic was used, whereas 45% of patients in the control group experienced diarrhoea ($p < 0.05$).

Significant reduction of antibiotic-associated diarrhoea in elderly patients by OMNi-BiOTiC® 10 AAD

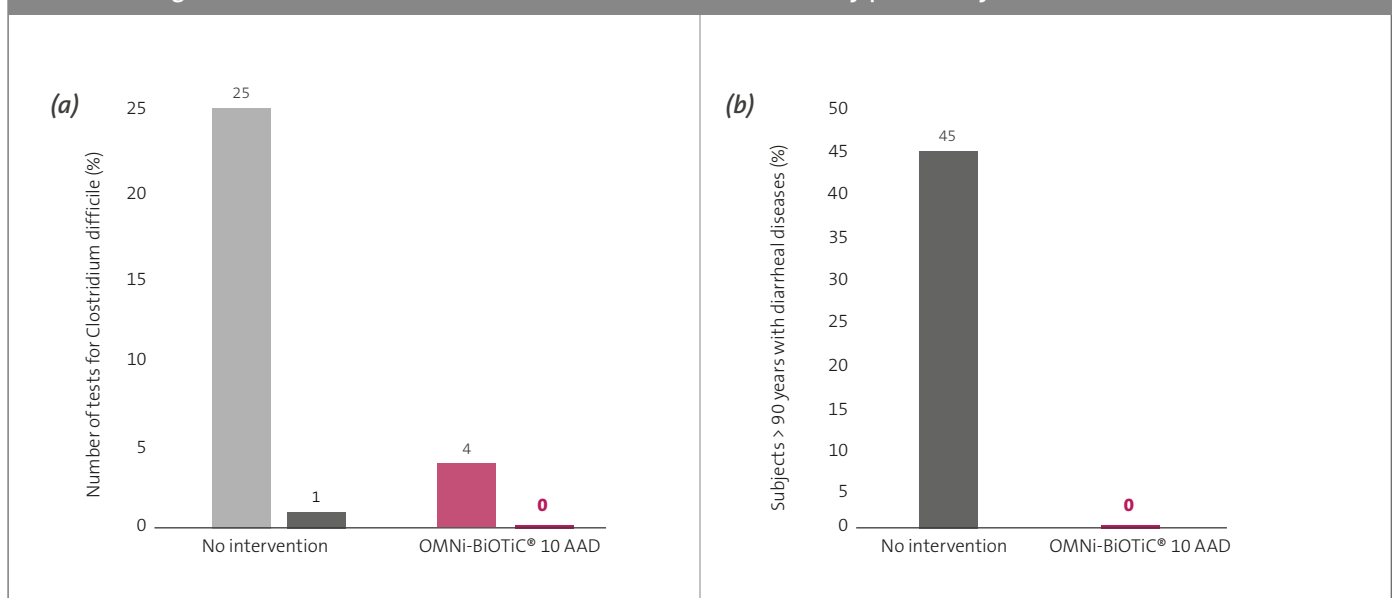


Figure: (a) Not a single case of *Clostridium difficile* infection occurred in the probiotics group.

(b) In the risk group of people over 90 years of age, not a single case of diarrhoea occurred during the intake of OMNi-BiOTiC® 10 AAD, while 45% of patients in the control group had diarrhoea ($p < 0.05$).

Discussion and conclusion

In summary, this study demonstrates the highly beneficial impact positive effect of OMNi-BiOTiC® 10 AAD in preventing AAD among elderly internal medicine patients. Timely use of this pathogen-inhibiting multi-species probiotic from the first day of antibiotic treat-

ment significantly reduces the risk of AAD and prevents *Clostridium difficile* infections. Consequently, this reduces additional healthcare costs and the need for further hygiene measures.

Successful Use of Probiotics in Infections with Multi-Resistant Pathogens in Geriatric Medicine

Zollner-Schwetzel *et al.*, *Nutrients*; 2020

Abstract

Infections with multi-resistant Gram-negative (MRGN) bacteria result in higher mortality rates and significant healthcare costs, predominantly impacting patients in hospitals and long-term care facilities. Asymptomatic carriers contribute to the spread of these pathogens. The use of antibiotics is counterproductive, as it encourages the development of further treatment-resistant bacteria. Therefore, new therapeutic strategies are urgently needed. It has already been demonstrated that probiotic bacterial strains can suppress colonisation with pathogenic organisms. This study examined the positive effect of OMNi-BiOTiC® 10 AAD (German trade name: OMNi-BiOTiC® 10) in reducing infections of the gastrointestinal tract and the skin with MRGN bacteria in geriatric patients over a period of 36 weeks.

Results

This study demonstrated that taking OMNi-BiOTiC® 10 AAD (5 g, totalling 1×10^{10} CFU, twice daily) for 12 weeks significantly reduced the incidence of infections with multi-resistant organisms both in the gut and on the skin of geriatric patients. Baseline analysis of the

gut microbiome revealed infection with multi-resistant organisms (*E. coli*, *Klebsiella spp.*, *Pseudomonas aeruginosa*) in all patients. Repeat analysis after treatment with this specific probiotic for 12 weeks demonstrated decreased colonisation with MRGN bacteria. Additionally, this indication-specific probiotic therapy resulted in a statistically significant increase in diversity, particularly within the Enterococcus genus. Following the discontinuation of the multi-species probiotic, a 58% reduction in the occurrence of multi-resistant pathogens was observed during the 12-week follow-up period.

Even more remarkable was the skin microbiome analysis, which showed a reduction in MRGN bacterial infections by up to 71%. However, after discontinuing probiotic therapy, reinfections of the gut and skin could not be entirely prevented in this geriatric patient population, as evidenced by a slight increase in the infection rate during the 24-week follow-up period.

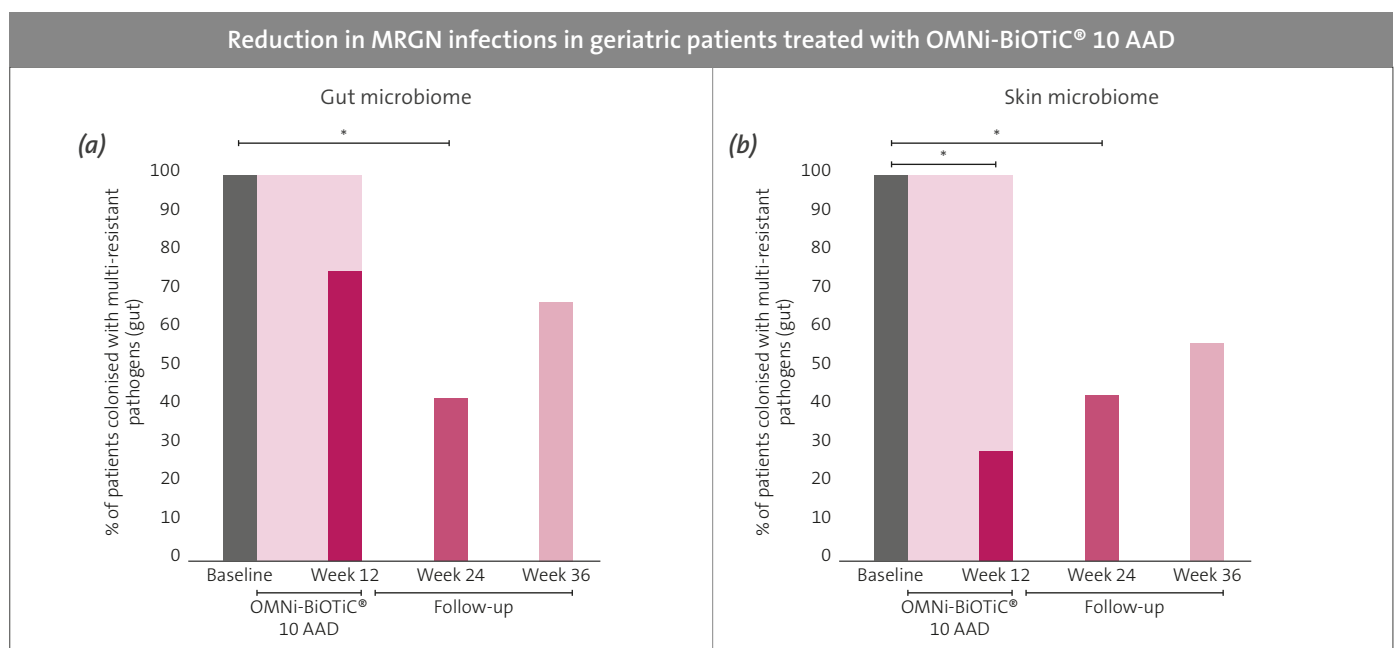


Figure: (a) Taking the probiotic for 12 weeks resulted in a sustained reduction in infections with MRGN bacteria in the gut. (b) Analysis of the skin microbiome showed a 71% reduction in colonisation with MRGN bacteria following the use of OMNi-BiOTiC® 10 AAD.

Discussion and conclusion

This study has provided significant results demonstrating the successful use of the OMNi-BiOTiC® 10 AAD multi-species probiotic in displacing multi-resistant bacteria in long-term care facilities. The reinfection with multi-resistant pathogens observed during the follow-up period highlights the ongoing challenge posed by the envi-

ronment in geriatric care facilities. Therefore, it is evident that chronic treatment with high-quality probiotics is a rational and effective strategy in the combating multi-resistant Gram-negative bacteria in care homes.

The Positive Effect of a Multi-Species Probiotic in the early Treatment of Sepsis – a randomized, Placebo-Controlled Study

Stadlbauer *et al.*, *Beneficial Microbes*; 2019



Abstract

Every year, millions of patients worldwide die from sepsis, a condition characterized by multi-organ failure triggered by a dysregulated immune response to bacteria, viruses, fungal infections, and parasites. Recent studies indicate that sepsis is consistently associated with a loss of microbial diversity and an increased abundance of pathogenic agents, suggesting a critical role for the intestines in its pathogenesis. However, it remains unclear whether alterations in the intestinal microbiome and barrier function occur in the early stages of sepsis or if the microbiome can be positively influenced during this phase.

In this randomized, controlled study, the effect of the multi-species probiotic OMNi-BiOTiC® 10 AAD (German trade name: OMNi-BiOTiC® 10) was investigated in the early stage of sepsis, along with its impact on the functional and structural diversity of the microbiome.

Results

The intestinal microbiome of 15 patients with early sepsis, exhibiting no signs of organ failure, was analysed before and after a 4-week intake of OMNi-BiOTiC® 10 AAD (2x5g daily, totalling 1.1×10^9 CFU). At the study's onset, these patients displayed a significant reduction in alpha diversity compared to healthy individuals. In the sepsis patients, the phyla *Bacteroidetes* and *Firmicutes* were clearly reduced, while *Actinobacteria* and *Firmicutes* were notably elevated.

Alpha diversity remained lower in the placebo group, whereas in the probiotic group, a significant increase in this crucial marker was observed after 7 and subsequently 28 days of administration. Furthermore, all patients in the probiotic group exhibited a significantly higher incidence of the strains supplied with OMNi-BiOTiC® 10 AAD, including *L. plantarum*, *L. salivarius*, and the beneficial *E. faecium*. It is particularly noteworthy that not a single patient receiving probiotics developed *Clostridium difficile* infection or diarrhoea.

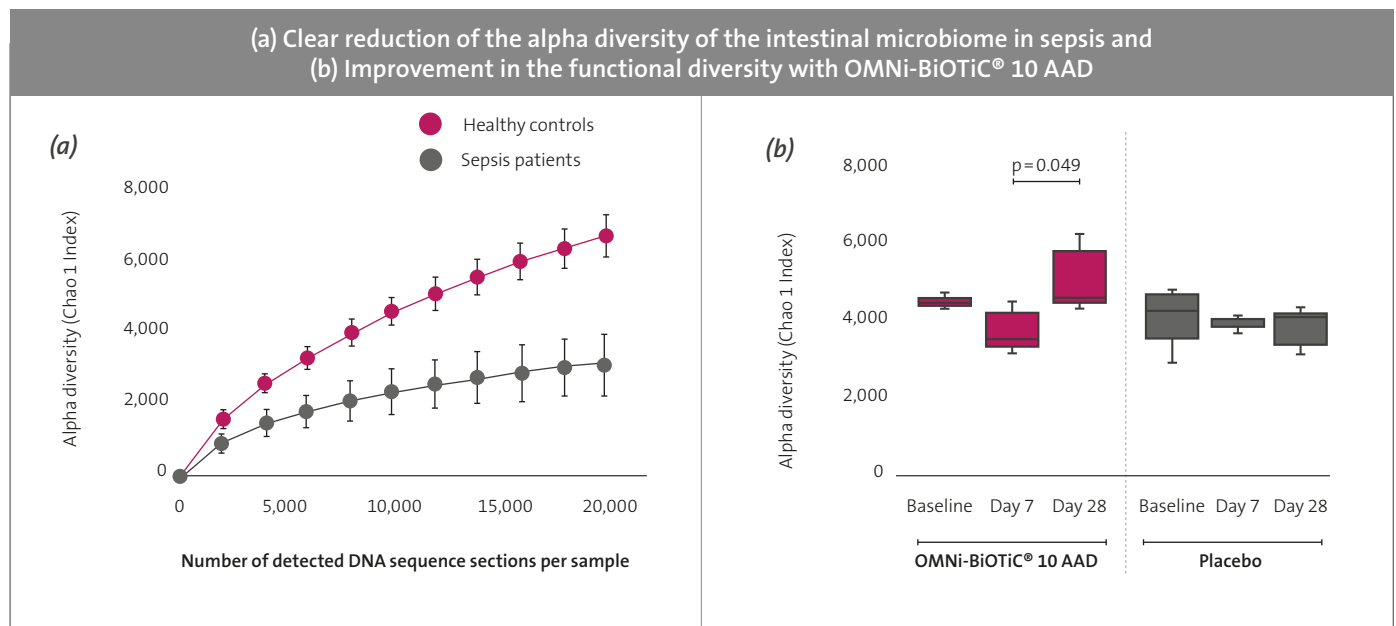


Figure: (a) Massive change in alpha diversity in sepsis patients compared to healthy controls.
(b) Positive effect on the functional alpha diversity after 7 and 28 days of the administration of probiotics.

Discussion and conclusion

This study represents the first clear demonstration that patients with early sepsis can benefit from high-quality multi-species probiotics. Regardless of the triggers for sepsis, a significant reduction in alpha diversity was observed before treatment initiation, specifically characterized by a decrease in *Bacteroidetes* and an overgrowth of facultatively pathogenic germs. The findings indicate that early inter-

vention with the high-quality multi-species probiotic OMNi-BiOTiC® 10 AAD significantly increases functional diversity and can positively modulate the microbiome. Therefore, OMNi-BiOTiC® 10 AAD holds great promise as an adjunctive treatment in addressing the structural and functional dysbiosis of early sepsis, thereby preventing further complications.

An Analysis of the Health-Promoting Potential of Postbiotic Substances from a Scientifically Tested, High-Quality Multi-Species Probiotic

Kienesberger *et al.*, *Nutrients*; 2022



Abstract

The success of scientifically tested multi-species probiotics often depends on the specific composition of selected bacterial strains. In this study, the metabolite production of bacterial strains used in OMNi-BiOTiC® 10 AAD (trade name in Germany: OMNi-BiOTiC® 10) and their positive effects on the intestinal microbiome of mice were analysed. Researchers cultured the bacterial strains contained in OMNi-BiOTiC® 10 AAD in co-culture using an in vitro approach. The supernatant of this bacterial culture, containing the metabolic products (postbiotics), was collected at different growth intervals and examined for its chemical composition, as well as its antibiotic and antifungal potential against pathogenic microorganisms.

In another set of experiments, 20 BALB/c mice were administered either the postbiotic or a sterile culture medium (control group) through their food. Stool samples from the mice were collected and analyzed before and after the intervention using 16S rRNA sequencing to identify changes in the diversity and composition of the intestinal microbiome induced by the postbiotic

Results

The postbiotic obtained from the cultivation of OMNi-BiOTiC® 10 AAD in the culture supernatant exhibited an inhibitory effect on the growth of *Listeria* and *Candida albicans*. Additionally, a total of 122 different metabolites and 34 volatile organic substances were identified, some of which could be assigned to specific strains. One particularly exciting finding was the significantly increased presence of *Faecalibacterium prausnitzii* following the administration of the postbiotic compared to the control group. Additionally, it was observed that the culture supernatant isolated after 48 hours exhibited stronger antimicrobial effects, while the postbiotic isolated after 196 hours had a greater impact on the mouse microbiome, especially in terms of the increased occurrence of *F. prausnitzii*.

The bacterial strains contained in OMNi-BiOTiC® 10 AAD produce metabolites which have a growth-inhibiting effect on various pathogens and promote the colonisation of *F. prausnitzii*.

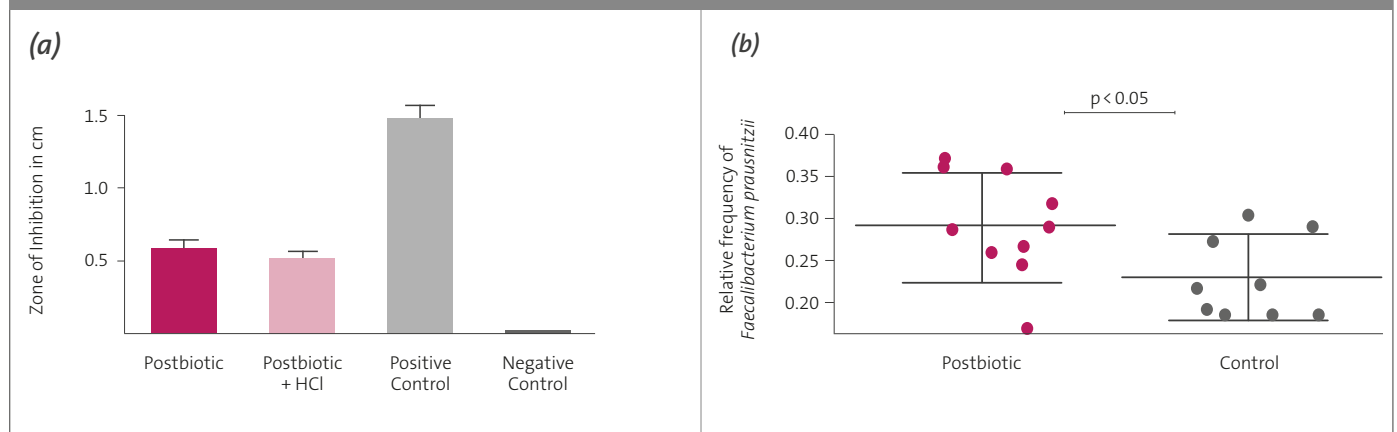


Figure: (a) Growth-inhibiting effect of probiotics on *Candida albicans*. The growth of *C. albicans* was inhibited in a petri dish experiment when the postbiotic was added, indicating an antifungal effect. (b) The intestinal microbiome of mice fed the postbiotic showed an increased abundance of *F. prausnitzii* in 16S rRNA sequencing.

Discussion and conclusion

The study clearly demonstrates the antibiotic and antifungal potential of the metabolites produced by the bacterial strains in OMNi-BiOTiC® 10 AAD. The application of the postbiotic resulted in a significant impact on the abundance of individual bacterial strains in the intestine. Particularly notable is the increased occurrence of *F. prausnitzii* compared to the control group. *F. prausnitzii* holds significant importance due to its anti-inflammatory properties and production of essential short-chain fatty acids, such as butyrate, which play

a crucial role in energizing the intestinal barrier. The positive effects of the metabolites produced by the bacterial strains in OMNi-BiOTiC® 10 AAD observed here, both in the mouse model and in vitro, underscore an essential aspect of indication-specific probiotics. Namely, the production of postbiotic substances is pivotal in combating pathogenic microorganisms and exhibits beneficial effects on the intestinal microbiome and the integrity of the intestinal barrier.

Successful Use of a Multi-Species Probiotic for Prophylaxis and Treatment of Travellers' Diarrhoea

Müller, Flugmedizin · Tropenmedizin · Reisemedizin; 2016

Abstract

Up to 50% of holidaymakers traveling abroad experience travelers' diarrhea, which can not only be unpleasant at the time but also lead to serious consequences afterward. In up to 30% of those affected, long-term gastrointestinal complaints can develop, ranging from post-infectious irritable bowel syndrome to chronic inflammatory bowel diseases. Particularly dangerous travel-related pathogens such as *Salmonella*, *Shigella*, *Listeria*, or *Campylobacter* can cause lasting damage to the intestinal mucosa and spread to other organs via the bloodstream. Selected probiotic bacterial strains have shown the ability to address the root cause of diarrhea, efficiently inhibit the growth of pathogens, and strengthen the integrity of the intestinal barrier. In this study, the effect of the indication-specific multi-species probiotic OMNi-BiOTiC® TRAVEL on the prophylaxis of travelers' diarrhea and on pre-existing gastrointestinal complaints was investigated in 264 travelers.

Results

By taking OMNi-BiOTiC® TRAVEL (1x daily 5 g with a total of 5×10^9 CFU) from the first day of the trip at the latest, travellers' diarrhoea was completely prevented in 88% of the test persons. Especially in high-risk countries like Egypt, symptoms were reduced to less than 10%.

Almost 50% of the study participants had already experienced various gastrointestinal problems before the trip, from flatulence to constipation to diarrhoea. They also benefited from taking the multi-species probiotic: 96% of these study participants experienced a noticeable improvement in their existing gastrointestinal complaints during treatment.

Significant reduction of travellers' diarrhoea and gastrointestinal complaints with OMNi-BiOTiC® TRAVEL

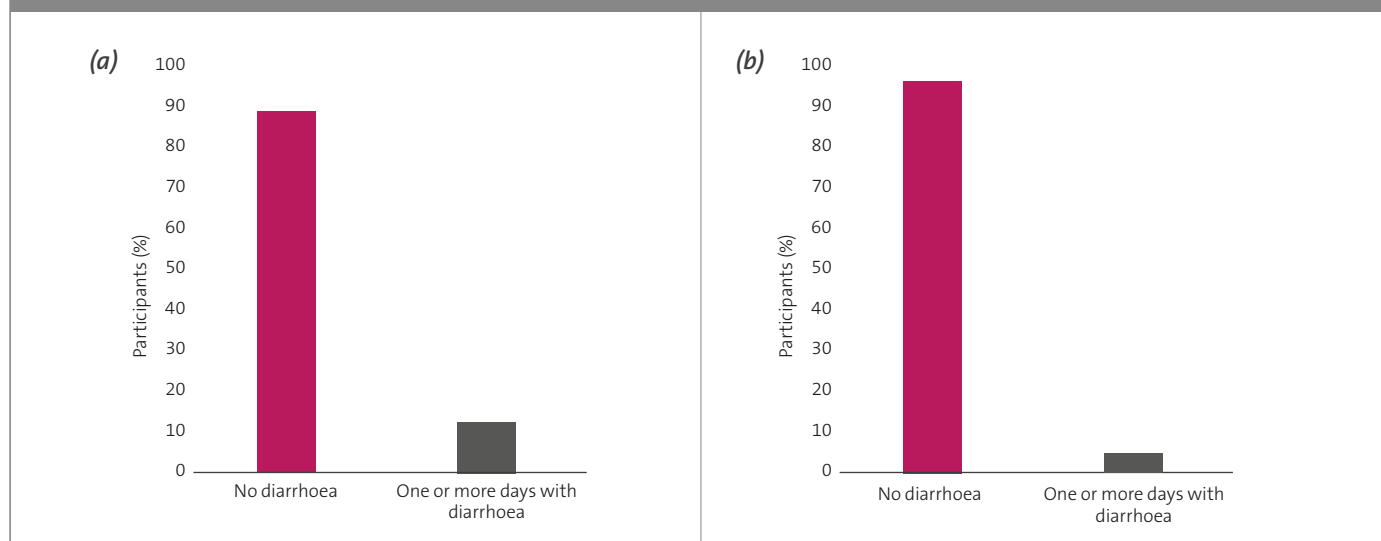


Figure: Taking the multi-species probiotic prevented the occurrence of travellers' diarrhoea in 88% of the participants. In addition, existing gastrointestinal complaints were improved in 96% of the subjects.

Discussion and conclusion

Travellers' diarrhea not only impacts short-term quality of life but can also lead to lifelong issues, as certain pathogens like *Salmonella*, *Campylobacter*, and *Shigella* can establish permanent residence in the intestinal epithelium, making them resistant to antibiotics. The indication-specific multi-species probiotic OMNi-BiOTiC® TRAVEL has proven effective in both preventing travelers' diarrhea and treating chronic digestive complaints. It is recommended as a reliable defense

against pathogenic germs, particularly prevalent in distant countries. Therefore, using a high-quality probiotic containing selected, pathogen-inhibiting bacterial strains daily during holidays, especially in southern regions, is advisable.

GASTROENTEROLOGY & HEPATOLOGY

2

BOWEL DISEASE 16–19

HELICOBACTER-PYLORI-ERADICATION-THERAPY 20

HEPATOLOGY 21–23



Personalized Treatment of Hirschsprung's Disease-Associated Enterocolitis with Probiotics

Singer *et al.*, Case Reports in Paediatrics; 2018

Abstract

Hirschsprung's disease is a congenital intestinal innervation disorder typically diagnosed in childhood due to functional obstruction. Approximately 40% of affected individuals experience Hirschsprung's associated enterocolitis (HAEC), clinically characterized by diarrhea, fever, and potentially leading to septic shock, yet its pathogenesis remains incompletely understood.

Scientific research has revealed that patients with Hirschsprung's disease and HAEC often exhibit a reduced intestinal microbiome. Moreover, studies have demonstrated that the use of probiotics can decrease the incidence and severity of HAEC. However, evidence regarding changes in the intestinal microbiome during HAEC episodes and symptom-free periods has been lacking.

Therefore, Singer *et al.* conducted a study to analyze the intestinal microbiome of a three-year-old patient with Hirschsprung's disease during episodes with and without enterocolitis, as well as over a three-month period of daily intake of the multi-species probiotics OMNi-BiOTiC® PANDA (3g, totaling 3×10^9 CFU) and OMNi-BiOTiC® 10 AAD (5g, totaling 5×10^9 CFU).

Results

Stool samples collected during three symptom-free periods and three HAEC episodes underwent analysis to identify differences in the composition of the intestinal microbiome using next-generation sequencing. Significant disparities in beta diversity were observed between healthy and HAEC episodes ($p=0.009$). Taxonomic analysis revealed dysbiosis characterized by a notable decrease in the relative abundance of *Actinobacteria* and a significant increase in *Bacteroidetes*, *Proteobacteria* and *Cyanobacteria* in stool samples during HAEC episodes ($p < 0.05$).

Over the three-month period of administering OMNi-BiOTiC® PANDA and OMNi-BiOTiC® 10 AAD, six stool samples were collected during diarrhea episodes and eight during symptom-free periods. Probiotic intake led to the stabilization of the intestinal microbiome and a significant increase in alpha diversity irrespective of the episode ($p < 0.05$). Specifically, there was a significant rise in bacteria of the genus *Bifidobacterium* and *Streptococcus* with probiotic treatment ($p < 0.05$).

Furthermore, the probiotic intervention resulted in a reduced occurrence of *Rikenellaceae*, *Pseudobutyrvibrio*, *Blautia* and *Lachnospiraceae* ($p < 0.05$). Notably, probiotic administration correlated with a decrease in the number of days with HAEC episodes, indicating a positive therapeutic effect.

Pro-inflammatory shift of the intestinal microbiome during HAEC episodes

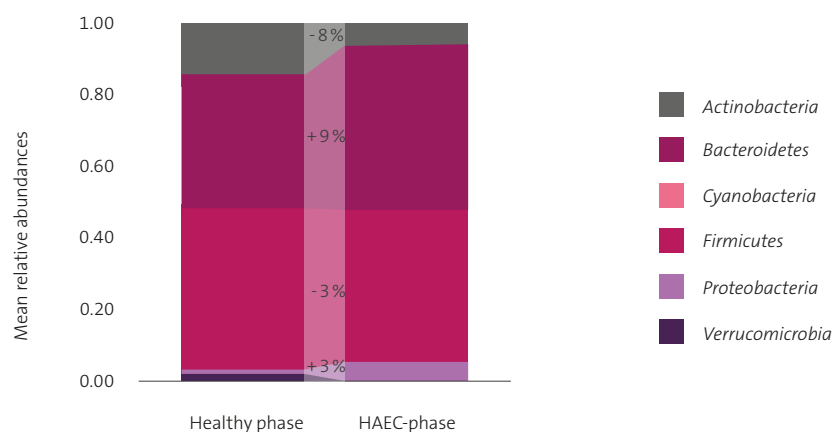


Figure: Compared to the symptom-free phase (= healthy phase) of Hirschsprung's disease, in the HAEC episodes patients showed changes in the composition of the intestinal microbiome, which are typical signs of intestinal dysbiosis.

Stabilization of the intestinal microbiome by OMNi-BiOTiC® PANDA and OMNi-BiOTiC® 10 AAD

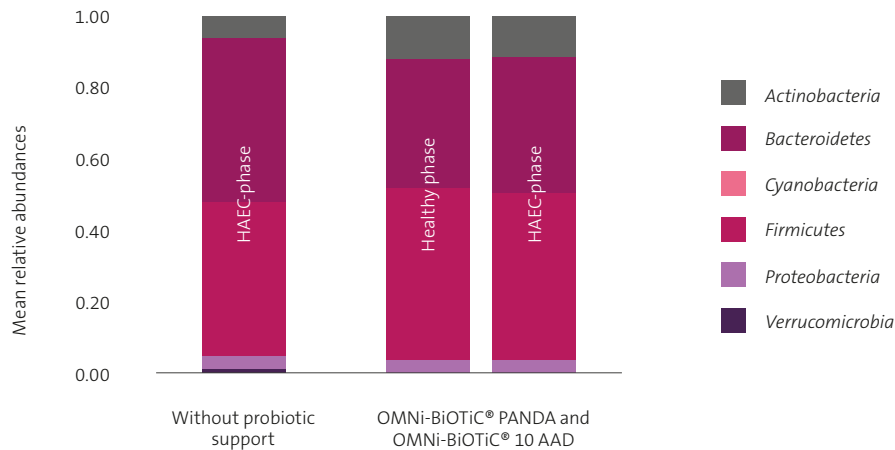


Figure: The administration of the multi-species probiotics lead to an improvement of the intestinal composition of the microbiome during HAEC phases.

Discussion and conclusion

Recent research highlights the significant role of a damaged intestinal barrier (leaky gut), adverse alterations in the gut microbiome, elevated inflammatory parameters, and infections with pathogenic germs like *Clostridium difficile* in the pathogenesis of Hirschsprung's disease-associated enterocolitis (HAEC).

This case study presents groundbreaking evidence demonstrating substantial changes in the gut microbiome during HAEC episodes for the first time. Furthermore, the administration of OMNi-BiOTiC® PANDA and OMNi-BiOTiC® 10 AAD proved to be effective during post-operative HAEC phases. This effectiveness was manifested through

the stabilization of the intestinal microbiome composition and a reduction in the frequency of HAEC episodes.

These findings underscore the therapeutic potential of probiotics in managing HAEC and suggest their utility in restoring gut health and mitigating disease severity in Hirschsprung's disease patients. Further research in larger cohorts is warranted to validate these results and explore the long-term benefits of probiotic interventions in HAEC management.

The Effect of a Multi-Species Probiotic on the Gastrointestinal Immune System and the Microbiome in Patients with the Diarrhoea-Type of irritable Bowel Syndrome

Moser *et al.*, European Journal of Nutrition; 2018

Abstract

Irritable bowel syndrome (IBS) is a functional disorder of the gastrointestinal tract. The global incidence of this condition is estimated to be between 10% and 20%, depending on diagnostic criteria and geographical region. Studies have demonstrated biochemical changes that explain the occurrence of symptoms. Inflammation of the intestinal mucosa is a typical characteristic of IBS. It is assumed that this inflammatory response is linked to changes and a reduction in the diversity of the intestinal microbiome.

This study analysed the positive effects of a multi-species probiotic (trade names: OMNi-BiOTiC® STRESS Repair (AT) and OMNi-BiOTiC® SR-9 (DE)) on the gastrointestinal microbiome and mucosa-associated immune cells, as well as the production of short-chain fatty acids in patients with the diarrhoea-predominant type of irritable bowel syndrome after four weeks of treatment. What distinguished this study was the analysis of both stool samples and the intestinal mucosa, achieved through endoscopies and biopsies.

Results

After a four-week treatment with OMNi-BiOTiC® STRESS Repair / SR-9 (3 g twice daily, totaling 15×10^9 CFUs), next-generation sequencing (NGS) revealed significantly improved bacterial diversity in biopsies of the stomach and small intestine mucosa ($p=0.008$ and $p=0.025$, respectively).

Compared to the start of treatment, biopsies of the ascending colon showed a significant reduction in CD4⁺ immune cells ($p=0.042$) following the administration of probiotics. Interactions between the microbiome and the immune system can lead to excessive reactions such as intestinal hypersensitivity and pain. It is already known from numerous studies that reduced diversity in the microbiome can influence the onset of pain and anxiety.

The analysis of stool samples using mass spectrometry displayed significantly elevated concentrations of the short-chain fatty acids butyrate and acetate after four weeks of probiotic treatment. Additionally, there was a significant decrease in faecal zonulin concentration (an important marker of leaky gut) compared to the start of treatment, indicating an improvement in intestinal barrier function ($p < 0.035$). Moreover, after four weeks of probiotic intake, the severity of the disease was significantly reduced compared to the start of treatment ($p=0.002$), as assessed using the IBS-SSS questionnaire to determine the severity of irritable bowel syndrome.

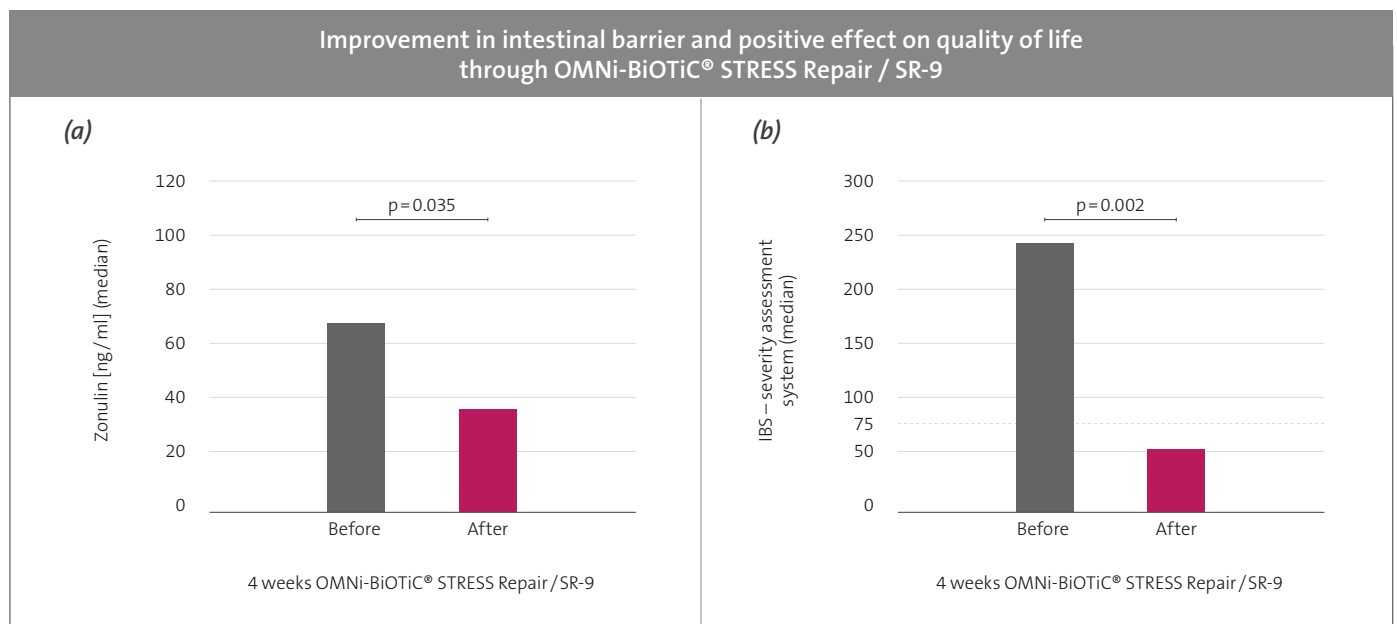


Figure: (a) Significant reduction in zonulin concentration in the stool after four weeks of probiotic treatment.

(b) The probiotic led to a significant reduction in the severity of IBS in a range of only minimal symptom manifestation (score < 75).

OMNi-BiOTiC® STRESS Repair / SR-9 has a positive effect on the metabolic activity of the intestinal microbiome

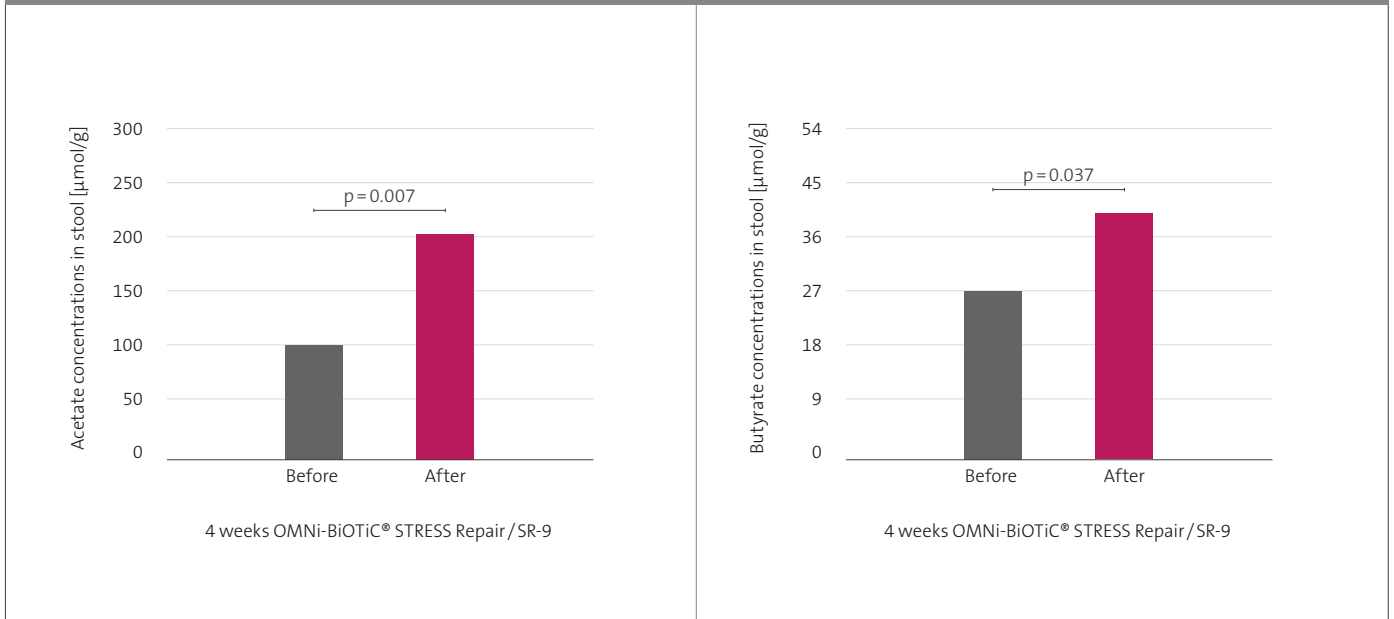


Figure: In comparison to the start of treatment, significantly increased production of the short-chain fatty acids butyrate and acetate was detected after four weeks of probiotics.

Discussion and conclusion

Irritable bowel syndrome (IBS) is one of the most prevalent gastrointestinal disorders, significantly impairing the quality of life for those affected. Increased mucosal inflammation is crucial in the pathogenesis of IBS, leading to disruptions in the mucosal barrier function. Scientific research has demonstrated that administering specific multi-species probiotics can restore the intestinal barrier and reduce inflammatory reactions

This pilot study showed that the administration of the multi-species probiotic OMNi-BiOTiC® STRESS Repair / SR-9 had a positive effect on the diversity of the mucosal microbiome of the upper gastrointestinal tract in IBS patients. In addition, there was an improvement in immune function, demonstrated by the reduction in mucosal

CD4⁺ T cells. The four-week treatment with probiotics also showed a positive influence on intestinal barrier function, evidenced by the significant reduction in the concentration of zonulin in the patients' stool. Furthermore, probiotic intake resulted in increased metabolic activity within the microbiome, particularly elevating levels of butyrate and acetate. These short-chain fatty acids are crucial for reducing inflammation and maintaining the health of the large intestine. Moreover, the administration of probiotics resulted in a significant reduction in the severity of IBS symptoms, thereby improving the patients' quality of life.

Probiotics Increase the Efficacy and Reduce Severe Side Effects of *Helicobacter-Pylori*-Eradication-Therapy

Deza *et al.*, The American Journal of Gastroenterology; 2025

Abstract

Almost half of the world's population is infected with *Helicobacter pylori* (HP), but in around 80% of those affected, the infection is asymptomatic. An HP infection is the most common cause of chronic gastritis and is also a causal factor for serious complications such as gastric carcinomas, ulcers in the stomach and duodenum (Malfert-heiner 2017) or gastric lymphomas. The treatment of HP has so far been based on a combination of strong acid inhibition, the use of several antibiotics and, in the case of quadruple therapy, the addition of bismuth. The present study is a non-interventional, prospective study presenting the results of the European Registry on *Helicobacter pylori* Management. In particular, the influence of probiotics on the efficacy and tolerability of HP therapies was investigated. A total of 36,699 treatments were recorded, of which 8,233 patients (22%) were prescribed a probiotic in addition to conventional therapy. The remaining patients were used as a control group.

Results

The present study impressively shows that the additional administration of probiotics in *Helicobacter pylori* therapies leads to a significantly higher eradication rate overall compared to the control group without probiotics (91% vs. 86%, $p < 0.0001$). Looking at the individual treatment regimens, triple therapy (89% vs. 83%, $p < 0.0001$), quadruple therapy (93% vs. 89%, $p < 0.0009$), bismuth quadruple therapy (91% vs. 86%, $p < 0.0001$) and sequential therapies (91% vs. 78%, $p < 0.0001$) showed a significant increase in the eradication rate when probiotics were added. Further impressive findings concern the occurrence of side effects: The incidence rate of severe side effects was significantly lower in the probiotics group compared to the control group (1.06% vs. 1.90%, $p < 0.0001$). The average duration of adverse events was also significantly shortened by the use of probiotics (6.41 vs. 8.17 days, $p < 0.0001$). The administration of lactobacilli in particular was associated with a higher efficacy of triple therapy and bismuth quadruple therapy, and the administration of bifidobacteria in particular resulted in fewer severe side effects.

The additional administration of probiotics significantly improves the effect and tolerability of *Helicobacter-pylori*-eradication-therapy

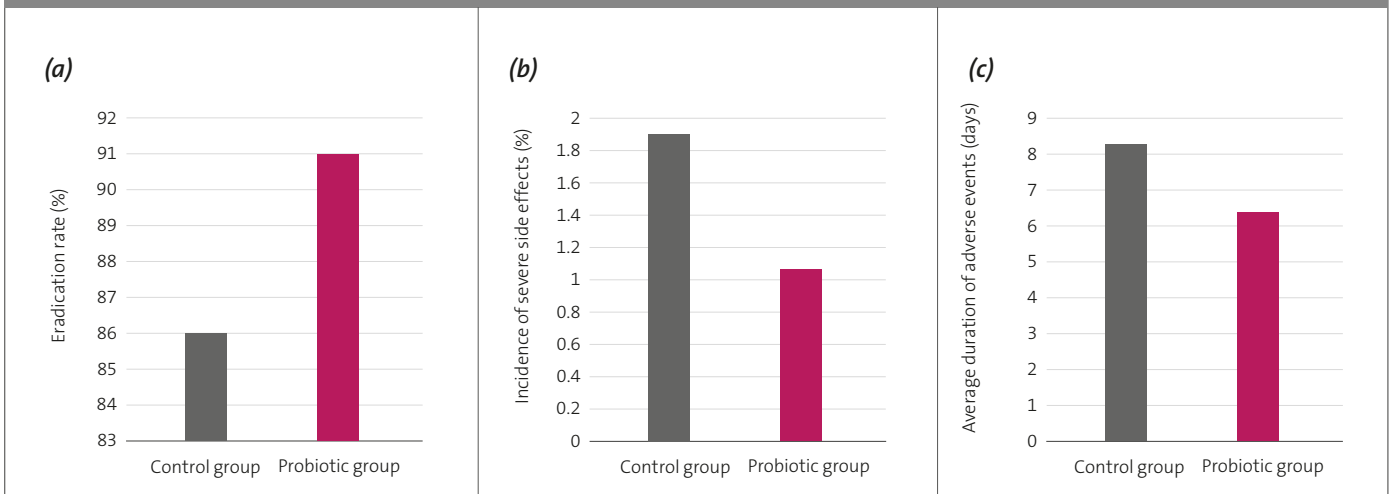


Figure: The use of probiotics in *Helicobacter pylori* therapies led to (a) a significantly higher eradication rate ($p < 0.0001$), (b) a significantly lower incidence of severe side effects ($p < 0.0001$) and (c) a significantly lower average duration of adverse events ($p < 0.0001$).

Discussion and conclusion

With a prevalence of around 50% worldwide, *Helicobacter pylori* is one of the most common bacterial infections, causing a range of gastric diseases such as chronic gastritis, gastric ulcers and even gastric cancer. Due to geographical differences in antibiotic resistance, no universally effective treatment regimen (with an eradication rate of at least 90%) has yet been established worldwide. Increasing clarithromycin resistance in particular reduces the

effectiveness of eradication therapies. However, the results of this study clearly show that the additional administration of probiotics significantly improves both the efficacy and tolerability of various treatment regimens. The problem of increasing antibiotic resistance and the frequency of side effects caused by taking antibiotics can therefore be effectively counteracted by the use of medically relevant probiotics.

The Influence of a Multi-Species Probiotic on Liver Function and the Lipid Profile in Rats

Skrypnik *et al.*, Acta Sci. Pol. Technol. Aliment.; 2018

Abstract

The intestinal microbiome plays a crucial role in nutrient metabolism by fermenting undigested carbohydrates, bile acids, and sterols, and synthesising hormones responsible for fat storage. It has been demonstrated that the intestinal microbiome increases the risk of cardiovascular diseases, and 'leaky gut' syndrome is a significant factor in the onset of non-alcoholic fatty liver disease, one of the most common liver diseases in obese patients. Therefore, the optimal composition of the intestinal microbiome is essential for protecting against cardiovascular diseases and maintaining liver function. Alongside high LDL (low-density lipoprotein) and low HDL (high-density lipoprotein) serum concentrations, triglycerides (TG) have emerged as a new target in the treatment and prevention of cardiovascular diseases. A high serum concentration of alanine aminotransferase (ALT) is a reliable marker in this regard. Probiotics have been shown to lower LDL and overall cholesterol concentrations in the blood, but their effect on TG and ALT has not yet been investigated. In the study by Skrypnik *et al.*,

the influence of the multi-species probiotic OMNi-BiOTiC® *METAtox* / OMNi-BiOTiC® *HETOX light* in two different doses (low-dose: 1 g with a total of 2.5×10^9 Colony Forming Units (CFU) per day and high-dose: 4 g with a total of 1×10^{10} CFU per day) was analysed in terms of changes in body weight, liver function, and lipid profile in 30 Wistar rats.

Results

After six weeks of treatment with probiotics, a significantly reduced liver weight was observed in both the high and low-dose probiotic groups compared to the control group. Additionally, significantly reduced alanine aminotransferase (ALT) and triglyceride (TG) concentrations in serum were observed in the high-dose probiotic group compared to the control group.

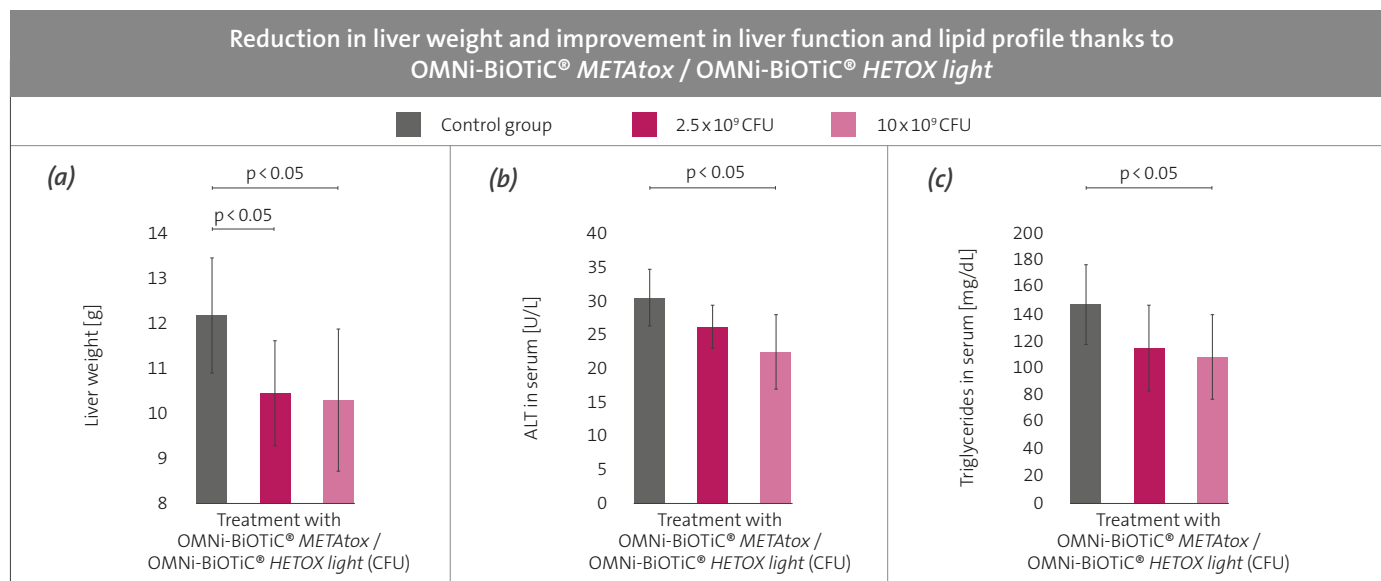


Figure: (a) Significant reduction in liver weight in both the high-dose and the low-dose OMNi-BiOTiC® *METAtox* / OMNi-BiOTiC® *HETOX light* group in comparison to the placebo group. (b) The ALT serum concentration was significantly reduced through the probiotic treatment in comparison to the placebo group. (c) The serum concentration of triglycerides was significantly reduced by the high dose (4 g) of the probiotic.

Discussion and conclusion

An enlarged liver not resulting from alcohol consumption is caused by oxidative stress and increased lipid accumulation in the liver. Non-alcoholic fatty liver disease (NAFLD) is associated with conditions such as type 2 diabetes mellitus, obesity, and metabolic syndrome, all of which are linked to an elevated risk of cardiovascular diseases. The results of this study indicate that supplementation with a multi-species probiotic mixture demonstrated a favorable, dose-dependent effect on liver function (lower serum ALT concentration) and lipid profile (lower serum TG concentration). Furthermore, the detection of low TG serum concentrations in the high-dose

probiotic group suggests that therapeutic intervention with probiotics may positively influence cardiovascular impairments and have cardioprotective effects. Overall, the six-week treatment with the multi-species probiotic OMNi-BiOTiC® *METAtox* / OMNi-BiOTiC® *HETOX light* had a dose-dependent, positive influence on liver function and lipid profiles in rats. Given the positive effect on blood concentrations of alanine transaminase and triglycerides, it can be concluded that treatment with a specific multi-species probiotic has beneficial effects on cardiovascular factors.

Effects of a Multi-Species Probiotic on innate Immune Function, Bacterial Translocation, and Intestinal Permeability in Patients with Liver Cirrhosis

Horvath *et al.*, *Aliment Pharmacol Ther*; 2016



Abstract

Liver cirrhosis is the final stage of chronic liver disease and is now one of the leading causes of death worldwide. The immune system of patients with liver cirrhosis is severely impaired, leading to increased susceptibility to infections. A damaged intestinal barrier (leaky gut) results in increased translocation of pathogenic microorganisms and endotoxins. Additionally, the composition of the intestinal microbiome is significantly disrupted in liver cirrhosis patients. Therefore, targeted positive modulation of the gut microbiome is an alternative approach to strengthen the gut barrier and counteract the endotoxin burden. In this randomised, double-blind, placebo-controlled study, the effect of a specially developed multi-species probiotic (OMNi-BiOTiC® HETOX) on 101 patients with compensated liver cirrhosis (Child-Pugh Score < 12) was investigated over an intervention period of six months and a further six-month follow-up.

Results

The six-month administration of OMNi-BiOTiC® HETOX (6g daily with a total of 1.5×10^{10} CFU) resulted in a significant improvement in liver function as measured by common liver function scores (Child-Pugh and MELD) compared to the placebo group, despite the probiotics group having significantly worse liver function at the beginning of the study. Macrophage activity (measured by neopterin in serum) showed a significant improvement after probiotic administration, with pathogenic germs being increasingly eradicated. Additionally, a significantly increased oxidative burst was detected with the administration of OMNi-BiOTiC® HETOX.

This positive immunological activity explains the reduced infection rate in the probiotics group (15 vs. 28 in the placebo group) during the intervention period. Compliance was excellent in the probiotics group (98.9% of doses were taken), and no other interactions with medication were documented. The significantly different drop-out rate between the probiotic group (n=1) and the placebo group (n=11) suggests a reduction of endotoxins by the probiotic.

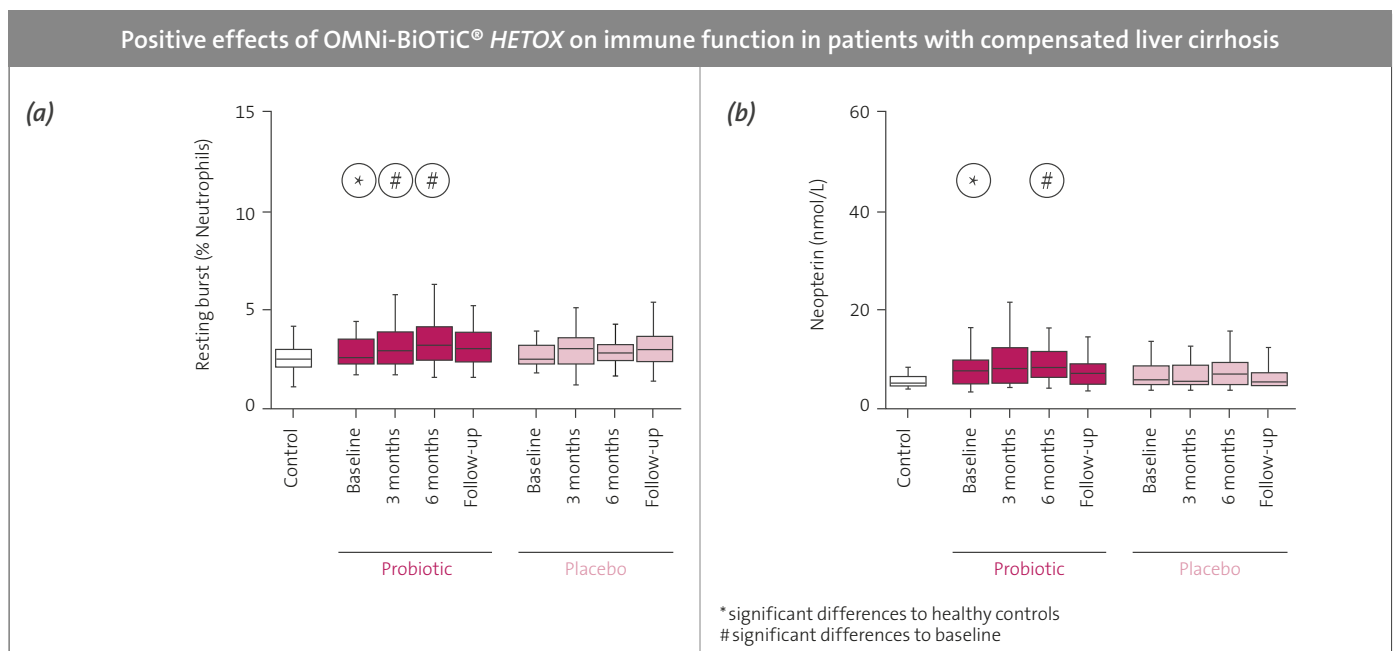


Figure: The 6-month administration of OMNi-BiOTiC® HETOX leads to a significant increase in neutrophil activity (a) and a significant increase in neopterin (b) compared to the baseline.

Discussion and conclusion

Overall, OMNi-BiOTiC® HETOX proved to be extremely effective in this high-risk patient group. Susceptibility to infections, which is common in patients with liver dysfunction, was reduced through improved immune function, as evidenced by increased serum neopterin levels and enhanced neutrophil resting burst activity. Most impor-

tantly, liver function was significantly improved according to common liver function scores. Therefore, for the first time, stabilization or improvement of liver function in patients with liver cirrhosis can be achieved without transplantation but with a multi-species probiotic.

Positive Modulation of the Intestinal Microbiome by a Multi-Species Probiotic in Liver Cirrhosis



Horvath et al., *Nutrients*; 2020 Jun; 12(6): 1874.

Abstract

Recent research indicates that liver cirrhosis is associated with dysbiotic changes in the intestinal microbiome. This dysbiosis results in an increase in potentially pathogenic microbes and a reduction in commensal bacteria, leading to impaired intestinal barrier function and increased systemic bacterial toxin levels (endotoxemia). The targeted enhancement of the intestinal microbiota through the administration of medically relevant multi-species probiotics can help alleviate liver stress by restoring the intestinal barrier and reducing pathogen load. This study investigates, for the first time, the positive effects of OMNi-BiOTiC® HETOX on the intestinal microbiome of patients with liver cirrhosis.

Results

In this study, a six-month regimen of OMNi-BiOTiC® HETOX (6 g per day, totaling 1.5×10^{10} CFU) was shown to positively alter the microbiome of patients with compensated liver cirrhosis. Specifically, the relative abundance of the butyrate-producing bacterium *Fae-*

calibacterium prausnitzii increased significantly compared to the placebo group, doubling in abundance and remaining elevated even six months after the cessation of probiotics. Additionally, the administration of this probiotic led to increases in the bacterial strains *Syntrophococcus sucromutans* and *Alistipes shahii*, both of which are capable of supplying the body with beneficial short-chain fatty acids (SCFAs).

Of particular interest is the finding that an increased abundance of *Prevotella sp.* and *Syntrophococcus sucromutans* was correlated with improved intestinal barrier function. This improvement was measured by a reduction in zonulin levels, the primary marker for leaky gut ($p=0.042$).

An increased abundance of *Alistipes shahii* is associated with elevated levels of neopterin, a crucial marker for the activation of cellular immune defense ($p=0.041$). Patients with liver cirrhosis often exhibit reduced neopterin levels, which are linked to a weakened immune system.

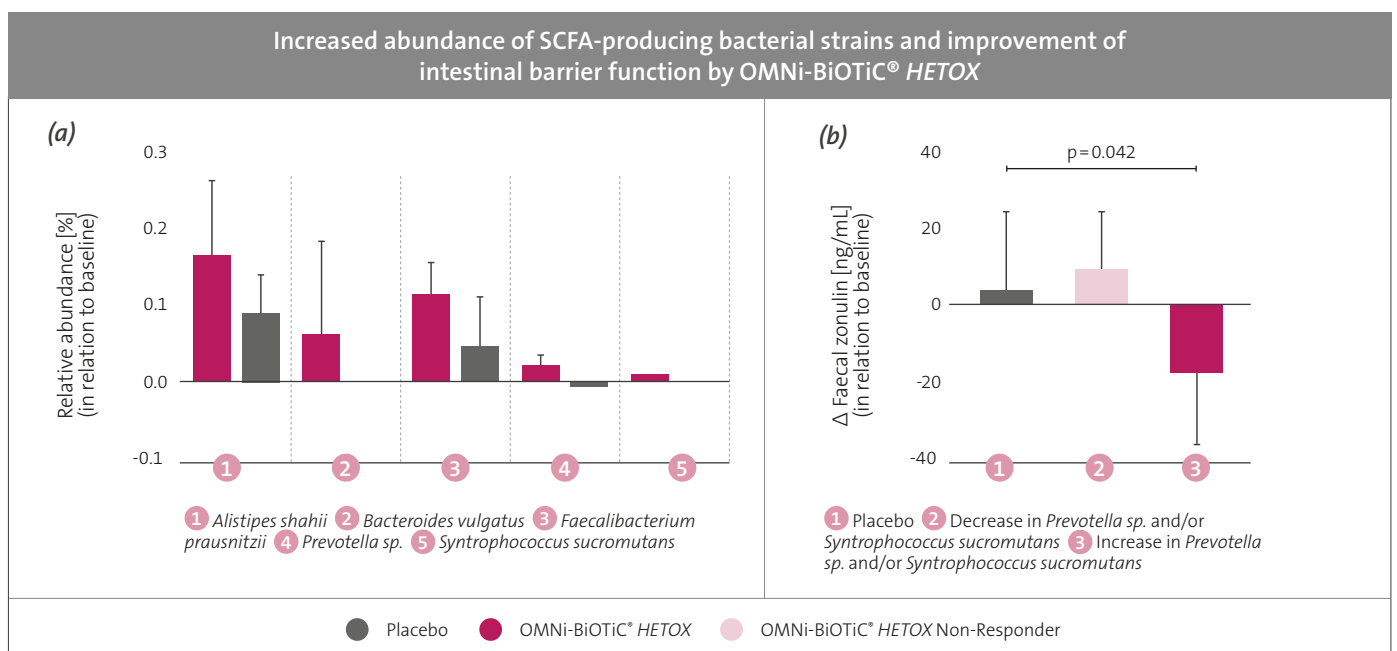


Figure: (a) 6 months of intake of OMNi-BiOTiC® HETOX led to significant increases in anti-inflammatory, SCFA-producing bacterial strains. (b) The increases in *Prevotella sp.* and *Syntrophococcus sucromutans* also correlated with significant improvement in intestinal barrier function, as measured by the reduction in the leaky-gut marker zonulin.

Discussion and conclusion

The present study offers conclusive evidence supporting the successful use of the multi-species probiotic OMNi-BiOTiC® HETOX in positively modulating the microbiome of liver cirrhosis patients. The positive changes in the intestinal microbiome were associated with activation of the immune system and improvement of the intestinal

barrier function. A previous study had already demonstrated the positive effect of the multi-species probiotic OMNi-BiOTiC® HETOX on susceptibility to infections, often seen in patients with hepatic dysfunction (Horvath *et al.* 2016).

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Successful Use of a Multi-Species Probiotic to Reduce Adverse Effects of Colonoscopy



Labenz *et al.*, *Frontiers in Oncology*; 2022

Abstract

Colonoscopy is considered the most critical medical examination for the prevention and early detection of colon cancer. The effectiveness of this procedure relies heavily on thorough bowel cleansing using an oral lavage solution. However, this solution not only removes fecal matter but also strips away mucus and beneficial intestinal bacteria. This process significantly alters the diversity and composition of the intestinal microbiome and is often associated with gastrointestinal symptoms. In this prospective, multicenter, randomized, double-blind, placebo-controlled study, the effect on the duration and intensity of side effects, as well as changes in microbial diversity, was examined using an indication-specific multi-species probiotic (OMNi-BiOTiC® COLONIZE) in 91 healthy volunteers following a colonoscopy

Results

A four-week regimen of the specially developed multi-species probiotic (2x daily, 3 g, 18×10^9 CFU total), starting immediately after colonoscopy, resulted in a significantly greater increase in the alpha diversity (Delta-Shannon-Index) of the intestinal microbiome compared to the placebo ($p = 0.036$). Notably, there was a significant increase in the abundance of *Enterococcus faecium*, a component of the probiotic, in the stool samples of the treatment group ($p < 0.05$). Additionally, participants taking the probiotic experienced significantly fewer days of constipation (Bristol stool scale 1–2) ($p = 0.044$). Moreover, the probiotic group reported fewer days with gastrointestinal issues, including diarrhea and flatulence.

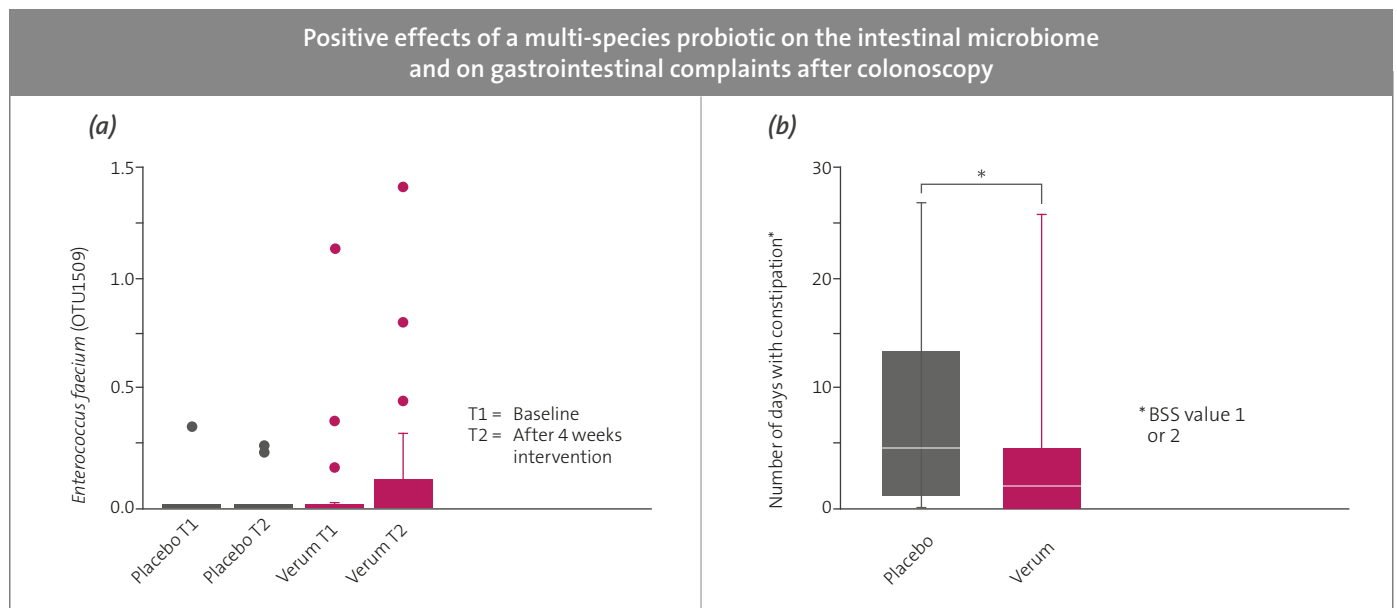


Figure: (a) The relative abundance of *Enterococcus faecium* was significantly increased after 4 weeks of probiotic intervention. (b) The intake of the medically relevant probiotic led to a significant reduction in days with constipation.

Discussion and conclusion

Colonoscopy is a crucial preventive examination for maintaining intestinal health and early detection of abnormal tissue changes. Despite being a routine procedure, many people avoid it due to potential gastrointestinal discomfort that often follows the examination. This study demonstrates that administering a specially formulated multi-species probiotic for four weeks after bowel lavage can significantly reduce post-interventional bowel symptoms. Additionally, taking these selected probiotic bacterial strains prevents colonization by pathogenic germs during this vulnerable period and positively influ-

ences the gut microbiome. These findings offer substantial potential to increase general acceptance of this vital check-up, which can lead to early detection and removal of precancerous polyps or abnormal tissue changes, thereby reducing the risk of bowel cancer.

Positive Effect of a Multi-Species Probiotic on Chemotherapy-Associated Side Effects



Obermüller *et al.*, *Nutrients*; 2023

Abstract

Chemotherapy is a crucial element of cancer treatment, yet it negatively impacts the intestinal epithelium, protective mucosa, and the intestinal microbiome. As a result, 50–80% of patients experience severe side effects, such as intestinal mucositis, nausea, vomiting, and diarrhea. Additionally, chemotherapy-induced cachexia, characterized by significant weight loss, is commonly observed. These side effects not only diminish patient's quality of life but can also necessitate the reduction or discontinuation of chemotherapy, thereby significantly increasing mortality. Intestinal mucositis primarily arises from inflammation of the intestinal wall and disruption of the intestinal barrier, leading to bacterial translocation and systemic inflammation. Positively influencing the gut microbiome can mitigate these adverse effects on the body.

In this study, we investigated the effects of the medically relevant multi-species probiotic OMNi-BiOTiC® 10 AAD (trade name in Germany: OMNi-BiOTiC® 10) during chemotherapy in a mouse model. Twenty-four mice received either the probiotic or water daily for four weeks. In the fourth week, the cytostatic drug cyclophosphamide (10

mg/ml, intraperitoneally) was also administered. Body weight, white adipose tissue, inflammatory parameters, gut microbiome, and gut permeability were analyzed at baseline and after four weeks of intervention.

Results

Administration of OMNi-BiOTiC® 10 AAD (1x daily, 1.2×10^9 CFU) significantly alleviated chemotherapy-associated cachexia. Mice in the probiotic group experienced less weight loss and better preservation of white adipose tissue compared to the control group. The multi-species probiotic also reduced inflammatory foci on the intestinal wall and significantly improved intestinal permeability. Microbiome analyses revealed an enhancement in beta diversity in the probiotics group. Notably, the intake of OMNi-BiOTiC® 10 AAD led to a significant reduction in systemic inflammation, as evidenced by decreased levels of proinflammatory cytokines in the blood.

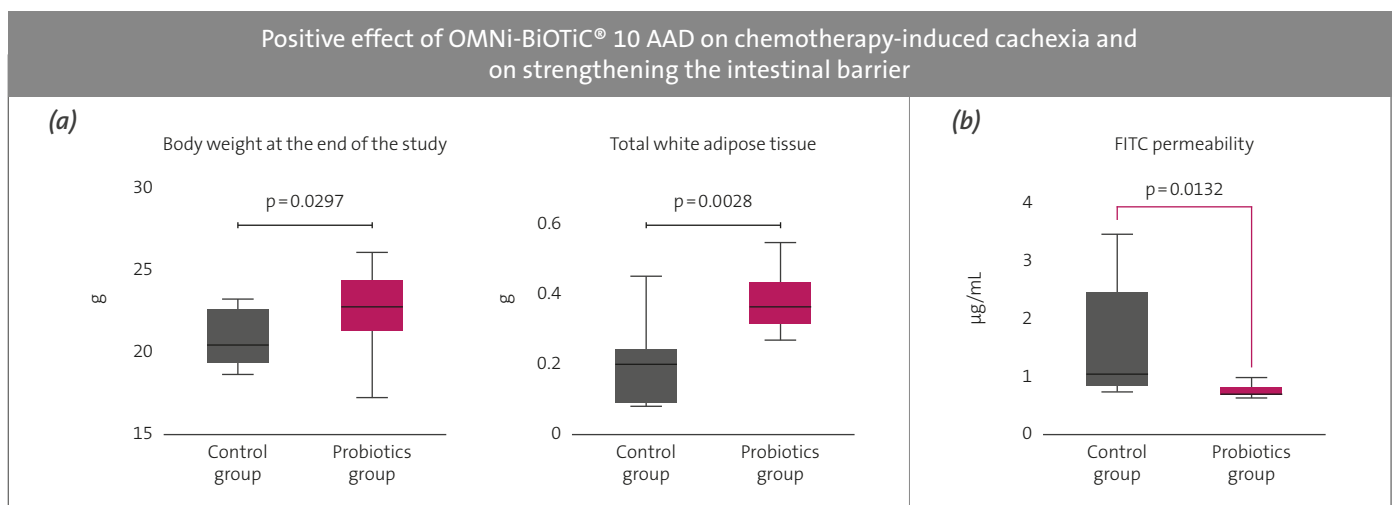


Figure: (a) The administration of OMNi-BiOTiC® 10 AAD leads to a significant reduction in chemotherapy-induced loss of body weight and fat tissue shrinkage. (b) Intestinal permeability was significantly reduced by the probiotics administered simultaneously with chemotherapy.

Discussion and conclusion

This study demonstrates that administering the multi-species probiotic OMNi-BiOTiC® 10 AAD effectively mitigates cyclophosphamide-induced cachexia. By positively modulating the intestinal microbiome and enhancing beta diversity, the probiotic significantly reduces intestinal wall inflammation and improves intestinal permeability, leading to a marked decrease in systemic inflammation. Consequently, using this medically relevant multi-species probiotic can contribute to a more optimal course of therapy and improved

quality of life. In summary, these impressive results support the potential for indication-specific formulated probiotics to become a standard adjunctive therapy in chemotherapy.

The Positive Influence of a Multi-Strain Probiotic on the Vaginal Microbiome of Women with Breast Carcinoma during Chemotherapy

Marschalek *et al.*, *Breast Care*; 2017



Abstract

During the treatment of gynecological tumors, chemotherapy and anti-estrogen therapy can induce urogenital syndrome, characterized by a deficiency of *Lactobacilli*. Although vaginal estrogen therapy can inhibit the colonization of pathogenic *Escherichia coli* and boost *Lactobacilli* levels, its application is frequently restricted in breast cancer patients because their tumors are hormone-sensitive. In recent years, medically relevant probiotics have gained importance in both gynecological and oncological therapy. This randomized, double-blind, placebo-controlled study analyzed the effects of the multi-strain probiotic OMNi-BiOTiC® FLORA plus on bacterial dysbiosis in breast cancer patients.

Results

The study demonstrated that the positive modulation of the vaginal microbiome through the administration of OMNi-BiOTiC® FLORA plus (2x2g daily, totaling 1×10^{10} CFUs) is a safe and effective treatment option for bacterial dysbiosis and urinary tract infections in breast cancer patients with urogenital syndrome. The administration of four *Lactobacillus* strains (*Lactobacillus crispatus* LBV88, *Lactobacillus rhamnosus* LBV96, *Lactobacillus gasseri* LBV150N, and *Lactobacillus jensenii* LBV116) during chemotherapy resulted in a significant improvement in the Nugent score, which evaluates vaginal dysbiosis, within just two weeks. Conversely, patients who received the placebo experienced a significant worsening of their condition after two weeks.

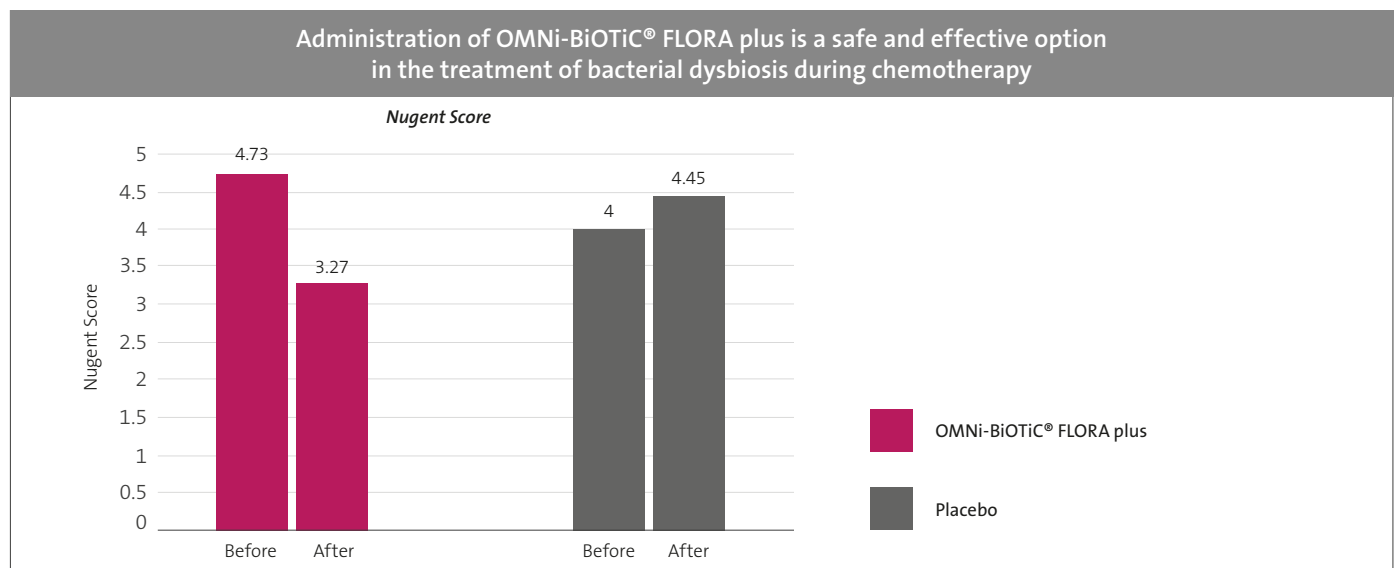


Figure: While the combination of four *Lactobacillus* strains leads to a significant improvement in the Nugent score, the scores in the placebo group deteriorate despite better baseline values.

Discussion and conclusion

A healthy vaginal microbiome, dominated by *Lactobacilli*, plays a crucial role in regulating the immune response and protecting against vaginal infections. A reduction in *Lactobacilli* in the vaginal microbiome is considered a pathological condition. This study demonstrated that oral administration of the multi-strain probiotic OMNi-BiOTiC® FLORA plus significantly improved the dysbiotic vaginal microbiome in postmenopausal breast cancer patients, as measured by the Nugent score. This treatment is especially advantageous

for patients with hormone-sensitive tumors, as it stabilizes the vaginal microbiome, reducing the risk of bacterial vaginosis and urinary tract infections, and thereby enhancing their quality of life.

The Positive Effect of a Multi-Strain Probiotic in Surgical Patients with Antibiotics



Rabl, Wiener klinisches Magazin; 2022

Abstract

Antibiotic-associated diarrhea (AAD) is a common and often limiting complication of antibiotic therapy in clinical practice. Up to 49% of patients may develop AAD, with up to 25% of these cases progressing to severe forms such as *Clostridium difficile* associated diarrhea (CDAD) or infection. Cytostatic drugs can also induce diarrhea by damaging the intestinal epithelium and protective mucosa, negatively impacting the intestinal microbiome. The timely administration of the medically relevant multi-species probiotic OMNi-BiOTiC® 10 AAD (German trade name: OMNi-BiOTiC® 10) from the first day of antibiotic treatment can protect the intestinal mucosa and inhibit the growth and toxin release of *C. difficile*, thereby preventing both AAD and CDAD. This study analyzed the positive effects of OMNi-BiOTiC® 10 AAD in 54 surgical patients, including 9 oncological patients, who received the probiotic alongside perioperative antibiotic administration.

Results

Patients were administered OMNi-BiOTiC® 10 AAD twice daily (totaling 1×10^{10} CFU) alongside their antibiotic or cytostatic therapy. This probiotic significantly reduced the incidence of antibiotic-associated diarrhea (AAD) to 5.5%, compared to a general incidence of 25% with similar medications. Furthermore, stool consistency improved in over 50% of patients with pre-existing diarrhea, as assessed by the Bristol Stool Scale. Among oncology patients receiving both chemotherapy and antibiotics, the results were even more striking: none of the patients developed diarrhea, despite the typically high prevalence of up to 60% for diarrhea with similar chemotherapy and antibiotic combinations.

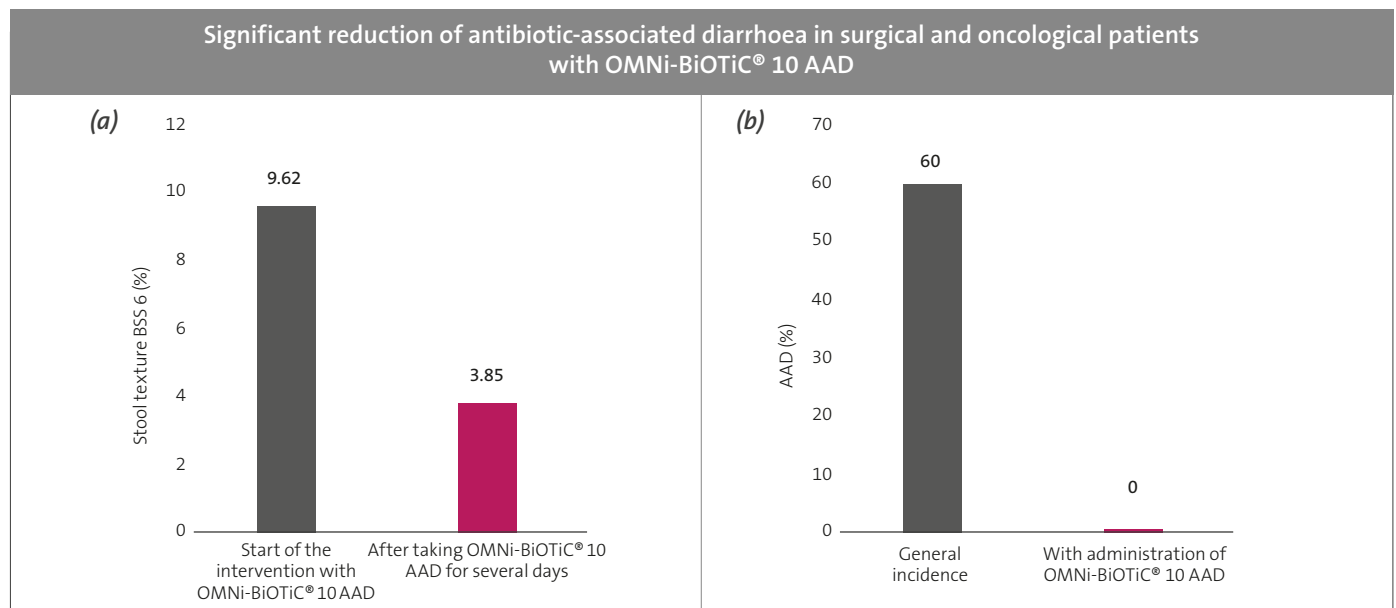


Figure: (a) While at the beginning of probiotic administration already 9.62% of the patients with AAD had a stool consistency and frequency corresponding to BSS 6 (= severe diarrhoea), this diarrhoea was reduced by more than 50% with the administration of OMNi-BiOTiC® 10 AAD. (b) The administration of probiotics did not cause diarrhoea in any of the chemotherapy patients, whereas the general incidence with comparable medication is 60%.

Discussion and conclusion

The present study clearly demonstrates that the timely administration of OMNi-BiOTiC® 10 AAD from the first day of antibiotic treatment can significantly reduce the incidence of AAD in surgical patients. In oncological patients, this clinically significant multi-species probiotic particularly contributes to a more effective therapy and improves the quality of life. In summary, these impres-

sive results suggest that specifically pathogen-inhibiting probiotics could become a standard complementary therapy alongside antibiotics, chemotherapy, and radiotherapy.

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Migraine Prevention with a Probiotic – an Observational Study with 1,020 Participants

Straube *et al.*, MMW Fortschritte der Medizin; 2018

Abstract

Migraines are the most common neurological disorder and are observed worldwide. The annual prevalence in Western industrial countries is approximately 10–14%, with women being affected 2.5 to 3 times more than men. Migraine patients frequently suffer gastrointestinal symptoms such as nausea and vomiting during an attack. Connections between migraines and gastrointestinal diseases such as irritable bowel syndrome, chronic inflammatory bowel diseases, and coeliac disease have been demonstrated in multiple clinical studies. These connections can be explained by the increased bowel permeability ('leaky gut') that occurs in patients with gastrointestinal diseases. A decrease in bowel permeability through the use of multi-species probiotics can therefore reduce the intensity and/or frequency of migraine attacks. In this study by Straube *et al.*, the effect of the multi-species probiotic OMNi-BiOTiC® *METAtox* / OMNi-BiOTiC® *HETOX light* on the intensity and frequency of migraine attacks, as well as on the reduction in painkiller consumption and migraine-related symptoms, was analysed in 1,020 patients with migraines over eight weeks.

Results

Probiotic therapy led to a significant reduction in migraine days, headache intensity, and painkiller consumption. Treatment with OMNi-BiOTiC® *METAtox* / OMNi-BiOTiC® *HETOX light* (3g, twice daily, totaling 15×10^9 CFU) significantly decreased the number of headache days over eight weeks ($p \leq 0.001$). Additionally, headache intensity diminished notably during the treatment period ($p \leq 0.001$). Remarkably, the 8-week probiotic treatment reduced migraine-related symptoms, including nausea, vomiting, constipation, and auras, by up to 80% ($p \leq 0.001$). The substantial reduction in painkiller use also contributed to an improved quality of life ($p \leq 0.001$).

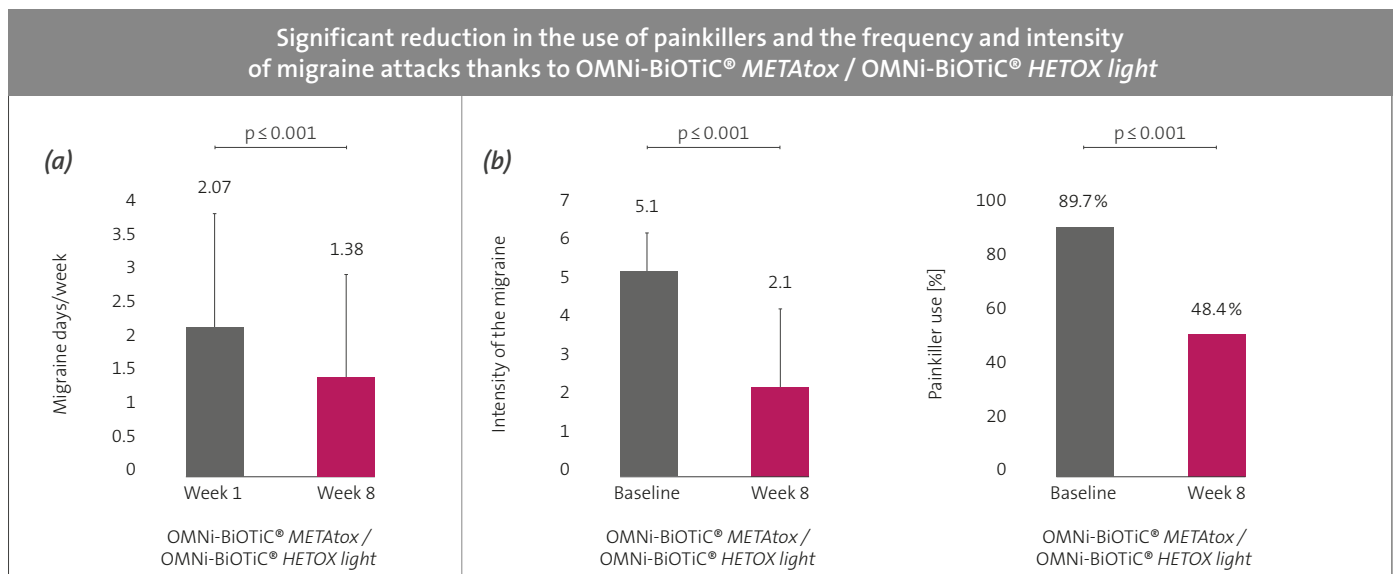


Figure: (a) Significantly lower number of migraine days per week during probiotic treatment.

(b) Reduction in migraine intensity (scale from 0 = none 6 = highly intensive) and painkiller consumption due to 8-week treatment with a multi-species probiotic.

Discussion and conclusion

Studies show that the intestinal microbiome plays a crucial role in neurological disorders. A positive change in the intestinal microbiome results in the restoration of the intestinal barrier and a reduction in inflammatory reactions, which are crucial in the pathogenesis of migraines. The use of probiotics and their beneficial effect on bowel permeability therefore presents a sensible and side effect-free treatment option for migraine patients. In the study conducted by Straube *et al.*, it was demonstrated that OMNi-BiOTiC® *METAtox* /

OMNi-BiOTiC® *HETOX light* can reduce the frequency and intensity of migraine attacks, as well as alleviate migraine-related symptoms. Given that the prophylactic use of painkillers in migraine patients often results in severe side effects and leads to discontinuation of treatment, the reduced reliance on painkillers observed with this multi-species probiotic is highly significant.

The Influence of Probiotics on Cognitive Parameters in Stable Patients with Bipolar Disorder – a Pilot Study

Reininghaus *et al.*, Neuropsychobiology; 2018

Abstract

A balanced interaction between the gastrointestinal tract and the brain is crucial not only for digestion but also for overall physical and mental health. The brain and the digestive tract continuously exchange information through the gut-brain axis, with the intestinal microbiome playing a significant role. Research on animal models and healthy humans has demonstrated that the microbiome can influence cognitive processes via the gut-brain axis. Consequently, dysbiosis, or an imbalance in the microbiome, can lead to a decline in cognitive performance.

Cognitive malfunctions are present in bipolar disorder patients during both depressive and manic phases. Even euthymic individuals with bipolar disorder (BD) may still experience cognitive impairment during stable periods, which limits their quality of life. In this pilot study by Reininghaus *et al.*, the effect of a multi-species probiotic (trade name: OMNi-BiOTiC® STRESS Repair (AT); OMNi-BiOTiC® SR-9 (DE)) on cognitive performance was analysed in twenty-seven individuals with bipolar disorder over a period of three months.

Results

After one or three months of treatment with OMNi-BiOTiC® STRESS Repair / SR-9 (3 g daily, totalling 7.5×10^9 CFUs), there was a significant improvement in concentration and processing speed as demonstrated by the digit symbol test, compared to the start of treatment ($p < 0.01$). Furthermore, the trail making test (TMT-B), which assesses visual and motor processing speed, showed significantly improved cognitive flexibility ($p < 0.05$) after three months of probiotic therapy, highlighting an enhanced ability to control actions in a targeted manner.

Improvement of attention and psychomotor processing speed after intake of OMNi-BiOTiC® STRESS Repair for three months

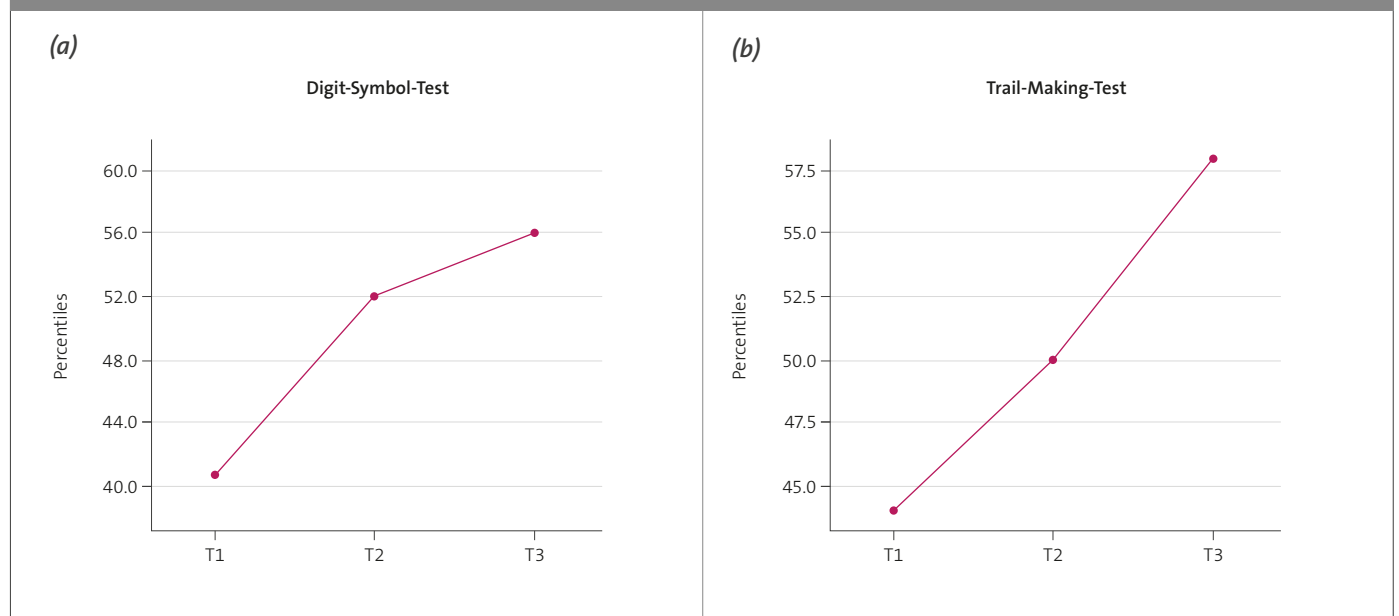


Figure: Neuropsychological tests to assess cognitive functions, (a) Digit Symbol Test: After one (T2) or three months (T3) of probiotic treatment, there was a significant improvement in terms of attention and speed of information processing in comparison to the start of treatment (T1). (b) Trail Making Test: The three-month intake of the multi-species probiotic (T3) led to a significant improvement in patients' cognitive flexibility in comparison to the start of treatment (T1). (Percentile 25–50 = below-average performance on the test; percentile 50–75 = above-average performance on the test).

Discussion and conclusion

Recent studies are increasingly focusing on the significance of the intestinal microbiome in the bidirectional communication between the intestines and the brain. The intestinal microbiome produces signalling molecules that play a role in the regulation of brain function and, consequently, human behaviour. This pilot study by Graz University Hospital confirmed the hypothesis that the administration of a multi-species probiotic has a positive impact on cognitive function in patients with bipolar disorder. It was shown that

euthymic individuals with bipolar disorder experienced a significant improvement in attention and psychomotor speed after three months of treatment with OMNi-BiOTiC® STRESS Repair / SR-9. The concept of the gut-brain axis represents an important approach in the development of new treatment strategies for mental illnesses, while at the same time helping to optimise patient outcomes and quality of life.

The Positive Influence of a Medically Relevant Multi-Species Probiotic on the Gut Microbiome and Cytokine Production in Patients with Depression

Reininghaus and Reiter *et al.*, *Nutrients*; 2020

Abstract

A balanced interaction between the gastrointestinal tract and the brain plays a significant role not only in digestion but also in physical and mental health. Constant communication occurs between the brain and the digestive tract through the gut-brain axis, with the intestinal microbiome playing a vital role in this process. Dysbiosis, or imbalance, of the gut microbiome can trigger the release of pro-inflammatory cytokines, compromise intestinal barrier function, and alter immune responses. These changes can lead to mental health disorders, including the development of depression.

Numerous evidence-based studies now demonstrate that medically relevant multi-species probiotics can positively modulate the intestinal microbiome and significantly contribute to mental health. This study investigated the positive effect of the specially anti-inflammatory formulated multi-species probiotic OMNi-BiOTiC® STRESS Repair (in Germany: OMNi-BiOTiC® SR-9) in combination with vitamin B7 on the intestinal microbiome and the reduction of gene expression of pro-inflammatory cytokines in 61 depressed patients.

Results

The 4-week administration of OMNi-BiOTiC® STRESS Repair (3 g daily, totalling 7.5×10^9 CFU) in combination with 125 mg D-Biotin (vitamin B7) led to a significant increase in beta diversity compared to the placebo group ($p=0.001$). Particularly noteworthy is the increased abundance of certain bacterial species that are considered producers of important short-chain fatty acids. *Ruminococcus gnavreuii* (an acetate producer) and *Coprococcus 3* (a butyrate producer) are often reduced in depressed patients compared to healthy individuals. Their significant increase through the intake of OMNi-BiOTiC® STRESS Repair underscores the positive modulation of the intestinal microbiome. Additionally, a significantly reduced gene expression of the pro-inflammatory interleukin 6 (IL-6) was observed in the treatment group.

Taking OMNi-BiOTiC® STRESS Repair leads to reduced mRNA gene expression of the pro-inflammatory cytokine IL-6

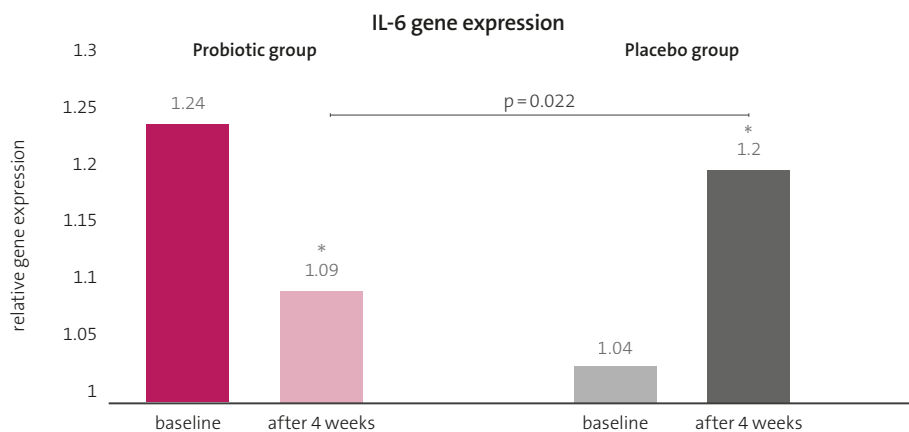


Figure: Gene expression of the pro-inflammatory cytokine interleukin-6 was significantly reduced by taking OMNi-BiOTiC® STRESS Repair. In the placebo group, there was even an increase in expression over the intervention period of four weeks.

Discussion and conclusion

The concept of the gut-brain axis offers a promising approach for developing new treatment strategies for mental illness, aiming to enhance the quality of life for affected patients. This study impressively shows that taking the multi-species probiotic OMNi-BiOTiC® STRESS Repair for only four weeks positively modulates the microbiome composition in patients with depression. In particular, acetate- and butyrate-producing bacterial strains show increased abundance, which is crucial for the maintenance of the blood-brain

barrier. Furthermore, the reduction of IL-6 gene expression in the treatment group highlights the positive influence of medically relevant probiotics on chronic inflammatory reactions present in depressive patients. OMNi-BiOTiC® STRESS Repair, therefore, represents a promising treatment option for this group of patients.

The Effects of Probiotics on the Intestinal Microbiome and its Effects on Cognitive and Emotional Behaviour



Bagga *et al.*, Gut Microbes; 2018

Abstract

The intestinal microbiome not only regulates bowel function but also influences mood, pain sensitivity, and emotions via the gut-brain axis. While the specific molecular mechanisms remain unclear, it is established that the intestinal microbiome modulates human behavior and brain functions, including pain perception, stress sensitivity, and prefrontal myelination. Most of the evidence for the link between the intestinal microbiome and behavior comes from studies on mouse models, with limited research conducted in humans. A 2018 study highlighted the close connection between emotion and perception, emphasizing that emotions play a key role in an individual's perception. Additionally, brain regions associated with emotional processes are closely linked to areas involved in memory and decision-making.

Given the influence of the intestinal microbiome on emotional processing, Bagga *et al.* study examined the effect of a multi-species probiotic (trade names: OMNi-BIOTIC® STRESS Repair (AT); OMNi-BIOTIC® SR-9 (DE)) on brain mechanisms controlling memory and decision-making. Participants were divided into probiotic (PRP), placebo (PLP), and non-intervention (NI) groups (see Figure 1a). The study, a double-blind, randomised, placebo-controlled trial, used MRI brain

scans of 45 healthy subjects to analyse the positive influence of a specific probiotic. Changes in behaviour and mood were assessed using self-reported scientific questionnaires.

Results

The PANAS (Positive and Negative Affect Schedule) score indicated a significant increase in positive emotional response in the group receiving the 4-week probiotic treatment compared to the placebo group. Regarding the LEIDEN index, which evaluates depression, probiotic treatment reduced the propensity towards depressive mood, specifically in terms of hopelessness (HOP) and risk avoidance (RAV).

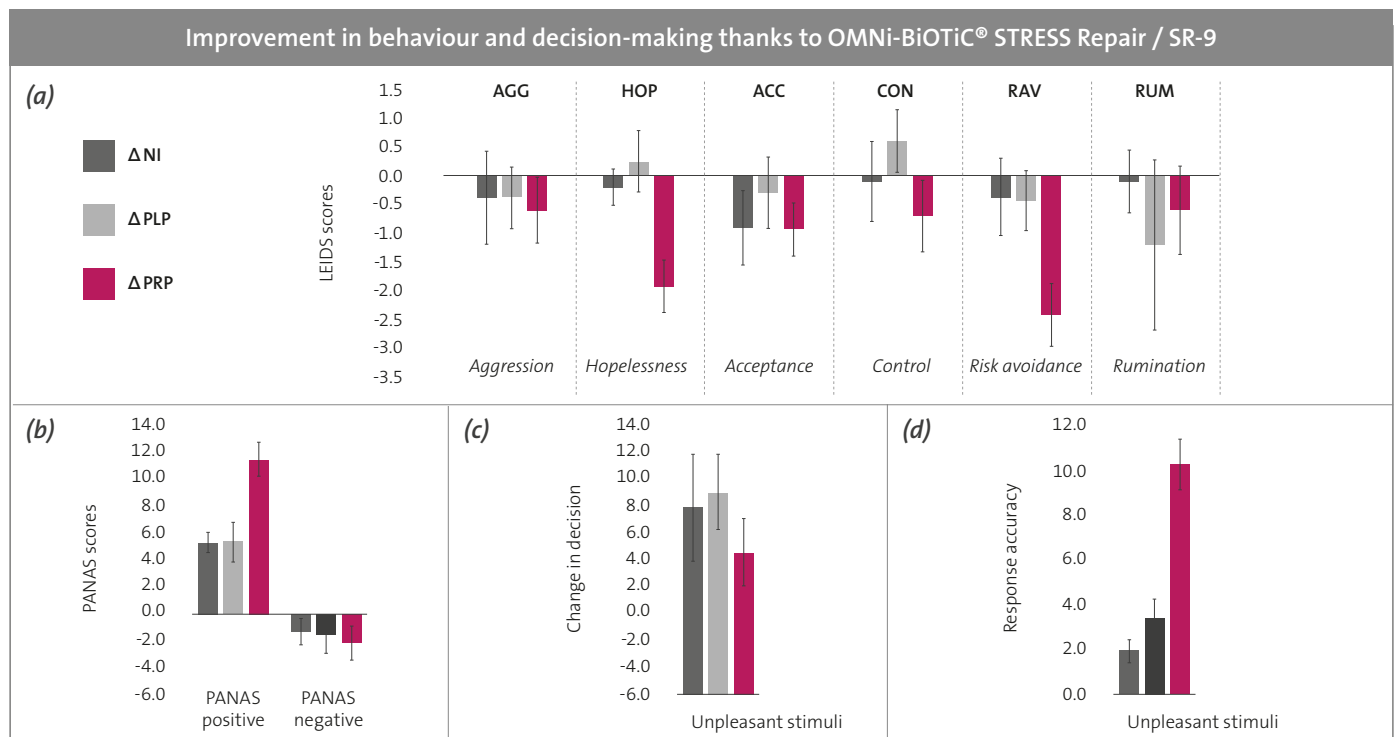


Figure 1: Behaviour tests, (a) Leiden index of depression severity (LEIDS) scores, (b) PANAS scores (positive and negative). The response to positive emotions was significantly increased through the 4-week administration of probiotics. In addition, the propensity towards depression in terms of hopelessness (HOP) and risk avoidance (RAV) was reduced. (c) Change in emotional decision-making and (d) effect on the response accuracy rate (RAU). In the recognition task with unpleasant images, the positive effect of probiotics was visible on a functional MRI.

Compared to the placebo and non-intervention groups, the probiotic group exhibited a positive change in emotional decision-making processes. Subjects taking the probiotic were more certain and resolute in their decisions. Functional MRI scans showed a positive influence on recognition tasks involving neutral (RAN – response accuracy neutral stimuli) and unpleasant stimuli (RAU – response accuracy unpleasant stimuli). In the probiotic group, increased activity was observed in specific brain regions (precuneus, mid-cingulate, temporal gyrus, inferior parietal lobule, and paracentral lobule). Additionally, there was increased activity in the left anterior cingulate compared to the control groups.

The composition of the intestinal microbiome was analysed using stool samples from the verum and placebo groups before treatment and after four weeks of probiotic administration. The results showed that neither the probiotic nor the placebo significantly altered the intestinal microbiome in terms of taxonomic unit and species. However, it is hypothesised that the probiotic induced changes through indirect effects, such as promoting acetate-producing bacterial strains. A significant correlation was also observed between microbiome composition and RAN or RAU in recall tests and HOP and GDS (General Depression Scale) in decision tests.

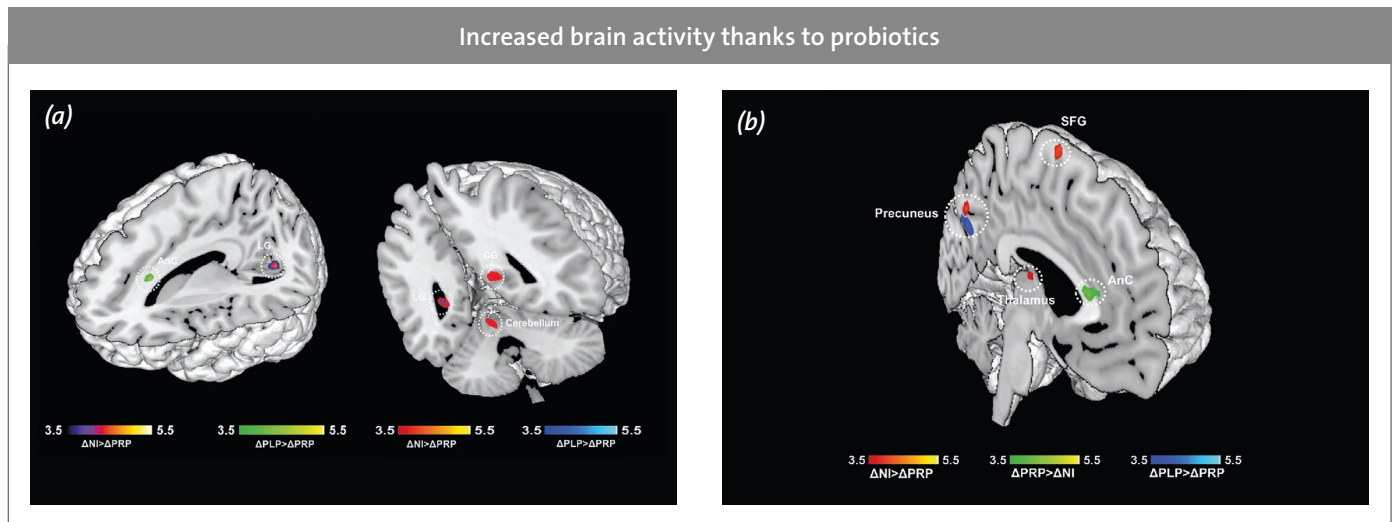


Figure 2: (a) Emotional recognition and (b) decision-making: The increase in activity in certain brain regions resulting from probiotic intake was visible in comparison to the placebo and non-intervention group

Discussion and conclusion

In summary, the study by Bagga *et al.* indicates that administering a multi-species probiotic significantly influences behaviour and specific brain areas responsible for decision-making and emotional memory. The data suggest a positive change in emotional decision-making processes in the probiotic group, with increased brain activity in relevant regions. Despite no significant change in the intestinal

microbiome composition, the probiotic may induce changes through indirect effects. These findings set the stage for future clinical trials to investigate the potential benefits of probiotics as alternative or adjunctive treatments for depression and related psychological conditions.

The Effect of a Multi-Species Probiotic on Stress Resilience during the COVID-19 Pandemic



Horvath *et al.*, Journal of Biotechnology and Biomedicine; 2023

Abstract

COVID-19, caused by the coronavirus SARS-CoV-2, primarily affects the upper respiratory tract but often also causes gastrointestinal problems. These symptoms can persist long after the acute infection. Health and social care professionals faced significant challenges during the pandemic, being at higher risk of infection and experiencing high levels of psychological stress. Stress manifests in symptoms such as depression, insomnia, and anxiety. Chronic stress has been scientifically proven to alter the intestinal microbiome, particularly affecting the intestinal mucosa. The gut-brain axis allows the intestinal microbiome to significantly influence behaviour and mood, presenting a potential avenue for developing new therapeutic strategies for mental illness.

Results

A situational analysis in Germany investigated the effect of probiotics on mental stress parameters in approximately 14,000 health professionals during the COVID-19 pandemic. Participants completed a health questionnaire before and after taking the medically relevant multi-species probiotic OMNi-BiOTiC® SR-9 with B vitamins (1 x daily 3 g, totalling 7.5×10^9 CFU) for two weeks. In addition to a remarkable and significant reduction in gastrointestinal complaints in 73% of participants, the probiotic intake led to a significantly higher percentage of individuals experiencing reduced fatigue and less mental exhaustion. This was associated with higher energy levels and significantly improved sleep quality.

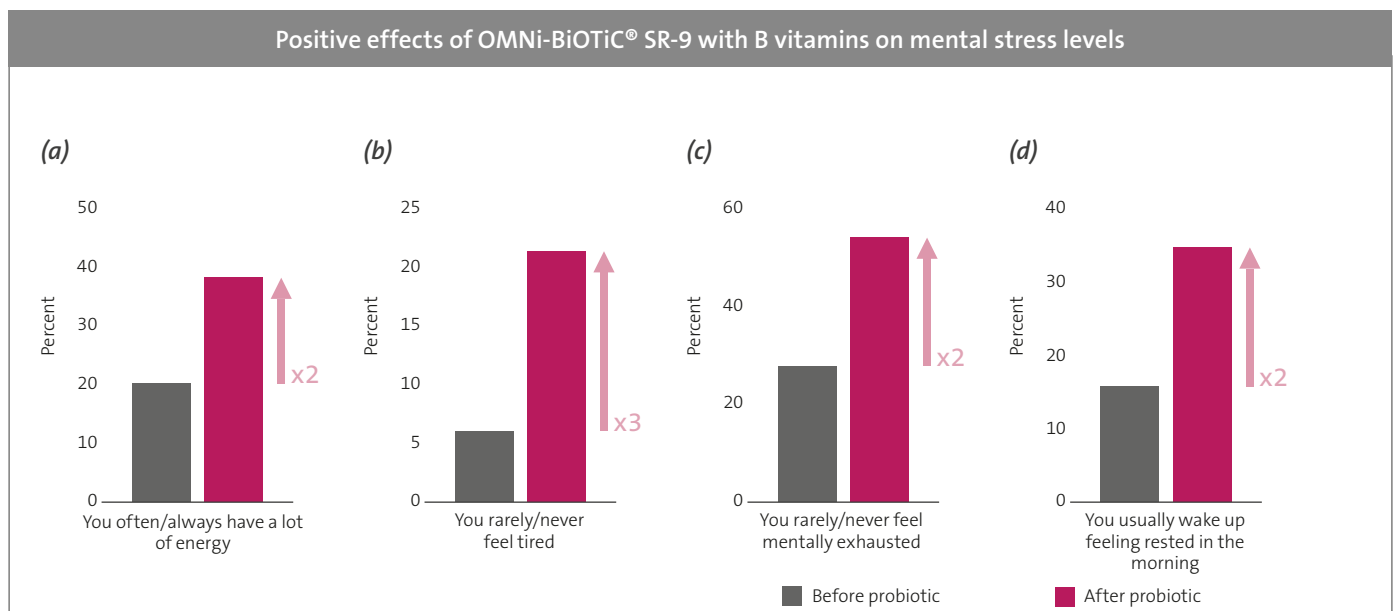


Figure: Taking the specific multi-species probiotic for 2 weeks increased energy levels (a) and reduced the occurrence of fatigue (b) and mental exhaustion (c). Extremely positive effects are also seen in the improvement of sleep quality (d).

Discussion and conclusion

The concept of the gut-brain axis offers a promising approach for developing new therapeutic strategies to mitigate the effects of stress. The results of this situational analysis demonstrate that the probiotic OMNi-BiOTiC® SR-9 with B vitamins, which specifically targets the gut-brain axis, improved mental and physical well-being during a highly stressful period. Within just two weeks, medically relevant probiotics can reduce stress-related complaints such as fatigue and mental exhaustion. Selected bacterial combinations with anti-inflammatory potential are suitable for individuals

with gastrointestinal sensitivity due to their good tolerability. High-quality probiotics can be used permanently and preventively, as no undesirable side effects are known.

Positive Effects of a Multi-Species probiotic on Metabolic Parameters in Depressed Patients – Results of the PROVIT study

Kreuzer *et al.*, *Metabolites*; 2022



Abstract

The composition and diversity of the gut microbiome play an essential role in brain function. Numerous evidence-based studies now show that medically relevant multi-species probiotics can positively modulate the intestinal microbiome and significantly contribute to mental health. Additionally, specific metabolites produced by intestinal bacteria are promising candidates for positively influencing inflammatory processes and brain function. To examine these connections, the PROVIT study was conducted as a randomised, double-blind, placebo-controlled trial involving 57 depressed patients. In their standard therapy, half of the patients received the probiotic (trade names: OMNi-BiOTiC® STRESS Repair (AT); OMNi-BiOTiC® SR-9 (DE)), which specifically acts on the gut-brain axis, over four weeks, while the control group received a placebo. Clinical examinations and inflammation parameter surveys, which showed a significant reduction, were complemented by microbiome analyses using 16S rRNA sequencing. Earlier publications on the PROVIT study already demonstrated impressive results. Additionally, the metabolic profile of the patients, including the occurrence and quantity of various metabolites and intermediates of biochemical reaction pathways, was examined in stool and serum via NMR spectroscopy.

Results

After four weeks of taking OMNi-BiOTiC® STRESS Repair / SR-9, significantly higher concentrations of important metabolites were measured in the stool samples of these patients compared to the placebo group. This included the short-chain fatty acid (SCFA) butyrate, a key metabolite for strengthening the intestinal barrier and activating cerebral microglia, as well as essential amino acids and other metabolites such as alanine, valine, isoleucine, lysine, sarcosine, and methylamine. Previous studies on animal models indicate that the concentration of essential amino acids in the stool is reduced in individuals with depression. These findings, along with other results, suggest that the probiotics used in this study can effectively counteract a disturbed amino acid balance in depressed individuals. The microbiome analyses also revealed a strong correlation between the significantly improved metabolite production and the bacterial composition in the gut. Notably, the butyrate concentrations correlated clearly with the increased occurrence of the important bacterium *Faecalibacterium prausnitzii*. In the placebo group, there were no observed changes in the metabolome in either stool or serum samples.

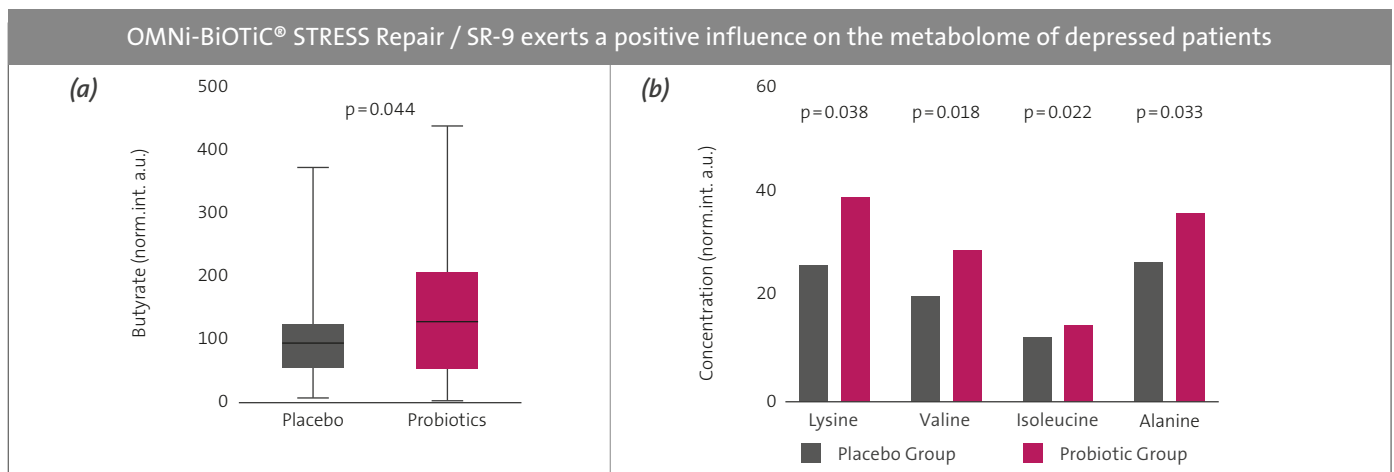


Figure: After taking the medically relevant probiotic, significantly higher concentrations of the short-chain fatty acid butyrate (a) and several essential amino acids (b) were detected in the stool of the patients compared to the control group.

Discussion and conclusion

The analyses conducted on depressed patients demonstrated a significant increase in essential metabolic products following the administration of OMNi-BiOTiC® STRESS Repair / SR-9, specifically formulated to positively affect the gut-brain axis. Of particular note was the elevated concentration of the short-chain fatty acid butyrate as a result of the probiotic treatment. These SCFAs are essential for maintaining an intact intestinal barrier, serve as an energy source for intestinal epithelial cells, and have anti-inflammatory properties. The significantly increased concentration of essential amino acids

is particularly important as it can counteract the metabolic effects of depression on amino acid metabolism. In summary, the study demonstrated that using a high-quality, indication-specific multi-species probiotic positively influences the metabolic profile of depressed patients. This suggests that modulating the gut microbiome could become a significant therapeutic approach in treating depression in the future.

An Indication-Specific Multi-Species Probiotic Improves Vagus Nerve Function in Patients with Depression



Mörkl *et al.*, Gut Microbes; 2025

Abstract

A balanced interaction between the gastrointestinal tract and the brain plays an important role not only in digestion but also in mental health. There is a constant exchange of information between the brain and the digestive tract via the gut-brain axis, with the intestinal microbiome being the most important factor in its functioning. Dysbiosis of the intestinal microbiome can lead to the release of pro-inflammatory cytokines, defects in the intestinal barrier function and an altered immune response. These changes can result in mental health disorders and can contribute to the development of depression. In depressed patients, the function of the vagus nerve (VN), measured by heart rate variability (HRV), is altered, with reduced HRV correlating with more severe depression. Numerous evidence-based studies have now shown that medically relevant multi-species probiotics can positively modulate the intestinal microbiome and make a significant contribution to mental health. This randomised, placebo-controlled study investigated the effects of the multi-species probiotic OMNi-BiOTiC® STRESS Repair/SR-9 (3 g twice daily with a total of 1.5×10^{10} CFU) specifically targeting the gut-brain axis on vagus nerve function, microbiome composition and sleep quality in 40 patients with depression and 46 healthy control subjects.

Results

The results of the study clearly show an increased morning heart rate and reduced morning vagus nerve function in depressed patients compared to healthy control subjects at the start of the study. Taking OMNi-BiOTiC® STRESS Repair/SR-9 over a period of 3 months resulted in a significantly reduced morning heart rate ($p=0.003$) and significantly improved morning vagus nerve function ($p=0.002$) in depressed patients compared to the placebo group. Analysis of the gut microbiome showed an increased proportion of Christensellales, in particular the mucus-producing Akkermansia muciniphila, in depressed patients after 3 months of probiotic intervention. Also noteworthy is the improved sleep quality (assessed using the Pittsburgh Sleep Quality Inventory – PSQI questionnaire) in depressed subjects in the probiotic group and the associated reduced need for sleep medication.

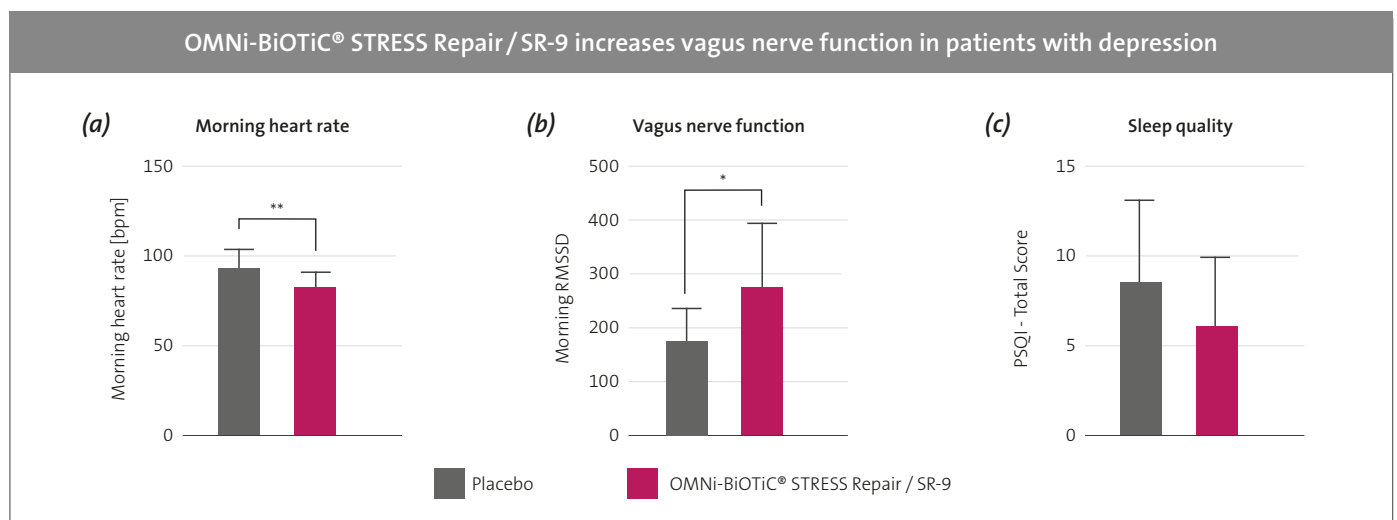


Figure: Taking OMNi-BiOTiC® STRESS Repair / SR-9 for 3 months significantly reduces morning heart rate ($p = 0.003$) (a), significantly increases vagus nerve function ($p = 0.002$) (b) and improves sleep quality (c) in patients with depression (a lower PSQI score means better sleep quality).

Discussion and conclusion

The vagus nerve is a central component of the parasympathetic nervous system and it plays an important role in bidirectional communication between the gut and the brain. Vagus nerve activity has been shown to be reduced in patients with depression. Studies also show that vagus nerve activity correlates significantly with the diversity of the gut microbiome. The present study impressively shows that taking OMNi-BiOTiC® STRESS Repair/SR-9 for three months

leads to significantly improved vagus nerve function and improved sleep quality in patients with depression. It is becoming increasingly clear that mental illnesses are an expression of a disturbed interaction between the immune system, nervous system and microbiome. The targeted use of high-quality, indication-specific probiotics will play a key role in the treatment of mental illnesses in the future.

Administration of Probiotics in Alzheimer's Patients – an Observational Study

Leblhuber *et al.*, *Curr Alzheimer Research*; 2018

Abstract

Dementia is an increasingly prevalent issue among the elderly population. Modern technological advances now enable us to detect age-related changes in the brain, allowing the identification of cognitive decline symptoms before they become clinically evident. Due to these technical advancements, the role of the intestinal microbiome in various neurodegenerative diseases has become a prominent research focus. The intestinal microbiome influences the regulation of inflammatory reactions, immunity, and neurological mechanisms. Dysbiosis leads to leaky gut syndrome, resulting in systemic inflammation that can trigger neuroinflammation, a relevant process in the pathogenesis of Alzheimer's disease. A healthy intestinal microbiome is therefore crucial and offers significant benefits for a patient's systemic immune defence and brain function. This study analysed the positive effects of a multi-species probiotic (trade names: OMNi-BiOTiC® STRESS Repair (AT); OMNi-BiOTiC® SR-9 (DE)) on biomarkers of immune activation, markers of leaky gut syndrome, and faecal microbiome composition in 18 Alzheimer's patients after four weeks of treatment.

Results

After four weeks of treatment with OMNi-BiOTiC® STRESS Repair / SR-9 (3 g daily, totaling 7.5×10^9 CFUs), there was a significant reduction in fecal zonulin concentration, an important marker of leaky gut. This reduction indicates an improvement in intestinal barrier function ($p < 0.001$) compared to the start of treatment. Additionally, there was an increased prevalence of the anti-inflammatory bacterium *Faecalibacterium prausnitzii* detected via qPCR (quantitative polymerase chain reaction) after four weeks of probiotic treatment ($p = 0.01$). Compared to the start of treatment, the concentration of kynurenine in serum was significantly elevated at the end of treatment period ($p < 0.05$). Kynurenic acid, a metabolic product of kynurenine, is known for its neuroprotective properties. Furthermore, the delta values (pre-treatment to post-treatment) of neopterin and the kynurenine-tryptophan ratio showed a statistically significant correlation ($p < 0.05$).

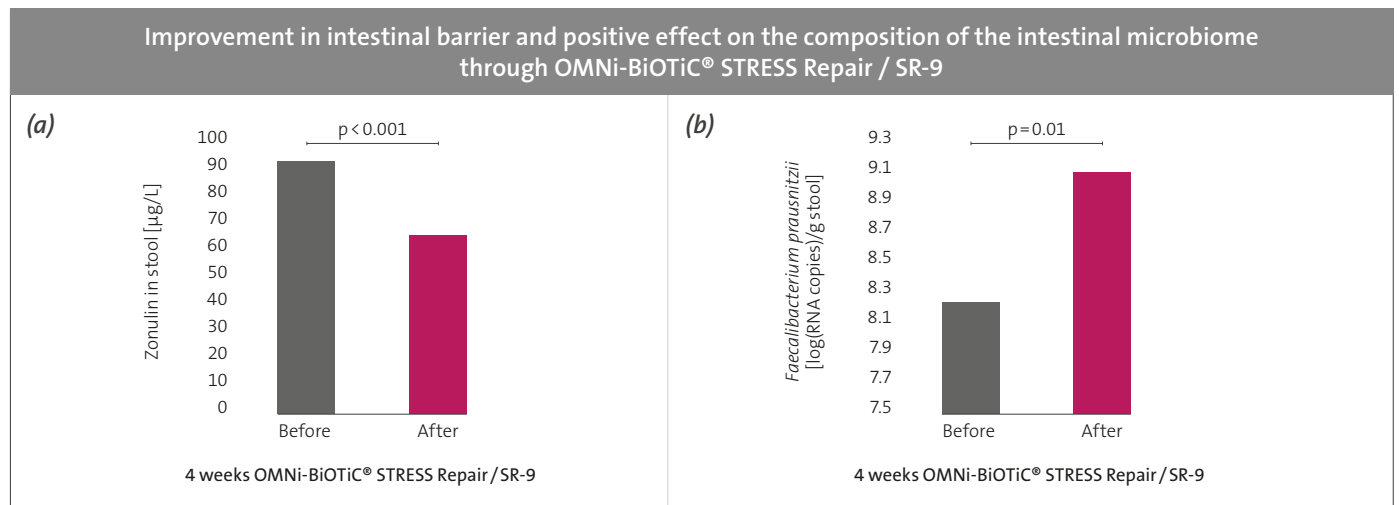


Figure: (a) Significant reduction in the concentration of zonulin in stool after four weeks of treatment with probiotics. (b) Significantly elevated population of *Faecalibacterium prausnitzii* after the administration of probiotics over four weeks.

Discussion and conclusion

The pathology of Alzheimer's disease is highly complex, and the symptoms of Alzheimer's dementia represent a major challenge for doctors and patients. Neuroinflammation is characteristic in the early phases of Alzheimer's disease. Studies indicate that the intestinal microbiome plays a crucial role in the immune mediation of inflammatory diseases such as neurodegeneration and dementia, presenting significant potential for discovering new diagnostic biomarkers and treatment strategies. Scientific evidence shows that administering specific multi-species probiotics can restore the intestinal barrier and reduce inflammation. The study by Leblhuber *et al.* demonstrated

that administering the multi-species probiotic positively influences both the composition of the intestinal microbiome and tryptophan metabolism in serum. The rise in kynurenine concentration after four weeks of treatment can be attributed to the activation of immunological processes. Moreover, probiotic treatment alleviated leaky gut syndrome, as evidenced by the significant reduction in zonulin concentration in the patients' stool.

Positive Effects of a Multi-Species Probiotic in Patients with Post-Infectious Fatigue



Obermoser K. *et al.* (Kurz K.) *Metabolites*, 2023

Abstract

Fatigue is a state of extreme physical and mental exhaustion that often follows viral infections and can persist for several months. Beyond severe tiredness, this condition can significantly impair physical and mental performance, reducing overall quality of life. Numerous studies have shown that dysbiosis of the intestinal microbiome can negatively impact both physical and mental health through the gut-brain axis, potentially leading to conditions such as depression. This double-blind, placebo-controlled study aimed to assess the effects of an indication-specific multi-species probiotic (trade names: OMNi-BiOTiC® STRESS Repair (AT) and OMNi-BiOTiC® SR-9 (DE)) on fatigue severity, depressive symptoms, and quality of life in 70 patients suffering from post-infectious fatigue.

Results

Taking OMNi-BiOTiC® STRESS Repair / SR-9 (1–2 times daily, 3 g with a total of 7.5×10^9 CFU) over six months proved to be highly effective in improving both physical exhaustion and mental well-being. While the placebo group showed only slight improvements over the six-month period ($p < 0.05$), the group taking the indication-specific probiotic experienced significant reductions in the severity of fatigue (measured by the Fatigue Severity Scale, FSS) and depressive symptoms (measured by the Beck Depression Inventory II, BDI-II) ($p < 0.001$). Additionally, the probiotic intervention led to a significant improvement in quality of life ($p < 0.001$), whereas patients receiving the placebo showed only marginal improvements in the subcategories of “physical limitation” and “energy.”

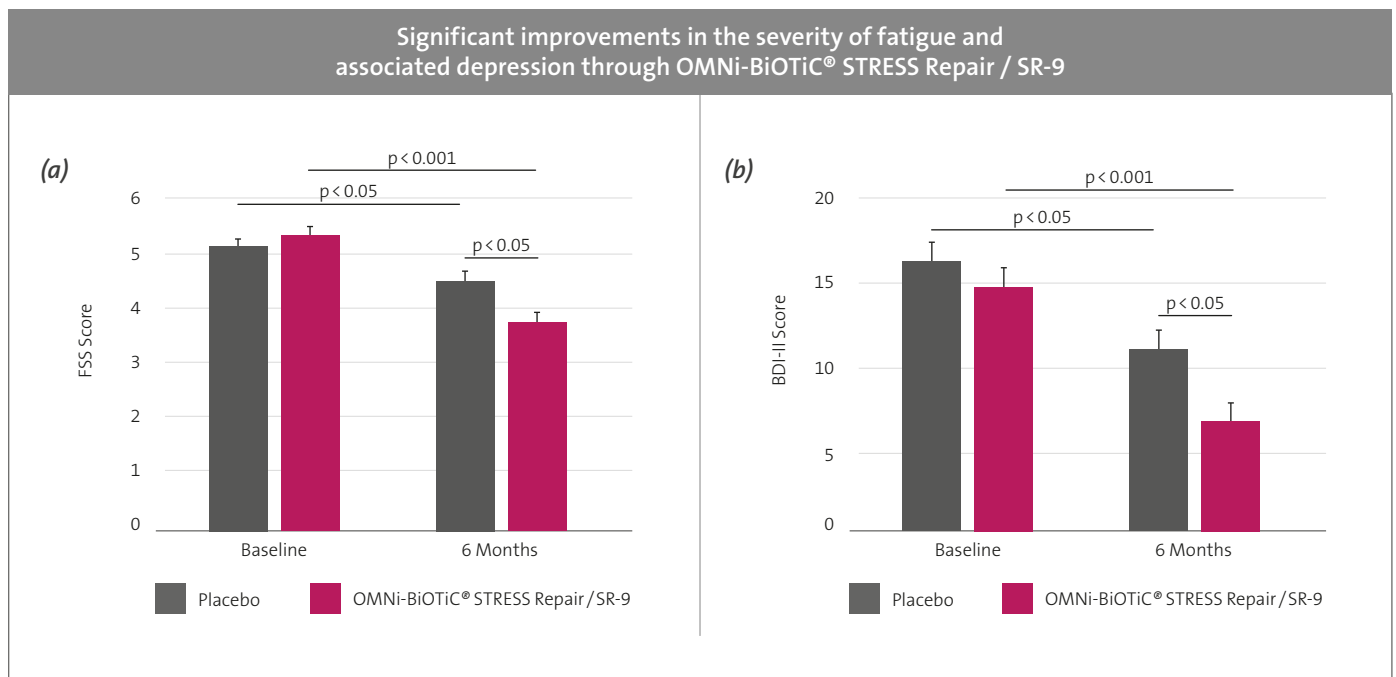


Figure: (a) Taking OMNi-BiOTiC® STRESS Repair / SR-9 for 6 months leads to a significant reduction in the severity of fatigue (Fatigue Severity Scale, FSS) (b) and the severity of depressive symptoms (Beck Depression Inventory II (BDI-II)).

Discussion and conclusion

This study highlights that patients with post-infectious fatigue frequently suffer from depression and experience significant limitations in their quality of life and subjective performance. Additionally, it provides the first evidence that administering the medically relevant probiotic OMNi-BiOTiC® STRESS Repair / SR-9 positively modulates the

gut-brain axis. Given the limited treatment options available in conventional medicine, these findings offer a highly valuable therapeutic approach for chronic fatigue syndrome.

A Multi-Species Probiotic Significantly Reduces the Effects of Functional Pain Syndrome via the Gut-Brain Axis

Castelletti *et al.*, World Journal of Neuroscience; 2024

Abstract

Functional pain syndrome is a chronic perception of pain in which the pain has lost its actual function as a warning and guiding signal and has become a disease in its own right. It is often accompanied by other symptoms, such as sleep disorders, loss of appetite, increased irritability and depressive moods. The gut-brain axis plays an important role here and influences both physical and mental health. The present study investigated the positive influence of a multi-species probiotic (trade name: OMNi-BiOTiC® STRESS Repair (AT); OMNi-BiOTiC® SR-9 (DE)) on various parameters of functional pain syndrome. As part of this study, 45 patients diagnosed with functional pain syndrome lasting at least 6 months received neurofeedback training as a non-invasive treatment and the medically relevant multi-species probiotic.

Results

After treatment with OMNi-BiOTiC® STRESS Repair / SR-9 (1 sachet containing 7.5×10^9 CFU once daily) over a period of 3 months, there was a significant reduction in perceived pain intensity of 69% ($p < 0.001$) compared to the start of treatment. Before the start of the study, chronic pain severely impaired the patients' everyday lives, but this was reduced by 71% as a result of the treatment ($p < 0.001$). It is noteworthy that the severity of anxiety disorders (as determined by the Hamilton Anxiety Scale) was also reduced by 57% ($p < 0.001$). Another impressive result was obtained from the measurement of evening cortisol levels in saliva, which were significantly reduced by 81% ($p < 0.001$) by taking the probiotic. The alpha-theta maximum (a measurement of brain waves during neurofeedback training) was increased from an average of 8.9% before treatment to 32.8% after treatment with OMNi-BiOTiC® STRESS Repair / SR-9, which represents a significant improvement in the brain's self-regulatory capacity ($p < 0.001$). It is particularly noteworthy that before treatment, all 45 patients were dependent on medication, some of which were strong painkillers, whereas after the probiotic intervention, 20 patients no longer required any medication (-44%) ($p < 0.001$). The remaining 25 patients were able to reduce their medication dosage.

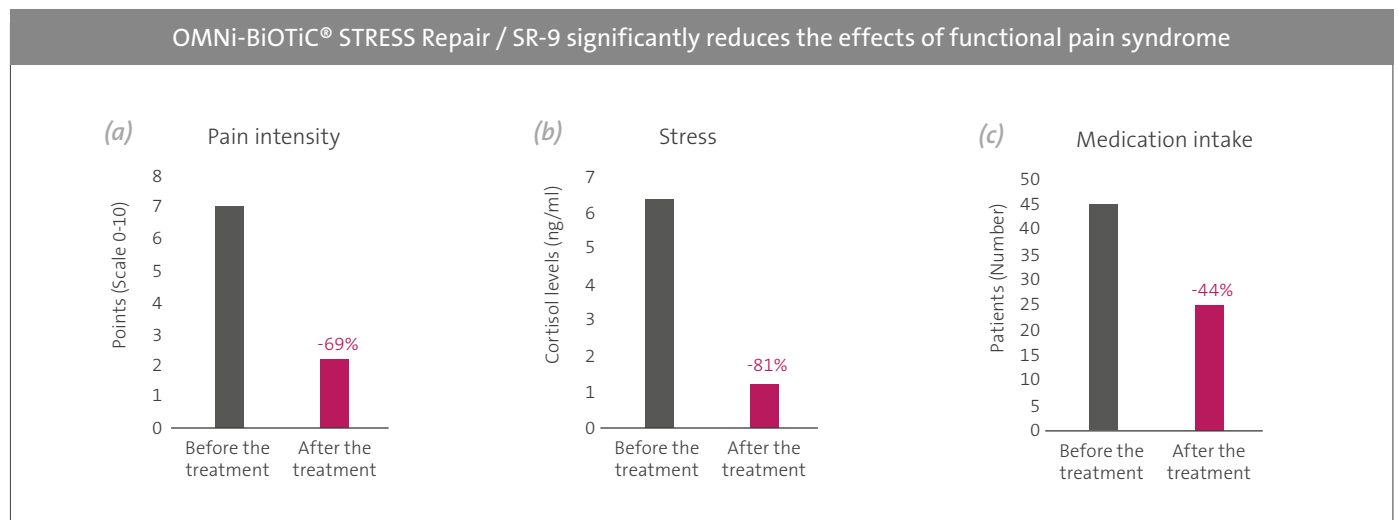


Figure: After 3 months of treatment, OMNi-BiOTiC® STRESS Repair / SR-9 reduced pain intensity (a), evening salivary cortisol levels as a stress indicator (b) and medication intake (c) ($p < 0.001$).

Discussion and conclusion

Functional pain syndrome affects more than 15% of the world's population and is associated with agonising, long-lasting symptoms. This study clearly shows that taking the indication-specific probiotic OMNi-BiOTiC® STRESS Repair / SR-9 for 3 months leads to a significant reduction in chronic pain through modulation of the gut-brain axis. As a result, impairments in everyday life, anxiety disorders and stress

decreased, which means a significant improvement in quality of life for the patients affected. Impressively, all patients were able to significantly reduce or even completely discontinue their medication.

IMMUNE SYSTEM

5

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Successful Use of a Multi-Species Probiotic with Anti-Inflammatory Activity in Psoriatic Arthritis

Haidmayer *et al.*, *Nutrients*; 2020

Abstract

Psoriatic arthritis (PsA) is a chronic inflammatory autoimmune disease of the joints that often accompanies psoriasis of the skin. The pathogenesis of PsA is defined by inflammatory processes that are mediated by T-cells and driven by the release of cytokines, particularly IL-17. These inflammatory processes adversely impact the musculoskeletal system.

A healthy gut microbiome and its metabolites have been shown to have immunomodulatory abilities, particularly through the action of short-chain fatty acids (SCFAs) in suppressing the release of IL-17 by TH17 immune cells. Recent studies have revealed that patients with PsA often have a dysbiotic gut microbiome and a disrupted intestinal barrier.

Therefore, positively modulating the intestinal microbiome with high-quality probiotics is a promising therapeutic strategy for managing this chronic inflammatory disease. This study examined the effects of the multi-species probiotic (trade names: OMNi-BiOTiC® STRESS Repair (AT); OMNi-BiOTiC® SR-9 (DE)) on disease activity, including pain and swelling, as well as on inflammatory markers and intestinal permeability in patients with PsA.

Results

This study demonstrated that a 12-week course of OMNi-BiOTiC® STRESS Repair / SR-9 (3 g daily, totalling 7.5×10^9 CFU) resulted in a marked reduction in inflammatory markers, specifically alpha-1 antitrypsin and calprotectin ($p < 0.05$). Additionally, there was a significant decrease in faecal zonulin concentration, a key marker of leaky gut, indicating improved intestinal barrier function ($p < 0.05$).

Notably, this probiotic therapy significantly improved signs and symptoms in patients with severe psoriatic arthritis who had not responded to state-of-the-art therapy ($p < 0.05$). Three patients with high baseline disease activity showed only mild signs and symptoms, as assessed by the modified Psoriatic Arthritis Disease Activity Score (mPASDAS), after taking the probiotic. A noteworthy finding was that the improvement in disease activity was associated with a decrease in TH17 cell abundance.

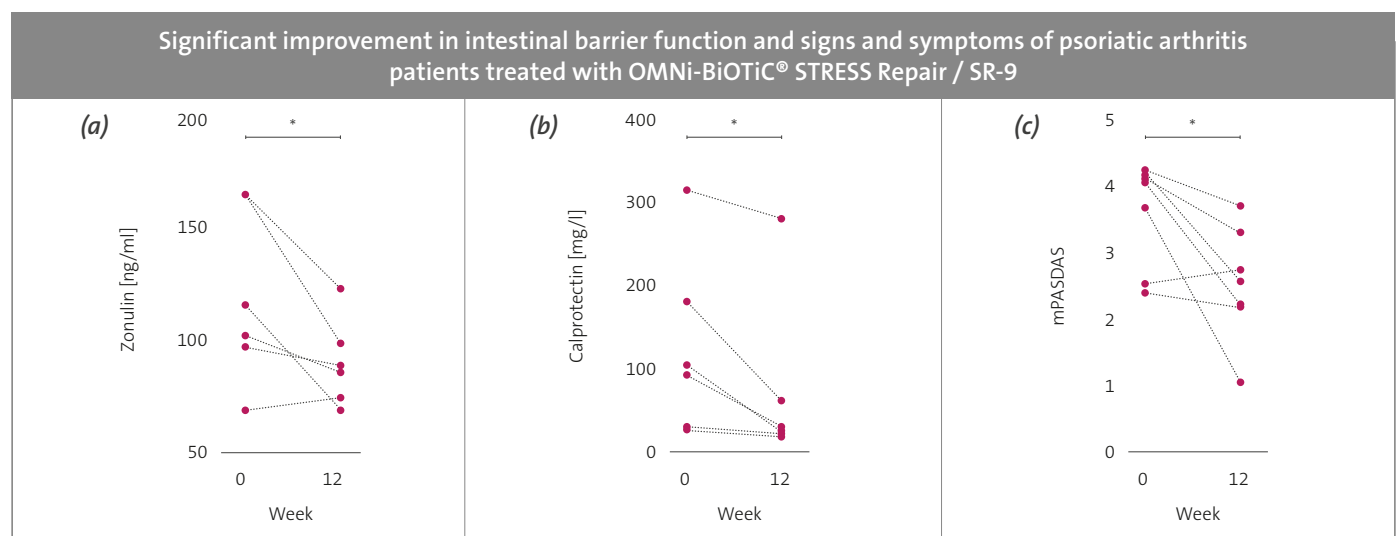


Figure: Significant reduction in leaky gut marker zonulin (a) and inflammatory marker calprotectin (b) by 12-week probiotic intervention. (c) Marked improvement in disease activity following specific probiotic therapy, as assessed by the modified Psoriatic Arthritis Disease Activity Score.

Discussion and conclusion

Recent scientific studies underscore the crucial role of the gut microbiome in immune-mediated inflammatory processes, such as those observed in rheumatic diseases. This study clearly demonstrated that administration of OMNi-BiOTiC® STRESS Repair / SR-9, a multi-species probiotic specifically formulated for anti-inflammatory activity, can reduce inflammatory reactions and restore the intestinal barrier in PsA patients. This improvement in patients' signs and

symptoms after a 12-week treatment course underscores the potential of high-quality probiotics effectively modulate PsA disease activity. OMNi-BiOTiC® STRESS Repair / SR-9 represents a promising treatment option for PsA, functioning similarly to conventional therapy by inhibiting IL-17.

The Preventive Effect of a Multi-Species Probiotic on the Development of Eczema in Newborns (PandA study)



L. Niers *et al.*, *Allergy*; 2009

Abstract

Scientific studies indicate that the prevalence of atopic and allergic diseases is increasing globally. This rise in childhood allergies is closely linked to reduced exposure to essential probiotic bacteria early in life. Multiple research studies have demonstrated a connection between the composition of children's gut microbiome and the pathogenesis of allergies. As a result, probiotic treatment and the resulting positive alterations in the intestinal microbiota are regarded as promising strategies for preventing allergic diseases. This double-blind, randomized, placebo-controlled study examined the impact of the multi-species probiotic OMNi-BiOTiC® PANDA, specifically designed for infants in their first year, on the development of eczema, early childhood microbial colonization, and the associated immune response in high-risk patients (those with a positive family history of allergic diseases). OMNi-BiOTiC® PANDA (1 x daily 3×10^9 CFUs) was administered prenatally to 156 women at increased risk of allergies during the last 6–8 weeks of pregnancy and postnatally to their pre-exposed infants for 12 months.

Results

Perinatal administration of the specific probiotic bacteria significantly reduced the occurrence of eczema in high-risk infants as early as 3 months of age. While 3 out of 50 children (6%) in the probiotics group were diagnosed with eczema by a doctor, 11 out of 52 children (21%) in the placebo group showed detectable eczema ($p < 0.05$). Although the cumulative incidence of eczema increased in both groups over the first 12 and 24 months, significantly fewer children in the probiotics group (12 months: 23/50; 24 months: 27/50) had eczema compared to the placebo group (12 months: 30/48; 24 months: 33/48). Notably, the intake of OMNi-BiOTiC® PANDA by children at 3 months of age led to a significant reduction in the pro-inflammatory interleukins IL-5 and IL-13, which are associated with atopic diseases.

Reduction in the incidence of diagnosed eczema with OMNi-BiOTiC® PANDA

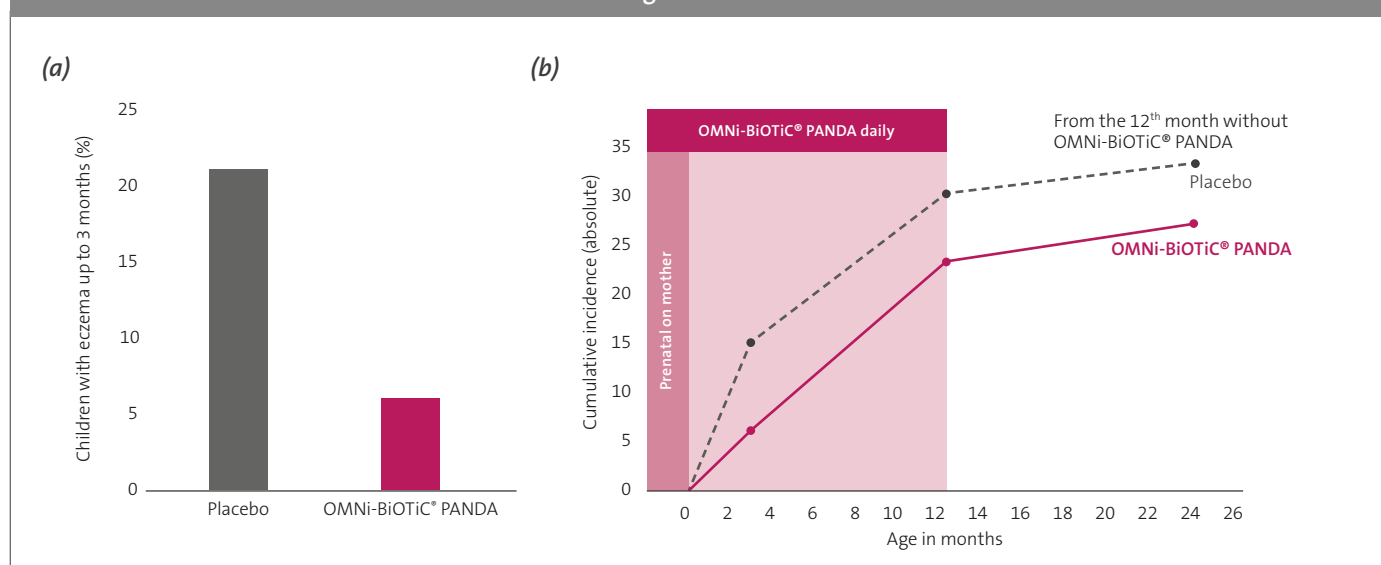


Figure: (a) After 3 months of therapy with OMNi-BiOTiC® PANDA, a significantly reduced occurrence of eczema was recorded compared to the placebo group. (b) The incidence of eczema increases in both groups in the first 24 months of life, but the probiotics group shows a much lower incidence.

Reduction of pro-inflammatory cytokines with OMNi-BiOTiC® PANDA

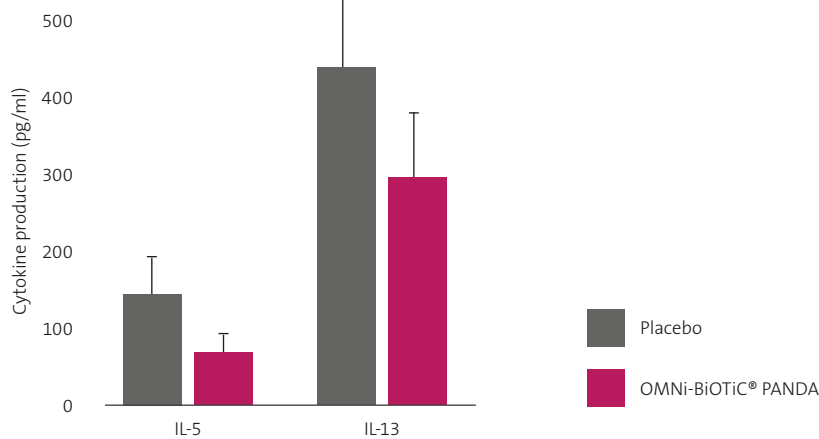


Figure: Already after 3 months of OMNi-BiOTiC® PANDA intake, both IL-5 and IL-13 were significantly reduced in the newborns, which is associated with a positive modulation of the immune system.

Discussion and conclusion

Atopic diseases and eczema often stem from a Th2-dominant immune response, a condition more commonly observed in babies delivered via caesarean section or who are bottle-fed. This study clearly demonstrated that perinatal administration of the multi-species probiotic OMNi-BiOTiC® PANDA not only positively affects the early colonisation of the child's gut with key probiotic bacteria but also supports immune regulation, considering that 70% of all

immune cells that produce antibodies are located in the intestine. The intake of this specially formulated probiotic significantly reduced the pro-inflammatory interleukins IL-5 and IL-13, correlating with a significantly reduced incidence of eczema. This study thus provides clear evidence of the preventive effect of OMNi-BiOTiC® PANDA on the development of atopic and allergic diseases in newborns.

Influence of a Multi-Species Probiotic on Secretory IgA Deficits

Jung *et al.*, Universität Mainz; 1999

Abstract

Secretory immunoglobulin A (sIgA) is an essential component of the body's immune system. It acts as the first line of defense in the intestine by preventing pathogenic germs from adhering to the intestinal mucosa. Low sIgA levels are associated with a weakened gut defence and a reduced number of symbiotic gut bacteria. Conversely, factors such as malnutrition, stress, medication, and excessive sport can impair sIgA formation. Magnesium and zinc deficiencies are also associated with reduced sIgA levels. This study investigated the effects of the multi-species probiotic OMNi-BiOTiC® 6, as well as magnesium and zinc supplements, on the normalisation of previously below-normal (< 2 U/g stool) sIgA levels in stool samples from 53 sports students. The students were divided into three groups: one group received a magnesium and zinc preparation, one group received OMNi-BiOTiC® 6, and the third group received the probiotic in combination with magnesium and zinc.

Results

The 4-week intake of the multi-species probiotic OMNi-BiOTiC® 6 (1x daily, 3×10^9 CFU total) led to a normalisation of sIgA values in 44% of the subjects ($p < 0.05$). The combined intake of the with magnesium (32.8 mg) and zinc (10 mg) showed a slightly increased effect on sIgA levels (normalisation at 47%). In contrast, the intake of magnesium and zinc alone showed minimal effect on the participants' sIgA titres (normalisation at 25%). These results demonstrate that positive modulation of the gut microbiome can significantly increase sIgA formation and thereby contribute to improved immune defence.

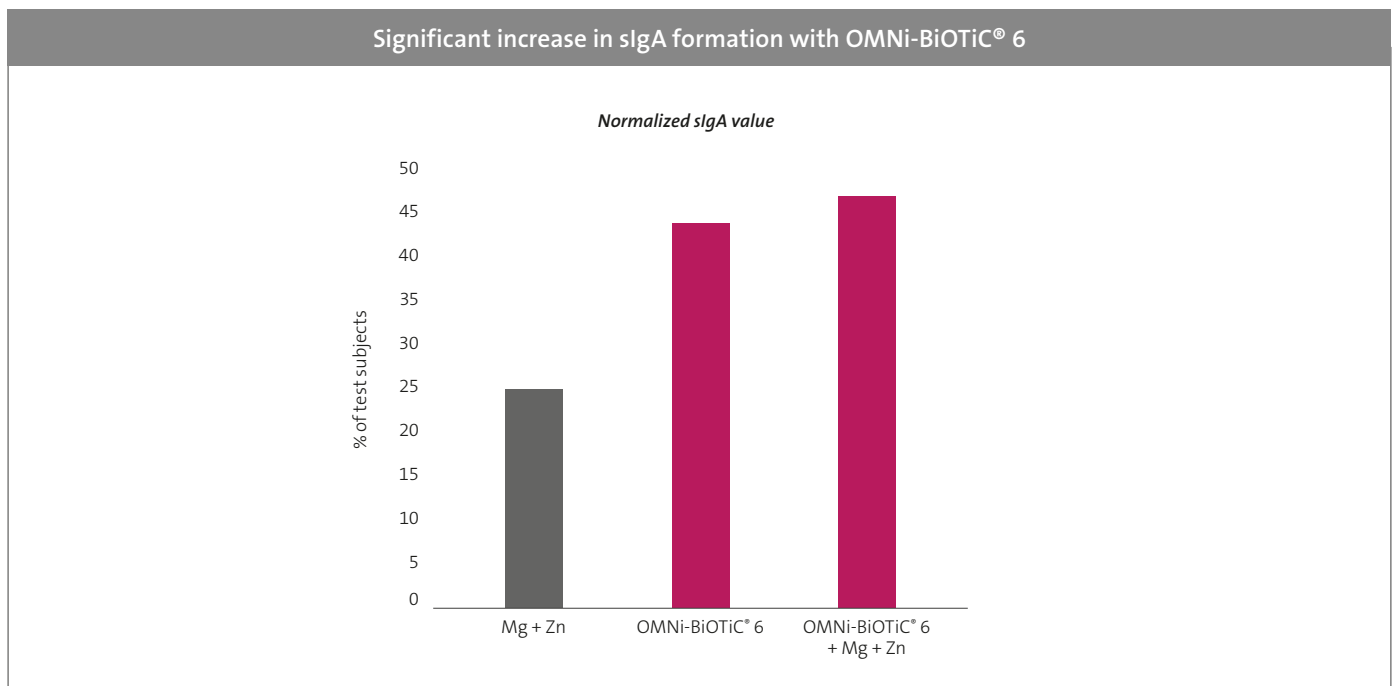


Figure: Taking OMNi-BiOTiC® 6 for 4 weeks normalised sIgA levels in 44% of participants ($p < 0.05$), whereas taking a magnesium/zinc preparation (Mg + Zn) normalised sIgA levels in only 25% of participants. The combined intake of the probiotic with Mg and Zn showed an improvement in 47% of the subjects ($p < 0.05$).

Discussion and conclusion

This study provides valuable insights into the regulation of sIgA production through the intestinal microbiome. The intake of specific beneficial, immunomodulating gut bacteria can normalize sIgA levels and thus contribute to stable immune performance. In contrast, magnesium and zinc supplementation alone have minimal

effect on sIgA levels. The results impressively show that the positive modulation of the intestinal microbiome with OMNi-BiOTiC® 6 can compensate for an sIgA deficiency and enhance the defences of the intestinal epithelium.

Multi-Species Probiotic Reduces the Duration of Acute Respiratory Illness in Older People



Strauss *et al.*, *Microorganisms*; 2023

Abstract

As we age, immune system function decreases significantly, greatly increasing the risk of infection. This decline is accompanied by age-related negative changes in the intestinal microbiome, including a reduction in immunomodulating *bifidobacteria* and *lactobacilli*. Consequently, acute respiratory tract infections (URTIs) occur more frequently in older people, often leading to persistent morbidity and mortality. The functionality of the intestinal microbiome and its immunological function is particularly important in respiratory diseases, as the intestine engages in bidirectional exchange with the lungs. The immune function can be improved by supporting the intestinal microbiome, reducing susceptibility to infections. This randomised, double-blind, placebo-controlled study investigated the effect of an indication-specific multi-species probiotic (trade name: OMNi-BiOTiC® *Active*) on the incidence, duration, and severity of URTIs in 95 subjects aged 65 and over.

Results

The 12-week administration of OMNi-BiOTiC® *Active* (2x daily 2g each with a total of 1×10^{10} CFU) led to a reduced incidence of respiratory tract infections (30.61% with probiotics vs. 36.96% with placebo). Particularly noteworthy is that the duration of these infections was significantly reduced in the probiotics group compared to the placebo group ($p=0.011$). Blood analyses also showed a significant improvement in the lymphocyte count ($p=0.009$) as well as in the number of eosinophil ($p=0.002$) and basophil ($p=0.001$) granulocytes. The significant reduction of these immune cells in the probiotics group compared to the start of the study as well as to the placebo group clearly indicates reduced inflammation due to the probiotic.

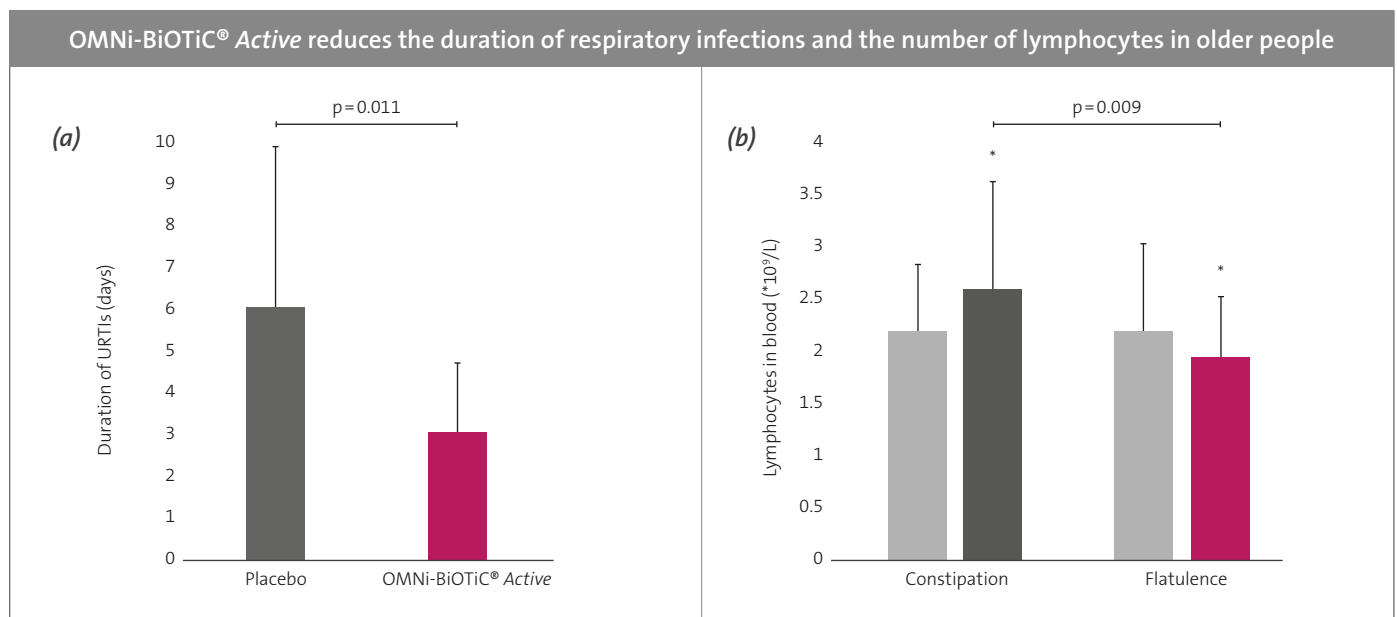


Figure 1: (a) Taking OMNi-BiOTiC® *Active* significantly shortened the duration of upper respiratory tract infections (URTIs) in older people. (b) While lymphocyte counts continued to increase in the placebo group, they were significantly reduced by the 12-week probiotic intervention, indicating a reduced inflammatory status in these subjects.

Discussion and conclusion

This study clearly shows that targeted support of the intestinal microbiota with the multi-species probiotic OMNi-BiOTiC® *Active* is particularly suitable for older adults. Positive modulation of the intestinal microbiome with the help of selected *bifidobacteria* and *lactobacilli* efficiently counteracts dysbiosis and significantly reduces

immunological deficits. Given the proven loss of intestinal microbiome diversity with age, it is recommended to take a high-quality probiotic daily to optimize immune system function starting from the intestine.



METABOLISM

6

TYPE 2 DIABETES 54–59

OBESITY THERAPY 60



The Effect of a Multi-Species Probiotic on Lipid Markers, Intestinal Permeability and Quality of Life in Type 2 Diabetes Mellitus Patients



Horvath *et al.*, European Journal of Nutrition; 2019

Abstract

Scientific research is increasingly highlighting the significant role of the intestinal microbiome in chronic diseases such as obesity, type 2 diabetes, and metabolic syndrome. Dysbiosis, or imbalance, in the gut microbiome linked to obesity is gaining attention as a potential therapeutic target for preventing and treating these conditions. The use of probiotics as an adjunctive treatment for insulin resistance is proving to be particularly promising. This double-blind randomized, placebo-controlled clinical study analyzed the effect of the multi-species probiotic OMNi-BiOTiC® HETOX in combination with the prebiotic OMNi-LOGiC® PLUS on lipid markers, quality of life and intestinal permeability in obese type 2 diabetes patients.

Results

A 6-month treatment with the multi-species probiotic OMNi-BiOTiC® HETOX (6 g daily with a total of 1×10^{10} CFU) in combination with the prebiotic OMNi-LOGiC® PLUS (10 g daily) lead to a clear reduction in hip measurement and a significant improvement in the quality of life ($p < 0.05$), which was ascertained using the SF36 questionnaire. These improvements were particularly evident in terms of increased physical activity. Furthermore, after 3 months of treatment, the probiotics group showed a significant reduction in intestinal permeability, as evidenced by lower levels of the leaky gut marker zonulin ($p < 0.05$). After a 6 month treatment period, a reduced lipoprotein concentration could be observed in the probiotic group. This is associated with a reduced risk for cardiovascular diseases.

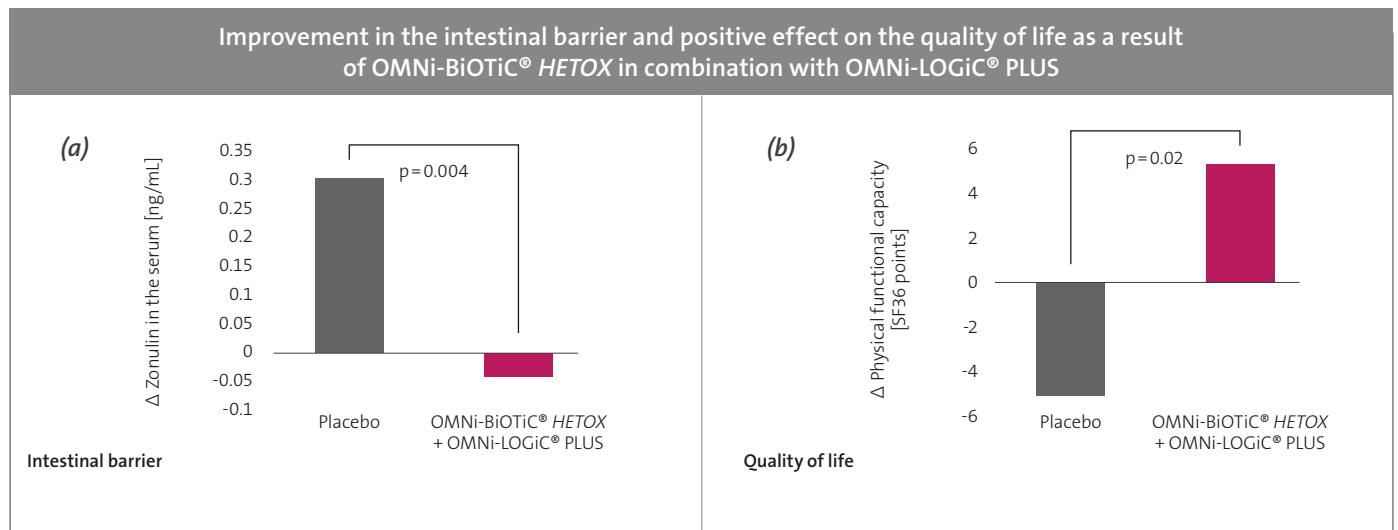


Figure: (a) Significant reduction in the concentration of zonulin in stools after 3 months of treatment with synbiotics. (b) After administering probiotics and prebiotics, a significantly improved quality of life in terms of improved physical functional capacity was demonstrated after only 3 months.

Discussion and conclusion

The positive modification of the intestinal microbiome presents a potential therapeutic approach in type 2 diabetes patients, given the established link between type 2 diabetes and the intestinal microbiome in scientific studies. The increase in the concentration of circulating insulin in diabetics leads to raised intestinal permeability. As a result, elevated numbers of endotoxins can enter the bloodstream and result in inflammation. Scientific evidence demonstrates that administering specific multi-species probiotics can restore the intestinal barrier, reducing the transfer of endotoxins and thereby mitigating inflammatory responses. Intervention with the multi-species

probiotic OMNi-BiOTiC® HETOX, combined with the pre-biotic OMNi-LOGiC® PLUS, significantly improves type 2 diabetes biomarkers, hip measurement, intestinal permeability and patients' quality of life. This underscores the value of using specially formulated, medically relevant multi-species probiotics as an effective adjunctive treatment for managing obesity and type 2 diabetes.

The Effect of the 12-week Administration of Probiotics on Endotoxin Levels and Cardiometabolic Profile in Treatment-Naive Patients with Type 2 Diabetes Mellitus



Sabico *et al.*, Journal of Translational Medicine; 2017

Abstract

Increasing evidence shows that the intestinal microbiome plays a crucial role in chronic diseases such as obesity, type 2 diabetes mellitus, and metabolic syndrome. Altering the intestinal microbiome, therefore, holds great potential for preventing and treating these conditions. Notably, probiotics are emerging as an effective adjuvant therapy in managing insulin-resistant diseases. In this double-blind, randomized, placebo-controlled clinical study, the effects of the multi-species probiotic (OMNi-BiOTiC® *METAtox* / OMNi-BiOTiC® *HETOX light*) on endotoxin levels (primary endpoint) and cardiometabolic biomarkers were analyzed in 96 treatment-naive patients with type 2 diabetes mellitus.

Results

After 12 weeks of administering probiotics (4 g daily with a total of 1×10^{10} CFU), the placebo and probiotic groups were compared using an 'intention to treat' analysis. In the probiotics group, there was a significant improvement in waist-to-hip ratio (WHR) and a clinically significant improvement in insulin resistance, as determined by the HOMA (homeostasis model assessment) index. Following the use of OMNi-BiOTiC® *METAtox* / OMNi-BiOTiC® *HETOX light*, the concentrations of glucose, insulin, and C-peptides were lower in the probiotic group than at the start of the treatment. Additionally, after three months, the probiotic group exhibited a statistically significant reduction in circulating triglycerides and LDL cholesterol levels. A significant negative correlation was found between endotoxin levels and HDL cholesterol in the probiotic group ($r = -0.35$). In this group, endotoxin levels also correlated with circulating triglycerides ($r = 0.37$) and the total/HDL cholesterol ratio ($r = 0.42$).

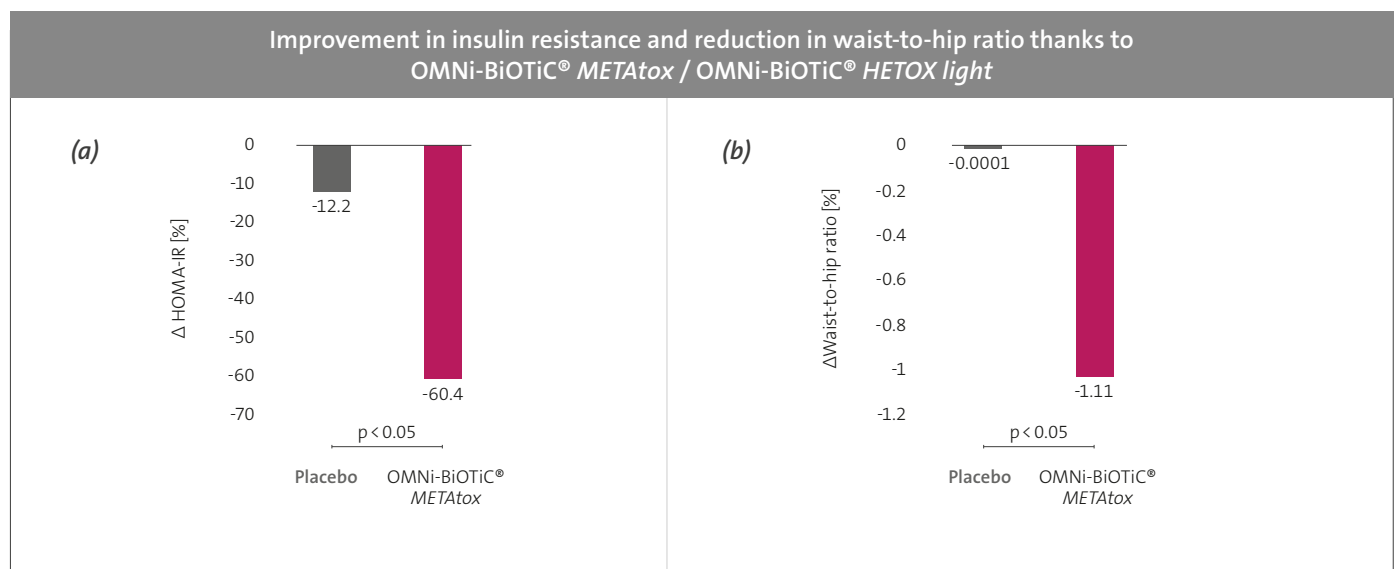


Figure: (a) Significant improvement in insulin resistance after the administration of probiotics for 12 weeks, calculated base on the HOMA index. (b) Significant reduction in waist-to-hip ratio after probiotic treatment over 12 weeks.

Discussion and conclusion

Patients with type 2 diabetes mellitus typically exhibit elevated endotoxemia compared to healthy individuals, which is attributed to increased intestinal permeability associated with elevated circulating insulin levels. Consequently, more endotoxins can enter the bloodstream and trigger inflammatory reactions. Scientific studies have shown that using specific multi-species probiotics can restore the intestinal barrier, preventing endotoxin transfer and reducing inflammation. In summary, the study by Sabico *et al.* demonstrated that a

12-week regimen of the multi-species probiotic OMNi-BiOTiC® *METAtox*/OMNi-BiOTiC® *HETOX light* in treatment-naive patients with type 2 diabetes mellitus resulted in statistically significant improvements in insulin resistance and abdominal obesity.

The Effect of Six Months of Probiotic Treatment on Inflammatory Parameters and Cardiometabolic Profile in Type 2 Diabetes Mellitus Patients



Sabico *et al.*, Clinical Nutrition; 2018

Abstract

Recent research indicates that the gut microbiome plays a crucial role in the pathogenesis of chronic diseases such as obesity, type 2 diabetes mellitus, and metabolic syndrome. In patients with type 2 diabetes mellitus, elevated insulin levels cause increased intestinal permeability, which allows more endotoxins to enter the bloodstream and trigger inflammatory reactions. Scientific evidence shows that administering specific multi-species probiotics can restore the intestinal barrier and subsequently reduce inflammatory responses.

Thus, positively altering the gut microbiome presents significant potential for preventing and treating this disease. In the present double-blind, randomised, placebo-controlled clinical trial by Sabico *et al.* the effect of the multi-species probiotic OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light on endotoxin levels, as well as other inflammatory and cardiometabolic biomarkers, was analysed in 61 previously untreated type 2 diabetes mellitus patients.

Results

After six months of daily probiotic administration (4g containing a total of 1×10^{10} CFU), there was a significant reduction in waist-to-hip ratio and a clinically significant improvement in insulin resistance, as measured by the HOMA (Homeostasis Model Assessment) index, compared to the placebo group. Glycaemic parameters improved significantly compared to the start of treatment, as evidenced by the reduction.

Endotoxin levels were notably lower after taking OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light compared to baseline. Additionally, the probiotics group demonstrated significant improvements in inflammatory markers after six months, with reductions in TNF- α ($p < 0.05$), IL-6 ($p < 0.05$), and CRP ($p < 0.05$). The probiotics group also showed significant reductions in circulating triglycerides ($p < 0.05$), total cholesterol ($p < 0.05$), and the total cholesterol/HDL ratio ($p < 0.05$).

Probiotic treatment led to a significant improvement in the glycaemic profile, as evidenced by reductions in median glucose ($p < 0.05$) and insulin ($p < 0.05$) levels, and a significant reduction in insulin resistance ($p < 0.01$).

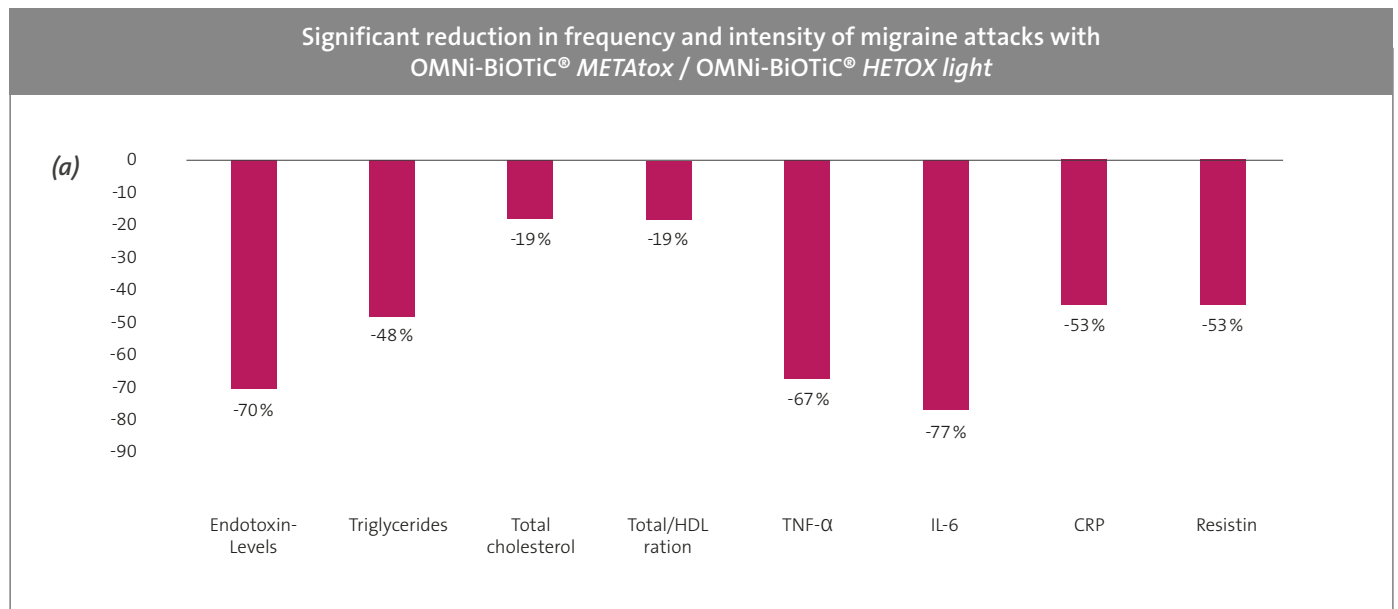


Figure: (a) Administration of OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light led to a reduction in endotoxin levels, blood lipids (cholesterol and triglycerides) and inflammatory markers (TNF- α , CRP, IL-6) after six months of treatment.

Improvement of insulin resistance with OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light

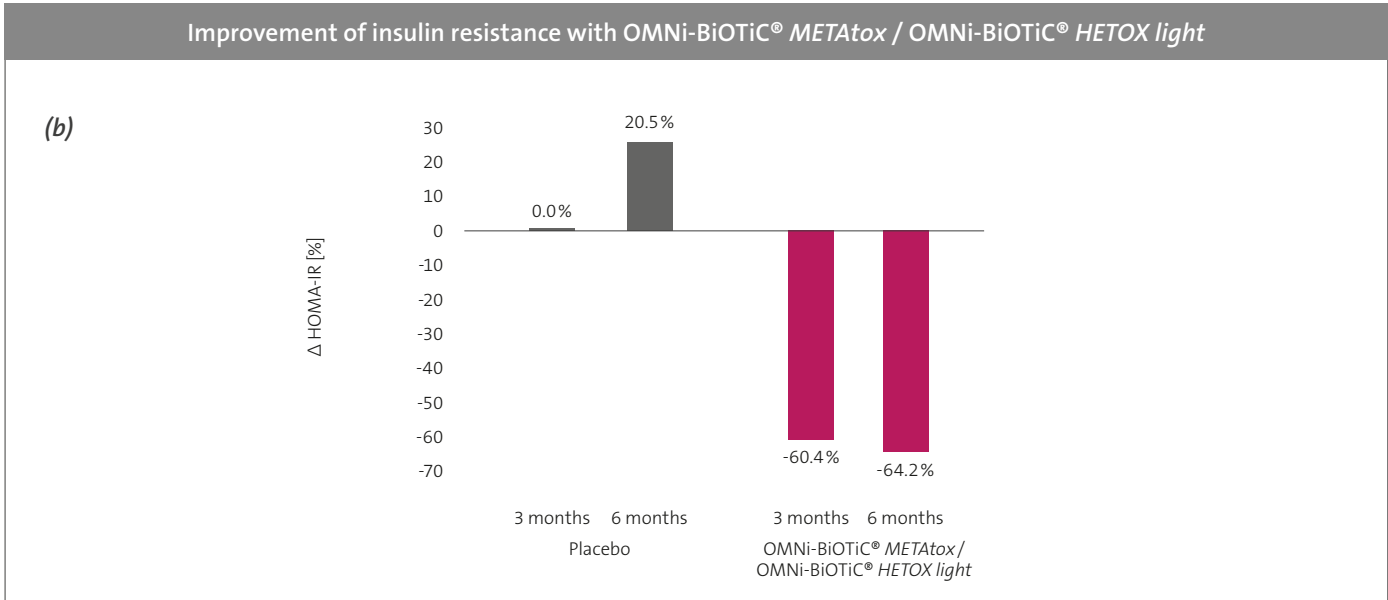


Figure: (b) Significant improvement in insulin resistance after three and six months of probiotic administration calculated by the HOMA index.

Discussion and conclusion

Patients with type 2 diabetes mellitus generally exhibit increased endotoxaemia compared to healthy individuals. The administration of clinically relevant multi-species probiotics strengthens the intestinal barrier and mitigates the transfer of endotoxins into the bloodstream. In summary, this study by Sabico *et al.* demonstrated that administering OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light

to previously untreated type 2 diabetes mellitus patients results in a statistically significant improvement in insulin resistance and beneficial effects on cardiometabolic markers. Furthermore, a reduction in inflammatory reactions was achieved, as evidenced by the decreased inflammation parameters.

The Effect of Multi-Species Probiotic on Lipopolysaccharide Levels and Cardiometabolic Profile in Obese Women after Menopause



Szulinska *et al.*, *Nutrients*; 2018

Abstract

According to the World Health Organisation (WHO), over 60% of women who have already undergone the menopause are overweight or obese. Metabolic diseases associated with obesity, such as dyslipidemia, insulin resistance, chronic inflammation or hyperuricemia are associated with an elevated risk of cardiovascular diseases and therefore represent the main cause of death in post-menopausal women.

Studies have demonstrated that changes in the intestinal microbiome play a significant role in the development of cardiometabolic diseases. Notably, research by Sabico *et al.* (2017) has shown that the multi-species probiotic OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light positively affects insulin resistance and obesity in patients with type 2 diabetes mellitus. To date, there has been no data on the effect of this probiotic on the cardiometabolic profile of obese post-menopausal women. Therefore, the randomized, placebo-controlled study by Szulinska *et al.* was the first to investigate the impact of OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light in two different doses (low-dose: 1g with total 2.5×10^9 Colony Forming Units (CFU) per day and high dose: 4g with total 1×10^{10} CFU per day) on lipopolysaccharide (LPS) levels and cardiometabolic parameters in 81 women with diagnosed obesity.

Results

The statistical analysis of the measured parameters revealed significant differences in both the high-dose and low-dose probiotics groups after 12 weeks of treatment compared to the start. In contrast, the placebo group showed no significant differences between the beginning and end of the treatment period.

Administering high-dose probiotics for 12 weeks resulted in reductions of 20.14% in lipopolysaccharide (LPS) levels, 1.7% in hip circumference, 3.44% in fat percentage, 7.32% in total cholesterol, 7.05% in triglycerides, 22.91% in subcutaneous fat, 11.13% in serum uric acid concentration, 3.99% in low-density lipoprotein (LDL), 7.92% in glucose, and 22.4% in insulin. The low-dose probiotic led to statistically significant reductions in hip circumference, fat percentage, visceral fat, and serum insulin concentrations.

The average change in parameters across the three groups showed statistically significant alterations in uric acid concentration, glucose, insulin, and LPS levels. Post-hoc tests confirmed significant changes between the high-dose probiotic group and the placebo group in all measured parameters, as well as between the high-dose and low-dose probiotic groups, except for LPS. In the low-dose probiotic group, a significant connection was found between changes in LPS levels and insulin resistance. In the high-dose probiotic group, the change in LPS serum levels correlated with the reduction in hip circumference.

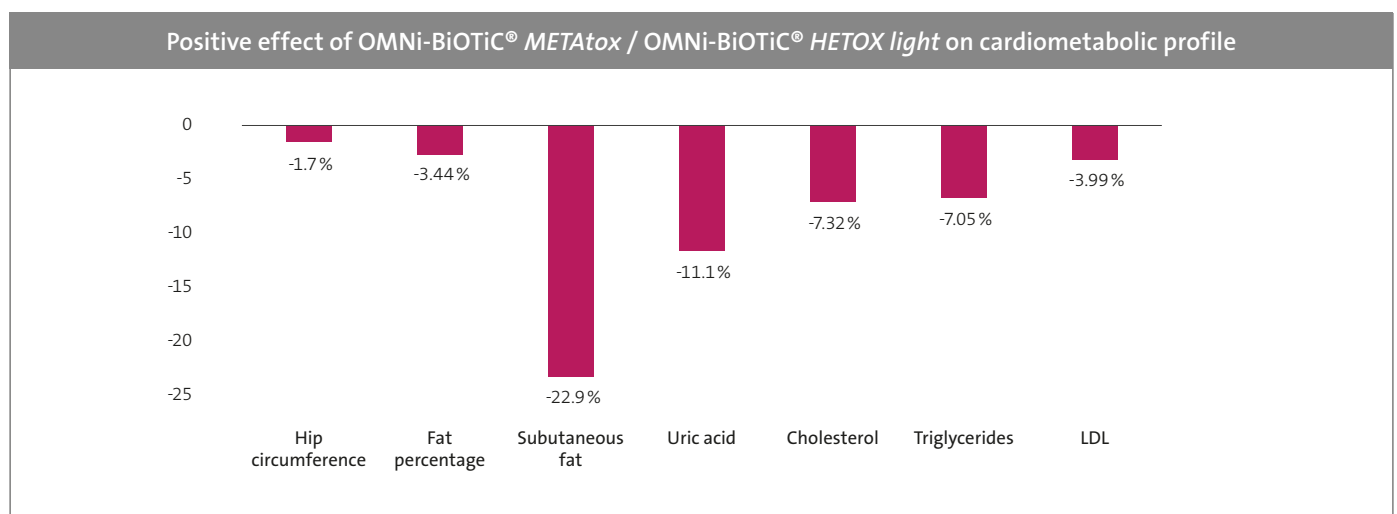


Figure: The administration of OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light (high-dose) led to a reduction in blood fats (LDL, cholesterol and triglycerides), waist and hip circumference and uric acid concentrations in serum after 12 weeks of treatment.

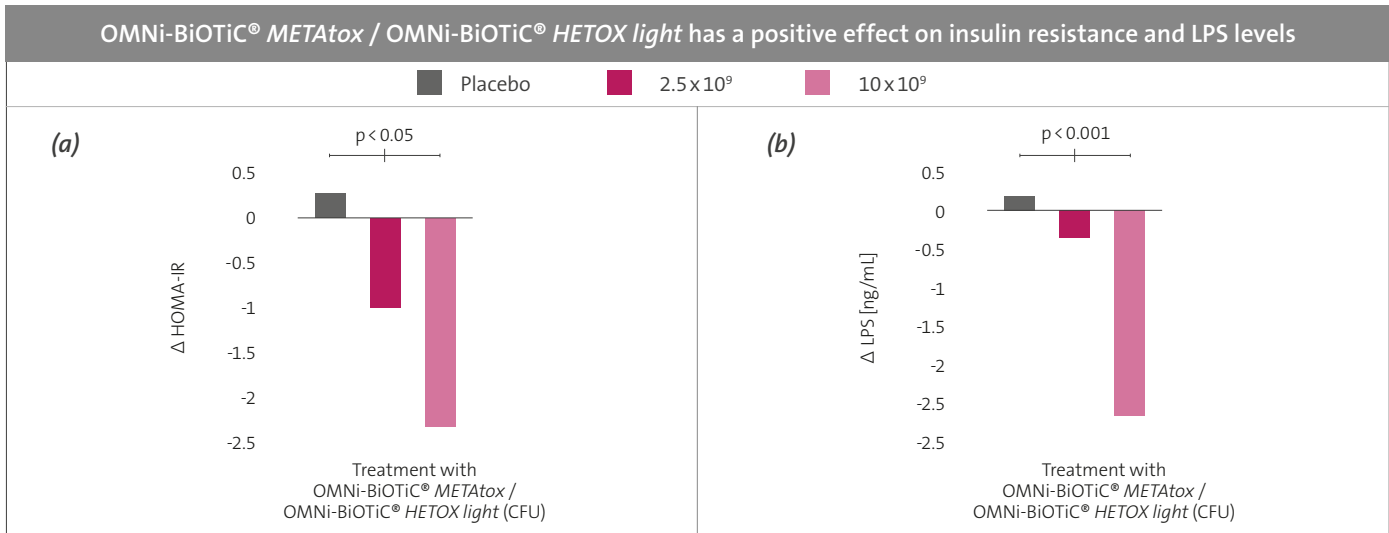


Figure: (a) Insulin resistance was reduced significantly by probiotic treatment (high and low-dose) in comparison to the placebo group. (b) Both the high-dose and the low-dose probiotic resulted in a significant reduction in LPS levels.

Discussion and conclusion

In this randomised, placebo-controlled study, it was demonstrated for the first time that the intake of the multi-species probiotic OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light has a beneficial effect on glucose metabolism, lipid profile, subcutaneous fat, uric acid levels, and LPS concentration in serum in obese, post-menopausal women. Additionally, probiotic administration effectively reduced insulin levels. It was observed that elevated insulin concentrations increase intestinal permeability, allowing bacterial toxins such as LPS to enter the bloodstream and trigger inflammatory reactions. This specially formulated probiotic can counteract many endotoxin-

induced metabolic diseases by altering LPS levels. Besides reducing LPS serum concentration, the probiotic also positively affected insulin resistance. In summary, the use of the multi-species probiotic OMNi-BiOTiC® METAtox / OMNi-BiOTiC® HETOX light represents a potential adjuvant therapy for obese, post-menopausal women. Other clinical trials are already in progress.

Synergistic Effect of a Multispecies Probiotic and a GLP-1 Agonist in Obesity Therapy

Mattioli *et al.*, Journal of pharmacy and pharmacology research; 2024

Abstract

Obesity is a widespread health problem with multiple challenges. The GLP-1 agonist liraglutide has shown promise in obesity treatment by not only helping to reduce weight but also to reduce cardiovascular risk. However, liraglutide treatment at usual dosage (3 mg/day) not only causes considerable costs, but also potential side effects, which requires careful patient monitoring. Studies show that the gut microbiome plays a central role in the regulation of sugar and fat metabolism. Positive modulation of the microbiome therefore offers an innovative approach to optimise obesity treatment. In this study, the synergistic effect of the specially developed multispecies probiotic OMNi-BiOTiC® METAtox and low-dose liraglutide was retrospectively investigated in 52 obese patients (BMI > 30 kg/m²). The control group received a personalised diet for 3 months, the probiotics group received OMNi-BiOTiC® METAtox (1x daily 3g with total 7.5 x 10⁹ CFU) and liraglutide (men: 0.6 mg/day for the first 10 days, then 1.2 mg/day for another 10 days, then 1.8 mg; women: 0.6 mg/day for the first 10 days, then 1.2 mg/day) in addition to the dietary change.

Results

The 3-month intake of OMNi-BiOTiC® METAtox in combination with low-dose liraglutide proved to be far more effective in all measured parameters compared to the diet alone. Particularly noteworthy is the significant reduction in body weight by 8.09 kg (-7.8%), whereas the control group only lost 4.42 kg (-4.4%) (p < 0.001). The BMI was also reduced significantly more with OMNi-BiOTiC® METAtox plus liraglutide compared to the control group (-3.02 kg/m² vs. -1.71 kg/m², p < 0.001). In addition, there were significant reductions in excess abdominal volume (p < 0.001) and waist, abdominal and hip circumferences (p < 0.05), which are considered significant indicators of cardiovascular disease.

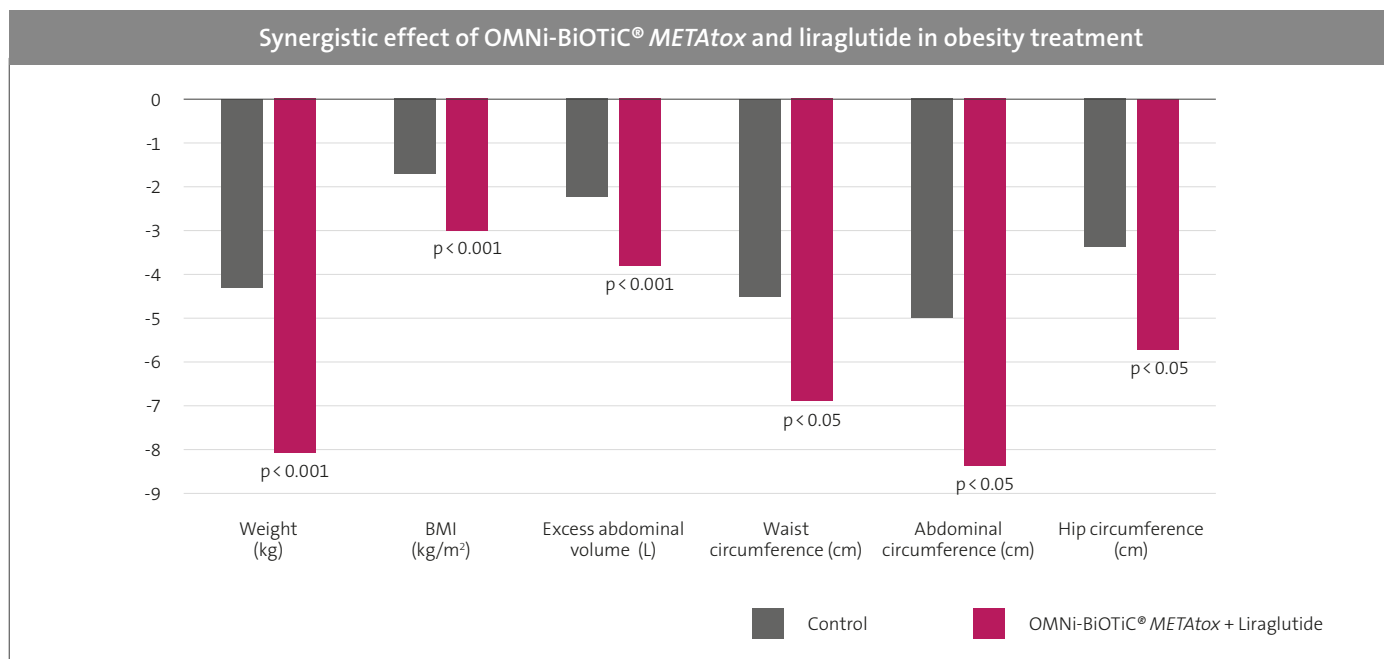


Figure: The combined intake of OMNi-BiOTiC® METAtox and low-dose liraglutide led to a significant reduction in body weight and BMI after just 3 months compared to the control group. Excess abdominal volume as well as waist, abdominal and hip circumferences were also significantly reduced.

Discussion and conclusion

This study impressively shows that OMNi-BiOTiC® METAtox optimally reinforces obesity treatment with liraglutide by positively modulating the intestinal microbiome. The positive effects in terms of weight reduction and waist circumference reduction are only comparable with studies in which a much higher liraglutide dosage (3 mg/day) was used. By using the specially

developed multispecies probiotic, the dosage of liraglutide can be greatly reduced, which also significantly reduces the side effects of the GLP-1 agonist and achieves a cost reduction of 40–60%.



GYNECOLOGY & PREGNANCY

7

VAGINAL FLORA 64–65

VAGINAL INFECTIONS 66–68

FERTILITY & PREGNANCY 69–70

**DIGESTIVE PROBLEMS OF
PREGNANT WOMEN & INFANTS** 71

MENOPAUSE 72–73



Evaluation and Selection of Potential Vaginal Probiotics of Human Origin



Domig *et al.*, Beneficial Microbes; 2014

Abstract

Frequently recurring infections in the female genitourinary tract not only significantly reduce the quality of life of the affected women but can also lead to complications such as an increased risk of sexually transmitted infections and a higher likelihood of premature births. *Lactobacilli* can displace pathogens and modulate the immune response and inflammatory cascade. Although vaginal capsules and suppositories containing probiotic bacteria have been available for some time and are generally effective in acute cases, they lack long-term sustainability and are therefore less effective for recurrent vaginal infections. A research group at the University of Vienna therefore focused on developing a probiotic formulation for gynaecological applications, now available as OMNI-BIOTIC® FLORA plus.

Results

Starting with 127 *Lactobacillus* strains from a healthy vaginal microbiome, which were confirmed to grow in MRS medium, the initial selection process was based on the similarity of their RAPD (randomly amplified polymorphic DNA) sequences. The second selection was determined by individual growth intensity, survivability in digestive acids, extracellular hydrogen peroxide production, and the ability to inhibit pathogenic microorganisms including (*E. coli*, *G. vaginalis*, *C. krusei*, *C. albicans*, and *C. glabrata* strains). In a final step, based on acid stability, detailed antibiotic sensitivity profiles, and mutual synergistic effects, four *Lactobacillus* strains were selected as particularly important for the health of the female urogenital tract: *Lactobacillus crispatus* LBV88, *Lactobacillus rhamnosus* LBV96, *Lactobacillus gasseri* LBV150N, and *Lactobacillus jensenii* LBV116.

Selection criteria for the probiotic bacterial strains in OMNI-BIOTIC® FLORA plus

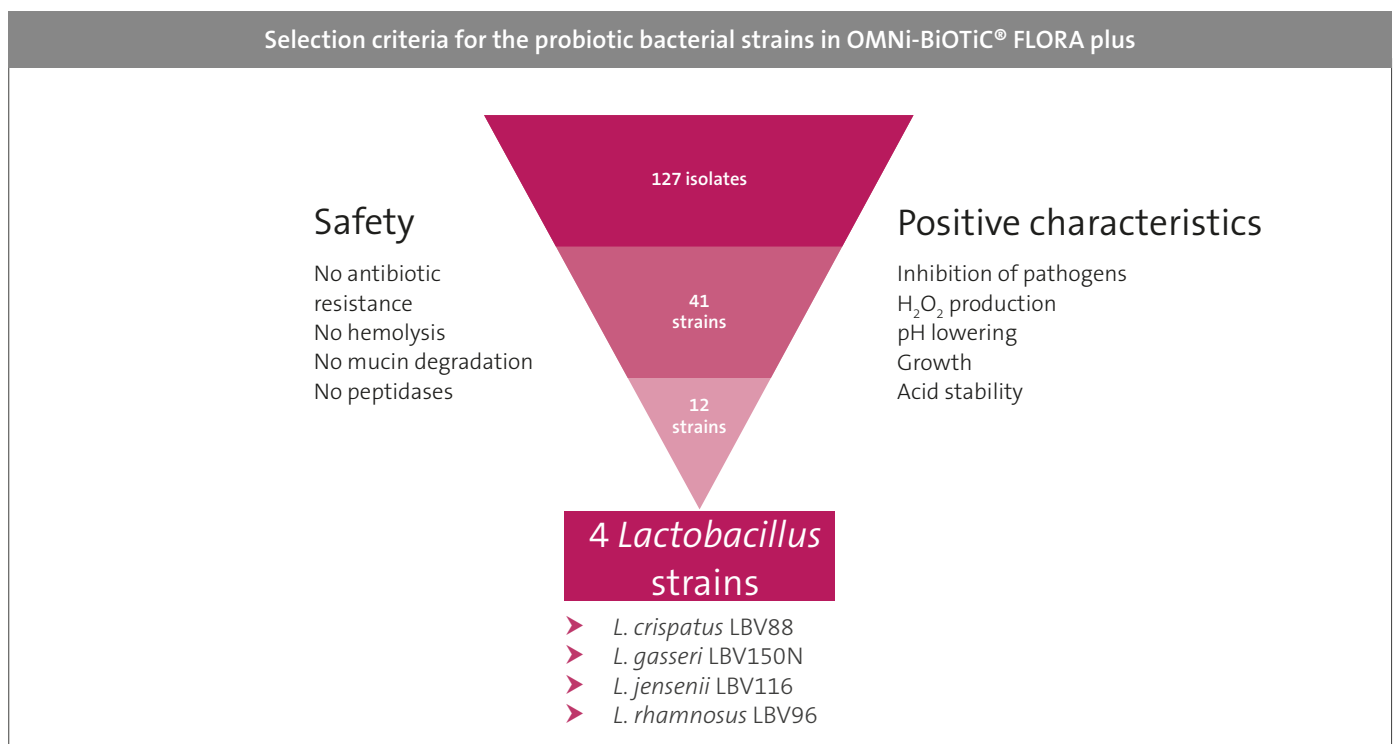


Figure: Selection of suitable bacterial strains according to safety and properties.

Discussion and conclusion

Through a scientifically based, step-by-step selection process, four *Lactobacillus* strains were identified that not only provide the highest safety but also effectively inhibit pathogenic microorganisms. The effectiveness of the combination of these four bacterial strains was subsequently analysed in various research studies and demonstrated superiority over all previously available preparations,

given that these symbionts were administered orally. This innovation has prompted a reevaluation and enhanced sustainability in the global gynecological treatment of bacterial vaginosis and candidiasis.

Successful Use of an Oral *Lactobacillus* Preparation to Build up the Neovaginal Microflora in Transsexual Women



Kaufmann *et al.*, Eur. J. Obstet. Gynecol. Reprod. Biol.; 2013

Abstract

The dysbiotic vaginal microbiome characteristic of bacterial vaginosis can also affect transsexual women. In the complex symbiosis of aerobic and anaerobic species, only a very limited number of *Lactobacilli* are detectable. This atypical colonisation of the vagina, especially with anaerobes, frequently triggers vaginal problems. Over the past few years, the use of medically relevant probiotics has gained importance in gynaecological practice. Microbiome research has not only identified effective bacterial strains but also shown that the optimal delivery method is oral ingestion of these probiotics, as it aligns with the natural physiological route of colonization. Passage through the intestinal tract results in deposits forming in the rectum, which serves as a reservoir for colonisation of the vagina. In the present randomised, double-blind, placebo-controlled study by Kaufmann *et al.*, the effect of the multi-species probiotic OMNi-BiOTiC® FLORA plus (*Lactobacillus crispatus* LBV88, *Lactobacillus rhamnosus* LBV96, *Lactobacillus gasseri* LBV150N, and *Lactobacillus jensenii* LBV116) on the microbial colonisation of the surgically created neovagina in 60 transsexual women was analysed.

Results

Before and after seven days of taking OMNi-BiOTiC® FLORA plus (2x2g daily with a total of 1×10^{10} CFUs), vaginal swabs were taken to analyse the vaginal microbiome and compared between the placebo and verum groups. Analysis of vaginal swabs showed that the neovaginas of transsexual women were colonised with *Lactobacilli* within a very short time after oral administration of the multi-species probiotic. In the placebo group, only marginal changes were observed. In the probiotics group, 48.5% of the transsexual women experienced a significant improvement in the Nugent score, whereas only 14.8% of the placebo group showed a positive change.

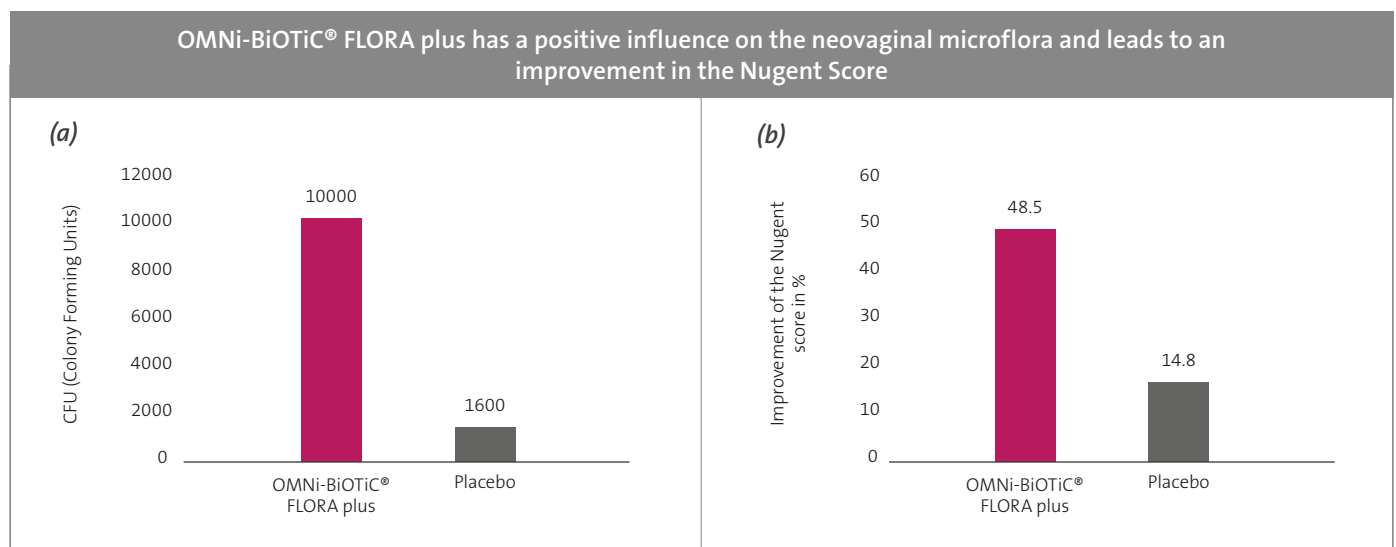


Figure: (a) Taking the probiotic resulted in a significant increase in *Lactobacilli* in the neovaginal microflora. (b) The administration of OMNi-BiOTiC® FLORA plus leads to a significant improvement of the Nugent score after 7 days of treatment.

Discussion and conclusion

The neovagina of transsexual women has a reduced number of *Lactobacilli*, allowing potentially pathogenic bacteria to settle and cause vaginal issues. Previous studies have already shown that the rectum acts as a reservoir for *Lactobacilli*, which migrate from the anus to the vagina. This study by Kaufmann *et al.* further demonstrates the positive effect of orally administered multi-species probiotics on vaginal colonisation with *Lactobacilli*. In summary, trans-

sexual women with a neovagina experienced a notable increase in *Lactobacilli* abundance and an associated improvement in the Nugent score, a result not seen in the placebo group.

The Successful Use of a Multi-Strain Probiotic in Pregnant Women with Herpes Virus Infections

Anoshina *et al.*, Perinatologiya I Pediatria; 2016

Abstract

The intestinal and vaginal microbiota of women represent the main source of microbial colonisation of their newborns, encompassing both commensal and pathogenic organisms. Vaginal dysbiosis in women of childbearing age, caused by various exogenous and endogenous factors, is steadily increasing. This is particularly relevant for patients with immunosuppression and/or existing herpes virus infection, as previous studies have demonstrated that such an imbalance can lead to complications like placental insufficiency, preterm birth, growth retardation, and postpartum endometriosis. It is already known that the rectum serves as a reservoir for *lactobacilli* that colonise the vaginal tract. This study by Anoshina *et al.* examined the effect of OMNi-BiOTiC® FLORA plus on the intestinal and vaginal microbiome in 60 pregnant women with herpes virus infection.

Results

After taking OMNi-BiOTiC® FLORA plus for 7 days (2 x 2 g daily with a total of 1×10^{10} CFU), the abundance of opportunistic pathogens was significantly reduced, and the presence of *lactobacilli* and *bifidobacteria* increased. The proportion of women with intestinal dysbiosis decreased from 66.7% to 46.7%. Additionally, gynaecological parameters improved: the relative number of *lactobacilli*, crucial for healthy vaginal microbiome, increased threefold, while the abundance of pathogenic germs and opportunistic pathogens significantly decreased. Symptoms associated with bacterial vaginosis, such as itching, swelling, discharge, and inflammation of the mucosa, were reduced by an average of 2.5 times. Notably, the probiotic intervention improved conditions for a successful gestational process, as evidenced by a reduction in placental insufficiency, pre-eclampsia, and fetal distress.

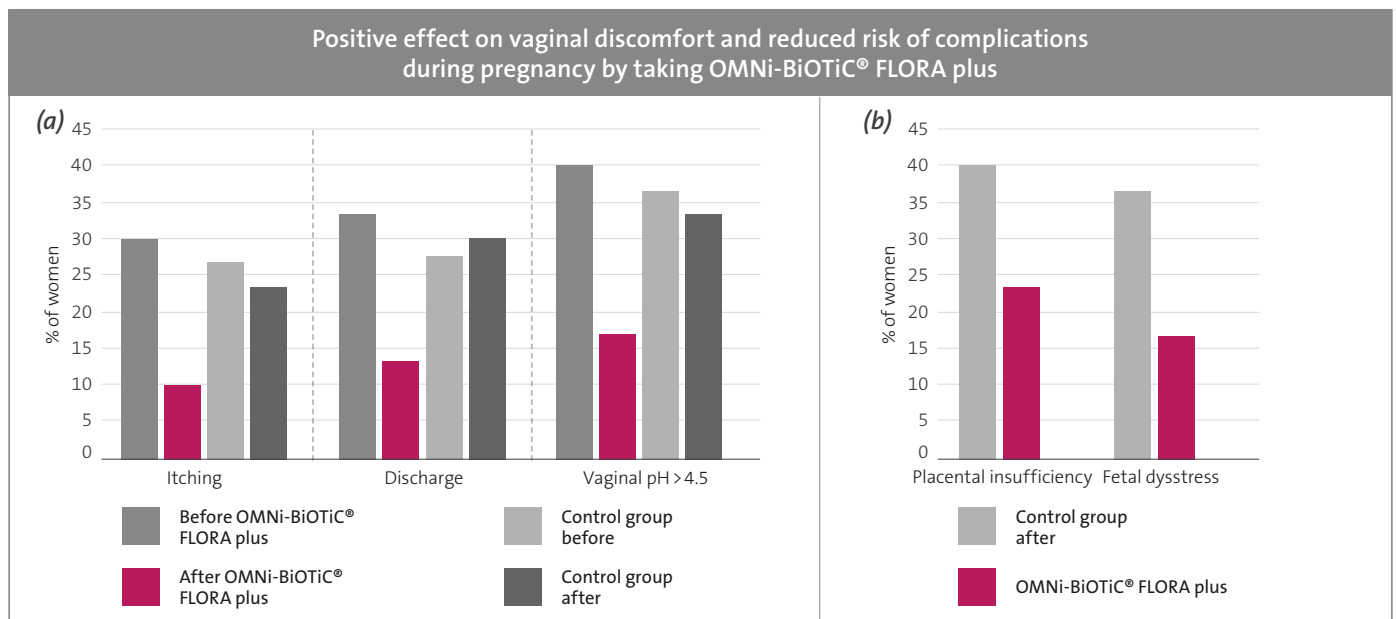


Figure: (a) Significant reduction of vaginal discomfort – itching, discharge, inflammation – by probiotic administration. (b) Reduced risk of pregnancy complications such as placental insufficiency and fetal distress with probiotic intervention.

Discussion and conclusion

During pregnancy, the vaginal epithelium is highly susceptible to herpesvirus infections due to physiological immunosuppression, making probiotic intervention for vaginal dysbiosis particularly beneficial for pregnant women. This study showed that OMNi-BiOTiC® FLORA plus positively modulates the intestinal and vaginal microbiome. The number of pathogenic germs was reduced, and commensal

populations significantly increased, alleviating vaginal discomfort. The results clearly demonstrate that administering a multi-strain probiotic consisting of *lactobacilli* can significantly reduce the risk of pregnancy complications caused by vaginal dysbiosis.

The Positive Effect of a Multi-Strain Probiotic on Bacterial Vaginosis – a Double-blind, Randomised, Controlled Clinical Study



Laue *et al.*, *Beneficial Microbes*; 2017

Abstract

The healthy vaginal microbiome is predominantly composed of *Lactobacillus* species, playing a crucial role in regulating immune responses and protecting against vaginal infections. In sexually mature women, the sex hormone oestrogen modulates vaginal colonisation with *lactobacilli* that metabolise glycogen to produce lactic acid. This process is vital for maintaining an acidic pH value of 3.8–4.4, which prevents the growth of pathogens. Bacterial vaginosis (BV), characterised by a deficiency in *lactobacilli* and an overgrowth of anaerobic bacteria (e.g., *Gardnerella vaginalis*, *Clostridialis*, *Prevotella*), involves microbiological disruptions in vaginal microbiome. These pathogens lead to both acute and chronic symptoms and increase the risk of sexually transmitted diseases, endometritis, urinary tract infections, and pregnancy complications.

In recent years, research on probiotics in gynaecology has yielded remarkable results. This double-blind, randomized, placebo-controlled study investigated the effect of the multi-strain probiotic OMNi-BiOTiC® FLORA plus on the condition of women diagnosed with bacterial vaginosis, particularly when administered alongside antibiotics.

Results

In 36 women (verum = 18, placebo = 18), the Amsel criteria and the Nugent score were assessed at the start of the study and after four weeks of taking OMNi-BiOTiC® FLORA plus (2g twice daily, totalling 1×10^{10} CFU) to evaluate vaginal dysbiosis. A comparison was made between the verum and placebo groups. The additional intake of the probiotic alongside a one-week course of the antibiotic metronidazole (2x500 mg daily) yielded impressive results. None of the patients in the verum group displayed symptoms of BV after a four-week observational period, in contrast to the placebo group, where 38% of the women still suffered from BV symptoms.

Notably, the administration of OMNi-BiOTiC® FLORA plus reduced the Nugent score from 7.06 to 2.44, within the physiologically healthy range. In contrast, the Nugent score in the placebo group was only reduced to 4.19. Over the course of the four-week probiotic treatment, vaginal pH values also improved to 4.19, within the desired acidic range, due to the recolonisation of *lactobacilli*.

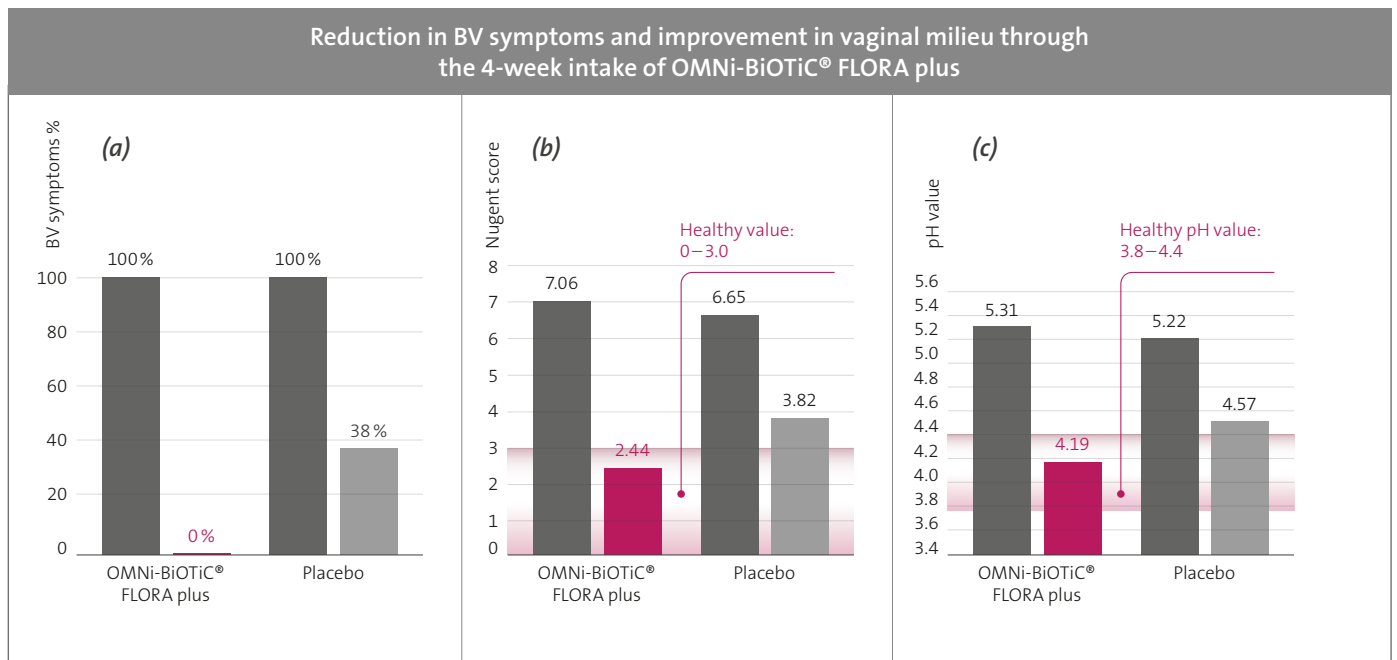


Figure: (a) Complete reduction in BV symptoms in the probiotic group in comparison to the placebo group. (b) The Nugent score was reduced to within the physiological range through the administration of probiotics. (c) Improvement in vaginal pH value by taking OMNi-BiOTiC® FLORA plus.

Discussion and conclusion

This study demonstrated that oral administration of the probiotic OMNI-BiOTiC® FLORA plus resulted in a significantly greater reduction in bacterial vaginosis (BV) symptoms compared to the placebo group. The study observed that a polymicrobial biofilm, characteristic of chronic BV infections, adhered to the vaginal epithelium and was not effectively eliminated by antibiotic treatment alone in the placebo group. The additional intake of the multi-strain probiotic OMNI-BiOTiC® FLORA plus, and the associated increase in *lactobacilli* coloni-

sation, achieved a 100% improvement in symptoms, assessed using the Amsel criteria and Nugent score. The study confirms that oral administration of probiotic bacterial strains, as contained in OMNI-BiOTiC® FLORA plus, can significantly improve recovery rates and symptoms of bacterial vaginosis and is well tolerated.

The Endometrial Microbiome Influences Implantation Success in Artificial Inseminations

Moreno *et al.*, American Journal of Obstetrics and Gynecology; 2016

Abstract

The human microbiome represents up to 3% of our body mass. While most microbiome research has focused on the gastrointestinal tract, there is growing interest in other microbial habitats, including the reproductive tract. This study aimed to verify the existence of an endometrial microbiome and characterize it taxonomically. The study investigated whether and how the endometrial microbiome differs from the vaginal microbiome, the influence of the hormonal cycle on the endometrial microbiome, and the impact of microbial colonization on the success of in vitro fertilization (IVF) in infertile women.

Results

The microbial comparison between endometrial fluid and vaginal swabs revealed significant differences in bacterial communities in some subjects. The endometrial microbiome, consisting of up to 191 operational taxonomic units, was categorized as either *Lactobacillus*-dominated (>90% *Lactobacillus* spp.) or non-*Lactobacillus*-dominated (<90% *Lactobacillus* spp.). The composition of the endometrial microbiota was not hormonally regulated during the acquisition of endometrial receptivity. However, a *Lactobacillus*-dominated microbiome in a hormonally receptive endometrium was associated with a significantly higher IVF implantation success rate (60.7% with *Lactobacillus*-dominated microbiome vs. 23.1% with non-*Lactobacillus*-dominated microbiome). Similar significant results were observed for pregnancy rate (70.6% vs. 33.3%), sustained pregnancy rate (58.8% vs. 13.3%), and live birth rate (58.8% vs. 6.7%).

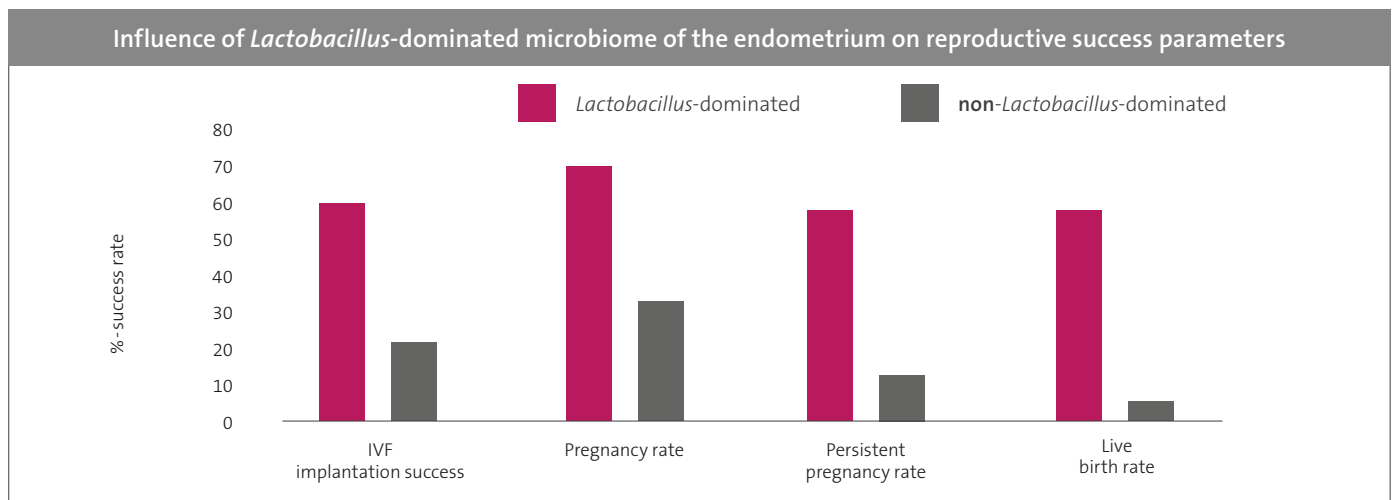


Figure: An endometrial microbiome dominated by lactobacilli is associated with significantly better success in terms of IVF implantation, (sustained) pregnancy rate and live birth rate.

Discussion and conclusion

The study provides clear evidence of an endometrial microbiome, independent of the hormonal cycle. The presence of non-*Lactobacillus* bacteria in the endometrium correlates with negative reproductive outcomes, suggesting a possible cause of implantation failure and miscarriage. These findings expand the assessment of endometrial receptivity to include microbiological factors. Microorganisms should be considered allies in reproductive medicine: probiotics

with specific *Lactobacillus* strains (such as OMNi-BiOTiC® FLORA plus) have shown positive effects on the vaginal microbiome and may also improve the endometrial microbiome in the future.

The Positive Effect of a Multi-Strain Probiotic in Women with an Unfulfilled Desire to Have Children



Schenk *et al.*, Reproductive BioMedicine Online; 2021

Abstract

Infertility is a widespread issue globally, with acute and chronic infections being significant factors alongside age, genetic predisposition, and lifestyle. In recent years, research in infertility treatment has increasingly focused on the vaginal microbiome. A healthy vaginal microbiota, predominantly composed of *Lactobacilli*, is essential for protecting against pathogenic organisms through the production of lactic acid. Vaginal dysbiosis, characterized by reduced *Lactobacilli* and overgrowth of anaerobic bacteria, can negatively impact reproductive ability. Vaginal colonization with *Ureaplasma parvum* is linked to infertility, perinatal diseases, and stillbirths. This randomized, placebo-controlled study investigated the effect of OMNi-BiOTiC® FLORA plus on the diversity and composition of the vaginal microbiome in 80 infertile women.

Results

At the study's onset and after four weeks of oral administration of OMNi-BiOTiC® FLORA plus (2 g once daily, totaling 5×10^9 CFUs), vaginal swabs were analyzed for the vaginal microbiome. 16S rRNA gene sequencing revealed a healthy, *Lactobacillus*-dominated vaginal flora in 75% of participants at the study's outset. Importantly, a significant difference in *Ureaplasma parvum* colonization was observed after administering OMNi-BiOTiC® FLORA plus compared to the placebo group. While *Ureaplasma parvum* colonization was minimal in the OMNi-BiOTiC® FLORA plus group, the placebo group exhibited a significant increase in the pathogen after four weeks ($p=0.021$). Thus, administering the probiotic OMNi-BiOTiC® FLORA plus prevented *Ureaplasma parvum* growth under normal conditions (without antibiotic treatment).

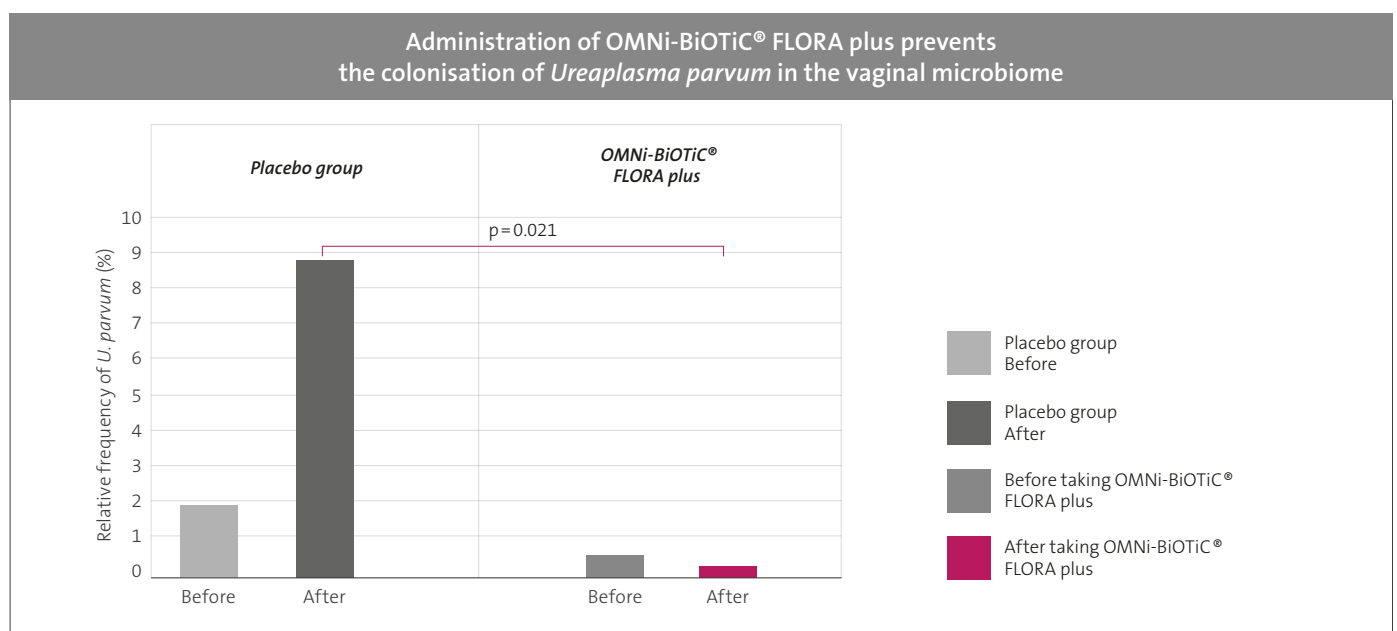


Figure: While in the placebo group the frequency of *Ureaplasma parvum* in the vaginal microbiome increases, the 4-week oral intake of the multi-strain probiotic suppresses the pathogen.

Discussion and conclusion

Dysbiosis due to reduced *Lactobacilli* can lead to lower implantation rates. This study demonstrates that OMNi-BiOTiC® FLORA plus administration has a protective effect by preventing colonization of the pathogen *Ureaplasma parvum* in the vaginal mucosa. The results highlight that probiotic *Lactobacillus* strains positively influence the vaginal flora by suppressing pathogenic bacteria. Consequently,

taking OMNi-BiOTiC® FLORA plus offers an optimal solution for maintaining a healthy vaginal microbiome, representing a supportive treatment option for women with infertility.

Multi-Species Probiotic Reduces Digestive Problems in Pregnancy and Infant Colic

Hofmann, Gynäkologie aktiv; 2015

Abstract

Infant colic, marked by excessive crying, affects 30% of newborns in their first 3 months. These infants often exhibit reduced gut microbiome diversity, fewer *Lactobacilli*, and an elevated presence of potentially pathogenic bacteria. Administering selected probiotic strains can foster optimal gut microbial colonization from birth and mitigate colic incidence. Expectant mothers frequently experience digestive issues in the final trimester, notably constipation and flatulence. This study assessed the effects of the indication-specific multi-strain probiotic OMNi-BiOTiC® PANDA (3 g daily, totaling 3×10^9 CFU) on digestive complaints in 148 expectant mothers during the last 2 months of pregnancy and colic development in their newborns within the first 4 months of life.

Results

While constipation and flatulence typically affect around 40% of pregnant women, OMNi-BiOTiC® PANDA administration drastically reduced these rates: constipation occurred in only 2.04% of pregnant women, with flatulence at 5.28%. Additionally, colic occurrence, measured by excessive crying duration in the first 124 days, was notably diminished to 4.9% with targeted probiotic bacterial administration.

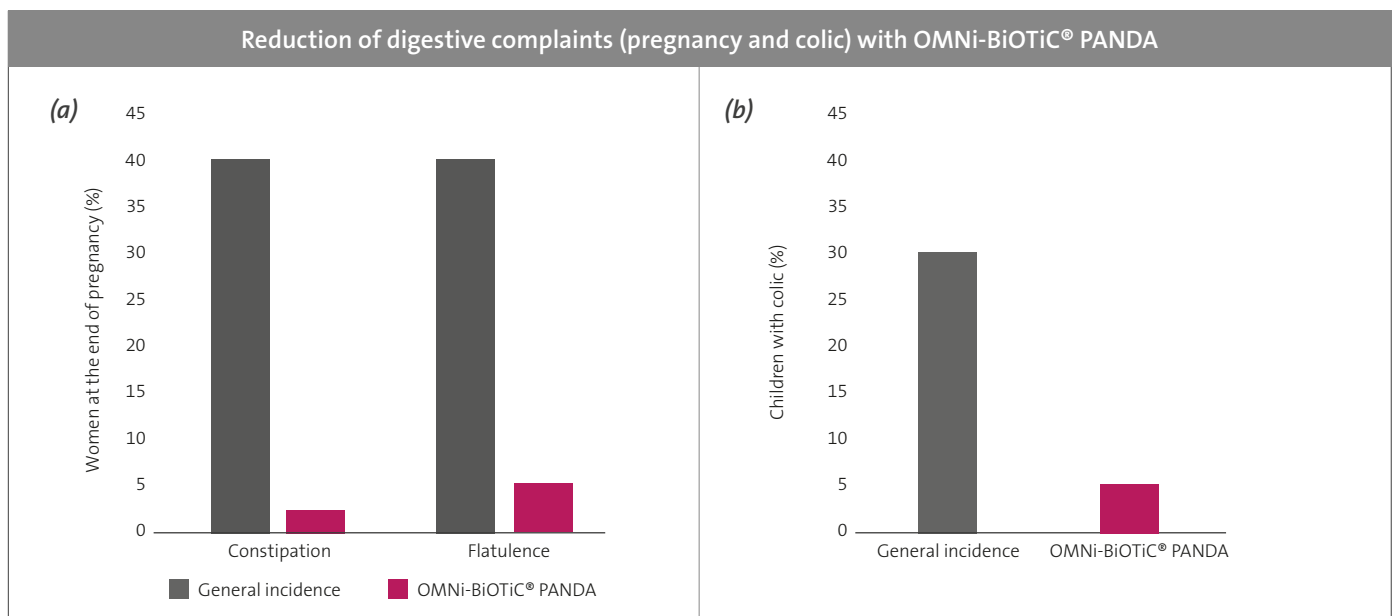


Figure: (a) The intake of OMNi-BiOTiC® PANDA by expectant mothers leads to a significant reduction in constipation and flatulence in the last two months of pregnancy. (b) Due to the probiotic intervention in their newborns, colic occurred in only 4.9% of the infants.

Discussion and conclusion

Studies indicate maternal gut microbiota transfer to newborns during birth, influencing allergy and gastrointestinal predisposition. Probiotic bacterial administration presents significant potential to rapidly improve gut microbiome composition, benefitting maternal and infant well-being. This study underscores the efficacy of the

multi-strain probiotic OMNi-BiOTiC® PANDA, alleviating expectant mothers' pregnancy-related flatulence and constipation while minimizing colic incidence in their babies.

The Effect of a Multi-Species Probiotic on Micronutrient Intake, Hormone Production, and Inflammatory Responses in Postmenopausal Women

Stiegelbauer *et al.*, OM & Ernährung; 2019

Abstract

As individuals age, they experience changes in capacity, hormone balance, and increased inflammation parameters. Modern microbiome research indicates that the intestine's ability to absorb essential nutrients and produce necessary vitamins declines over time. However, maintaining a sufficient quantity and diversity of health-promoting bacteria is crucial for optimal nutrient absorption at any age. Administering specifically formulated multi-species probiotics can positively reinforce the intestinal microbiota, enhance the integrity of the intestinal barrier, mitigate systemic and intestinal inflammation in older adults, and thereby restore optimal micronutrient absorption and stabilize hormone production. To verify these statements, a study was conducted with 20 postmenopausal, objectively healthy women, examining the effects of a nine-week administration of the high-quality multi-species probiotic OMNi-BiOTiC® Active (2 g once daily with a total of 5×10^9 CFU) on nutrient uptake, hormone production, and inflammatory reactions.

Results

Following treatment with OMNi-BiOTiC® Active, there was a notable enhancement in the cellular availability of vitamins and minerals, especially zinc, iron, and vitamin B12 ($p < 0.05$). Additionally, the estradiol/progesterone ratio was stabilized within the normal range, all without the use of nutritional supplements or hormone treatments. Compared to the start of the study, stool analyses conducted post-treatment showed a significantly increased presence of the butyrate-forming bacterial strain *Faecalibacterium prausnitzii* ($p < 0.05$). Additionally, after a nine-week intervention, significant improvements were observed in the inflammation markers alpha-1 antitrypsin and calprotectin ($p < 0.05$), along with a reduction in the leaky gut marker zonulin ($p < 0.05$).

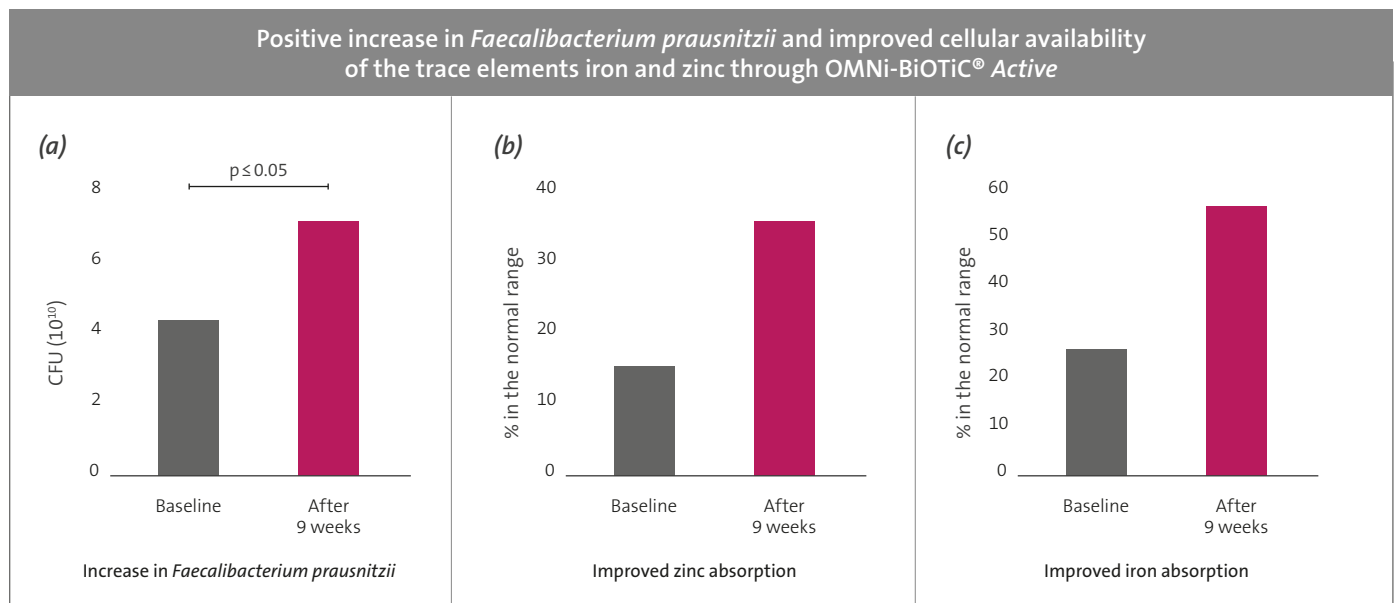


Figure: (a) Significantly increased abundance of *Faecalibacterium prausnitzii* after 9 weeks of OMNi-BiOTiC® Active administration. (b) Through the positive modulation of the intestinal microbiome, the absorption of the trace elements zinc and iron could be improved in the normal range.

Discussion and conclusion

In summary, this study demonstrates a clear positive effect of the indication-specific formulated multi-species probiotic OMNi-BiOTiC® Active on the intake of micronutrients, the reduction of systemic and bowel-associated inflammation, and the composition of the intestinal

microbiota in healthy postmenopausal women. Additionally, probiotic supplementation positively affected the hormonal balance of women and their quality of life.

Positive Effects of a Multi-Species Probiotic on the Relief of Menopausal Symptoms

Kolleritsch S., OM & Ernährung; 2024

Abstract

Menopause, the end of a woman's fertile phase, is associated with hormonal changes that can lead to extremely unpleasant symptoms. Menopausal women often suffer from hot flashes, sleep disturbances, muscle and joint pain, as well as problems with skin and hair. The gut microbiome plays an important role in regulating the body's estrogen levels and therefore has a significant influence on the severity of menopausal symptoms. The present market analysis investigated the positive influence of an indication-specific multi-species probiotic (trade name: OMNi-BiOTiC® Active) on various menopausal symptoms in 139 women who finished the survey completely. The study participants took the probiotic twice daily for 8 weeks and completed a questionnaire on menopausal symptoms before and after the intake.

Results

A significant improvement in all menopausal symptoms was observed after just 8 weeks intake of OMNi-BiOTiC® Active (2g twice daily with a total of 1×10^{10} CFU). Impressively, around 60% of women experienced a significant reduction in hot flashes and fatigue. In addition, the majority of affected women reported reduced muscle and joint pain, as well as improvements in skin appearance and a decrease in hair loss. Other physical complaints such as headaches, palpitations and dry eyes were also noticeably reduced in the majority of participants. Interestingly, more than half of the women also reported an increase in libido. Overall, the probiotic intervention led to a significant improvement in all menopausal symptoms, as summarized by the menopause score.

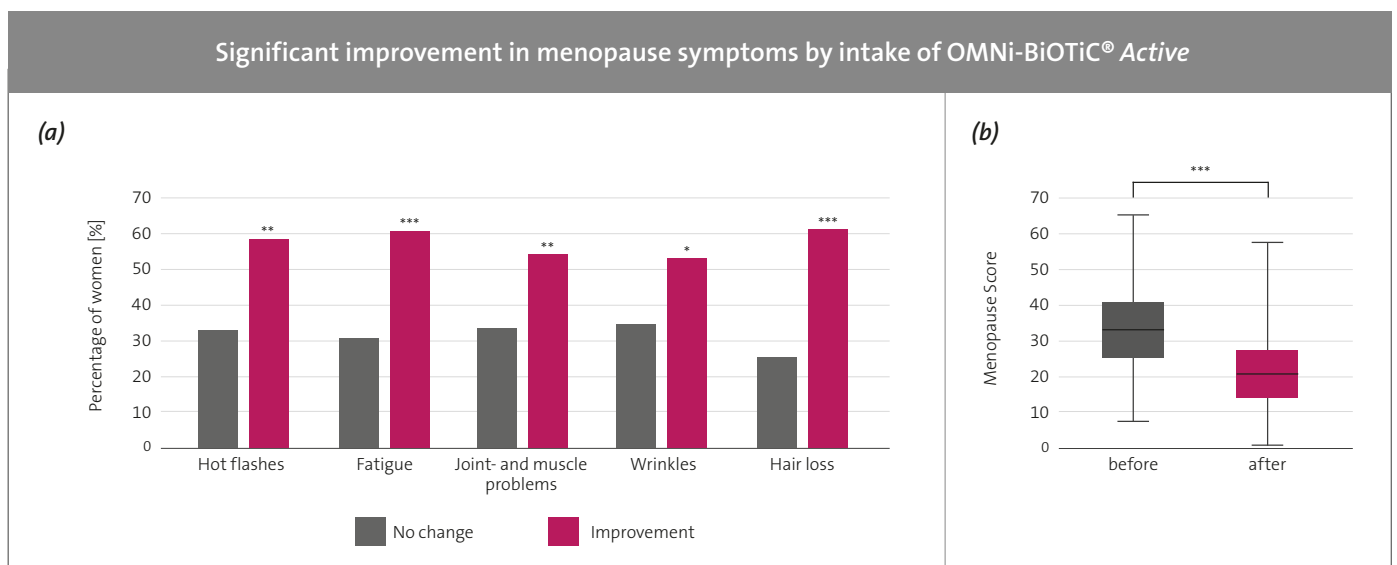


Figure: (a) Taking OMNi-BiOTiC® Active for 8 weeks significantly reduces hot flashes, fatigue, muscle and joint problems, wrinkles, and hair loss. (b) The menopause score demonstrates that probiotic intake leads to a highly significant overall improvement in menopausal symptoms (*, $p < 0.05$; **, $p < 0.01$; ***, $p < 0.001$).

Discussion and conclusion

This study clearly demonstrates that the use of the indication-specific multi-strain probiotic OMNi-BiOTiC® Active significantly contributes to an improvement of menopausal symptoms via the positive modulation of the gut microbiome. The underlying cause could be the improved absorption of micronutrients facilitated by OMNi-BiOTiC® Active, as impressively shown by a study* involving postmenopausal women. These new findings provide a valuable contribution

to a better understanding of the role of a balanced gut microbiome in hormone regulation, especially in women undergoing menopause. Moreover, the remarkable effects of OMNi-BiOTiC® Active underscore the enormous potential of medically relevant probiotics to alleviate hormone-related complaints and offer valuable insights for innovative preventive and therapeutic approaches incorporating probiotic medicine.

* Stiegelbauer et al., OM & Ernährung; 2019

DERMATOLOGY

8

WOUND HEALING IN DIABETES 76–77

ATOPIC DERMATITIS 78–79



Positive Effect of an Oral Multi-Species Probiotic on Wound Healing in Patients with Diabetes

Stürmer E.K. *et al.*, *Journal of Wound Care*, 2024

Abstract

The prevalence of diabetes mellitus has increased rapidly worldwide over the last 30 years. Chronic wounds are a common complication of this metabolic disease and represent an enormous physical and psychological burden for patients. Pathogenic bacteria, which are typically found in non-healing wounds, hinder the healing process and are a major risk factor for the development of local and systemic infections. Studies show that probiotic bacteria are able to displace pathogenic bacteria, stimulate immune function and reduce inflammation, thereby exerting a positive effect on the skin microbiome and mucous membranes.

The gut and skin microbiomes are closely interconnected through the gut-skin axis. Positive modulation of the gut microbiome with medically relevant probiotics can enhance the skin microbiome through immune system mechanisms. This study therefore investigated the effect of an orally administered, indication-specific multi-species probiotic (trade name: OMNi-BiOTiC® HETOX) on the suppression of pathogenic wound bacteria, the improvement of wound healing and the quality of life (Wound-QOL-17) in 21 chronic wound patients with diabetes.

Results

The 6-month intake of OMNi-BiOTiC® HETOX (1x daily 6g with a total of 1.5×10^{10} CFU) led to a significant improvement in wound healing in all patients. Although wound care remained unchanged, 46.2% of patients' wounds were reduced in size by more than half and 38.4% were completely healed. The patients also reported a significant improvement in their quality of life with wounds, in particular the positive effects on pain and mobility.

The microbiome analyses of the skin swabs revealed significant changes in the wound microbiome over the course of the probiotic intervention. Fully healed wounds were associated with a significantly increased abundance of *Staphylococcus epidermidis* ($p < 0.05$). In contrast, *Pseudomonas aeruginosa* and *Staphylococcus aureus* were predominantly present in wounds that did not heal completely during the intervention period ($p < 0.05$).

In addition, there was a remarkable effect of OMNi-BiOTiC® HETOX on the dental health of the patients. The periodontitis screening showed a significant improvement in periodontal health, measured by the reduction in tooth pocket depth, gingival recession and clinical attachment loss (=destruction of the periodontium), despite unchanged oral hygiene and without the use of mechanical or anti-septic therapies.

Complete wound closure through OMNi-BiOTiC® HETOX



Figure: (a) Right sole of the foot of a 53-year-old woman with a typical diabetic ulcer at the first examination (V0). (b) The wound heals after two months (V2) with the use of OMNi-BiOTiC® HETOX. (c) The wound remains permanently closed after three months (V3).

Significant reduction in wound size and pain intensity
in all chronic wound patients with OMNi-BiOTiC® HETOX

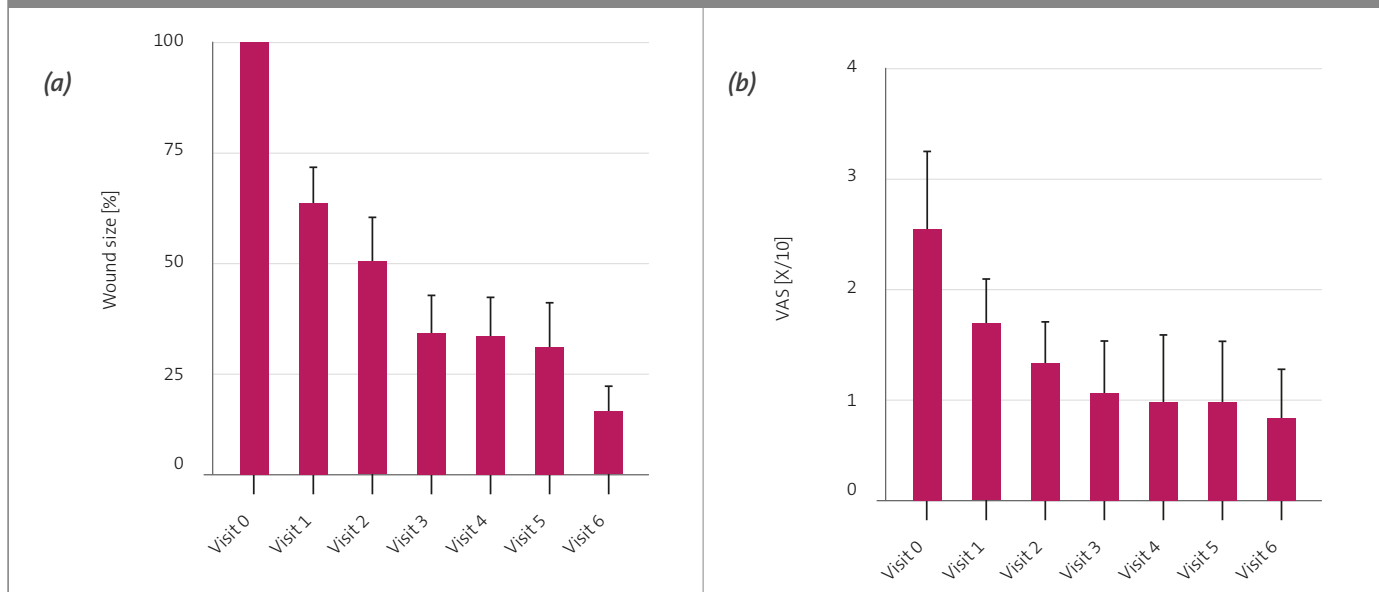


Figure: (a) Taking OMNi-BiOTiC® HETOX for 6 months leads to a significant reduction in wound size in diabetic patients with chronic wounds. (b) The pain intensity (Visual Analogue Scale, VAS) of the wounds is also significantly reduced by the probiotic intervention.

Discussion and conclusion

Diabetic ulcers cause enormous suffering for the patients affected and are a burden on the healthcare system. This study was the first to show that the medically relevant multi-species probiotic OMNi-BiOTiC® HETOX has a noticeable positive effect on wound healing in diabetic patients with chronic wound healing disorders.

Daily intake of this probiotic for six months had a significant effect on wound closure, the wound microbiome and improved quality of life. In addition, the patients' periodontal health, which is typically impaired in diabetes, improved. This clearly shows that the positive modulation of the intestinal microbiome also influences systemic

health. Oral indication-specific probiotics such as OMNi-BiOTiC® HETOX, offer a unique opportunity to positively influence both the skin and wound microbiome through the gut-skin axis, as well as the oral microbiome through the gut-mouth axis. This makes them an innovative treatment option for patients with chronic wound healing disorders.

A Probiotic Ointment Significantly Reduces the Symptoms of Atopic Dermatitis

Kolleritsch *et al.*, OM & Ernährung; 2025

Abstract

Atopic dermatitis is a chronic skin disease that drastically affects the quality of life of those affected and their relatives due to dry skin, scaly skin, inflammation, itching and the resulting sleep disorders. Atopic dermatitis often breaks out in infancy. Although it can improve spontaneously with age, around two thirds of children have spontaneous relapses in early childhood as well as in adolescence and adulthood and the disease flares up again and again. The tendency to atopic dermatitis and its outbreak are associated with a dysbiosis of the skin microbiome. In particular, the degree of colonisation by the pathogenic strain *Staphylococcus aureus* correlates with the severity of the clinical symptoms. The effect of OMNI-BIOTIC SKIN® Intensive Care Ointment on the symptoms of atopic dermatitis was investigated as part of an observational study with 20 participants aged between 2 and 65 years. The Ointment contains nine human, viable, probiotic bacterial strains that have been proven to displace *Staphylococcus aureus*, but also stabilise the skin barrier and have a positive effect on the dermal immune system. The test subjects applied the

ointment to the affected areas twice a day for four weeks. At the beginning of the study and once a week during the intervention period, skin complaints and sleep quality were recorded using a questionnaire.

Results

Remarkably, a noticeable improvement in atopic dermatitis symptoms was observed after just one week of using the OMNI-BIOTIC SKIN® Intensive Care Ointment. After three weeks, treatment with the probiotic ointment led to a significant reduction in skin complaints, which was also clearly demonstrated by comparing the affected areas using photo documentation before and after the intervention. Skin dryness and scaling in particular improved in 86% and over 60% of participants respectively. The reduction in symptoms also meant that 86% of the test subjects stated that they were able to sleep much better.

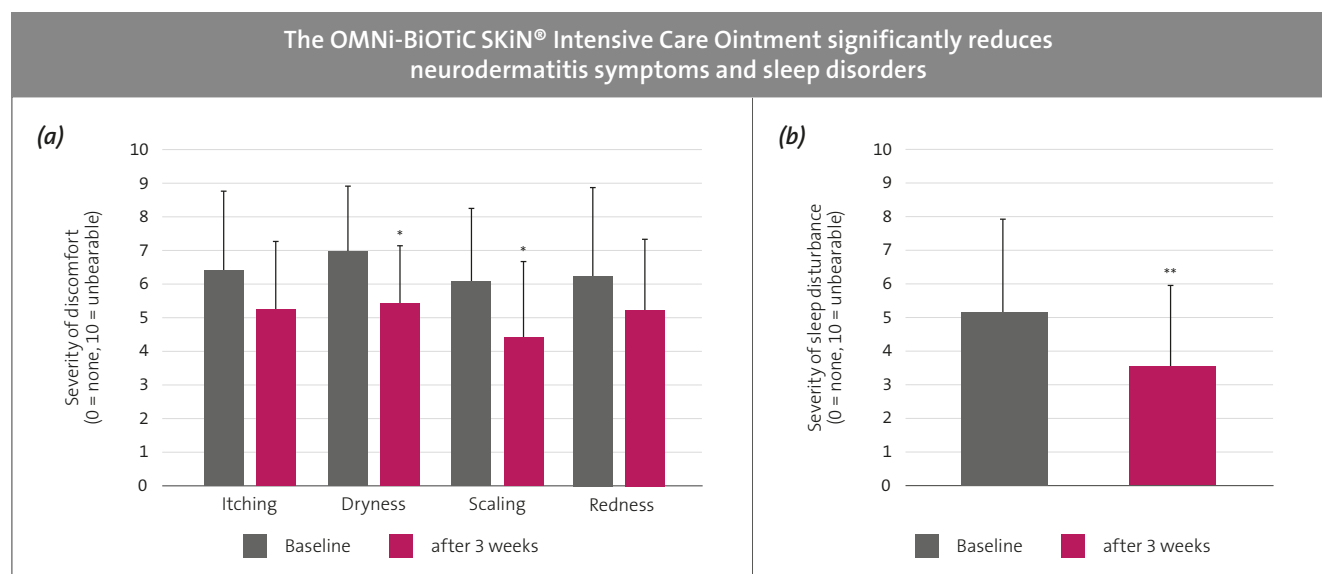


Figure: The 3-week application of the probiotic ointment significantly reduced (a) atopic dermatitis symptoms and (b) sleep disorders (*, $p < 0.05$; **, $p < 0.01$).

Discussion and conclusion

A healthy skin microbiome is a prerequisite for healthy skin. The bacterial strains contained in OMNI-BIOTIC SKIN® have the ability to displace pathogenic strains such as *Staphylococcus aureus*, which usually dominates the skin microbiome of atopic dermatitis patients. The present study clearly shows that the application of the probiotic OMNI-BIOTIC SKIN® Intensive Care Ointment significantly improves atopic dermatitis symptoms

and leads to a better quality of sleep and life for those affected. A medically relevant combination of active probiotic bacterial strains also contributes in topical form to the recovery of an optimal skin microbiome and is therefore a valuable therapy option for atopic dermatitis – both for treatment and for the prevention of flare-ups.

The Positive Effect of a Probiotic Skin Bath on the Symptoms of Atopic Dermatitis and on the Suppression of *Staphylococcus aureus*

Axt-Gadermann *et al.*, Hautarzt; 2021



Abstract

Atopic dermatitis (AD) – also known as neurodermatitis – is a chronic inflammatory skin condition characterised by dry skin, scaling, inflammatory skin changes and excruciating itching. AD impairs the skin's barrier function and causes dysregulation of the immune system. The epidermal microbiome plays a key role in this process: studies show a significantly reduced bacterial diversity of the skin microbiome in acute AD flare-ups, with *Staphylococcus aureus* usually dominating the epidermal microbiome of affected patients. Positive modulation of the epidermal microbiome through medically relevant probiotics therefore represents a possible starting point for therapeutic or supportive measures in AD. The present study investigated how 2 weeks of use of OMNi-BiOTiC SKiN® Intensive Skin Bath – containing 4.5×10^9 or 9×10^9 colony-forming units (CFU) per litre – affects the symptoms and skin microbiome in 22 AD patients aged 5 to 71 years. The skin bath contains 9 selected bacterial strains that are distinguished by their ability to modulate the epidermal immune system, positively influence the barrier function and inhibit the spread of pathogenic species. The AD symptoms were assessed using the validated SCORAD (SCORing Atopic Dermatitis) symptom score by the doctor and supplemented by a self-assessment by the patients. In addition, the affected skin areas were documented photographically and skin swabs were taken for microbiological examination.

Results

The results of the study clearly show that the probiotic partial baths with OMNi-BiOTiC SKiN® Intensive Skin Bath – both at a concentration of 4.5×10^9 CFU/l and at a concentration of 9×10^9 CFU/l – achieved a significant reduction in SCORAD after just 7 days of use ($p < 0.05$). The parameters of skin dryness and itching recorded by the patients improved significantly ($p < 0.05$), which in turn significantly improved the quality of life of those affected. Skin microbiome analysis showed an increase in alpha diversity (richness). This topical treatment increased the relative abundance of the genera *Lactobacillus* and *Bifidobacterium*, which are components of the probiotic skin bath. It should be noted that the abundance of the pathogenic strain *Staphylococcus aureus* was reduced by 83% ($p < 0.05$). The improved clinical symptoms were also impressively demonstrated by the photographic documentation of the affected skin areas.

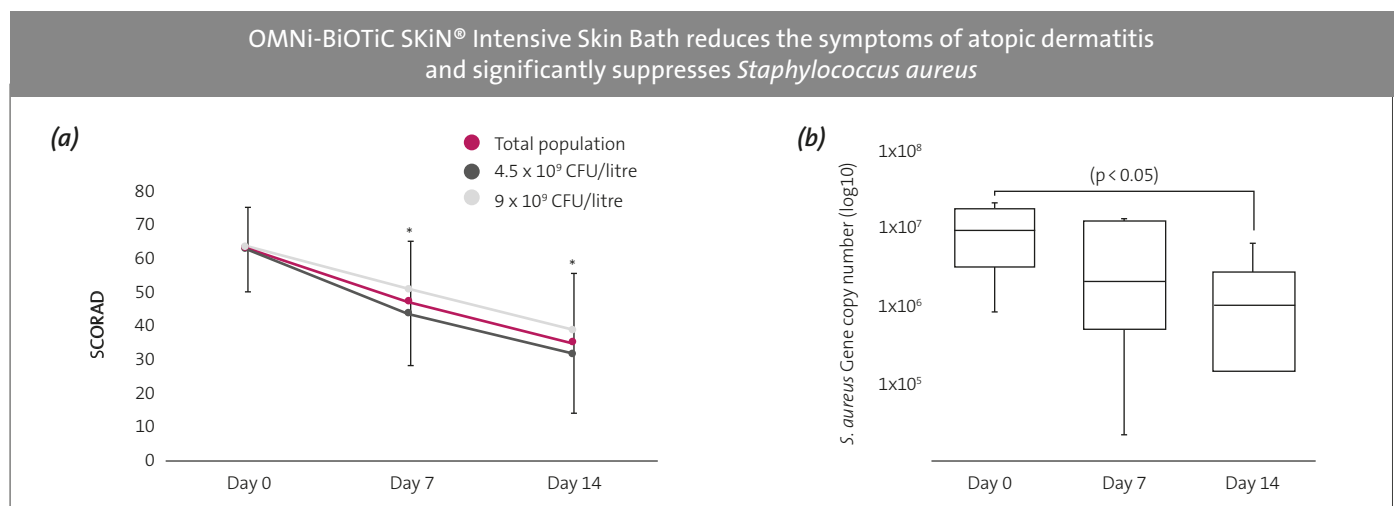


Figure: Two weeks of treatment with OMNi-BiOTiC SKiN® Intensive Skin Bath resulted in (a) a significant reduction in AD symptoms and (b) a significant decrease in the abundance of *S. aureus* (*, $p < 0.05$).

Discussion and conclusion

Atopic dermatitis is characterised in acute flare-ups by reduced bacterial diversity in the skin microbiome and a dominance of the pathogenic strain *Staphylococcus aureus*, with the degree of colonisation correlating with the severity of clinical symptoms. This finding offers starting points for completely new, innovative and side-effect-free forms of therapy, which are urgently needed due to the chronic course and high prevalence of AD (10–15% in childhood,

2–5% in adulthood). This study impressively shows that the 2-week probiotic intervention with OMNi-BiOTiC SKiN® Intensive Skin Bath leads to a significant reduction in AD symptoms, such as dry skin and itching, as well as to a significant displacement of *S. aureus*. The use of this probiotic bath is therefore a promising treatment option for AD and leads to a significant improvement in the quality of life of those affected.

SPORT PHYSIOLOGY

9

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REDUCTION OF INFLAMMATION 83–85



The Successful Use of a Probiotic Against Upper Respiratory Tract Infections in Competitive Athletes



Strasser *et al.*, *Nutrients*; 2016

Abstract

Certain factors can initiate “silent inflammation”, which may eventually result in leaky gut. Furthermore, excessive stress causes a higher release of the enzyme IDO-1, which metabolizes tryptophan and has an immunosuppressive effect. As a result, a deficiency in tryptophan is linked to a diminished immune response and an increased susceptibility to infections.

Over the course of this study, the effect of the multi-species probiotic OMNi-BiOTiC® POWER on susceptibility to infection in competitive athletes, especially cross-country skiers, was investigated.

Results

Over 12 weeks, intake of OMNi-BiOTiC® POWER significantly reduced the incidence of upper respiratory tract infections, showing a notable decrease compared to the study's onset. In contrast, the placebo group experienced a 220% increase in respiratory tract infections. Intensive training sessions at the study's start led to reduced tryptophan levels in both groups, with athletes exhibiting pronounced tryptophan depletion being more susceptible to respiratory infections. OMNi-BiOTiC® POWER intake effectively mitigated tryptophan degradation, as indicated by higher blood levels of tryptophan in athletes from the treatment group.

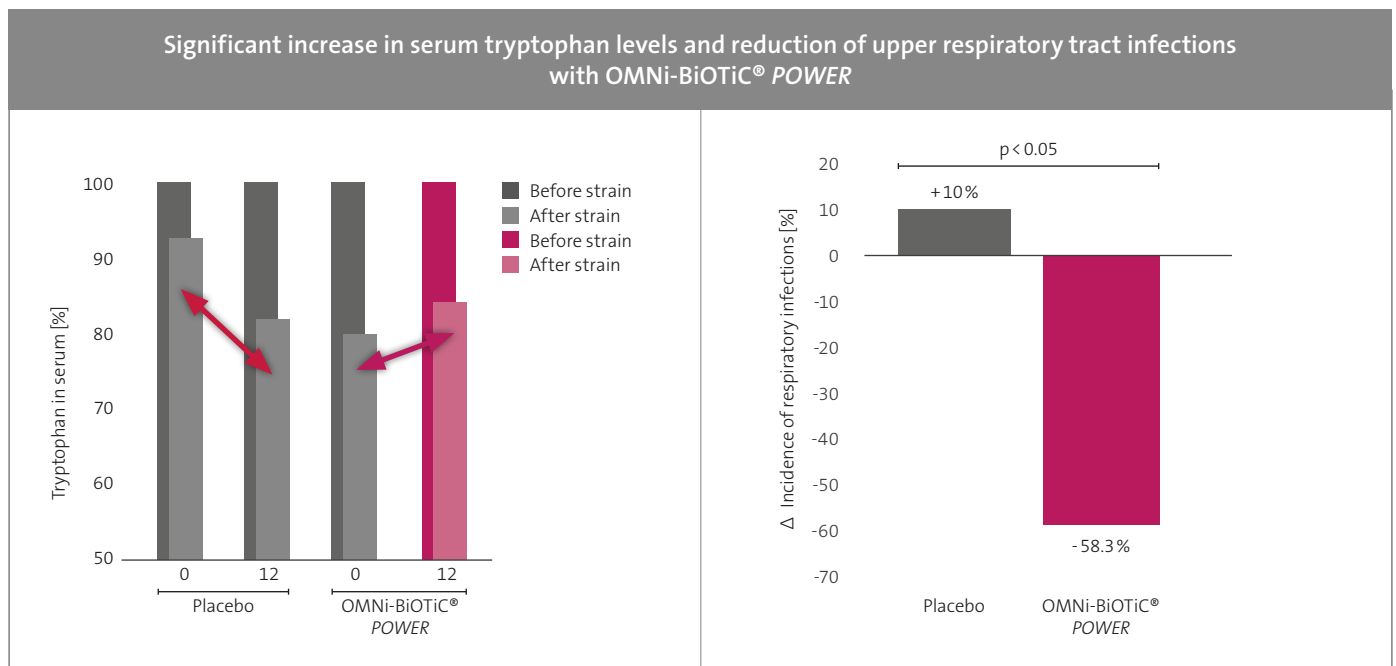


Figure: The 12-week intake of OMNi-BiOTiC® POWER resulted in significantly increased tryptophan serum levels. The incidence of upper respiratory tract infections was significantly reduced by probiotic therapy.

Discussion and conclusion

This study demonstrates the efficacy of OMNi-BiOTiC® POWER in reducing upper respiratory tract infections among athletes undergoing endurance training. Probiotic intake was associated with

decreased tryptophan degradation, which correlates with improved immune function and overall well-being.

The Intake of a Specially Developed Probiotic Improves the Intestinal Barrier as well as Important Markers in Oxidative Stress and Inflammatory Processes in Competitive Athletes



Lamprecht *et al.*, *J Int Soc Sports Nutr*; 2012

Abstract

Prolonged and intense physical stress, common among competitive athletes, affects intestinal barrier permeability and function, altering the intestinal microbiome composition. Extensive training diverts blood supply from the intestines to the active muscles, leading to gastrointestinal issues such as indigestion, diarrhea, and abdominal pain. Targeted modification of the intestinal microbiome with specific probiotics can restore intestinal barrier integrity, reducing inflammatory reactions and gastrointestinal problems. This randomized, placebo-controlled, double-blind study investigated the effects of the multi-species probiotic OMNi-BiOTiC® POWER (4 g daily, totaling 1×10^{10} CFU) over 14 weeks in endurance athletes. Blood samples were analyzed for inflammatory marker tumor necrosis factor-alpha (TNF- α) and oxidative stress marker carbonyl protein (CP). Stool samples were analyzed for intestinal permeability marker zonulin at the study's start and after 14 weeks.

Results

Initially, both groups had elevated zonulin levels. After 14 weeks, the OMNi-BiOTiC® POWER group showed a statistically significant reduction in stool zonulin levels, indicating improved intestinal barrier function compared to the placebo group ($p=0.019$). The probiotics group also exhibited reductions in blood TNF- α and CP levels.

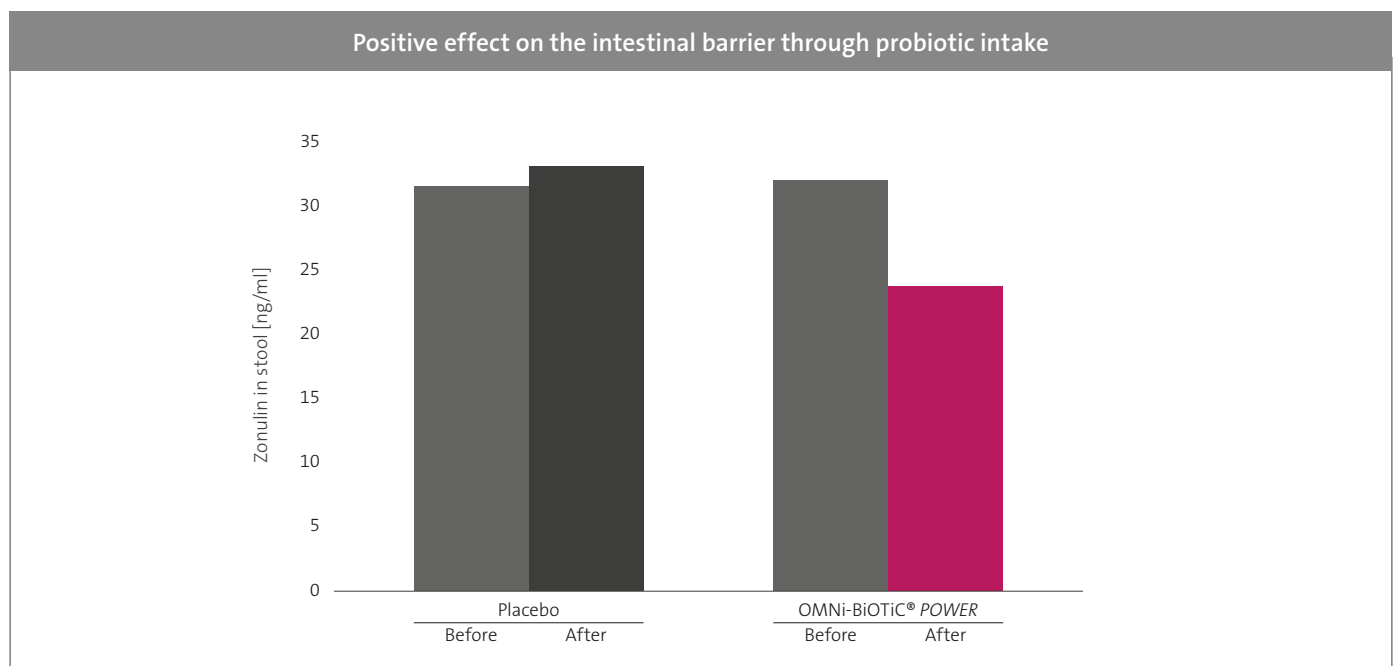


Figure: The reduction of CP indicates less oxidative stress in the body, which is associated with a reduced risk of cellular damage.

Discussion and conclusion

This study demonstrates that the administration of OMNi-BiOTiC® POWER significantly strengthens the intestinal barrier and reduces inflammatory reactions in competitive athletes. This is evidenced by the significant reduction in zonulin levels and the decreased levels of CP and TNF- α in the blood. The reduction in CP suggests

lower oxidative stress and a reduced risk of cellular damage, highlighting the probiotic's potential in enhancing overall intestinal and immune health in athletes.

The Effect of Multi-Species Probiotics on Intestinal Barrier Function, Inflammatory Response, and Performance in Athletes

Lazik *et al.*, OM & Ernährung; 2019

Abstract

Extended, intense physical exertion experienced by competitive athletes can impact the permeability and function of the intestinal barrier, potentially altering the intestinal microbiome and compromising immune function. These symptoms are associated with recurrent illnesses and poor performance in athletes. Targeted positive modulation of the intestinal microbiome via specific probiotics can restore intestinal barrier integrity, reducing inflammatory reactions and gastrointestinal symptoms.

This study investigated the effects of a six-month administration of high-quality multi-species probiotics on performance and inflammation parameters in 36 football players from a German national league team. Athletes were randomized into three groups: (1) individual group (assigned OMNi-BiOTiC® STRESS Repair [1x daily 3g, totaling 7.5×10^9 CFU] or OMNi-BiOTiC® 6 [1x daily 1g, totaling 1×10^9 CFU] based on stool analysis), (2) OMNi-BiOTiC® POWER group (1x daily 4g, totaling 1×10^{10} CFU) to counteract physical strain damage, and (3) non-intervention group.

Results

Post-treatment, athletes in the individual group showed improved performance in tests compared to the non-intervention group. Stool analyses in the individual group, conducted two weeks and six months after administration of OMNi-BiOTiC® STRESS Repair or OMNi-BiOTiC® 6, revealed increased levels of anti-inflammatory *Faecalibacterium prausnitzii* and mucus-producing *Akkermansia muciniphila*. Additionally, a reduction in inflammation, indicated by lower alpha-1 antitrypsin levels, was detectable six months post-treatment. Performance improvements were notable in all three probiotic groups, with the most pronounced enhancement observed in athletes taking OMNi-BiOTiC® POWER for six months.

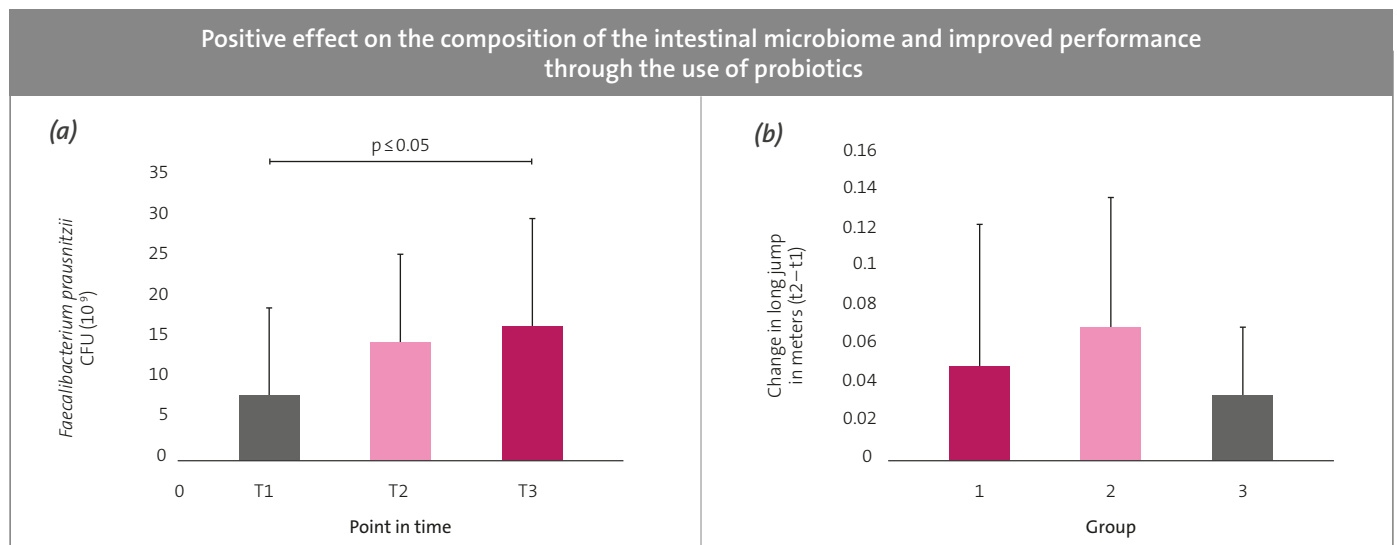


Figure: (a) Positive increase in the anti-inflammatory bacterial strain *Faecalibacterium prausnitzii* both two weeks (T2) and 6 months (T3) after probiotic treatment. (b) Change in performance in the long jump through probiotic intervention. Compared to the non-intervention group, the performance test in the group with OMNi-BiOTiC® STRESS Repair or OMNi-BiOTiC® 6 as well as in the group with the antioxidant OMNi-BiOTiC® POWER showed a clear improvement in the long jump, measured by using the change in jumping distance before and after probiotic intervention (group 1 = individual group, group 2 = OMNi-BiOTiC® POWER group, group 3 = non-intervention group).

Discussion and conclusion

This study confirms the positive effects of multi-species probiotics on epithelial barrier function, the enhancement of butyrate and mucus-forming microbiota, and the reduction of inflammatory reactions in competitive athletes, consistent with findings by Lamprecht

et al. and Prüller-Strasser *et al.* Moreover, all three probiotics positively influenced athletic performance.



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Successful Use of OMNi-BiOTiC® *iMMUND* in the Prevention of Streptococcal Pharyngotonsillitis and Acute Otitis Media in Children

Di Pierro *et al.*, Int J Gen Med; 2012

Abstract

In pediatrics, pharyngitis and tonsillitis are among the most common reasons for doctor visits and contribute to high antibiotic usage. *Streptococcus salivarius* K12, a probiotic bacterial strain naturally present in the oral and pharyngeal flora, inhibits the growth of closely related species, including *Streptococcus pyogenes*, the primary cause of bacterial pharyngitis and middle ear infections.

This study evaluated the effects of *Streptococcus salivarius* K12 in reducing the incidence of streptococcal pharyngotonsillitis and acute otitis media (middle ear infection) in 82 children aged 3 to 12 years. Among these, 65 children had recurrent oral streptococcal infections, and 17 children had no prior diagnosis. The study spanned a treatment period of 90 days, followed by a six-month observation period. Of the children with a history of recurrent infections, 45 received one

OMNi-BiOTiC® *iMMUND* lozenge (containing *Streptococcus salivarius* K12, 1×10^9 CFU) daily during the treatment period, while 20 served as a control group. The 17 children without a prior diagnosis also served as a control group.

Results

During the treatment period, the intervention group experienced a 95% reduction in the incidence of pharyngotonsillitis compared to the control group with similar pre-existing conditions. Additionally, the incidence of acute otitis media decreased by 72% with the use of OMNi-BiOTiC® *iMMUND*. Notably, even after six months, the incidence of both pharyngotonsillitis and acute otitis media remained 65% lower in the intervention group compared to the control group. The product was well tolerated, with no reported side effects.

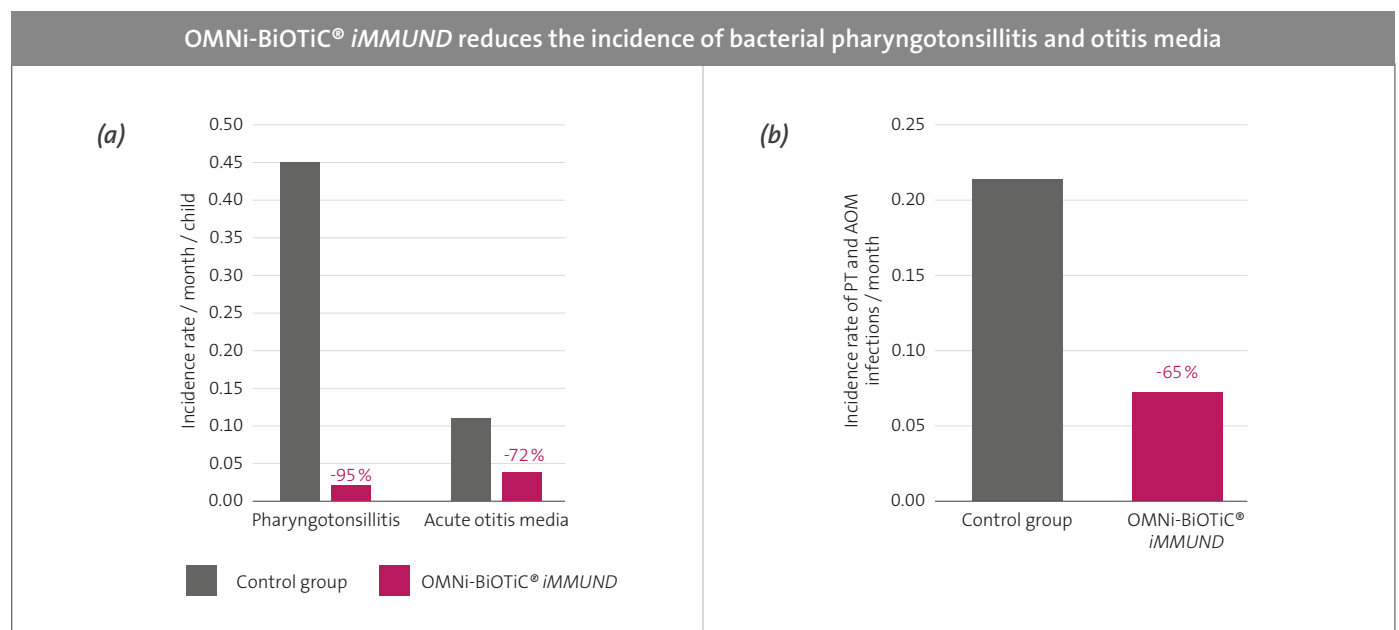


Figure: OMNi-BiOTiC® *iMMUND* reduces the incidence of bacterial ENT infections (pharyngotonsillitis, PT; acute otitis media, AOM) in the treatment period of 90 days (a) and in the 6 subsequent months (b).

Discussion and conclusion

The incidence of pharyngotonsillitis and acute otitis media was significantly reduced in children with recurrent streptococcal infections who took OMNi-BiOTiC® *iMMUND* for 90 days. These positive effects persisted for an additional six months. *Streptococcus salivarius* K12 demonstrates lasting colonization of the upper respiratory

tract and has an excellent safety profile. Consequently, prophylactic treatment with OMNi-BiOTiC® *iMMUND* presents a viable alternative to conventional antibiotic therapy.

OMNi-BiOTiC® *immUND* Reduces the Incidence of Pharyngotonsillitis in Adults

Di Pierro *et al.*, Expert Opin Biol Ther; 2013

Abstract

Both children and adults suffer from acute or chronic pharyngotonsillitis, primarily caused by bacteria, especially during the winter months. *Streptococcus salivarius* K12 is a probiotic bacterial strain naturally occurring in the mouth and throat. It produces BLIS (bacteriocin-like inhibitory substances), specifically salivaricin A2 and salivaricin B, which inhibit the growth of closely related species, including *Streptococcus pyogenes*, the main cause of pharyngotonsillitis.

This study tested the efficacy of *Streptococcus salivarius* K12 in preventing pharyngotonsillitis in adults. Forty adults aged 25 to 45 years with recurrent streptococcal pharyngotonsillitis were monitored over a 90-day intervention period and a 6-month follow-up period. Half of the participants received an OMNi-BiOTiC® *immUND* lozenge (containing *Streptococcus salivarius* K12, 1×10^9 CFU) daily for 90 days, while the other half served as a control group.

Results

The intake of OMNi-BiOTiC® *immUND* resulted in a significant 84% reduction in repeated pharyngotonsillitis caused by *Streptococcus pyogenes* compared to the previous year ($p < 0.01$). During the 6-month follow-up period, the incidence of infection in the intervention group was reduced by 62% compared to the control group ($p = 0.04$). Additionally, the product was well-tolerated and accepted by the participants.

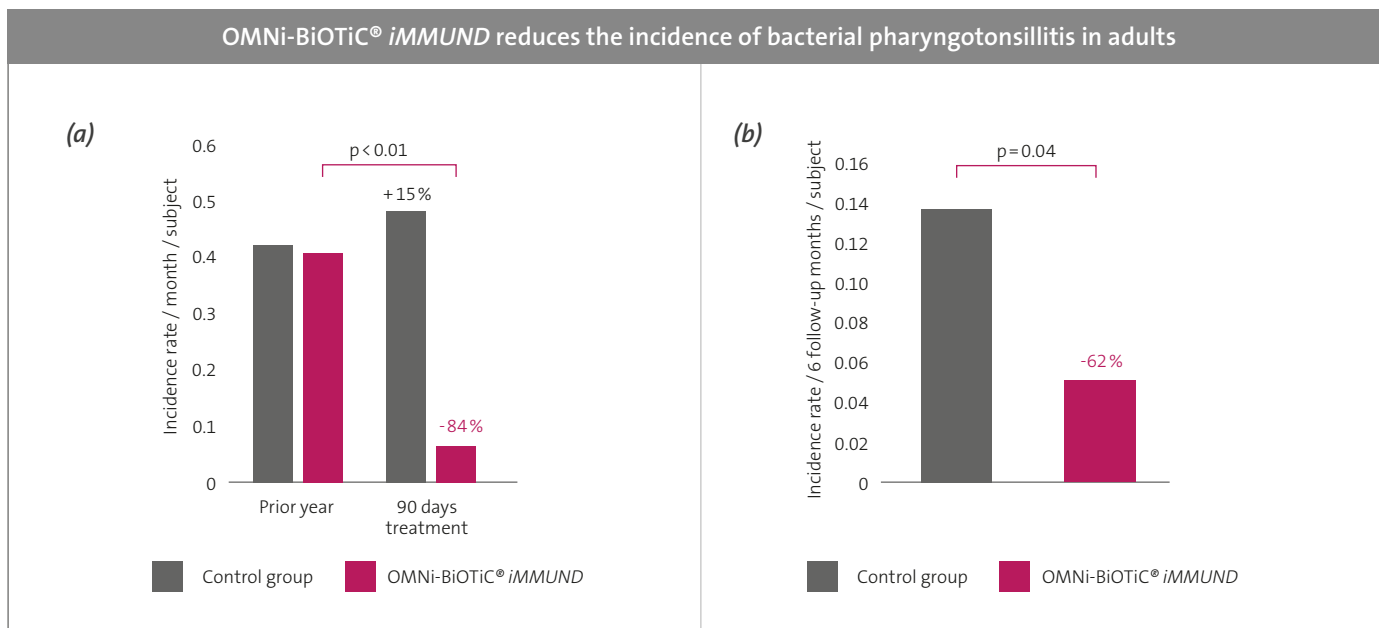


Figure: Significant reduction of streptococcal pharyngotonsillitis during the treatment period (a) and within six follow-up months (b) after taking OMNi-BiOTiC® *immUND*.

Discussion and conclusion

This study demonstrates that *Streptococcus salivarius* K12 significantly reduces episodes of bacterial pharyngitis and tonsillitis in adults during a 90-day course of OMNi-BiOTiC® *immUND*, with effects persisting for an additional six months. Probiotic treatment with OMNi-BiOTiC® *immUND* effectively reduces the incidence of re-

current oral streptococcal infections, offering a viable alternative to conventional antibiotic treatment for both children and adults.

Use of OMNi-BiOTiC® *i*MMUND to Reduce the Incidence of Pharyngotonsillitis and Acute Otitis Media in Children without Recurrent Illness

Di Pierro *et al.*, *Minerva Pediatrica*; 2018

Abstract

Previous studies have shown that the use of the bacteriocin-producing probiotic strain *Streptococcus salivarius* K12 for 90 days can significantly reduce the incidence of acute otitis media (AOM) and both bacterial and viral pharyngitis. This study investigated the beneficial effects of *Streptococcus salivarius* K12 over two separate trimesters on the incidence of viral and bacterial pharyngotonsillitis (pharyngitis and tonsillitis) and AOM in children without recurrent streptococcal-related infections. The retrospective analysis included 133 children aged 3 to 14 years. The incidences of these diseases in the first year were compared to those in the following year, during which OMNi-BiOTiC® *i*MMUND (*Streptococcus salivarius* K12, 1×10^9 CFU) was used daily for two trimesters.

Results

The study demonstrated that the incidence of both streptococcal-associated and non-streptococcal-associated pharyngotonsillitis was reduced by over 90% with the use of *Streptococcus salivarius* K12 compared to the control group ($p < 0.001$). The incidence of AOM was also significantly reduced by 71% ($p < 0.001$). As a result, the use of antibiotics and antipyretics decreased by over 85%, and the number of days absent from school was reduced by nearly 85% compared to the previous year ($p < 0.01$).

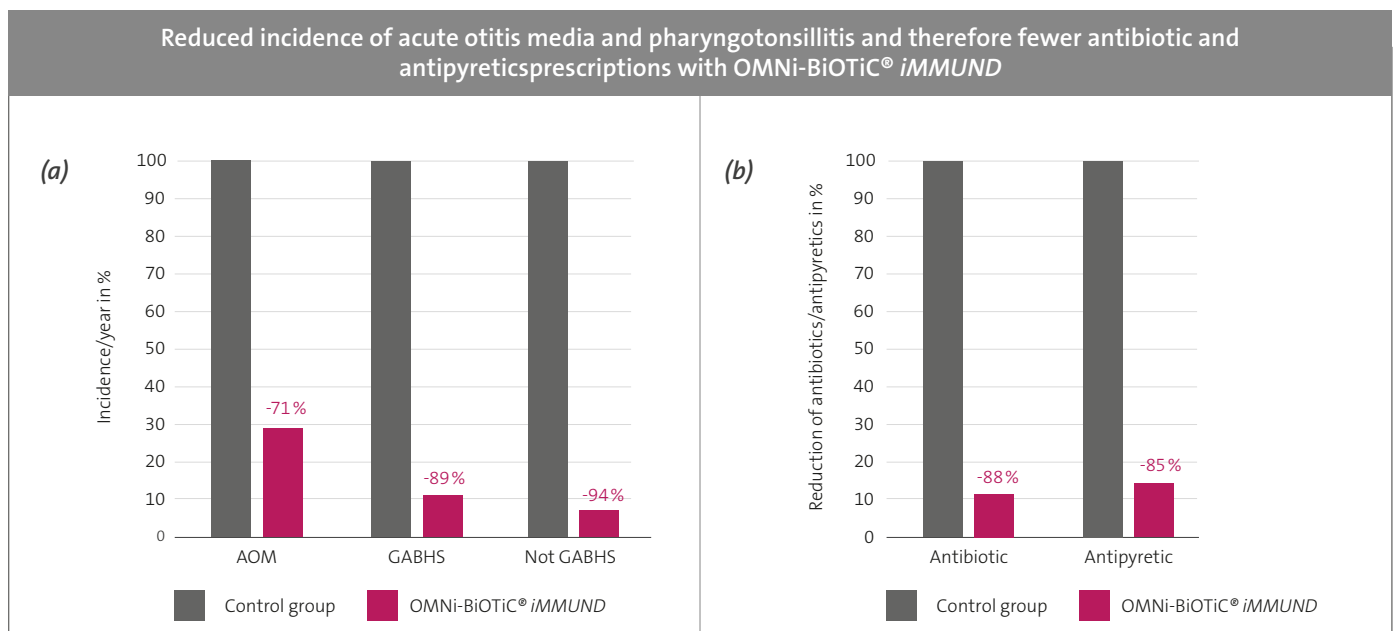


Figure: (a) OMNi-BiOTiC® *i*MMUND reduced the incidence of acute otitis media as well as group A beta-haemolytic streptococci (GABHS)-induced and non-streptococcal (Not GABHS) pharyngotonsillitis. (b) The prescription of antibiotics and antipyretics was also drastically reduced.

Discussion and conclusion

The retrospective analysis underscores the beneficial effects of prophylactic use of OMNi-BiOTiC® *i*MMUND over two trimesters in children prone to frequent episodes of streptococcal and viral pharyngotonsillitis, as well as acute otitis media (AOM). The significant reduction in the incidences of these infectious diseases after probiotic intervention in children without recurrent streptococcal-

associated infections highlights the beneficial impact of *Streptococcus salivarius* K12. Notably, the reduction in ENT inflammations, which are common in children, also leads to a marked decrease in the use of antibiotics and antipyretics and helps prevent school absences.

Reduction of *Streptococcus*-Related Pharyngitis and Tonsillitis Through the Use of the Oral Probiotic OMNi-BiOTiC® *iMMUND*

Gregori *et al.*, Therapeutics and Clinical Risk Management; 2016

Abstract

Pharyngitis and tonsillitis, frequently caused by group A beta-haemolytic *streptococci* (GABHS), are common in young children and often result in significant pain and frequent antibiotic use. *Streptococcus salivarius* K12, a probiotic strain naturally occurring in the mouth and throat, produces bacteriocin-like inhibitory substances (BLIS), namely salivaricin A2 and salivaricin B, which inhibit the growth of related bacteria, including GABHS.

This retrospective observational study investigated the incidence of pharyngotonsillitis, otitis media (middle ear infection), bronchitis, and chronic sinusitis in 130 children with recurrent GABHS infections over a 12-month period. Seventy-six children received one OMNi-BiOTiC® *iMMUND* lozenge (containing *Streptococcus salivarius* K12, 1×10^9 CFU) daily for 90 days, while 54 children served as a control group.

Results

The intake of OMNi-BiOTiC® *iMMUND* resulted in a highly significant 85% reduction in the incidence of GABHS infections compared to the control group ($p < 0.001$). The number of infections in the intervention group remained low during the subsequent nine-month observation period. Even nine months after treatment, there was a residual efficacy, with an 80% reduction in infections compared to the control group ($p < 0.001$).

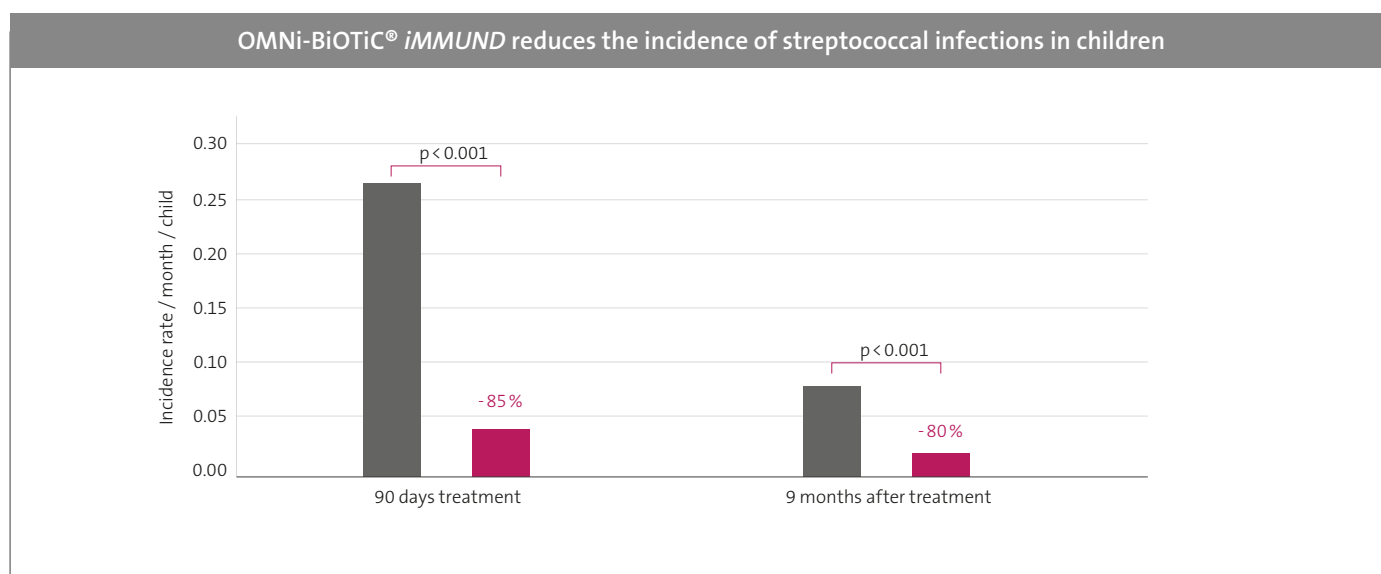


Figure: OMNi-BiOTiC® *iMMUND* significantly reduces the occurrence of streptococcal infections compared to the control group in the 3-month treatment period (-85%), as well as in 9 months following (-80%).

Discussion and conclusion

This study demonstrates that the prophylactic use of OMNi-BiOTiC® *iMMUND* lozenges significantly reduces episodes of bacterial pharyngotonsillitis in children. Notably, even nine months after the treatment period, the incidence of infections remained significantly reduced. This sustained prevention against recurrent strep-

tococcal infections highlights the effectiveness of OMNi-BiOTiC® *iMMUND* in reducing the need for antibiotic treatments and their associated side effects.

Clinical Evaluation of the Benefit of the Oral Probiotic OMNi-BiOTiC® *IMMUND* in Recurrent Pharyngitis and Tonsillitis

Gun *et al.*, Indian Journal of Research; 2017

Abstract

The most common cause of bacterial throat infections is the bacterium *Streptococcus pyogenes*. The naturally occurring probiotic strain *Streptococcus salivarius* K12, isolated from healthy children, is known for its ability to inhibit the growth of *Streptococcus pyogenes* through the production of bacteriocins, specifically salivaricin A2 and salivaricin B.

Based on this finding, this study investigated the effect of *Streptococcus salivarius* K12 on the incidence of *streptococcus*-associated pharyngitis and tonsillitis. The study involved daily probiotic treatment with *Streptococcus salivarius* K12 over a period of 90 days, with a follow-up after three months. The experimental group (n = 34) consisted of individuals aged 12 to 45 years with recurrent pharyngitis or tonsillitis. Within this group, 20 subjects were treated with *Streptococcus salivarius* K12 (OMNi-BiOTiC® *IMMUND*), while 14 subjects served as a control group. Additionally, 10 healthy volunteers were included as controls.

Results

The group treated with *Streptococcus salivarius* K12 showed a highly significant reduction in the incidence of oral *streptococcus*-associated infections, exceeding 90% compared to the previous year. In contrast, no difference was observed in the control groups. Notably, even during the three-month follow-up period, the OMNi-BiOTiC® *IMMUND* group experienced 80% fewer *streptococcus*-associated infections.

OMNi-BiOTiC® *IMMUND* reduces the incidence of *streptococcus*-associated pharyngitis/tonsillitis significantly

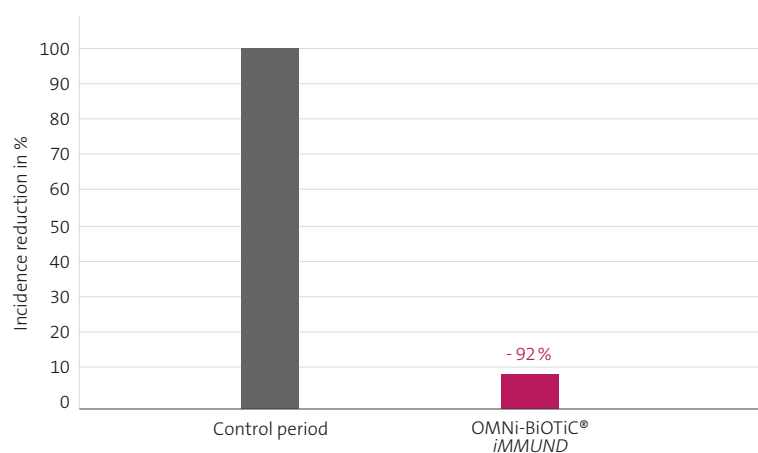


Figure: The use of OMNi-BiOTiC® *IMMUND* for 90 days resulted in a significant reduction in throat infections.

Discussion and conclusion

This study highlights the significant potential of using the medically relevant probiotic OMNi-BiOTiC® *IMMUND* as a prophylactic measure to reduce the incidence of *streptococcus*-associated pharyngitis and tonsillitis in individuals with recurrent infections. The findings underscore the crucial role of a healthy oral microbiome in defending

against pathogens. This defense is facilitated through specific immunological mechanisms, such as bacteriocin production, and the proven ability to inhibit the attachment of viral and bacterial pathogens.

Efficacy of the Oral Bacterial Strain *Streptococcus salivarius* K12 in the Prevention of Pharyngotonsillitis and the Avoidance of Surgical Interventions in the Form of Tonsillectomy

Marini *et al.*, Int J Gen Med; 2019

Abstract

Pharyngotonsillitis (pharyngitis and tonsillitis) is the leading cause of antibiotic use in pediatrics. Recurrent infections can render standard treatments ineffective, often necessitating a tonsillectomy. *Streptococcus salivarius* K12, a probiotic strain of the oral microbiome, inhibits the growth of closely related pathogens by producing BLIS (bacteriocin-like inhibitory substances). This includes *Streptococcus pyogenes*, a common cause of ENT infections.

This study evaluated the efficacy of *Streptococcus salivarius* K12 in preventing recurrent infections to potentially avoid tonsillectomy. Over a 12-month period, 100 children (average age 7 years) with recurrent pharyngotonsillitis were monitored. Half of the children received one OMNi-BiOTiC® *iMMUND* lozenge (containing *Streptococcus salivarius* K12, 1×10^9 CFU) daily for 90 days, while the other half served as a control group.

Results

The intervention group experienced a significant 49% reduction in the number of infections compared to the control group. Additionally, there was a notable 62% decrease in the use of painkillers and antibiotics among the probiotic group. Consequently, children in the intervention group had fewer school absences (8.58 days per child) compared to the control group (18.54 days per child; $p < 0.01$). Impressively, only 14 children in the probiotic group required the planned tonsillectomy, compared to all 50 children in the control group, resulting in a 72% reduction in surgeries.

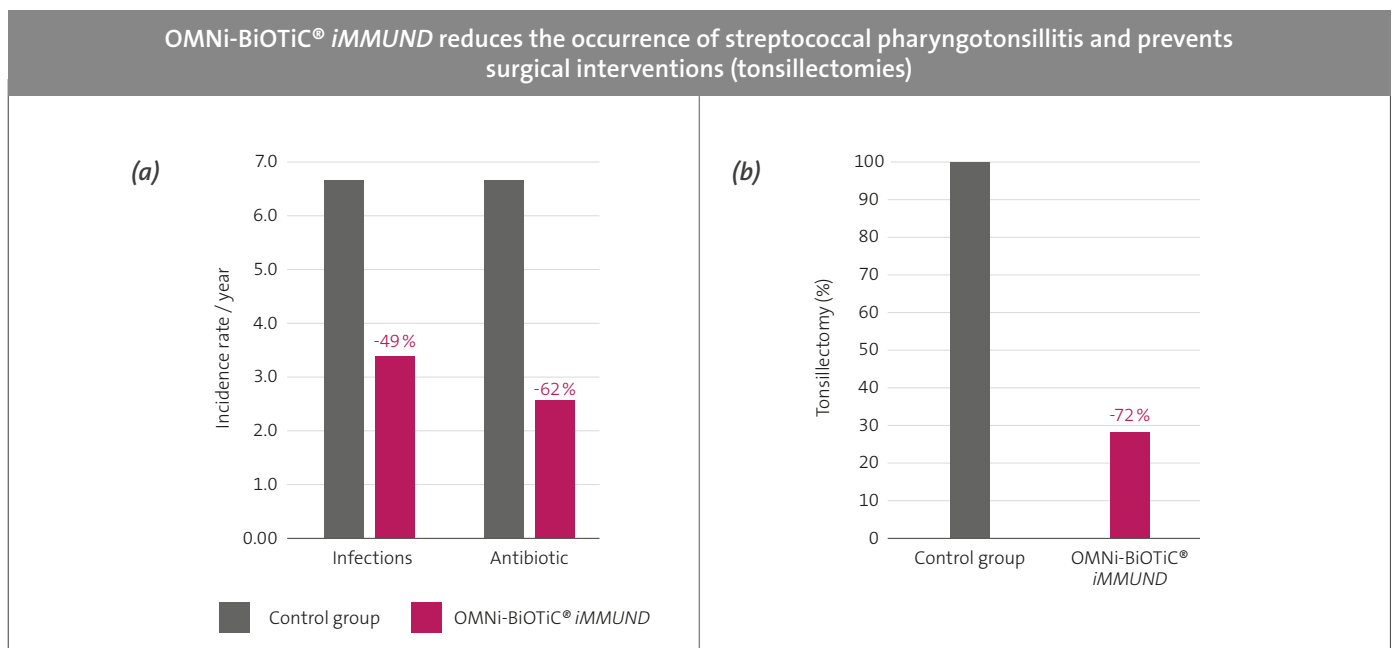


Figure: (a) OMNi-BiOTiC® *iMMUND* reduced the incidence of pharyngotonsillitis by 49% and the necessary treatment days with antibiotics by 62% over a period of 12 months.
(b) Treatment with OMNi-BiOTiC® *iMMUND* prevented 72% of planned tonsillectomies.

Discussion and conclusion

This study clearly demonstrates that a 90-day prophylactic regimen of OMNi-BiOTiC® *iMMUND* significantly reduces episodes of bacterial pharyngotonsillitis, as well as the use of antibiotics and painkillers over the course of a year. This reduction leads to an overall improvement in quality of life and fewer school absences. Notably, the study highlights the substantial potential of *Streptococcus salivarius* K12 in preventing the need for planned tonsillectomies.

Given its sustained colonization in the upper respiratory tract and its excellent safety profile, OMNi-BiOTiC® *iMMUND* represents an optimal alternative to conventional antibiotic treatments for bacterial pharyngotonsillitis.

Streptococcus salivarius K12 Significantly Reduces the Incidence of Acute Respiratory Infections in Kindergarten Children

Kryuchko *et al.*, Nutrafoods; 2021

Abstract

Acute respiratory diseases, such as colds or inflammation of the throat, tonsils or middle ear, are among the most common infections in children. Increased contact with pathogens, especially when children start nursery school, leads to a rise in the frequency of upper respiratory tract infections, often requiring the use of antibiotics and/or fever-reducing medication. The probiotic bacterial strain *Streptococcus salivarius* K12, which naturally colonises the mouth and throat shortly after birth, offers a reliable preventive measure against these diseases. It blocks the receptor binding of pathogens, promotes mucus production and forms inhibitors that have an antimicrobial effect. The present study investigated the prophylactic effect of the oral probiotic OMNi-BiOTiC® *immUND* in powder form (*S. salivarius* K12, 1 sachet with 1×10^9 CFU once daily) in 58 healthy children between the ages of two and four. Of these, 28 children were given the probiotic once daily for 90 days. Another 30 children did not receive the probiotic and served as a control group.

Results

Taking OMNi-BiOTiC® *immUND* led to a significant reduction in the incidence of acute respiratory infections such as tonsillopharyngitis, tracheitis and laryngitis (tracheitis, laryngitis), colds (rhinitis) and middle ear infections (otitis media) ($p < 0.01$). In particular, the incidence of tonsillopharyngitis and otitis media was reduced by more than 90%. It is particularly noteworthy that after taking OMNi-BiOTiC® *immUND*, the incidence of respiratory tract infections remained significantly reduced in the six months following treatment compared to the control group ($p < 0.01$). As a result, the use of antibiotics (-67.1%) and antipyretics (-74.3%) was reduced in the probiotic group, and there was a significant reduction in days of absence from kindergarten by 64% compared to the control group.

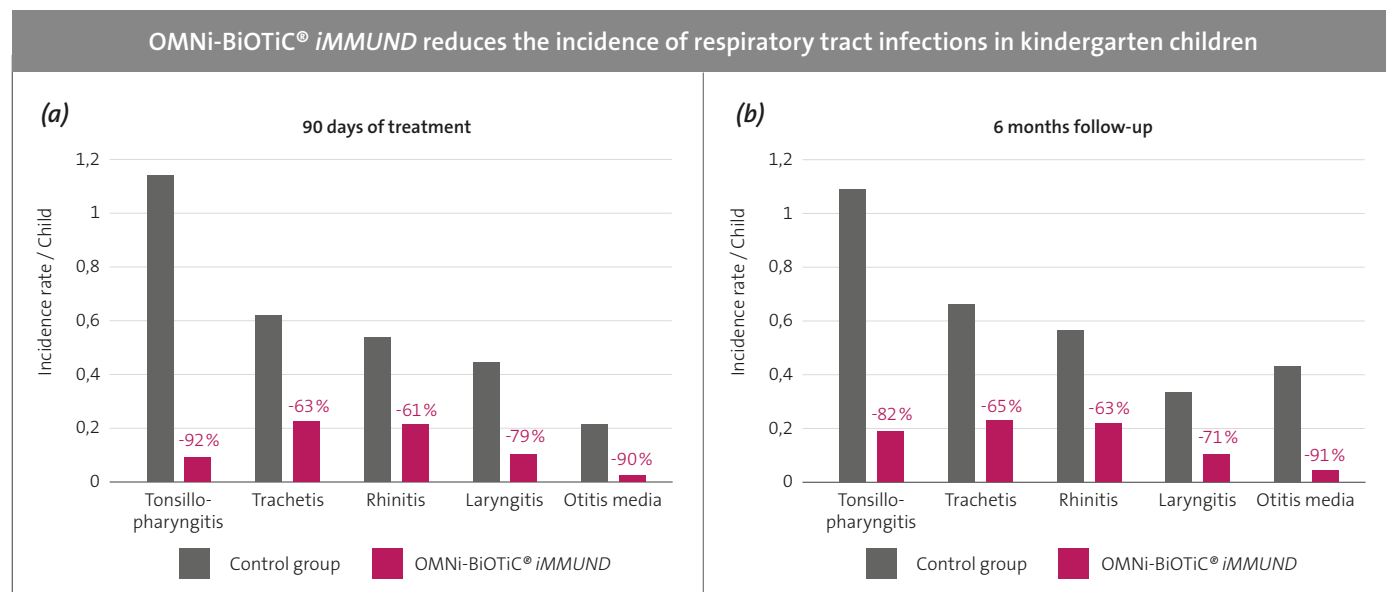


Figure: OMNi-BiOTiC® *immUND* significantly reduces the incidence of respiratory tract infections compared to the control group during the 90-day treatment period (a) and in the six months following treatment (b) ($p < 0.01$).

Discussion and conclusion

This study clearly shows that the prophylactic use of OMNi-BiOTiC® *immUND* in kindergarten children, who are exposed to a high number of pathogens, significantly reduces the incidence of respiratory diseases. The positive effect was observed both during the 90-day treatment period and in the following six months, indicating sustained colonisation of the probiotic bacterial strain *Streptococcus salivarius* K12 in the mouth and throat. As a result, *Streptococcus*

salivarius K12 reduced the need for antibiotic treatment with severe side effects, fever-reducing medication and absences from kindergarten. In summary, it can be said that the administration of OMNi-BiOTiC® *immUND* not only protects children from unpleasant and often painful respiratory infections, but also relieves parents by reducing the number of days they have to care for their sick children.

Streptococcus salivarius K12 Significantly Reduces the Incidence of Respiratory Diseases in Babies and Young Children

Kryuchko *et al.*, Nutrafoods; 2021

Abstract

Throat infections (pharyngitis), accompanied by sometimes severe sore throats, are among the most common reasons for babies and toddlers to visit the doctor. Group A beta-haemolytic streptococci (GABHS) are the most common cause of acute bacterial pharyngitis. GABHS cause approximately 616 million cases of pharyngitis worldwide each year. Bacterial pharyngitis is treated in practice with antibiotics and, if necessary, with fever-reducing agents (antipyretics). *Streptococcus salivarius* K12, a probiotic strain that naturally colonises the mouth and throat shortly after birth, is able to inhibit the spread of pathogens. It produces so-called BLIS (bacteriocin-like inhibitory substances), which primarily inhibit the growth of closely related species, including GABHS. The present study therefore investigated the prophylactic effect of the oral probiotic OMNi-BiOTiC® *iMMUND* in powder form (*Streptococcus salivarius* K12, 1 sachet once daily with a total of 1×10^9 CFU) in 62 healthy babies and toddlers aged 6 to 24 months. 32 children received the probiotic once daily over a period of 30 days. The remaining 30 children served as a control group.

Results

Preventive use of OMNi-BiOTiC® *iMMUND* over a period of 30 days resulted in significantly fewer acute respiratory infections throughout the entire observation period – compared to the control group, there were 63% fewer viral infections and even 75% fewer bacterial infections ($p < 0.01$). As a result, significantly fewer visits to the ear, nose and throat doctor were necessary (-85%). It is particularly noteworthy that, thanks to OMNi-BiOTiC® *iMMUND*, babies and toddlers had a significantly reduced need for medication with side effects, such as antibiotics (-87%) and antipyretics (-52%) ($p < 0.01$).

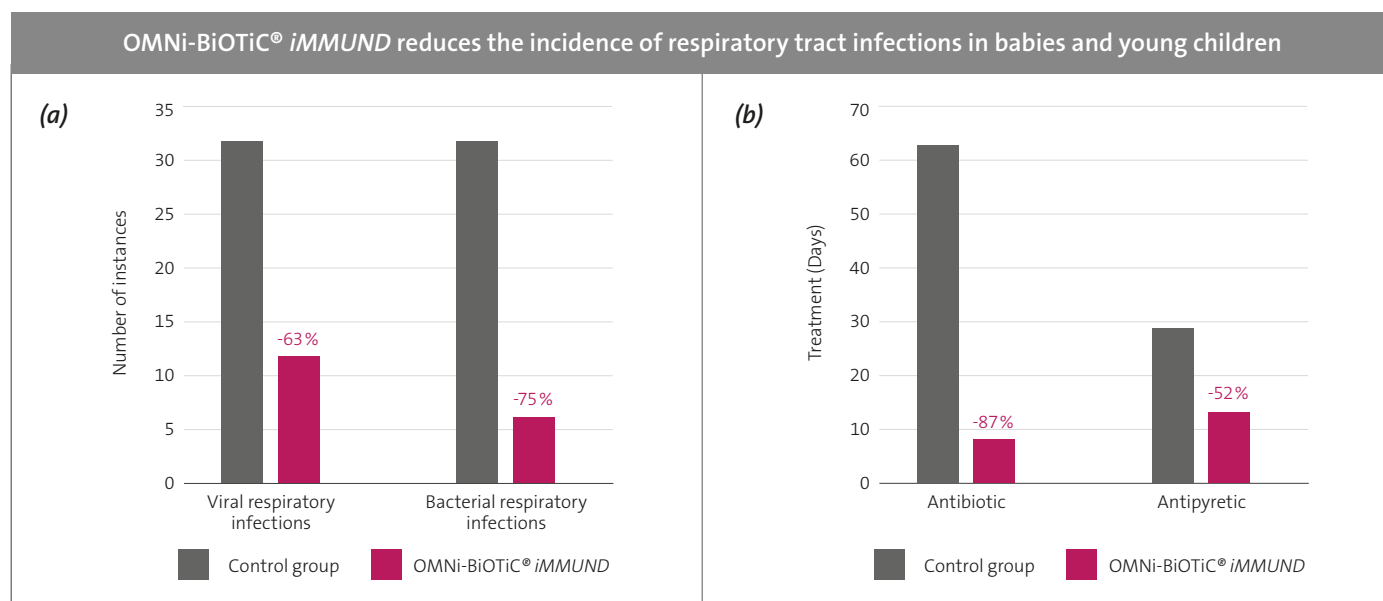


Figure: Taking OMNi-BiOTiC® *iMMUND* for 30 days significantly reduced the incidence of viral and bacterial respiratory tract infections (a) and decreased the need for medication (b) compared to the control group during the 4-month observation period ($p < 0.01$).

Discussion and conclusion

This study clearly shows that the incidence of both viral and bacterial respiratory tract infections in babies and young children can be significantly reduced by administering the probiotic OMNi-BiOTiC® *iMMUND*. The positive effect persisted over a period of four months, suggesting sustained colonisation of the probiotic bacterial strain *Streptococcus salivarius* K12 in the mouth and throat.

Of particular relevance is the fact that the probiotic also significantly reduced the need for antibiotic treatment with severe side effects and the need for antipyretic medication. It should also be emphasised that OMNi-BiOTiC® *iMMUND* in powder form is the optimal dosage form for babies and toddlers, as lozenges must not be used in children under three years of age due to the risk of aspiration.

Streptococcus Salivarius K12 Counteracts Dysbiosis in the upper Respiratory Tract in Children with Recurrent Respiratory Tract Infections

Ilchenko *et al.*, Clinical Pediatrics; 2019

Abstract

The mouth, nose and throat are the first entry points for foreign germs and pollutants. The oral microbiome forms an important defense system against these pathogenic environmental factors. It produces antibodies and displaces pathogenic germs. If dysbiosis is present, the oral microbiome can no longer fully function as it should. The present study investigated the efficacy of the oral probiotic OMNi-BiOTiC® *immUND* in powder form (with *Streptococcus salivarius* K12 - the most important key microbial strain of the oral microbiome) against dysbiosis of the microbiome in the upper respiratory tract in children with recurrent respiratory tract infections. 46 children were divided into three groups: The first group included 18 children (mean age 4.6 ± 0.04 years) with microaspiration syndrome who suffered from prolonged and recurrent bronchitis. The second group consisted of 12 infants (mean age 1.2 ± 0.04 years) suffering from rumination (= regurgitation of food) and recurrent viral infections. The control group comprised 16 respiratory asymptomatic infants (mean age 13.3 ± 8.9 months) with rumination. The probiotic was taken twice over 30 days with a 3-month break (1 sachet containing 1×10^9 CFU once a day). The clinical and bacteriological data were evaluated after 6 months.

Results

The use of OMNi-BiOTiC® *immUND* in children with recurrent respiratory tract infections had a pronounced positive effect on the microbial colonisation of the mucous membranes of the upper respiratory tract. In the first group, this was reflected in a decrease in colonisation of *Klebsiella pneumoniae* (-75%) and *Pseudomonas aeruginosa* (-57%) and the elimination of *Staphylococcus aureus* ($p < 0.05$), *Streptococcus epidermis*, *Streptococcus pyogenes* ($p < 0.05$) and *Candida albicans* ($p < 0.05$). Notably, the abundance of the pathogen (*Streptococcus salivarius* K12), which causes caries, was reduced by 66%. In the second group, there was also a significant reduction in *Staphylococcus aureus* (-63%) ($p < 0.05$), *Streptococcus epidermis* (-50%) and *Streptococcus pyogenes* (-60%) ($p < 0.05$). *Streptococcus mutans*, *Klebsiella pneumoniae*, *Escherichia coli* and *Candida albicans* were completely suppressed. This led to a significant reduction in the frequency and duration of respiratory tract infections.

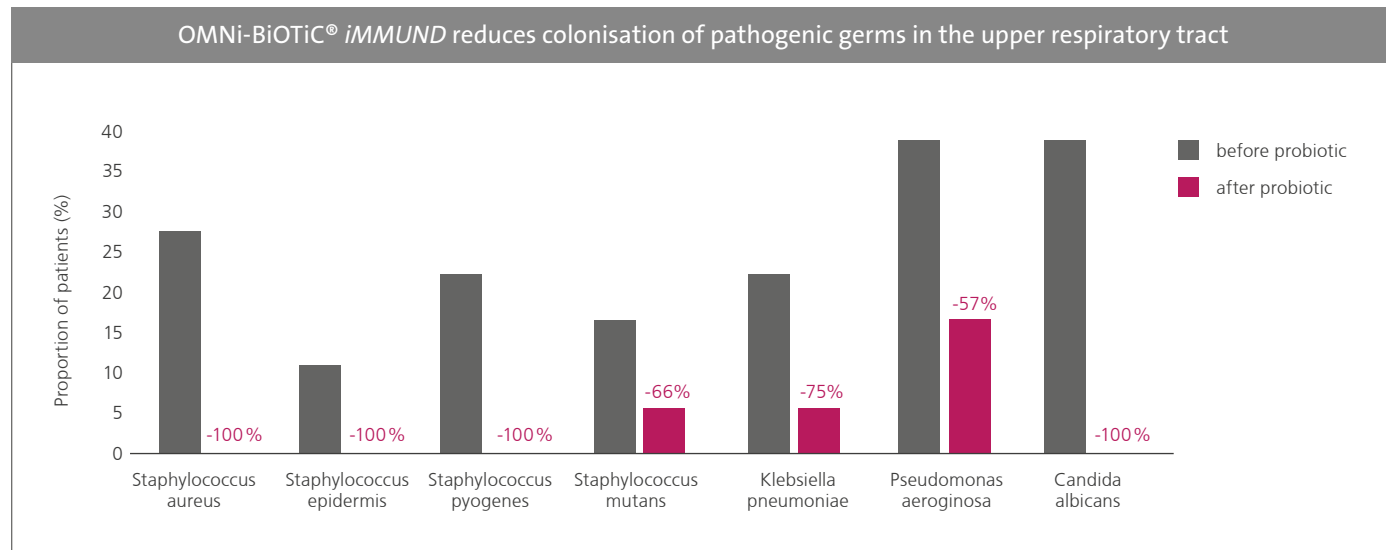


Figure: Taking OMNi-BiOTiC® *immUND* twice for 30 days greatly reduced the incidence of pathogenic germs in the upper respiratory tract in children with microaspiration syndrome and recurrent bronchitis.

Discussion and conclusion

This study clearly shows that microaspiration syndrome or rumination in combination with recurrent respiratory tract infections in children are associated with dysbiosis of the upper respiratory tract. The administration of the probiotic OMNi-BiOTiC® *immUND* is therefore extremely useful, as pathogenic germs on the mucous membranes of the upper respiratory tract are greatly reduced or even

eliminated by *Streptococcus salivarius* K12. This can reduce both the frequency and duration of respiratory tract infections. Another remarkable result was the displacement of the pathogen *Streptococcus mutans* by the probiotic, which contributes significantly to the dental health of young patients.

Streptococcus salivarius K12 Significantly Reduces the Incidence, Duration and Severity of Radiation-Induced Severe Oral Mucositis

Peng *et al.*, Journal of Clinical Oncology; 2024



Abstract

Radiotherapy (RT) is one of the most common methods used to treat malignant tumors in the head and neck area. One side effect that occurs in almost all patients is oral mucositis (OM), an inflammation of the mucous membranes of the mouth and throat. Approximately 65% of patients even develop severe oral mucositis during treatment (severity grades 3 and 4 according to the WHO classification). This placebo-controlled clinical trial investigated the effect of the probiotic strain *Streptococcus salivarius* K12, the most important key microbial strain in the oral microbiome, on the frequency and duration of severe OM (SOM). A total of 143 patients with malignant head and neck tumors who underwent radiotherapy 5 times a week for 6 weeks were randomised and divided into the placebo to the probiotics group (n = 71) or the placebo group (n = 72). Over the duration of the radiotherapy, 1 OMNi-BiOTiC® *immUND* lozenge (*Streptococcus salivarius* K12, 1×10^9 CFU per tablet) was taken 3 times a day. The course of mucositis was examined twice a week during treatment and then once a week for 8 weeks.

Results

Administration of OMNi-BiOTiC® *immUND* led to a remarkable reduction in the average severity of oral mucositis over the entire period of radiotherapy compared to the placebo group. Significantly fewer patients in the probiotics group developed severe oral mucositis (36.6% compared to 54.2% in the placebo group; $p = 0.0351$). The incidence of fourth-degree oral mucositis was even reduced by 82% (2.8% compared to 15.3%; $p = 0.0169$). Impressively, the average duration of SOM was reduced by half by taking OMNi-BiOTiC® *immUND* (8.9 days compared to 18.3 days; $p = 0.0084$). It should also be emphasised that the occurrence of OM during radiotherapy was significantly delayed by the probiotic from 17.5 to 28 days after the start of treatment ($p < 0.0001$). The results of genetic sequencing of the patients oral microbiome, which was carried out alongside treatment, showed that the administration of *Streptococcus salivarius* K12 inhibited opportunistic pathogens and that the abundance of oral commensals could be maintained during radiotherapy.

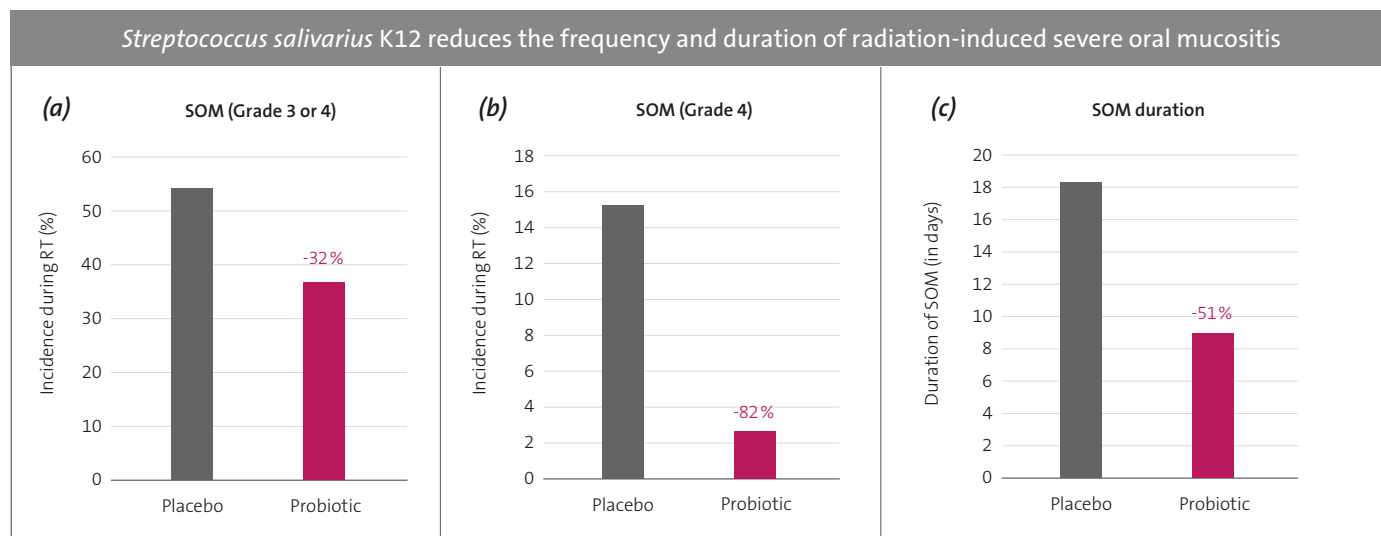


Figure: Taking the probiotic OMNi-BiOTiC® *immUND* during radiotherapy significantly reduced (a) the incidence of severe oral mucositis (grade 3 or 4) ($p = 0.0351$), (b) the occurrence of grade 4 SOM ($p = 0.0169$) and (c) the average duration of SOM ($p = 0.0084$).

Discussion and conclusion

Radiotherapy-induced oral mucositis can cause severe pain in the mouth and throat of affected patients. It can lead to difficulties in chewing, swallowing and speaking, which has a massive impact on quality of life. The more severe the mucositis, the greater the risk of (life-threatening) infections. This study clearly shows that taking OMNi-BiOTiC® *immUND* lozenges significantly reduces the

frequency, duration and severity of oral mucositis. The displacement of opportunistic pathogens and the favouring of commensal bacteria such as *Streptococcus salivarius* K12 play a key role in this. In summary, OMNi-BiOTiC® *immUND* offers a new option in the treatment of oral mucositis, for which no drugs were previously available.

Successful Use of the Probiotic Bacterial Strain *Streptococcus salivarius* K12 in Medical Personnel in the Prevention of COVID-19 Infections

Wang *et al.*, *Frontiers in Bioengineering and Biotechnology*; 2021

Abstract

The highly infectious SARS-CoV-2 virus primarily enters the body through the oral cavity, leading to a range of symptoms, predominantly affecting the upper respiratory tract. Healthcare workers, especially those in close daily contact with hospitalized COVID-19 patients, face a increased risk of infection. The oral microbiome plays a key role in preventing and managing both bacterial and viral infections. Thus, positively modulating the oral microbiome may be a promising strategy to protect individuals from respiratory infections, including COVID-19.

This randomized controlled trial evaluated the impact of the oral probiotic OMNi-BiOTiC® *immUND* on the prevention of respiratory infections among medical staff (193 doctors and nurses) at hospitals in Wuhan, who were frequently exposed to COVID-19 patients.

Results

Daily administration of OMNi-BiOTiC® *immUND* (*Streptococcus salivarius* K12, 2×10^9 CFU) twice a day for 30 days resulted in a 65% reduction in the incidence of respiratory infections ($p < 0.01$). Additionally, participants in the probiotic group experienced a 78% decrease in the duration of respiratory symptoms ($p < 0.01$) and a 96% reduction in days away from work ($p < 0.01$). Unlike the control group, these participants did not require antibacterial, antiviral, or anti-inflammatory medications. Furthermore, medical personnel receiving OMNi-BiOTiC® *immUND* exhibited sustained protection against respiratory infections starting from day 10 of probiotic administration.

Sustained protection against respiratory infections from day 10 of OMNi-BiOTiC® *immUND* administration

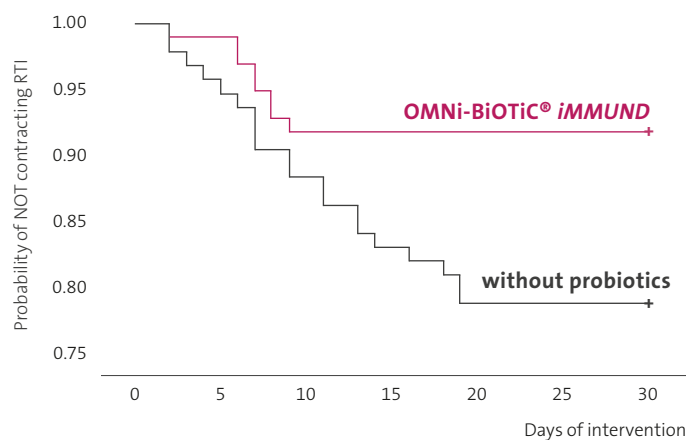


Figure: Kaplan-Meier curve of the probability of not contracting respiratory tract infections (RTI). In the probiotics group, the cumulative incidence of RTI does not increase from day 10. In contrast, the control group shows a significantly higher probability of respiratory infections.

Discussion and conclusion

This study provides encouraging preliminary evidence for using oral probiotics in combating COVID-19. Since SARS-CoV-2, like other pathogens, must pass through the oral mucosa to enter the body, the research underscores the benefits of enhancing the oral microbiome with the probiotic strain *Streptococcus salivarius* K12. The findings show that OMNi-BiOTiC® *immUND* significantly reduces both the incidence and duration of respiratory infections among medical personnel exposed to high levels of the virus.

Notably, within just ten days of regular intake, this probiotic strain provides sustained protection against respiratory infections, including SARS-CoV-2, underscoring the effectiveness of *Streptococcus salivarius* K12 in maintaining oral mucosal colonization and supporting long-term immunity.

Reduction of the Rate of SARS-CoV-2 Infections in Children by Ingestion of *Streptococcus salivarius* K12

Di Pierro *et al.*, *Minerva Med*; 2021

Abstract

The coronavirus pandemic (COVID-19), caused by the SARS-CoV-2 virus, has resulted in millions of infections and deaths worldwide since late 2019. Since the oral cavity is the primary entry point for the virus, current research is increasingly exploring the relationship between the oral and pulmonary microbiomes. Studies have shown a reduced diversity of commensal microorganisms in the oral, lung, and gut microbiomes of COVID-19 patients. This pilot study examined the preventive effect of the oral bacterial strain *Streptococcus salivarius* K12, administered as OMNi-BiOTiC® *i*MMUND lozenges (1×10^9 CFU) daily for 90 days, on the risk of SARS-CoV-2 infection in 128 schoolchildren.

Results

Children were tested for SARS-CoV-2 based on typical COVID-19 symptoms or their status as contact persons. In the probiotic intervention group, no COVID-19 infections were confirmed across 33 tests, including 8 tests conducted due to symptoms. In contrast, the control group had 24 symptomatic children who tested positive for SARS-CoV-2 out of 46 tests. These results indicate that the administration of OMNi-BiOTiC® *i*MMUND significantly reduces both the incidence of symptoms ($p < 0.05$) and the rate of COVID-19 infections ($p < 0.01$).

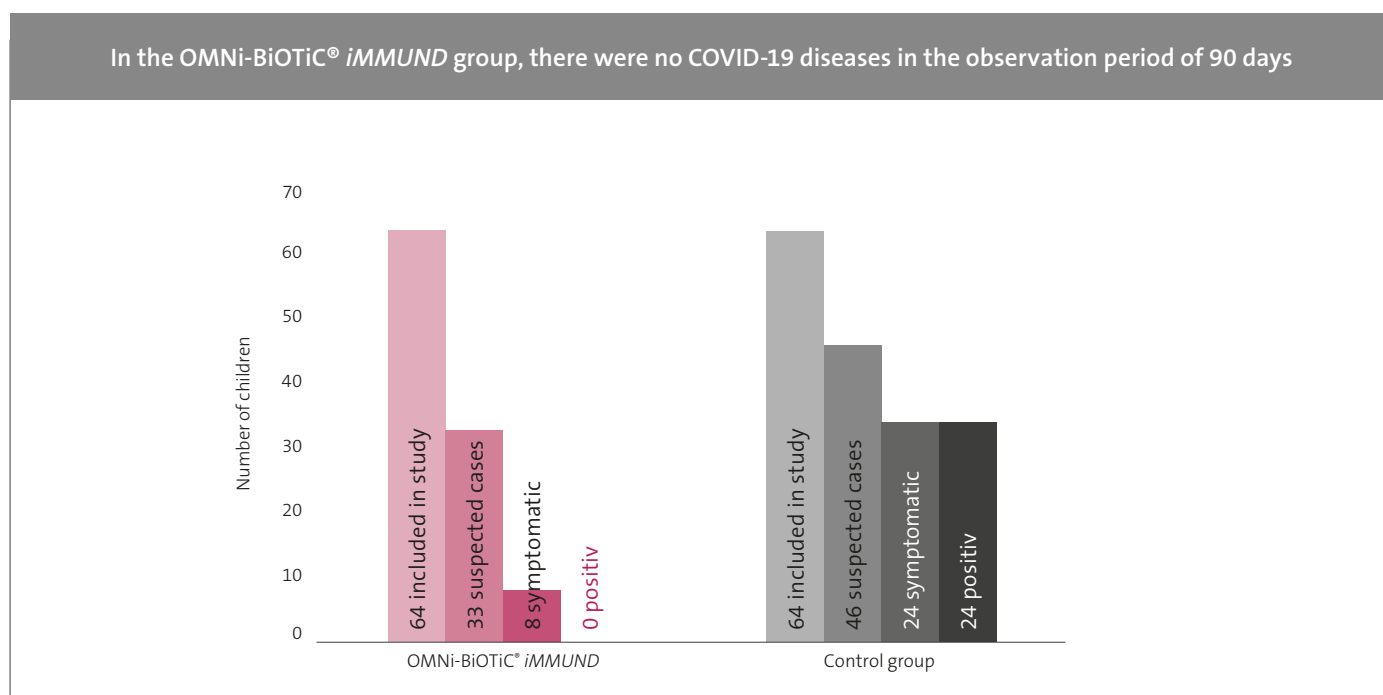


Figure: OMNi-BiOTiC® *i*MMUND significantly reduces the occurrence of clinical symptoms ($p < 0.05$) as well as the rate of COVID-19 infections in children ($p < 0.01$).

Discussion and conclusion

As a primary entry point for viruses and bacteria, the oral cavity plays a crucial role in the microbial colonization of the lungs. Thus, improving the oral microbiome can positively influence the lung microbiome and aid in combating infections through immune modulation. This study demonstrates that preventive administration

of the oral probiotic strain *Streptococcus salivarius* K12 significantly reduces the incidence of SARS-CoV-2 infections in children. These findings suggest that OMNi-BiOTiC® *i*MMUND could be an effective preventive measure against COVID-19.

The Positive Effect of a Multispecies Probiotic on Post-COVID-19 Symptoms



Horvath *et al.*, *Nutrients*; 2024

Abstract

Post-COVID syndrome continues to be the focus of research even after the coronavirus pandemic, as many people are still suffering from the long-term effects of having survived a coronavirus infection. Typical symptoms include fatigue (constant, severe tiredness), reduced performance, coughing and shortness of breath. Research shows that even patients with a mild to moderate course of the infection can develop damage to the lung tissue, which can lead to long-term complications in the lungs. One potential therapeutic target to alleviate post-COVID syndrome is the gut flora, with studies showing that COVID-19 patients have a dysbiotic gut microbiome and that the infection process in the lungs can be influenced via the gut-lung axis. In this double-blind, placebo-controlled study, the positive effect of the indication-specific multispecies probiotic OMNi-BiOTiC® Pro-Vi 5 (2 × 1 sachet daily with 5×10^9 CFU each for 6 months) on post-COVID symptoms was demonstrated.

Results

The study clearly shows that patients with severe COVID-19 had significantly more severe physical and psychological symp-

toms than patients with a mild course of the disease ($p=0.041$). After just 3 months of taking OMNi-BiOTiC® Pro-Vi 5, significantly fewer patients suffered from fatigue ($p=0.014$) and psychological stress ($p=0.022$) compared to the placebo group, as demonstrated by the ARTIQ questionnaire (acute respiratory tract infection questionnaire). The 16S sequencing of the stool samples showed a reduced diversity of the intestinal microbiome in severe COVID-19 disease. This was significantly increased again after just 3 months ($p=0.047$) by the administration of the probiotic and showed further improvements after 6 months ($p=0.014$). Further very interesting results were provided by the metabolome analyses, including an increase in the level of 3,4-dihydroxybenzoic acid (DOPAC) ($p=0.015$) and the anti-inflammatory short-chain fatty acid butyrate ($p=0.024$) after 6 months of taking OMNi-BiOTiC® Pro-Vi 5. According to studies, an increase in DOPAC is associated with improved mental health and quality of life. After just 3 months of taking probiotics, significantly lower ROS production, and therefore reduced oxidative stress, was also observed ($p<0.05$). Due to the increase in butyrate, it is not surprising that there was a significant decrease in pro-inflammatory CD4+ TEMRA immune cells in the probiotic group after just 3 months of intervention, while there was even an increase in the placebo group ($p=0.022$), which can be attributed to the chronic inflammatory state.

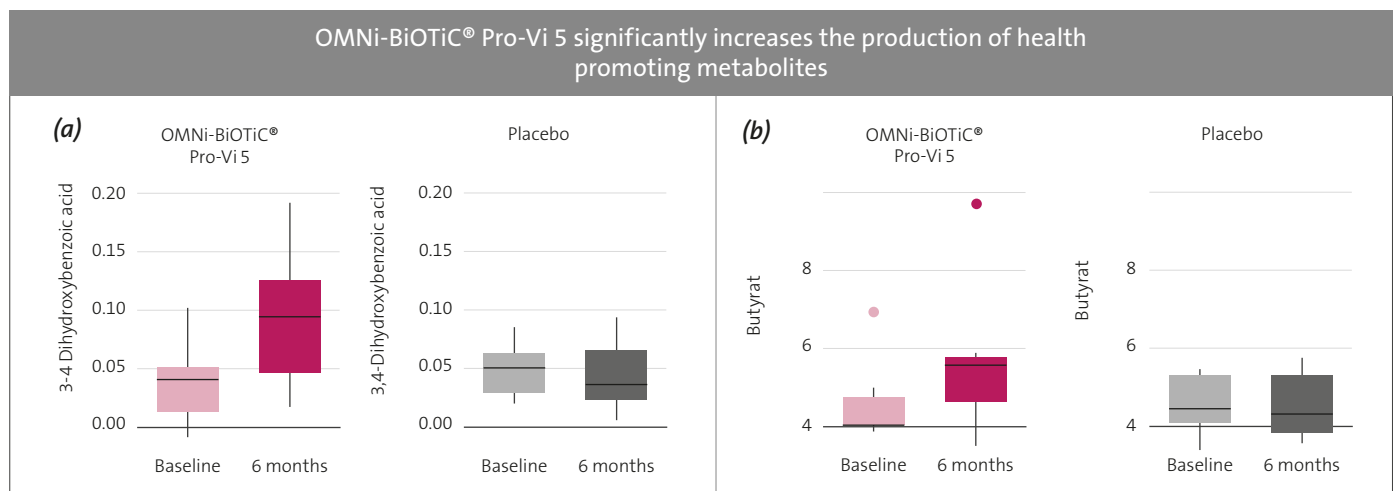


Figure: Taking OMNi-BiOTiC® Pro-Vi 5 for 6 months leads to a significantly increased level of (a) 3,4-dihydroxybenzoic acid and (b) the short-chain fatty acid butyrate.

Discussion and conclusion

The symptoms of post-COVID syndrome are wide-ranging. The most common include prolonged fatigue, reduced performance, lung weakness and inflammatory reactions. The psyche is also frequently affected, which manifests itself in the form of anxiety, depression and sleep disorders. This study clearly shows that taking the multispecies probiotic OMNi-BiOTiC® Pro-Vi 5 for 6 months leads to significant improvements in various post-COVID-associated symptoms. The positive effect of a multispecies

probiotic on post-COVID-19 was reduced, while the diversity of the gut microbiome and health-promoting microbial metabolites were significantly increased. Since post-COVID sufferers are sometimes severely restricted in their quality of life and everyday life and are under great suffering, intervention with medically relevant probiotics is a valuable therapeutic option that not only helps to relieve the burden on patients and their relatives, but also significantly reduces costs for the healthcare system.

A Multi-Species Probiotic Significantly Improves the Beta Diversity of the Microbiome in Acute COVID-19 Infections

Horvath *et al.*, *Nutrients*; 2024

Abstract

COVID-19 is primarily, but not exclusively, a disease of the respiratory tract. Typical symptoms are fever, shortness of breath and a dry cough. Loss of taste and odour can be early and characteristic symptoms. However, quite a few patients also show gastrointestinal symptoms such as loss of appetite, nausea, vomiting, diarrhoea and abdominal pain, in some cases even as the only symptom. This randomised, double-blind, placebo-controlled remote study investigated the positive effect of the pathogen-inhibiting multispecies probiotic OMNi-BiOTiC® 10 AAD (trade name in Germany: OMNi-BiOTiC® 10) on the symptoms of acute COVID-19 infections. 30 COVID-19 patients in quarantine received the probiotic (2 x 5 g per day with a total of 1×10^{10} CFU) or the placebo for 30 days. Over the 30-day treatment period, gastrointestinal symptoms were surveyed online and a total of 5 stool samples per patient were collected for microbiome and metabolome analyses.

Results

The results of the present study clearly show that even a mild COVID-19 infection led to a significant reduction in alpha diversity, the measure of species diversity of the microbiome, compared to the healthy control group. Particularly striking in the stool microbiome analyses of COVID-19 patients was the reduced abundance of *Christensenellaceae*, which is also seen in metabolic diseases, as well as the reduction of *Ruminococcaceae*, which is associated with numerous gastrointestinal complaints. The faecal metabolome also showed significant changes in COVID-19 infected individuals compared to healthy controls. For example, the health-promoting 3,4-dihydroxybenzoic acid and the neurotransmitter precursor tyrosine were reduced. Impressively, taking the multispecies probiotic for 30 days significantly increased beta diversity ($p=0.001$). In addition, a constant increase in *Enterococcus faecium*, a strain contained in OMNi-BiOTiC® 10 AAD, was demonstrated in patients in the probiotic groups over the duration of the study.

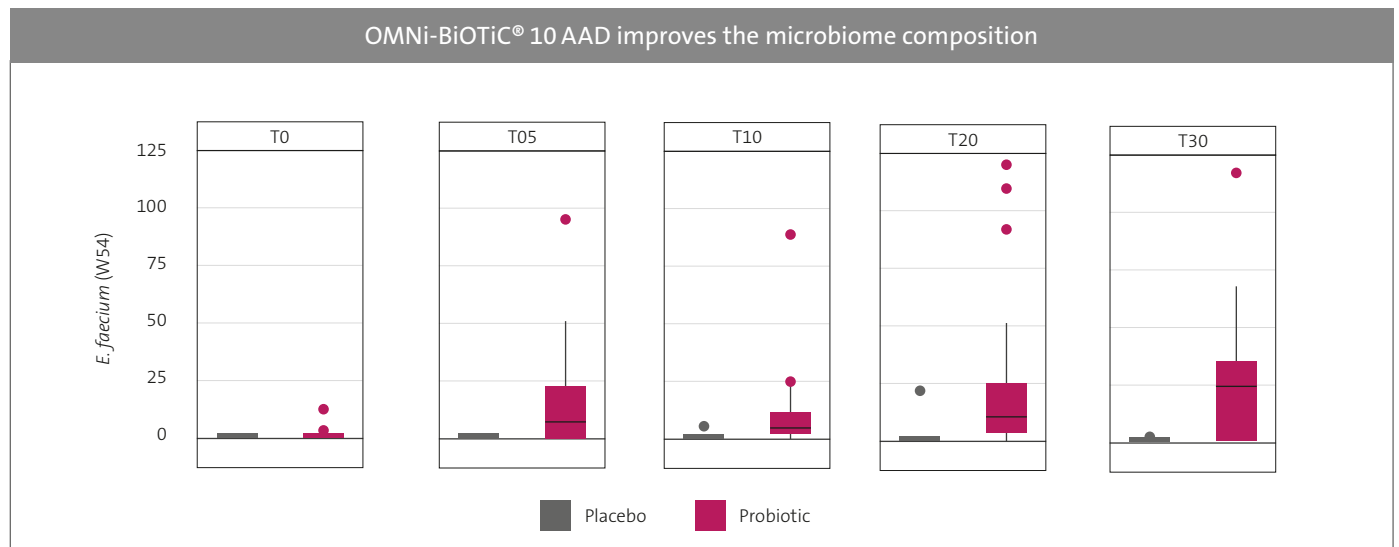


Figure: Taking OMNi-BiOTiC® 10 AAD for 30 days led to a constant increase in *Enterococcus faecium*, a strain contained in the probiotic.

Discussion and conclusion

COVID-19 not only attacks the respiratory tract, but in many cases also damages other organs, such as those of the gastrointestinal tract, with up to 50% of those infected showing gastrointestinal symptoms. Via the ACE2 receptors, which are not only found in high concentrations in epithelial cells of the respiratory tract and parenchymal cells of the lungs, but also in enterocytes of the gastrointestinal tract, the virus also enters the intestine and triggers abdominal symptoms such as diarrhoea. This study clearly shows that a SARS-CoV infection leads to a reduction in the diversity of the microbiome, which in turn can have a negative impact on the entire

body. A multispecies probiotic significantly improves the beta diversity of the microbiome in acute COVID-19 infections Horvath *et al.*, *Nutrients*; 2024. By taking the medically relevant probiotic OMNi-BiOTiC® 10 AAD, beta diversity could be significantly increased. Particularly noteworthy is the increased abundance of *Enterococcus faecium* contained in the probiotic in the stool samples of the verum group, a strain that has proven particularly effective in the treatment of diarrhoea of various origins. The intake of medically relevant probiotics therefore offers great potential to counteract the negative effects of a COVID-19 infection on the gut microbiome.

A Multispecies Probiotic Reduces Susceptibility to COVID-19 Infections

Nguyen-Alley *et al.*, Particle and Fibre Toxicology; 2024

Abstract

After entering the body, the SARS-CoV-2 coronavirus is cleaved and activated by transmembrane serine protease 2 (TMPRSS2) or furin protease. A prerequisite for the infection of cells with SARS-CoV-2 is the presence of membrane-bound angiotensin-converting enzyme 2 (ACE2). This protein serves as a receptor to which the virus initially docks and is found in high concentrations in epithelial cells of the respiratory tract and lungs. The androgen receptor (AR) regulates both TMPRSS2 and ACE2 protein expression. Neupilin-1 (NRP1) is also a known coreceptor for SARS-CoV-2. Increased expression (=synthesis) of all these proteins can increase susceptibility to COVID-19 disease. In addition, exposure to environmental pollutants and obesity also contribute to increased susceptibility and severity of COVID-19 infections. Therefore, the present study investigated the effect of diesel exhaust particles (DEP) in combination with a high-fat diet on the expression of proteins of the pulmonary SARS-CoV-2 infection pathway. For this purpose, mice on a high-fat diet were exposed to 35 µg of these diesel exhaust particles (DEP)

via oropharyngeal aspiration twice a week for 30 days. To determine whether probiotics can prevent the changes mediated by DEP exposure, another group of mice on a high-fat diet with DEP exposure were additionally treated with the medically relevant multispecies probiotic OMNi-BiOTiC® HETOX (0.3 g/day in drinking water).

Results

The results of the study clearly show a significant increase in TMPRSS2, furin, ACE2, AR and NRP1 protein expression in the bronchioles of fat-fed mice after 30 days of exposure to diesel exhaust particles ($p < 0.05$). Remarkably, the administration of OMNi-BiOTiC® HETOX significantly reduced the expression of all these proteins of the pulmonary SARS-CoV-2 infection pathway again ($p < 0.05$), which consequently reduces susceptibility to COVID-19 infections.

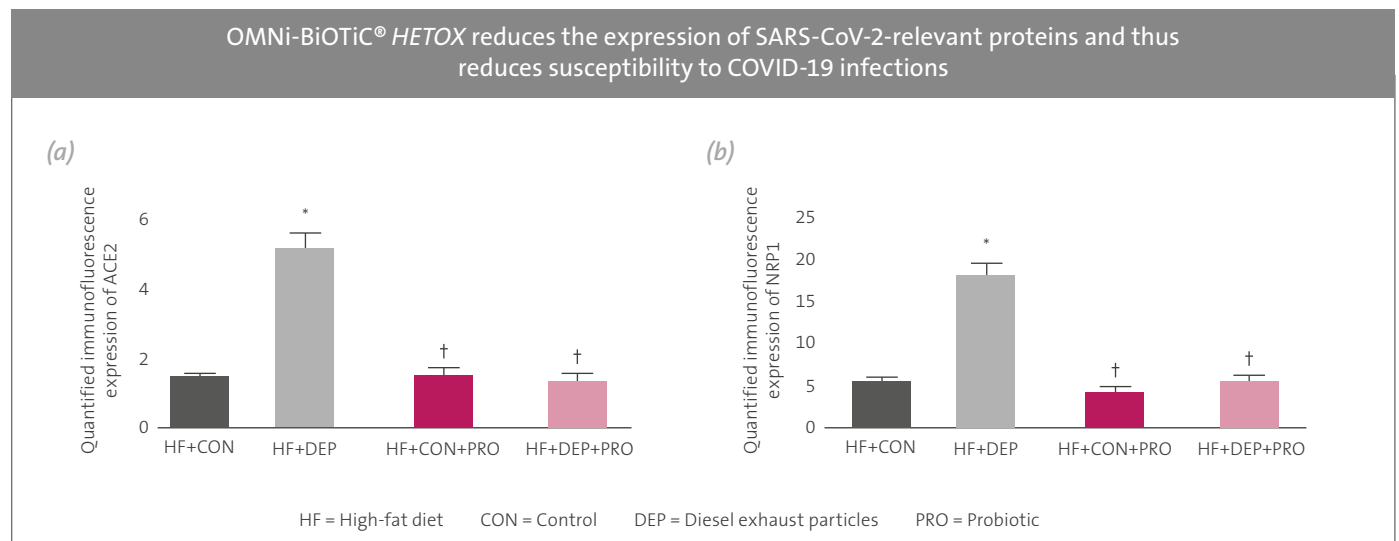


Figure: Exposure to diesel exhaust particles (DEP) for 30 days led to significantly increased synthesis of (a) the ACE2 receptor and (b) the NRP1 protein ($p < 0.05$) in mice fed a high-fat diet. The administration of the probiotic OMNi-BiOTiC® HETOX significantly reduced their expression and thus the susceptibility to SARS-CoV-2 infection ($p < 0.05$).

Discussion and conclusion

The COVID-19 pandemic is the most extensive pandemic of the 21st century to date and it has had a drastic impact in many countries. Environmental air pollutants can negatively affect the composition of the lung and gut microbiome as well as inflammatory processes in the body. The present study clearly shows that exposure to diesel exhaust particles in combination with a high-fat diet leads to a

higher susceptibility of the lungs to SARS-CoV-2 infection. Impressively, the intake of the multispecies probiotic OMNi-BiOTiC® HETOX reduces these negative changes and thus curbs the harmful effects of air pollutants via the gut-lung axis. Medically relevant probiotics therefore represent a sensible preventive measure to prevent or mitigate COVID-19 infections.

The Positive Effect of a Multi-Species Probiotic on the Negative Effects of Diesel Exhaust Particles on the Lung and Gut Microbiome

Daniel *et al.*, Particle and Fibre Toxicology; 2021 | Phillippi *et al.*, Particle and Fibre Toxicology; 2022

Abstract

Exposure to traffic-related emissions is a recognized trigger of inflammatory processes and is associated with the onset and progression of inflammatory lung diseases, such as chronic obstructive pulmonary disease (COPD). Nevertheless, the specific effects of particulate matter pollutants on the lung microbiome are not well understood. These two studies aimed to explore the impact of diesel exhaust particles (DEP) on commensal bacteria in the lungs and gut, as well as on immune and inflammatory responses.

Mice on a high-fat diet were exposed to 35 µg of DEP via oropharyngeal aspiration twice a week for 30 days. To assess whether probiotics could mitigate DEP-induced damage and microbiome alterations, a separate group of high-fat diet mice with DEP exposure was given a multi-species probiotic (0.3 g/day in water).

Results

The studies demonstrated that inhaled exhaust particles led to significant alterations in both lung and gut microbiomes, characterized by an increase in *Proteobacteria* and a decrease in beneficial bacterial phyla. Notably, the administration of OMNi-BiOTiC® HETOX had a positive impact on both microbiomes, counteracting some of the detrimental effects induced by the exhaust particles. The probiotic reduced the prevalence of *Proteobacteria* and promoted the colonization of health-promoting bacteria, such as *Firmicutes* and *Actinobacteria*, in both the lungs and intestines.

Inflammatory markers were notably affected as well. The high-fat diet combined with DEP exposure resulted in elevated inflammatory markers in the blood (e.g., LPS, interleukin-3, TNF-alpha) and lung tissue (e.g., TNF-alpha, NF-α B p65, TLR-2). Exhaust particles also induced pathological changes in the lungs, characterized by increased oxidative stress and collagen deposition around the bronchioles, indicative of fibrosis. Probiotic administration significantly reduced both systemic inflammation and fibrotic changes in the lungs, demonstrating its potential to counteract the adverse effects of traffic-related pollutants.

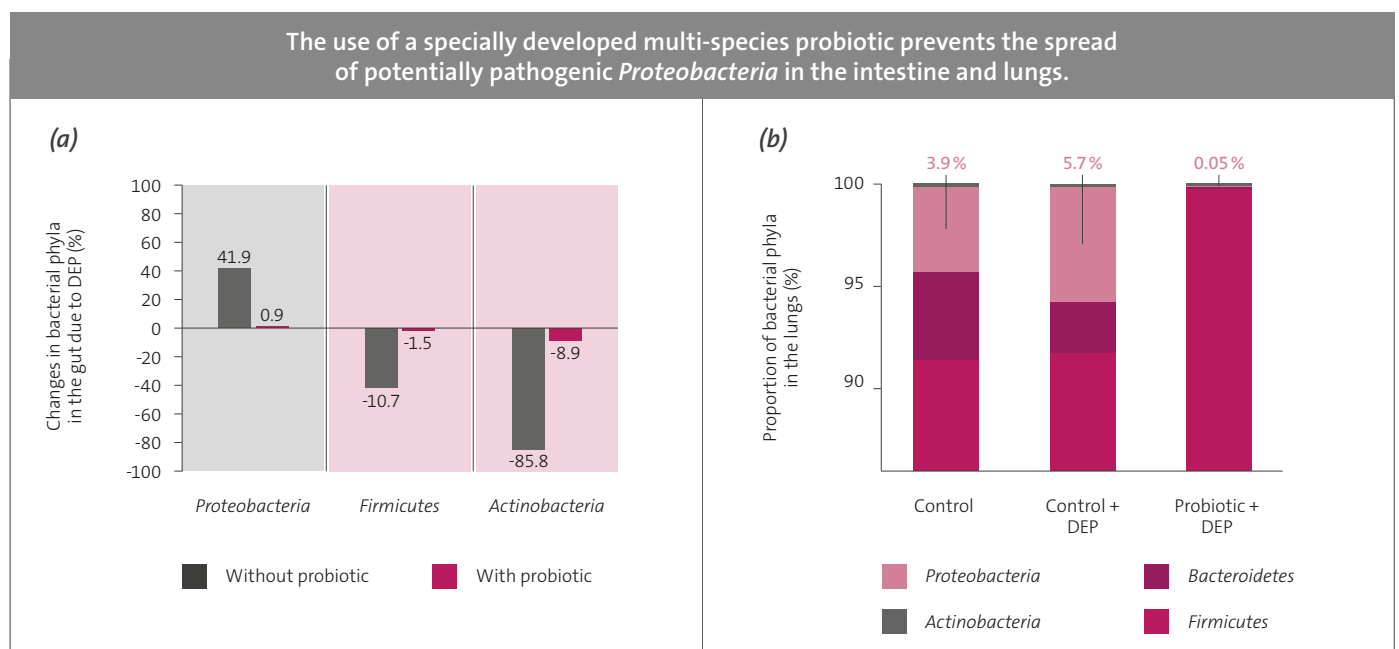


Figure 1: Microbial changes caused by diesel exhaust particles (DEP) are significantly reduced by probiotic intake. The administration of the multi-species probiotic prevents the spread of *Proteobacteria* and at the same time promotes increased colonisation of health-promoting bacteria (*Firmicutes*, *Actinobacteria*) in the intestine (a) as well as in the lungs (b).

The administration of a specially developed multi-species probiotic reduces both systemic inflammatory reactions and the inflammatory process in the lungs.

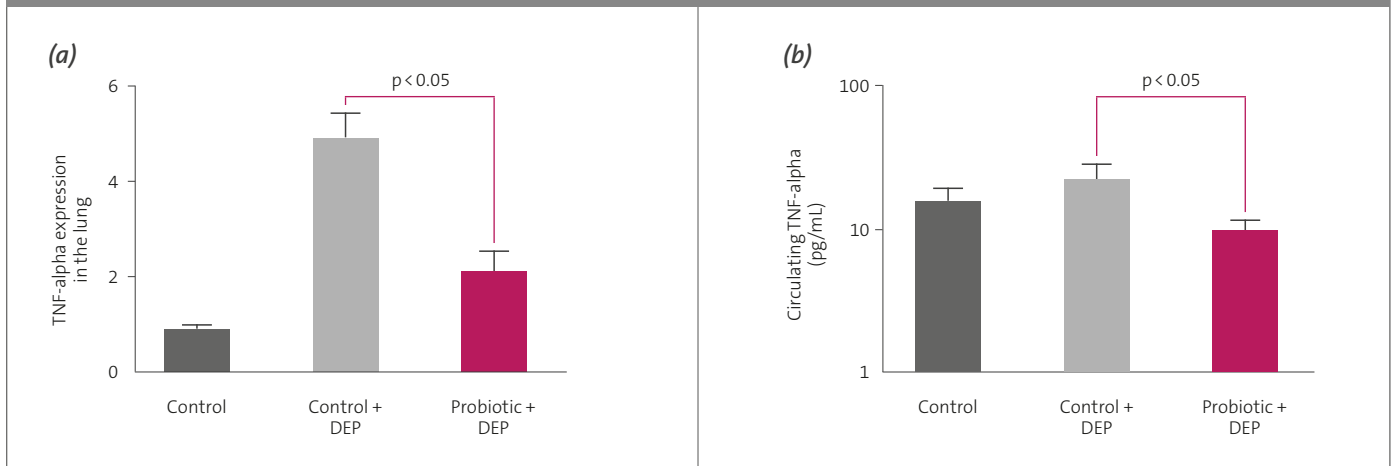


Figure: Microbial changes caused by diesel exhaust particles (DEP) are significantly reduced by probiotic intake. The administration of the multi-species probiotic leads to a significant reduction of TNF-alpha in the lungs (a) as well as in the blood (b).

Significant reduction of fibrosis in the lungs using the specially developed multi-species probiotic

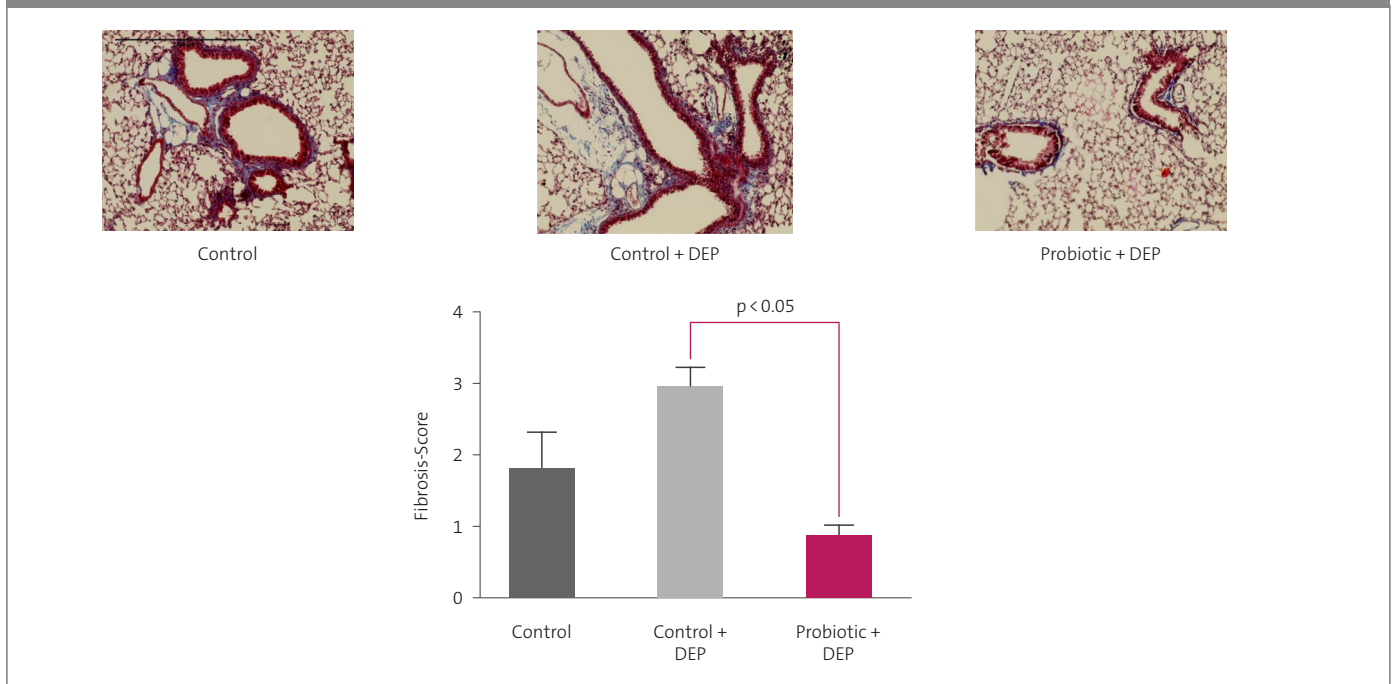


Figure: The use of the multi-species probiotic significantly reduces collagen deposition around the bronchioles caused by diesel exhaust particles (DEP).

Discussion and conclusion

These findings provide essential insights into how environmental pollutants affect the lung and gut microbiomes and their role in inflammatory processes. The targeted use of specific bacterial strains during exposure to diesel exhaust particles (DEP) was shown to stabilize microbial diversity and abundance in the gut, while preventing the colonization of potentially pathogenic *Proteobacteria* in both the gut and lungs. Additionally, this probiotic administration significantly reduced systemic inflammatory responses and lung in-

flammation. These studies clearly demonstrate that medically relevant multi-species probiotics can effectively mitigate the negative health impacts of air pollutants through the gut-lung axis.

Tooth Cavity Prevention Through the Use of Specific, Medically Relevant Probiotics

Poorni *et al.*, *Cureus*; 2022

Abstract

In this randomized, controlled study involving 42 subjects at high risk of developing tooth cavities, we evaluated the effectiveness of two probiotic bacterial strains found in the mouth and throat for cavity prevention over a 90-day period. Tooth decay is increasingly recognized as closely linked to the oral microbiome, and prior research has highlighted the beneficial effects of the probiotic strain *Streptococcus salivarius* K12 – present in OMNi-BiOTiC® *iMMUND* – on reducing ENT diseases across various age groups. Consequently, this established strain was included in our study.

Participants were divided into three groups: two groups received lozenges containing either *S. salivarius* K12 (2.5×10^9 CFU) or *S. salivarius* M18 (2.5×10^9 CFU) once daily in the evening after brushing their teeth, while the third group served as a control. The risk of tooth decay was assessed using the “Cariogram” application, which evaluates multiple factors such as diet, plaque, microbiome composition, and salivary flow for a comprehensive risk assessment.

Results

At the study's outset, there was no significant difference in cavity risk among the three groups. However, after just three months, a notable difference emerged ($p=0.047$). While the control group showed only a slight increase in the probability of avoiding new cavities, the probiotic treatments resulted in a significant improvement. Specifically, the likelihood of avoiding new cavities increased from 16% to over 47% in the group receiving *S. salivarius* K12. Furthermore, pairwise comparisons revealed a significant reduction in cavity risk in the *S. salivarius* K12 group compared to the control group ($p=0.02$).

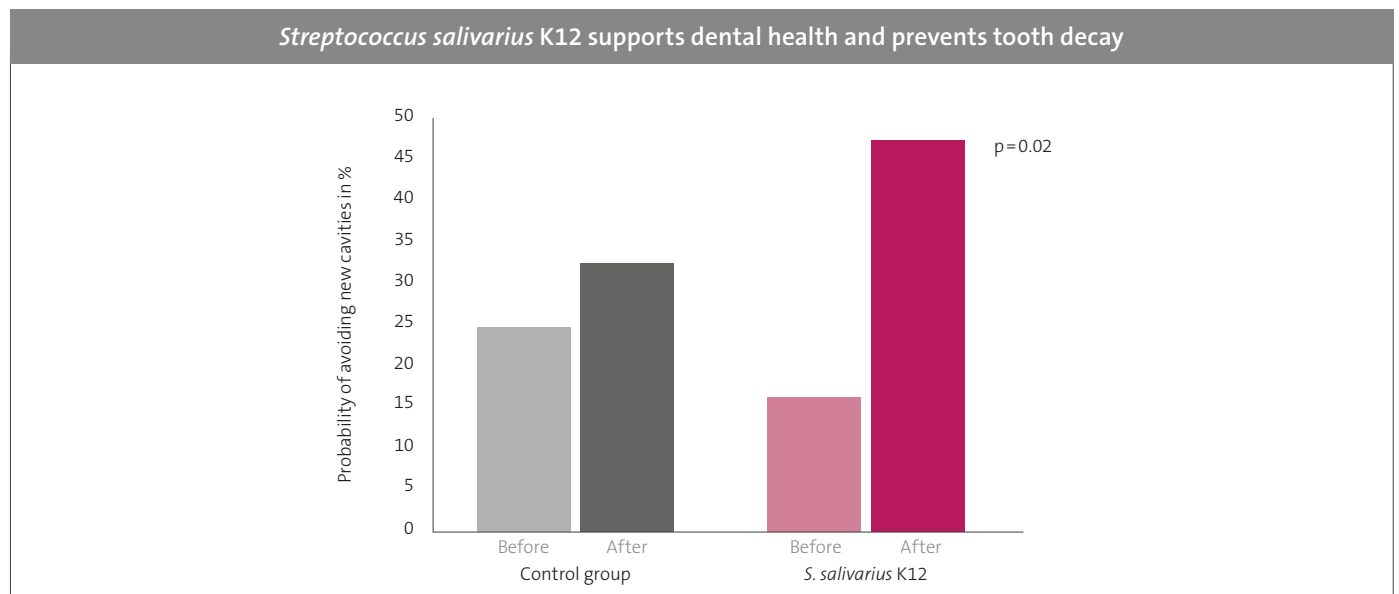


Figure: The risk assessment showed only minor changes in the control group (gray). In contrast, the use of *S. salivarius* K12 (magenta) showed an almost three times higher probability of avoiding the recurrence of cavities after application.

Discussion and conclusion

The study clearly demonstrates the substantial benefits of using high-quality, specifically developed probiotics for dental health. Patients at high risk of cavities who received *S. salivarius* K12 were three times more likely to avoid new cavities after just three months of treatment. This underscores the significant advantages of this well-

established probiotic strain. Based on these findings, OMNi-BiOTiC® *iMMUND* emerges not only as an effective preventive measure for ENT diseases but also as a valuable option for enhancing dental health.

MEDICALLY RELEVANT PROBIOTICS – BACKGROUND INFORMATION

11

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Security and Quality Aspects to be Considered for the Development of High-Class Multi-Species Probiotics



Grumet *et al.*, *Nutrients*; 2020

In medical research, the connection between the gut microbiome and the pathogenesis of a wide range of diseases (e.g., antibiotic-associated diarrhea, metabolic syndrome, allergies, or neurological diseases) has become increasingly important in recent decades. Given the multifactorial nature of many diseases, the probiotic bacterial strains used to positively modulate the microbiome must also induce multiple effects in combination. Therefore, certain safety and quality aspects are essential during the production of evidence-based and indication-specific multi-species probiotics.

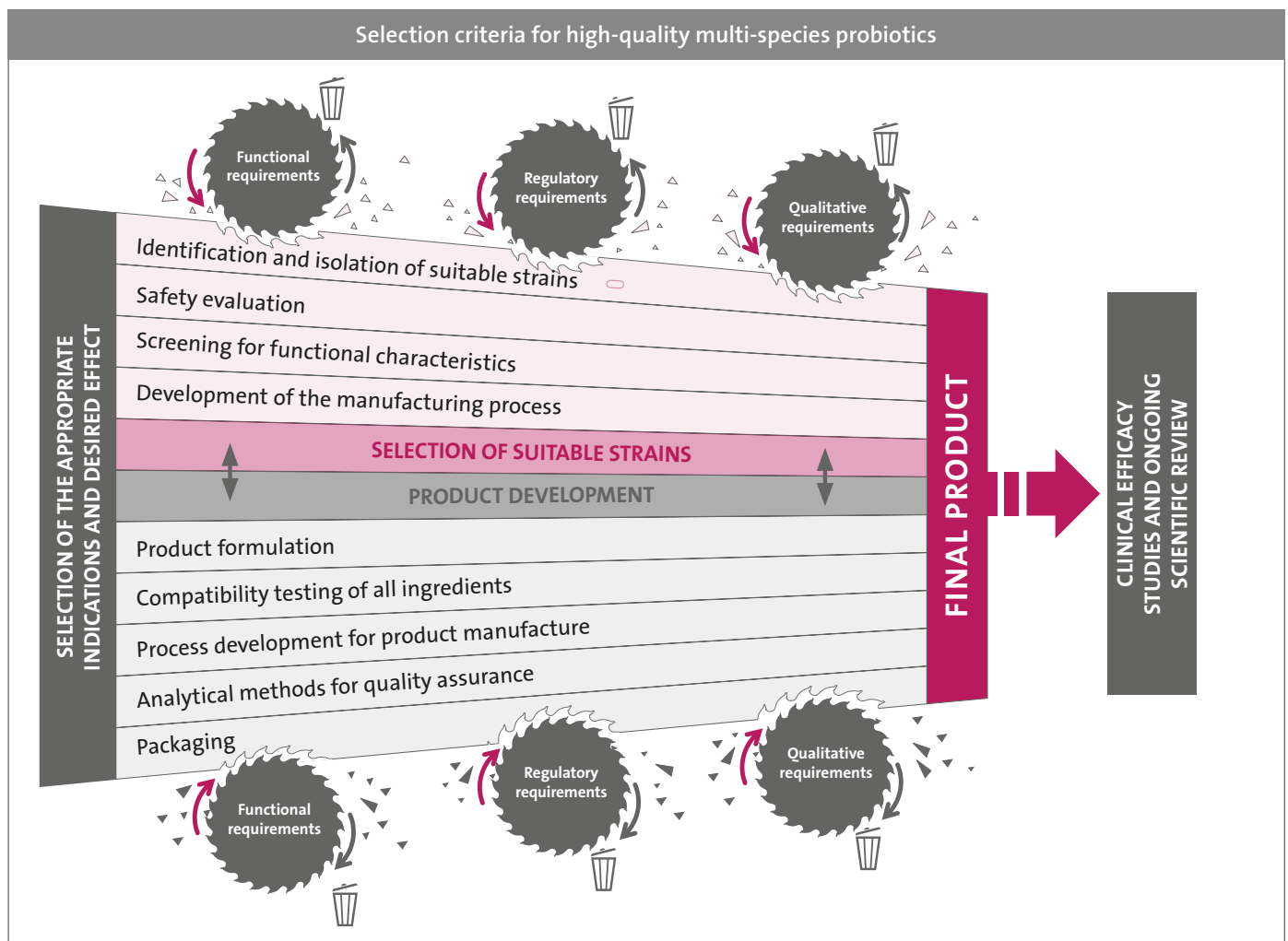
production of antimicrobial peptides or the ability of microorganisms to occupy binding sites on host cells, preventing pathogen entry. A key aspect is the modulation of the immune system by probiotic bacteria. In vitro assays are used to assess the capacity of these bacteria to stimulate immune cells and promote the production of anti-inflammatory substances.

The selection of suitable strains – screening of potential candidates

Screening methods for identifying suitable probiotic strains usually involve in vitro and ex vivo studies, animal models, and clinical studies. In vitro assays investigate the mechanisms underlying interactions between probiotic and pathogenic germs, as well as between microbes and the host. Common parameters studied include growth inhibition of pathogens by probiotic bacteria and the release of antimicrobial metabolites (e.g., lactic acid). Other parameters cover the

Safety criteria for probiotic strains

The safety of probiotic products must be proven according to legal regulations. This includes clear and unambiguous taxonomic identification using biochemical, physiological, and molecular biological methods. The unique assignment of the respective bacterial strain is followed by a safety assessment (QPS or GRAS status). Before administering microorganisms in probiotic formulations, it must be demonstrated that they do not transmit antibiotic resistance, possess toxic, pathogenic, or virulent properties, or exhibit metabolic activities detrimental to the host.



Production process and cultivation of the bacterial strains

Probiotics consist of viable, highly concentrated, and stable formulations of bacteria produced separately by strain. Every step in the production process must adhere to strict criteria, including media and substances used, and the fermentation and freeze-drying of bacteria. These requirements must be met by every product through the selection of appropriate strains and the scientific formulation of the prebiotic matrix to activate the bacteria during rehydration.

Product formulation and production of a multi-species probiotic

The freeze-dried bacterial strains, along with the matrix and active ingredients such as vitamins, are combined to ensure stability, metabolic activity, and gastrointestinal survival. The selected packaging – whether sachets or glass jars – must effectively maintain shelf life and stability for up to 24 months at room temperature.

Quality criteria of a probiotic formulation

The viability of microorganisms in the product and their undamaged passage through the acidic environment of the digestive tract (gastrointestinal survivability) should be guaranteed with high-quality probiotics. These requirements must be met through the selection of suitable strains and the special composition of the matrix. The metabolic activity of a probiotic, such as lactic acid production, is a crucial indicator of its quality.

Clinical efficacy of probiotic products

Proof of clinical efficacy is essential despite all previous *in vitro* and *in vivo* testing. High-quality multi-species probiotics should be tested in randomized, placebo-controlled trials to verify their indication-specific effects. For example, studies have demonstrated the successful use of probiotic products in antibiotic-associated diarrhea, metabolic syndrome, diabetes, immune system development in newborns, prevention of eczema in young children, liver dysfunction, and neurodegenerative and psychiatric diseases 6,7,8.

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The Positive Effect of Bifidobacteria on the Protective Function of the Intestinal Mucosa

Segui-Perez *et al.*, Scientific Reports; 2025

Abstract

Around 5 million people worldwide suffer from chronic inflammatory bowel diseases (IBD), such as Crohn's disease or ulcerative colitis. Painful symptoms, such as severe cramps, diarrhoea and even bleeding, severely impair the quality of life of those affected. A healthy gut microbiome is essential for an intact intestinal mucosa, as probiotic bacteria are responsible for defending against pathogens and have a significant influence on the barrier function. In this study, the positive effect of two *Bifidobacterium bifidum* strains (W23 and W28) on the protective function of the intestinal mucosa was analysed. In this study, cell culture experiments were used to investigate the influence of the probiotic strains on the mucins in the intestinal mucosa, which are essential for the formation of the mucus layer. The modulation of a specific mucin and its effect on the intestinal barrier function were analysed in more detail over the course of this study.

Results

A human intestinal epithelial cell line (HRT-18) was used as a model for the human intestine and treated with the two *B. bifidum* strains W23 and W25. The effect on the mucins, which form the mucous layer of the intestinal mucosa and therefore protect it, was then analysed. It was demonstrated that treatment of the intestinal cell line with these specific bifidobacteria led to a significant reduction in the permeability of the intestinal barrier ($p < 0.01$). In this process, an essential mucin (MUC13) is modulated in such a way that it is able to strengthen the intestinal barrier via a tight junction interaction. This process was visualised using fluorescence cell staining, whereby the lower the measured fluorescence signal, the lower the permeability of the epithelial layer. In a further analysis, the intestinal epithelial cells were triggered with inflammatory factors for 2 hours. In the following 28 hours of treatment with the two probiotic strains, a highly significant regenerative effect ($p < 0.0001$) was detected, which significantly improved the integrity of the intestinal barrier.

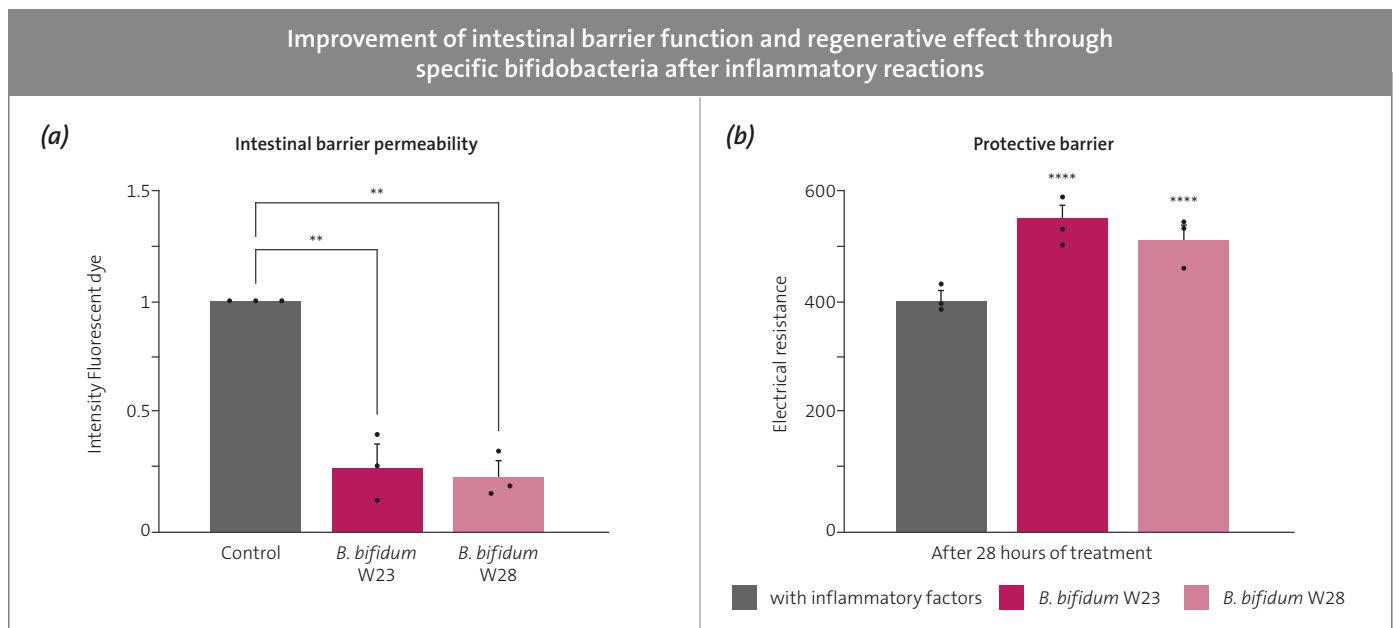


Figure: The specific probiotic bacterial strains *B. bifidum* W23 and W28 cause (a) a significant reduction in intestinal barrier permeability by modulating the mucin MUC13 and (b) a significant regenerative effect on the intestinal epithelium in cases of inflammation, measurable by the increased electrical resistance associated with an improvement in barrier integrity.

Discussion and conclusion

IBD is one of the most common diseases of the gastrointestinal tract and it severely impairs patient's quality of life. Mucins are protective mucous substances in the intestinal mucosa and are essential for maintaining a functional intestinal barrier, which is disrupted in IBD, leading to severe inflammatory reactions. Cell culture experiments have impressively demonstrated the positive influence of two *bifidobacteria* strains (*B. bifidum* W23 and W28) on the important mucin MUC13, resulting in a significant improvement in the

protective effect on the intestinal epithelium and thus counteracting the development of leaky gut. Our study-tested, indication-specific probiotics OMNi-BiOTiC® HETOX and OMNi-BiOTiC® STRESS Repair / SR-9 contain the strain *Bifidobacterium bifidum* W23 investigated in this study. These two multi-species probiotics have already shown excellent effects on intestinal barrier function and the reduction of leaky gut in several clinical studies.



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*The bacterial combinations used in the studies are available under different trade names in different countries.

The background of the entire page is a dark blue field filled with numerous 3D-rendered, semi-transparent blue and light blue microorganisms. These include various shapes of bacteria, such as spheres, rods, and chains, as well as larger, more complex structures that resemble fungi or spores. The microorganisms are scattered across the page, creating a sense of a diverse and active microbiome.

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