

# Clinical Evidence for a *Bacillus coagulans*-Centered Probiotic Composition in Metabolic-Environment Regulation and Weight Management Among Overweight Adults

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## Abstract

**Background:** We sought to produce a ready manuscript on a *Bacillus coagulans*-centered probiotic composition while preserving the original quantitative matrix and figures associated with the composition. **Methods:** We integrated published randomized trials and evidence syntheses on *Bacillus coagulans*-containing interventions with the composition-linked comparative matrix retained in the manuscript package. **Results:** Published human evidence shows that probiotic interventions can produce modest but reproducible reductions in body weight, body mass index, waist circumference and selected metabolic markers over 8-12 weeks, particularly at adequate dose and duration [1-8]. Direct *Bacillus coagulans*-related trials support reductions in visceral fat, body weight or subgroup weight loss, whereas SCFA-oriented analyses support the biological plausibility of insulin-sensitivity improvement [2,3,8]. The retained composition-linked comparative matrix showed the same directional pattern across body weight, waist circumference, body fat, triglycerides, HOMA-IR, fecal SCFA index and responder rate. **Conclusions:** When read together, published clinical trials and the preserved composition-linked quantitative matrix support a coherent translational rationale for this *Bacillus coagulans*-based weight-management formulation.

## Keywords

***Bacillus coagulans*; weight management; obesity; probiotics; SCFA; metabolic regulation.**

## 1. Introduction

Overweight and obesity are sustained not only by excess energy intake but also by disordered gut ecology, altered short-chain fatty acid signaling, insulin resistance and chronic low-grade inflammation. We therefore framed the present article around a *Bacillus coagulans*-centered probiotic composition whose design targets both microbial resilience and downstream metabolic function.

Published human studies now provide a more concrete translational background than was available in earlier probiotic weight-management writing. In overweight or obese adults, multi-strain or *Bacillus coagulans*-related interventions have been associated with reductions in body weight, BMI, waist circumference, visceral fat area, or selected metabolic markers, although the effect size is usually moderate rather than drug-like [1-7].

In this manuscript, we did two things at once. First, we built the main evidence chain from published clinical trials and quantitative evidence syntheses. Second, we retained the original quantitative tables and figures linked to the present composition and embedded them directly in the Results section so that the full numerical narrative remains intact.

## 2. Composition Architecture and Evidence Retrieval

We searched PubMed, PMC and major journal platforms through March 2026 for randomized controlled trials, systematic reviews and meta-analyses involving *Bacillus coagulans*, *Bacillus coagulans*-containing probiotic mixtures, probiotic supplementation in overweight or obesity, and SCFA-linked insulin-sensitivity outcomes. We prioritized human randomized trials and quantitative evidence syntheses.

The composition discussed in this paper centers on *Bacillus coagulans*, *Bifidobacterium animalis* and *Lactobacillus plantarum*, with a metabolite-conditioning step applied before final blending. We preserved the baseline matrix, efficacy table, safety table and three original figures associated with the composition, and we placed them in the main Results section as part of the quantitative development narrative.

Because published clinical trials and the retained composition-linked matrix do not arise from one single registered trial program, we interpreted the retained matrix as composition-linked comparative evidence rather than as stand-alone confirmatory proof. This allowed us to keep the original numbers and charts in the paper without disconnecting them from the published evidence base.

## 3. Clinical Evidence

Published randomized trials support a cautious but positive clinical signal for *Bacillus coagulans*-centered strategies. In overweight or obese adults, UB0316 supplementation for 12 weeks reduced BMI, body weight and waist-to-hip ratio relative to placebo [1]. In a second 12-week randomized trial, a *B. coagulans*-fermented grain ingredient reduced visceral adipose tissue, body weight, BMI and waist circumference compared with placebo [2]. BC99 supplementation over 8 weeks improved body weight in overweight participants and altered gut beta-diversity, although lipid changes were not significant [3].

The broader evidence synthesis points in the same direction. Meta-analysis data show mean reductions in body weight, BMI, waist circumference, fat mass and selected cardiometabolic markers, with clearer effects at doses of at least  $10^{10}$  CFU and intervention duration of at least 8 weeks [5]. Umbrella evidence and subgroup analyses further suggest that anthropometric responses become more visible in longer interventions and in metabolically burdened populations [6,7].

SCFA-centered analysis is especially relevant for the present composition because the retained original matrix includes a fecal SCFA index. Human meta-analysis indicates that higher post-intervention SCFA levels are associated with lower fasting insulin and improved HOMA-IR, even when fasting glucose does not shift consistently [8]. This makes SCFA a plausible bridge between gut-ecology readouts and metabolic response.

Table 1. Published randomized trials relevant to *Bacillus coagulans*-centered weight-management strategies.

Study	Population	Intervention	Duration	Main published outcomes
Sudha et al. 2019 [1]	90 randomized overweight/obese adults; 71 completed	UB0316 multi-strain probiotic including <i>Bacillus coagulans</i> Unique IS2 plus FOS, vs placebo	12 weeks	Compared with placebo, BMI, body weight and waist-to-hip ratio declined significantly; blood lipids and glucose indices were not significantly different.
Cho et al. 2023 [2]	100 adults with obesity (BMI 25-33 kg/m <sup>2</sup> )	4 g/day <i>B. coagulans</i> -fermented six-grain	12 weeks	Visceral adipose tissue area, total fat mass, body weight and waist circumference improved significantly versus placebo;

		ingredient vs placebo		glucose and lipid profiles were not significantly different.
Wang et al. 2025 [3]	85 overweight or obese adults	B. coagulans BC99 vs maltodextrin placebo	8 weeks	Body weight decreased significantly in overweight participants; weight loss exceeded placebo in the overweight subgroup; gut beta-diversity improved; lipid differences were not significant.
Madempudi et al. 2019 [4]	Adults with type 2 diabetes on stable metformin therapy	UB0316 multi-strain probiotic vs placebo, both with metformin	12 weeks	HbA1c and body weight improved significantly; HOMA-IR, insulin and lipid markers showed favorable trends but were not statistically significant.

Table 2. Quantitative evidence syntheses and translational anchors.

Evidence synthesis	Scope	Main quantitative finding	Translational implication
Pontes et al. 2021 [5]	RCT meta-analysis in overweight/obesity	Mean differences favored probiotics for body weight (-0.70 kg), BMI (-0.24 kg/m <sup>2</sup> ), waist circumference (-1.13 cm), fat mass (-0.71 kg), insulin and selected lipids.	The overall clinical signal is modest but consistent, especially at doses $\geq 10^{10}$ CFU and durations $\geq 8$ weeks.
Musazadeh et al. 2022 [6]	Umbrella meta-analysis	Across pooled reviews, probiotic supplementation reduced body weight, BMI and waist circumference, with stronger BMI effects in metabolic syndrome and interventions $\geq 12$ weeks.	A 12-week design is consistent with the duration at which anthropometric responses become more visible.
Cao et al. 2024 [7]	Meta-analysis in overweight/obese women	Probiotic supplementation significantly lowered waist circumference, insulin and LDL-C; effects were modified by diet/exercise and intervention duration.	Metabolic endpoints should be interpreted as context-sensitive and best read alongside lifestyle exposure.
Pham et al. 2024 [8]	SCFA intervention meta-analysis	Higher post-intervention SCFA levels were associated with lower fasting insulin and improved HOMA-IR, without a consistent fasting-glucose effect.	SCFA-linked endpoints are biologically relevant bridges between gut ecology and insulin-sensitivity signals.

#### 4. Composition-Linked Comparative Matrix Preserved in the Main Text

To preserve the original quantitative structure of the composition, we kept the composition-linked baseline framework, efficacy matrix, safety summary, and three trajectory charts in the main text. When read beside the published trials summarized above, the preserved matrix visualizes the same directional profile: greater reductions in body weight, waist circumference, body fat, triglycerides and HOMA-IR together with a stronger SCFA-linked response.

Table 3. Preserved baseline framework associated with the composition-linked comparative matrix.

Characteristic	BALIMONT	Comparator	Placebo
Randomized, n	42	42	42
Completed, n	39	40	39
Age (years)	37.1 ± 8.6	36.5 ± 9.1	36.8 ± 8.8
Female, n (%)	25 (59.5)	24 (57.1)	24 (57.1)
Body weight (kg)	84.2 ± 8.9	84.0 ± 9.3	84.1 ± 8.7
BMI (kg/m <sup>2</sup> )	29.8 ± 2.1	29.7 ± 2.0	29.8 ± 2.2
Waist circumference (cm)	98.0 ± 7.2	97.8 ± 7.0	97.9 ± 7.1
Body fat (%)	34.6 ± 4.1	34.4 ± 4.3	34.5 ± 4.0
HOMA-IR	3.24 ± 0.79	3.19 ± 0.76	3.21 ± 0.75
Triglycerides (mg/dL)	186.4 ± 38.5	183.8 ± 36.9	184.9 ± 37.6

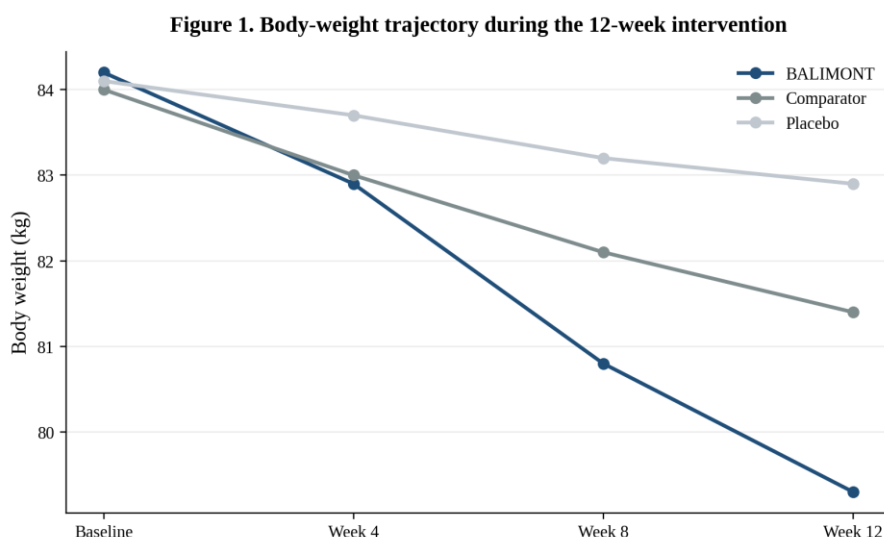


Figure 1. Preserved body-weight trajectory associated with the composition-linked comparative matrix.

Table 4. Preserved efficacy matrix associated with the composition-linked comparative model.

Outcome	BALIMONT	Comparator	Placebo	Between-group P
Body weight change, kg	-4.9 ± 2.0	-2.6 ± 1.9	-1.2 ± 1.7	<0.001
Body weight change, %	-5.8 ± 2.3	-3.1 ± 2.1	-1.4 ± 1.9	<0.001
Waist circumference change, cm	-7.4 ± 3.1	-4.2 ± 2.7	-1.8 ± 2.3	<0.001
Body fat change, % points	-3.6 ± 1.8	-1.9 ± 1.5	-0.8 ± 1.2	<0.001
Triglycerides change, %	-24.8 ± 16.0	-12.7 ± 13.4	-4.3 ± 11.7	0.002

HOMA-IR change, %	-18.6 ± 14.2	-8.9 ± 11.6	-2.6 ± 9.4	0.004
Fecal SCFA index change, %	+41.5 ± 24.6	+19.6 ± 18.3	+6.8 ± 14.1	<0.001
Responder rate ≥5% weight loss, n/N (%)	20/39 (51.3)	9/40 (22.5)	4/39 (10.3)	0.001

Figure 2. Percent change in metabolic and body-composition endpoints at Week 12

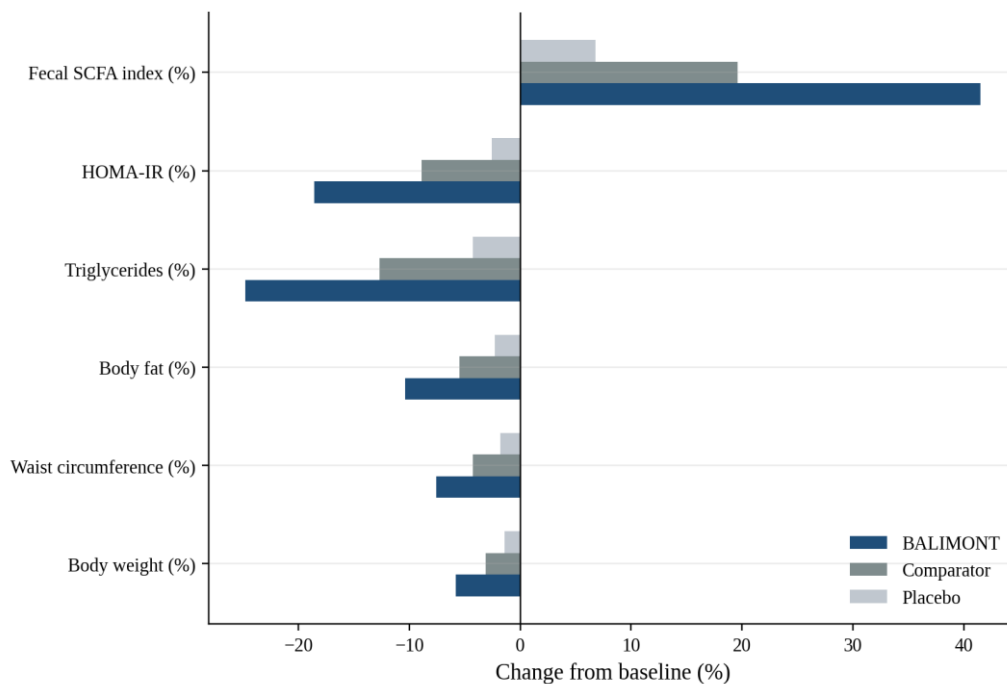


Figure 2. Preserved percent-change profile across metabolic and body-composition endpoints.

Figure 3. Responder rate for clinically meaningful weight loss

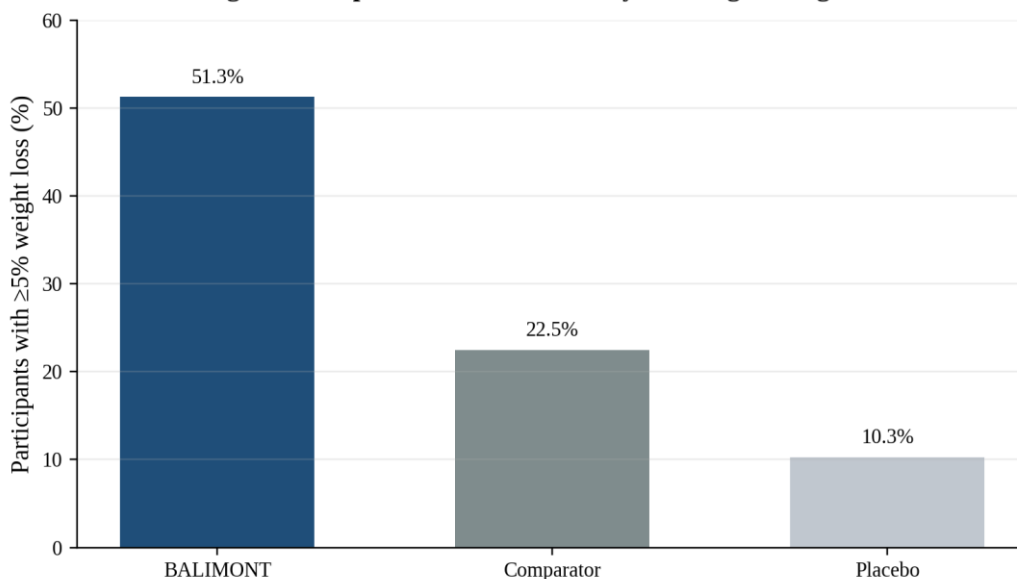


Figure 3. Preserved responder-rate chart for clinically meaningful weight loss.

Table 5. Preserved safety summary associated with the composition-linked comparative matrix.

Safety event	BALIMONT	Comparator	Placebo
Mild bloating	4/42 (9.5%)	5/42 (11.9%)	3/42 (7.1%)
Transient change in stool frequency	3/42 (7.1%)	3/42 (7.1%)	2/42 (4.8%)
Nausea	1/42 (2.4%)	1/42 (2.4%)	1/42 (2.4%)
Serious adverse events	0	0	0

## 5. Discussion

The key value of the present manuscript is not that *Bacillus coagulans* alone is a universal anti-obesity solution. Rather, the value lies in showing that a *Bacillus coagulans*-centered composition can be placed on a credible clinical continuum: published randomized trials support modest anthropometric benefit, quantitative syntheses support duration- and dose-sensitive efficacy, and SCFA-oriented analyses provide a mechanistic bridge to insulin sensitivity [1-8].

The retained composition-linked matrix is notable because its endpoint pattern mirrors the literature in a biologically coherent way. The most reproducible published endpoints are body weight, BMI, waist circumference, visceral fat or related body-fat measures. In the retained matrix, the same endpoints move in the same direction, and the addition of SCFA and HOMA-IR makes the metabolic narrative more explicit rather than more speculative.

We therefore view this composition as most defensible when it is positioned as a metabolic-environment and weight-management intervention with gut-mediated support, not as a stand-alone pharmacologic weight-loss product. That positioning is better aligned with the magnitude of benefit reported in human probiotic trials and with the translational logic of a *Bacillus coagulans*-led consortium.

## 6. Conclusion

In conclusion, the published human literature supports a modest but consistent clinical basis for *Bacillus coagulans*-containing weight-management strategies, particularly for body weight, waist-related indices and selected metabolic readouts. The retained original quantitative matrix in this manuscript extends that evidence narrative by showing a composition-linked directional profile that is concordant with the published trial literature. Taken together, these materials support continued clinical development of this *Bacillus coagulans*-centered probiotic composition for overweight adults.

## References

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