WHITE PAPER

Bacillus subtilis DE111®

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Many factors can affect human health and the microbiota

The gut microbiota is a complex system that contributes significantly to maintenance of human health. The microbiota can affect several systems and functions in the body, including bowel function and the immune system. A change in the composition of bacteria in the gut microbiota can, among others, contribute to digestive discomfort. Many factors can influence the composition at all ages, as well as specific groups. Stress, changes in diet, medication such as antibiotics, and infections are all factors that can influence digestive health, as well as the immune system.

Signs of digestive discomfort are common

Digestive discomfort includes a number of symptoms indicating an abnormal behavior of the gastrointestinal (GI) tract, with constipation, bloating, flatulence, stomach rumbling and abdominal pain being the most frequent. Most people occasionally experience these signs of irregular GI tract function. Estimates suggest that up to 26% of the general population are affected[1]. Constipation is often lifestyle related and can be caused by e.g. stress and changes in the diet. Furthermore, constipation is more prevalent in the elderly, particularly amongst elderly who reside in nursing homes, and constipation is more common in women than in men[2,3]. These signs are also common for people with irritable bowel syndrome (IBS), who typically attend doctors more frequently, consume more medication and have a lower quality of life than people without IBS[4].
Many people experiencing digestive discomfort rely on self-medication and never consult their doctor.

Heavy exercise can affect the immune system

Normally, the immune system is effective in recognizing and eliminating threats, as well as identifying agents to be tolerated. However, the immune system can be disturbed by several external factors. One of these is stress, both mentally and physically. In general, regular physical exercise is regarded as an important tool to maintain general health. Yet, when the body undergoes high-intensity exercise for a longer period of time, which is the case especially for endurance athletes, the body is exposed to a continuous high level of stress, which can suppress the immune system. This has among others been shown to increase the risk of infections in athletes[5,6].

Probiotics can provide several benefits

Probiotic bacteria are "live microorganisms which when administered in adequate amounts confer a health benefit on the host"[7].

Probiotics work in a similar fashion as the gut microbiota by producing bacteriocins, facilitating competitive inhibition of pathogenic bacteria, inhibiting bacterial adherence, reducing luminal pH, enhancing the intestinal barrier function by increasing mucus production, and by modulating the immune system (figure 1)[8,9].

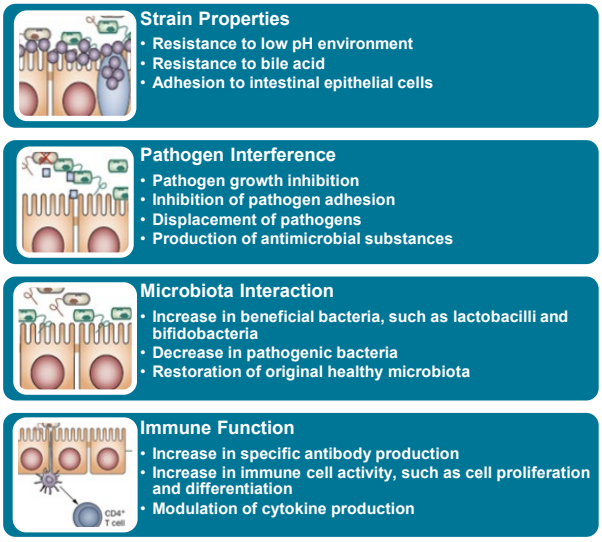

Figure 1: Potential mechanisms of actions that probiotic can utilize to positively affect the gut microbiota and the host. Adapted from Gareau 2010([10]).

The effects and mechanisms of probiotics have primarily been shown for *Lactobacillus* and *Bifidobacterium*[11,12]. However, other types of probiotic bacteria also exist, namely of the genus *Bacillus*, which have also shown the ability to utilize the mechanisms described above to induce beneficial effects[13–17]. The effects of the probiotic *Bacillus* bacteria have also been shown for the immune system[18], especially among athletes in which the immune system is known to be disturbed during heavy training sessions[19–21].

Unique probiotic bacterium with selected properties

The probiotic strain, *Bacillus subtilis* DE111, is one of the strains of *Bacillus*, which have provided interesting results in relation to digestive health and immune health, especially in athletes.

General benefits

To substantiate the safety of *Bacillus subtilis* DE111, a study was conducted with healthy participants. In total, forty-one subjects were recruited to the study, which showed that *Bacillus subtilis* DE111 was safe to consume, as assessed by a range of biochemical blood markers. In addition to be safe for consumption, the study also showed an increase in *Bifidobacterium* in the study group consuming the probiotic bacteria – bifidobacteria are generally known to have a beneficial effect. Furthermore, a decrease in blood glucose level was also observed in the probiotic group, as well as a maintenance of triglyceride levels compared to the placebo group, indicating a potential effect on general metabolism[22].

In another study, the effect of *Bacillus subtilis* DE111 consumption on digestive health was investigated, primarily focusing on improvement of bowel movement patterns. A total of 50 participants were included in the study, all of whom occasionally experienced gastrointestinal irregularity (constipation and/or diarrhea). The participants were to consume *Bacillus subtilis* DE111 in the form of one capsule daily ($1x10^9$ CFU pr. capsule) or placebo for 90 days. The effect of probiotic consumption on the bowel movement patterns was assessed using the Bristol Stool Chart – a commonly used standardized method to evaluate if stools appear normal.

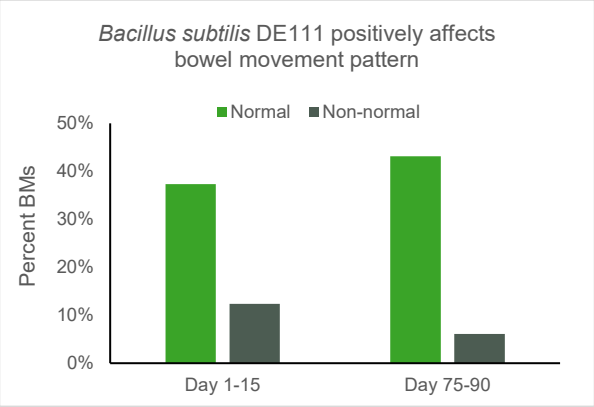

Figure 2: The consumption of *Bacillus subtilis* DE111 for 90 days lead to an increase in persons with normal stools, according to the Bristol Stool chart.

As seen from figure 2 above, consumption of *Bacillus subtilis* DE111 for 90 days increased the percentage of persons with normal stools, based on the Bristol Stool chart. The percentage of persons with normal stools increased from 37% during the first period (day 1-15) to 43% during the last period (days 75-90). This was a significant increase compared to the placebo group[23].

Consumption of *Bacillus subtilis* DE111 has also been shown to reduce the duration of gastrointestinal (GI) symptoms. These benefits were a result of a study, where 102 healthy children attending day-care were included. The children consumed *Bacillus subtilis* DE111 ($1x10^9$ CFU) or placebo daily for 8 weeks. Subsequently, the children were followed for 4 weeks during which they did not consume probiotics of placebo. To evaluate the effect of *Bacillus subtilis* DE111 on GI health, the incidence and duration of GI infections and GI symptoms, including diarrhea, hard stools and constipation were recorded. Furthermore, incidence and duration of respiratory infections were also reported.

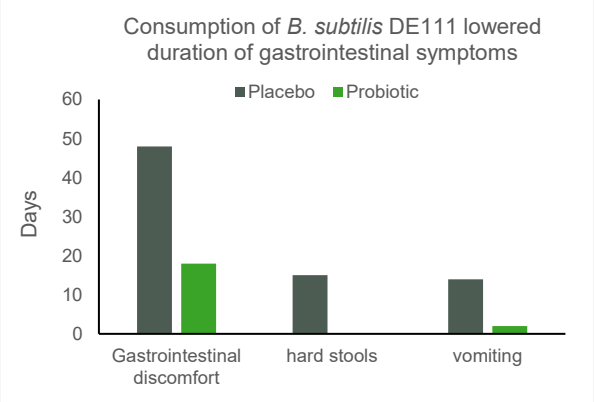

Figure 3: The consumption of *Bacillus subtilis* DE111 resulted in significant decreases in duration of GI symptoms. Especially duration of hard stools was markedly reduced, as no reports on hard stools were reported in the probiotic group. The figure is adapted from ref. 24

In figure 3 above, the duration of various GI symptoms is depicted. The consumption of *Bacillus subtilis* DE111 clearly shows a reduction in the duration of several GI symptoms, when compared to placebo[24]. This corroborates conclusions from previous studies that *Bacillus subtilis* DE111 supports general gastrointestinal health.

From the same study population, the effect on the gut microbiome was also investigated. To analyze the gastrointestinal microbiota, fecal samples were obtained before probiotic or placebo consumption was initiated, and after 8 weeks of intervention. The fecal analyses showed that the probiotic consumption led to an increase in microbial diversity with changes in specific types of bacteria. These bacteria included among others *Alistipes* and *Bacteroides*, which are normally associated with a healthy microbiota. Furthermore, the changes to the microbiota also induced a decrease in the Firmicutes/Bacteroidetes (F/B) ratio[25]. A high ratio has previously been associated with obesity[26–28].

Benefits in sports

Another area in which the effect of *Bacillus subtilis* DE111 has been investigated is athlete health. In a recent study, *Bacillus subtilis* DE111 was consumed over a period of 10 weeks ($5x10^9$ CFU daily) in connection with a resistance training program. Physiological measurements (body composition and muscle thickness) and a performance test were conducted on 23 female athletes, both before initiation of the resistance program and after the program had finished. In this study it was found that consumption of *Bacillus subtilis* DE111 resulted in a greater reduction of body fat percentage compared to placebo (-2% vs -0.2%, probiotic vs. placebo, respectively)[29]. The difference in body fat percentage is illustrated in figure 4 below.

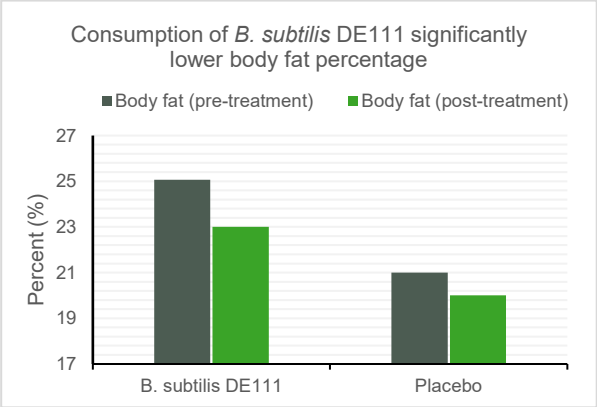

Figure 4: The consumption of *B. subtilis* DE111 led to a significant decrease in body fat percentage in athletes, when compared to placebo. The figure is adapted from ref. 29.

In another study, with a similar study setup, the effect of *Bacillus subtilis* DE111 consumption on male athletes was investigated. Here, 25 male athletes were included in the study, in which they were to follow a 12-week resistance training program. During the training program, the athletes consumed *Bacillus subtilis* DE111 ($1x10^9$ CFU daily) or placebo. Before and after the training program, a range of physiological analyses (body composition and muscle thickness), performance tests and biochemical measurements, which included immunological marker assessment, were made.

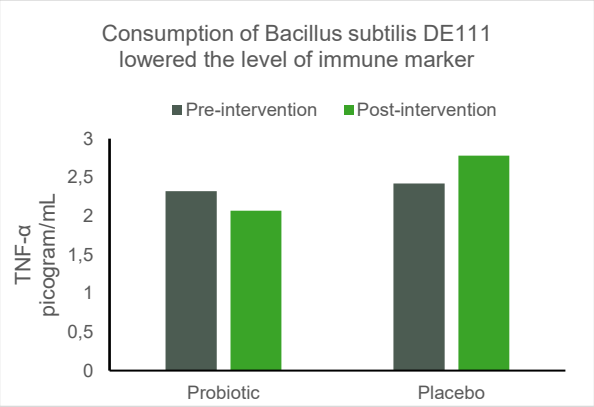

Figure 5: Consumption of *Bacillus subtilis* DE111 over a 12-week period resulted in a decrease of TNF-alpha. In the placebo group, an increase was observed after the 12-week training program.

In figure 5 above, the effect of probiotic and placebo consumption on the immune marker TNF-α is shown – this immune marker is generally known to be associated with a pro-inflammatory state or response. After the intervention period, a decrease in the level of TNF-α could be observed for the probiotic group, which was significantly different from the placebo group, where an increase was seen[30].

Heart Health

Recently, *Bacillus subtilis* DE111 has also been shown to positively affect levels of cholesterol. In a human study, 94 healthy individuals were recruited. The study participants were divided into 4 groups with one being a placebo group and another a group consuming *Bacillus subtilis* DE111 ($1x10^9$ CFU) daily. Different measurements were performed before and after the intervention, which lasted for 4 weeks. The measurements included levels of lipids and cholesterol in blood, as well as blood pressure and vascular function.

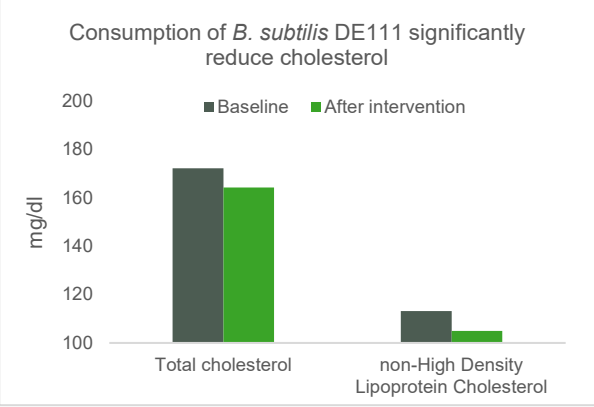

Figure 6: The consumption of *B. subtilis* DE111 significantly reduced the level of total cholesterol and cholesterol bound by high-density lipoprotein. Such a reduction was not seen in the other groups. Figure adapted from ref.31.

As can be seen from figure 6 above, the consumption of *Bacillus subtilis* DE111 led to a reduction in total cholesterol and non-HDL-cholesterol levels. A similar development was not seen in the other study groups[31]. Thus, the results indicate that *Bacillus subtilis* DE111 can provide beneficial effects in relation to heart health.

In summary, studies with *Bacillus subtilis* DE111 have shown that it is safe to consume. Furthermore, consumption of *Bacillus subtilis* DE111 has been shown to positively affect bowel movement patterns, resulting in a higher degree of normal stools.
In addition, consumption of *Bacillus subtilis* DE111 has been shown to positively affect health and physiology of athletes, in terms of body composition as well as the immune system, which is often suppressed or disturbed in athletes. Thus, consumption of *Bacillus subtilis* DE111 may provide benefits related to both digestive health and immune health, especially for athletes.

Additional resources

- Product catalogue
- The science behind DE111®
- Why probiotic gummies should be in your new product lineup
- Probiotics for sports nutrition
- Spore stability
- Documented for safety / QPS
- Documented for safety / GRASS

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