

BiomeBliss™ Clinical Studies

BiomeBliss has been examined in two separate clinical studies published in peer-reviewed journals in 2015. These rigorous studies were conducted under the direction of Dr. Frank Greenway of the Pennington Biomedical Research Center in Baton Rouge, Louisiana, one of the nation's leading centers for nutrition research.

Study 1 showed BiomeBliss was effective in reducing the desire to eat and in reducing the amount of food anticipated or considered enough at the next meal. Study 2 showed improved regularity from occasional GI disturbances. Both studies showed BiomeBliss helped to manage blood glucose (sugar) when already in the normal range. BiomeBliss also appears to help protect and prepare the GI immune system. *

Study 1: Published Study Shows BiomeBliss Supports Healthy Glucose Regulation and Helps Control Hunger in Overweight Subjects *

Our first study, published in the *Journal of Diabetes and Its Complications*¹, assessed the effectiveness of BiomeBliss on metabolic parameters and satiety, the term for the feeling of satisfaction and reduced hunger when we eat. Evidence supports the significant role of the gut microbiota in the biochemistry involved in satiety, including the desire for smaller portions at mealtime.

This placebo-controlled double-blinded study measured changes in mealtime blood glucose in participants who took BiomeBliss twice a day for four weeks, without other changes to their daily meal routine. Statistically significant results indicated BiomeBliss helped control hunger and helped manage mealtime blood sugar when already in the normal range as measured by the oral glucose tolerance test. *

Note: The clinical studies refer to BiomeBliss as NM504

DIETS HIGH IN EASILY DIGESTIBLE, SIMPLE CARBOHYDRATES

A diet high in easily digestible, simple carbohydrates (carbs) isn't as healthy as a diet containing fiber and prebiotics. These simple carbs have a high glycemic index and lead to blood glucose (sugar) spikes, and eventually to weight gain. Recently, scientists have begun to understand at a biochemical level how diets high in digestible carbs, but low in fiber and prebiotics, affect our body.

There are several types of fiber in vegetables, grains and fruits that provide more than just roughage. The non-digestible, complex carbohydrates (collectively referred to as prebiotics) are key to a balanced and healthy GI microbiome, via a complex series of events.

Prebiotics can't be digested by humans and are transported to the large intestine where most microbiota live. Prebiotics are fermentable, meaning they serve as food for the gut microbiota in your large intestine.

As microbiota eat the prebiotics, they produce molecules called short chain fatty acids (SCFAs) that trigger the release of gut hormones. These hormones signal satiety in the brain, thereby influencing desired meal size. This can be delayed by several hours due to the time it takes for the fermentation process in the GI to take place. This is why eating meals at regular intervals, including breakfast, is important.

If we don't consume enough prebiotics, this signaling process is not strong enough. The gut microbiome doesn't get nourished, the microorganisms don't produce the SCFAs, and the brain doesn't get the signal that it's time to stop eating. In other words, we are far more likely to overeat. *

* These statements have not been reviewed by the FDA. BiomeBliss is not intended to diagnose, treat, cure, or prevent disease.

Study 2: Published Study Shows BiomeBliss Provides Nutritional Support to Inadvertent GI Effects of a Common Medication *

Not all orally-administered drugs are completely absorbed into the blood. Some may remain in the gastrointestinal (GI) tract where there is potential for interactions with the microbiota responsible for metabolism of certain nutrients.

Our second study, published in the *Journal of Diabetes Science and Technology*², showed that BiomeBliss provides nutritional support to counterbalance the occasional inadvertent GI effects in some people that accompanies use of metformin, the most common oral glucose-lowering drug. The study indicated that the blend of prebiotic nutrients in BiomeBliss nourishes and shifts the microbiota to support their metabolism, thereby helping to maintain GI osmotic homeostasis (the maintenance of optimal fluid balances and concentrations) with the aim of reducing the potential for occasional GI disturbances. *

Effective glucose-lowering therapeutics such as metformin are generally well-tolerated, but can lead to occasional diarrhea, occasional constipation, heartburn and nausea in some people, making it a challenge to achieve the recommended dosing.

This placebo-controlled, double-blind, randomized, cross-over study assessed participants known to have occasional GI disturbances from their standard blood glucose treatment. The study measured frequency and consistency of bowel movements and changes in mealtime blood glucose. Participants took BiomeBliss twice a day for four weeks, without other changes to their daily meal routine.

Statistically significant study results indicated that BiomeBliss helped improve bowel movement regularity and consistency without compromising the drug therapy's effect in regulating glucose levels. Participants taking BiomeBliss also were better able to maintain dosing of the drug. *

1 Journal of Diabetes and Its Complications, 29(8), 1272-1276. <http://doi.org/10.1016/j.jdiacomp.2015.08.023>

2 Journal of Diabetes Science and Technology, 9(4), 808-814. <http://doi.org/10.1177/1932296815577425>

* These statements have not been reviewed by the FDA. BiomeBliss is not intended to diagnose, treat, cure, or prevent disease.

BIOMEBLISS™

BiomeBliss is a strategically-formulated and proprietary blend of three active ingredients that work together to promote a diverse and healthy functioning gut microbiome.

One of these ingredients is **inulin**, derived from the agave plant. Inulin is a prebiotic that nourishes the microbiota populations, leading to an increased production of short chain fatty acids (SCFAs),

These SCFAs stimulate the release of gut hormones that play important roles in glucose regulation, and satiety and gastric emptying, thus leading to reduced hunger and overeating. *

With the nourishment achieved by inulin, the second ingredient—**polyphenols** from blueberries—then help shift the microbiome activity from biota that might otherwise produce methane and hydrogen sulfide to those specialized to produce acetate, a key SCFA. *

Along with the nourishment and shifting activity, the third ingredient—**Beta-glucan**—with its smooth texture, protects the GI by acting as an edible substrate for the biota to consume. In its absence, they may digest the protective mucosal lining. Beta-glucan also primes the immune system. *

In summary, BiomeBliss supplies key prebiotics to the GI microbiome that are often missing from modern diets:

- Inulin from plants provides nutrients that **nourish** the growth of microorganism populations
- Polyphenol antioxidants from blueberries **shifts** the growth and activity of certain bacteria associated with a healthy microbiome
- Beta-glucan from oats **protects** the GI's mucosal lining and supports the immune system. *

NOURISHES – SHIFTS – PROTECTS
TO BUILD A BETTER BIOME