

PREBIOTICS/
PROBIOTICS

Healthy living: Mental and immunity burden in the era of COVID-19

SILVIA CASTEGNARO
Product Manager Nutraceutical

Roelmi HPC
Via Celeste Milani, 24 / 26
21040 Origgio (VA), Italia
www.roelmihpc.com

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Via delle Azalee, 11
20147 Milano - Italy
Tel. +39 02 4120269
www.b5srl.com
info@b5srl.com

According to last Euromonitor update, one of the new arising Megatrend this year is the “healthy living”, strongly pushed by the COVID-19 pandemic spread.

Healthy life style habits inside and outside home are becoming the “new” normal way of living, thus leading to get a look towards a more holistic approach to wellness.

Even though uncertainty remains high, economies are clearly pushing towards a proactive way of living as now more than ever, consumers prefer to prevent any kind of distress by eating well, taking supplement and performing sport, instead of curing a disease by taking drugs. It has been reported that 23% of consumers worldwide are buying more vitamins and supplements or stockpiling them (1). On the other side, 35% of the end consumers, have begun eating foods that boost their immune health more frequently. Indeed, the huge commitment to health of end consumers is reflected also by considering that eight out of ten say they will make greater attempts to stay healthier in the future (2).

But what does holistic mean? The primary aspect of optimal health is caring of both mental and physical well-being that, especially in this moment, is needed to be reinforced. The future is moving forward to a more open-minded vision, trying not to fight the symptoms but rather understanding the cause that hides behind a distress. As our ancient said “mens sana in corpore sano”.

Before pandemic, immunity enhancement was the third top of

consumer’s reason to take food supplements and, combined with digestive health claim, reached the 20% of the global market share. A survey from FMCG Gurus reveals that almost 60% of consumers worldwide said that since COVID-19 emerged this year they have become more conscious about their immunity. According to IQVIA data there was a 110% increase in European retail sell-out of health supplements in pharmacy during March pandemic peak and a 64% increase for cough, cold and other non-prescription respiratory-targeting products. Last, Nutrition Business Journal’s foresees that immune health category will grow up to 50% making it one of the fastest-growing segment in our industry (3).

On the other hand, while boosting immunity is mandatory, taking care on mental wellness is not far behind.

In the past, mental health category has always provided solutions to booster mental performance and relaxation but now this market has changed focusing the attention to a wider aspect of mental wellbeing associated to modern living, stress management, mental fatigue, concentration & memory performances, sleep quality and depression. According to Market Research Future, the global cognitive health ingredients market alone is set to register 8% compound annual growth rate from 2019 - 2024 resulting a market size approximately of 1.4 billion dollars. The major area of consumer concern is related to stress management: from a European market survey made by Innova Market insights, the 47% of consumers associated it with bad

mood, while the 41% linked with sleep disruptions. It is worth noting that COVID-19 pandemic situation has further upset the global population way of living and its implication are reflecting on the cognitive health market (4). Together with the high demand of immune booster supplements, national lockdowns have led to an increase of anxiety, low mood, depression and uncertainty-related stress with a natural increment of nootropic supplements. This enhanced interest may be also explained thanks to the several researches done in the last years that connect the brain, the gut and the immune system, and nowadays there have been studied and developed different ingredients such as probiotics and prebiotics with proven scientific effect in managing stress and related drawbacks.

Linked to this megatrend, scientific research is becoming the most important aspect to be considered with the aim to establish credibility within consumers. Thus, they want to hear more information on the nutritional benefit of the product, and in addition, they are becoming more conscious and open-minded towards solutions to support their immune health. Moving forward, as a consumer knowledge grows, the importance of clinical evidence is the only parameter to increase trust and credibility: the 39% of global consumers admit that seeing research or scientific data claims would encourage them to buy a healthy lifestyle product (5).

Although the best-seller immune supplements are vitamins and botanicals, NBJ estimated that probiotics product targeted for immunity should grow from 322\$ million USD to 450\$ by the end of 2020, making nearly 40% sales increase this year alone (3). Thus, consumers are now realising that probiotics could be one of the best immune strategy due to their connection between the gut health and immunity.

In the last decade, probiotics have been subjected to a very high number of studies since their versatility in supporting host metabolism in everyday life. Starting with the easiest connection with the gut through their recognized abilities in supporting women's health, then linking the gut microbiota dysbiosis with a series of chronic diseases, reaching sometimes very uncommon applications as mental wellbeing.

Considering the huge demand of both immune and mental supporting supplements, a strong constrain comes from their verified abilities. Not all microorganisms may have the same effect on the host due to the heterogeneity of bacteria species as well as strain specificity in terms of functional performance. Thus, the correct use of probiotics as therapeutic

or preventive agents necessarily goes through the precise knowledge of their activity. This is ROELMI HPC philosophy: screen its library of property probiotic strains, through different *in-vitro* assays, in order to select the best performing ones for a specific field of interest and then test them in clinical trials. Through this approach, ROELMI HPC has developed science based probiotic concepts to be in line with latest market requests.

As immunity booster ingredient, ROELMI HPC has designed and developed a probiotic complex that showed to strengthen the immune system and to rebalance gut eubiotic status.

The strains *L. plantarum* - PBS067, *L. acidophilus* PBS066 and *B. lactis* BL050 have been selected as the most effective strains in the modulation of the inflammatory cascade, for their antioxidant potential and the enhancement of antioxidant enzymatic activity, all important factors to be boosted during seasonal changes. These strains then have been clinically tested in a randomized double blind placebo control clinical trial which has enrolled 50 subjects (randomized as 25 actives /25 placebo) involved in a 4 weeks treatment, followed by 28 days of wash-out. Patients were evaluated through a collection of daily questionnaire reporting inflammatory symptoms assessment, collection of stool and saliva samples and genomic analysis of stool for determination of microbiota composition in terms of phylum & genera. Results revealed an improvement of the selected biochemical markers together with a reduction of symptoms duration. Phylum & genera analysis showed a biodiversity restoration at gastrointestinal level, which reflects the overall positive clinical response of the active group versus placebo.

The same approach was applied for developing an ingredient targeted for stress-management: the two strains *Lactobacillus reuteri* PBS072 and

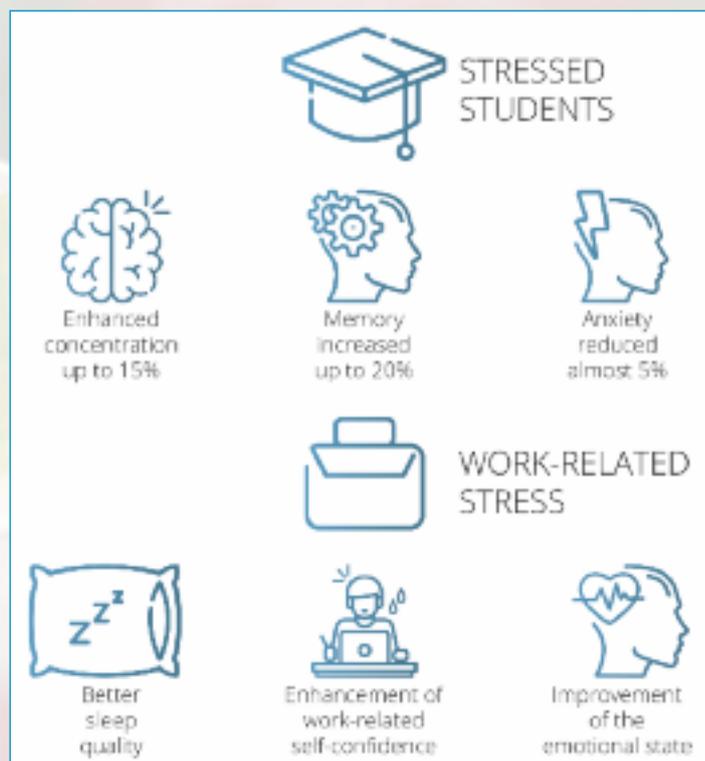


Figure 1 – Summary of previous evidence.

Bifidumbacterium breve BB077, after the *in-vitro* screening based on the improvement of serotonin and GABA synthesis and the enhancement of Lysine-Specific Demethylase1 (LSD1), have been clinically tested in a proof-of concept clinical trial which has enrolled 30 stressed university students with the aim to determine the effectiveness of the probiotic complex in improving cognitive function, sleep quality and anxiety. The students have been involved for 4 weeks treatment; at the beginning and at the end of the trial they have been evaluated for the improvement of attention, memory, executive performance and for the reduction of perceived stress level, salivary cortisol, skin conductance. Results demonstrate the improvement of cognitive functions, such as short-term memory, attention and problem solving flexibility with a better responsiveness, corresponding to the right answer in a shorter time with respect to the beginning. Moreover, positive results have been recorded also for sleep quality and anxiety.

Another cross-over clinical trial has been carried out to evaluate the improvement of work-related stress on white collars. 30 subjects were randomly assigned to different arms, thus receiving each treatment in a random order. Volunteers took one capsule of product per day (15 Active / 15 Placebo) for a period of 30 days, followed by a wash out period of 30 days. After this break, each volunteer took one capsule a day of the other treatment (15 Placebo/15 Active) for another 30 days. The evaluated

parameters were related to work self-perception, sleep quality and their emotional state. Preliminary results reported an overall statistical improvement of the selected parameter for the active treatment with respect to the beginning. Further data analysis is on-going to determine the efficacy with respect to placebo (Figure 1).

Last, since mental health has recently become one of the biggest concern and usually is declined in different shades of stress, ROELMI HPC has invested in another model of potential mood impairment for healthy subjects. A randomized double blind clinical trial is running to evaluate the effect of this

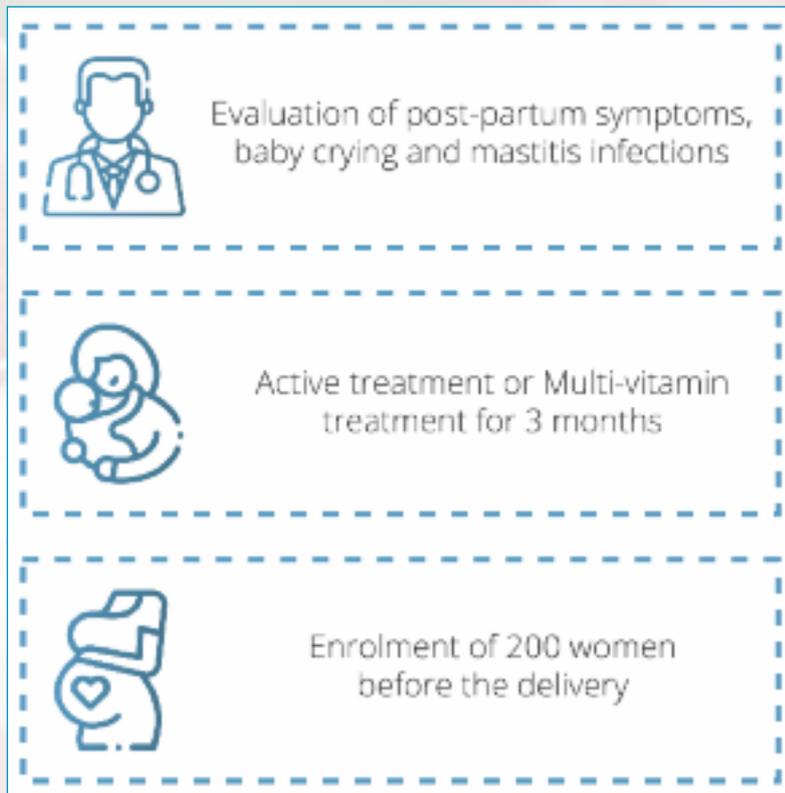


Figure 2 – Clinical trial flow-chart.

probiotic complex on 200 healthy women after delivery, in terms of modulation of new mothers mood-related status and to assess the quality of breastfeeding through the reduction of baby's crying and mastitis occurrence (Figure 2).

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