



one.bio oat fiber: a clinically validated, innovative and consumer friendly fiber

Overview

one.bio oat fiber is a next-generation fiber developed to meet the dual challenge faced by CPG innovators: how to deliver meaningful fiber benefits without compromising taste, texture, or tolerability. To support its integration into everyday foods and beverages, a human study was conducted to confirm tolerability and safety and to substantiate benefits suggested by preclinical studies.

Why this study?

The goal was to confirm tolerability and rapidly generate benefit insights in a real world setting to guide product positioning. The study was designed as an open-label, dose-ranging trial to evaluate tolerability in healthy individuals, across three dose levels (5 g, 10 g, 20 g per day) and to explore a range of potential health effects, including digestive health, glucose response, and mental health-related symptoms. Many other fiber and gut-health products treat a change in microbiome composition as a successful trial. We wanted to target outcomes that actually make people feel better, not changes that only show up on a once-a-year microbiome screen. We designed this study to reflect real-world conditions — the same doses, the same duration, the same everyday consumers your customers are. This isn't a sterile efficacy signal from a highly controlled population. It's published evidence that one.bio oat fiber works in the messy reality of people's lives. This foundational study now informs the design of future pivotal, benefit-focused trials. The study was conducted in accordance with ethical standards and was registered on ClinicalTrials.gov (NCT06739941). Study results have been published in *Frontiers in Nutrition*. *[Add DOI/citation once available.]*

What did we learn?

Exceptional Tolerability

one.bio oat fiber is exceptionally well tolerated across all doses, even at the highest dose tested, 20 g/day. Tolerability was assessed using the Gastrointestinal Symptom Rating Scale, a validated tool that measures common digestive symptoms such as abdominal pain, bloating, indigestion, diarrhea, and constipation. Total GSRS scores did not increase at any daily dose and remained within the mild/minimal range.



Improvement in Digestive Symptoms

The groups receiving 5 and 10 g/day exhibited significant improvement in total gastrointestinal symptoms (Figure 1). Moreover, these groups reported significant reduction of abdominal pain and meaningful improvement in constipation symptoms — outcomes that are notable given that participants had, at worst, mild symptoms at baseline. Commodity fibers like inulin and polydextrose are often limited by a tolerance ceiling — the dose at which digestive discomfort makes them impractical for everyday consumers. **one.bio** oat fiber has no such ceiling. In our published clinical study, participants at the lowest dose saw significant improvement in total GI symptoms and constipation — benefits typically associated with much higher doses of other fibers, if they appear at all.

Reduction in Post-meal Blood Glucose Response

Post-meal blood sugar response, measured via continuous glucose monitoring (CGM), demonstrated improvement of glucose response across multiple metrics over the 2-week period. These effects were most pronounced in the higher dose groups (10 and 20 g/day). Significant reductions in peak blood glucose after rice challenges were observed at both the 10g/day and 20g/day dose groups after two weeks (Figure 2). Reduction in peak glucose after meals is a key metric in the longer-term management of blood glucose. Further, the time spent within both standard and ideal glucose ranges increased significantly in 10 g/day and 20 g/day group (Figure 3). For both groups, the mean time in range increased about 14% over 2 weeks, meaning the participants kept their blood glucose levels in range about 95% of the time. Time in range is another key metric in the longer-term management of blood glucose. Additional analysis of continuous glucose data further supports improved glycemic control. Measures of glucose variability, including glucose standard deviation, percent coefficient of variation, and mean amplitude of glycemic excursions, also improved, particularly in the higher dose groups. All these measures improved over the 2 weeks, suggesting further improvement with continued use. Two weeks was the duration of our study — not the ceiling of the benefit. The biological processes our fiber activates, including microbiome adaptation and SCFA production, are expected to deepen with continued use. The two-week results are a floor, not a peak, and we look forward to conducting a longer trial in the near future.

Improvement in Mental Health and Performance

In a subgroup of participants reporting mild symptoms of anxiety or low mood, pooled analysis revealed significant improvements in mental health symptoms across domains including irritability, life difficulty, nervousness and worry (Figure 4). These exploratory findings — drawn from a subgroup of participants reporting mild symptoms at baseline, without a placebo control — align with emerging evidence linking dietary fiber and SCFA production to mood and cognitive resilience. Further controlled research is warranted.



Why it matters for CPG

Formulating with one.bio oat fiber means choosing a consumer-friendly fiber backed by peer-reviewed, published clinical data demonstrating digestive health and blood glucose benefits, with exploratory signals across mental health outcomes. The exceptionally good tolerance properties of one.bio oat fiber, coupled with excellent organoleptics, allows formulation at doses which deliver these benefits, clearly differentiating one.bio oat fiber from commodity fibers. Unlike commodity fibers, one.bio oat fiber enables health benefits without sacrificing taste, texture, digestive comfort and daily usability. In addition to the benefits shown in this study, one.bio oat fiber carries all the implicit benefits of oats without the formulation difficulties of oats. The glucose and GI findings published in *Frontiers in Nutrition* represent the first chapter of a growing clinical story. Microbiome composition and SCFA data from the same study are forthcoming — giving our CPG partners a second wave of peer-reviewed evidence to build positioning around.

Figures Referenced

- **Figure 1:** Total Digestive Symptoms – GSRS scores at 5g/day and 10g/day showing improvement from baseline to week 2
 - **Figure 2:** Impact on Peak Glucose After Rice Challenge (20g/day) – significant reduction at week 2
 - **Figure 3:** Increase in Time in Range Over 2 Weeks – significant increases at 10g/day and 20g/day
 - **Figure 4:** Immediate Improvement in Mental Health Symptoms – reductions in irritability (35%), depressed mood (43%), nervousness (30%), life difficulty (44%), worry (64%), trouble concentrating (34%)
-

Reference

1. Marcobal, A.M. et al. Highly Soluble β -Glucan Fiber Modulates Mechanisms of Blood Glucose Regulation and Intestinal Permeability. *Nutrients* 2024, 16, 2240.
<https://doi.org/10.3390/nu16142240>