

Taking care of mental wellbeing: updates from the nutraceutical market

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Stress has been defined as the “Health Epidemic of the 21st Century” by the World Health Organization, since it represented a big burden for many people (1) and pandemic outbreak has further emphasized this condition. The panic for the health as well as the fear of future uncertainty had totally turned around many aspect of everyday life. Not to mention, the restrictive measures worsen the people emotional status leading to an increase of stress and anxiety at worldwide level. As a consequence, cognitive health market now is rapidly expanding and is projected to reach US\$10.7 billion by 2025 (2).

The major area of consumers’ concern is linked to stress management: according to 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 (3). On the same trend, another

survey made by American Psychological Association found that around 67% of American adults claim to have experienced a stress increment throughout the Covid-19 outbreak, with 78% stating that the pandemic is a significant source of stress in their lives (4).

In this scenario, supplements can offer an elegant solution to support customers in improving their mood, sleep and cognitive function during a stressful period. 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, leading to the development of different ingredients proven to manage stress and related drawbacks. In the past, mental health category has provided solutions to boost mental performance and relaxation but now the market is 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. Moreover, the pursuit of happiness is having a renaissance moment,

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especially in these two years of great challenges, and consumers are seeking for the silver linings to make them able to deal with life's difficulties.

It is well known that minerals or other herbal extract are proven to support sleep and mental well-



being: from magnesium to saffron extract for anxiety, or Ashwagandha for a better sleep, the market is filling up with a diversified selection according to the claim needed to advertise the products. However, another ingredient who is taking an important slice of the cake are probiotics. In the last decade, probiotics have been subjected to a very high number of studies due to 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 special applications as mental wellbeing. According to the analysis, performed by Lumina intelligence, on the "Microbiome online search trends" the growth of consumers' online interest of gut-brain category has increased by over 50% in the 2020-2021 with respect to 2019-2020. The top three key words on this topic (based on consumer Google research) linked probiotics to *depression, anxiety and the best probiotic to support mental wellbeing*. One of the most interesting sentence was: "Probiotics cure my anxiety". From this data is clear that the end-consumer is more interested and aware about the connection between the gut and the brain as well as the support of probiotics on mental wellness. This could be the starting point in

investigating more on this topic, collecting additional evidence and then gain consumers trust and increase the demand. In line with this research, the worldwide consumer's online engagement for probiotic supplements in managing mood and stress is very low, involving only few countries (US, Italy and Germany) with a small number of specific products (5).

There are several ways by which probiotics are able to modulate the brain through oral intake: thanks to the gut-brain axis the gut microbiota

influences the immune response as well as the endocrine one keeping body's homeostasis. However, 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. The two strains *Lactobacillus reuteri* PBS072 and *Bifidumbacterium breve* BBO77 have been selected through *in-vitro* screening based on the improvement of serotonin and GABA synthesis and the enhancement of Lysine-Specific Demethylase1 (LSD1). According to *in-vitro* results, a proof-of-concept trial was carried out on 30 stressed students to evaluate *L. reuteri*

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PBS072 and *B. breve* BB077 (4B CFU/day) ability in improving stress-related parameters for 28 days. 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, and skin conductance. Results demonstrated a significant improvement ($p < 0.05$) 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. Following, a double blind crossover clinical trial was carried out to evaluate probiotics ability on mood and sleep during pandemic. A total of 33 volunteers were randomly assigned into two groups, A and B, with an inverted administration of probiotic supplement (4B CFU/day) and placebo for 30 days each, with a 4-week intermediate wash-out. The efficacy on stress response, in terms of mood and sleep behavior, were assessed using the following questionnaires: The Pittsburgh Sleep Quality Index (PSQI) and the Profile of Mood State (POMS). Results of the crossover clinical trial showed that both POMS and PSQI questionnaires reported a significant lower score after 30 days, while the placebo reported a higher score reflecting a worsening of mood and sleep quality. Moreover, according to the above mentioned results, *L. reuteri* PBS072 and *B. breve* BB077 are now under investigation on another model of potential mood impairment for healthy

subjects. A randomized double blind clinical trial is now on going to evaluate the effect of this 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. From this perspective, probiotics can easily enter in the mental health market considering also the advances in formulation research that have open up the opportunity to develop new pharmaceutical forms allowing the combination of probiotics with botanicals, in order to exploit the best of both worlds. This understanding put the basis to further develop new approaches, combining different actives together with the aim to provide a 360° support on mental health.

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