

Impact of a Probiotic-Fiber Blend on Body Weight, Metabolic Regulation, and Digestive Function in Obese Adults: A Randomized, Placebo-Controlled, Multicentric Trial

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Abstract

Introduction: Obesity is closely associated with metabolic syndrome, a cluster of conditions including abdominal obesity, high triglycerides, low high-density lipoprotein (HDL) cholesterol, elevated blood pressure, and impaired glucose metabolism. Emerging research suggests that gut dysbiosis, an imbalance in gut microbiota, plays a key role in metabolic syndrome, influencing insulin resistance, inflammation, and lipid metabolism. The gut microbiome has gained attention for its impact on energy balance, fat storage, and metabolic regulation. This randomized, double-blind, placebo-controlled, multicentric clinical study evaluated the efficacy and safety of probiotic-fiber blend formulation in obese adults.

Methods: Obese adults (body mass index (BMI) 30-40 kg/m², aged 30-45; male: 46.15%, female: 53.85%) were randomly assigned to receive either the probiotic-fiber blend formulation or a placebo for 90 days, along with lifestyle counseling. Primary outcomes included body weight, BMI, waist/hip circumference, and body fat percentage. Secondary outcomes assessed biochemical parameters, digestive health, quality of life, perceived stress, and metabolic syndrome severity Z (MetS-Z) score. One hundred four participants completed the study.

Results: The probiotic-fiber blend formulation (n = 53) demonstrated statistically significant (p < 0.001) improvements compared to placebo (n = 51), including reductions in body weight (12.01%), BMI (12.14%), waist circumference (9.64%), and hip circumference (9.63%) compared to placebo. Additionally, statistically significant reductions were observed in the MetS-Z score (54.02%), triglycerides (25.75%), and perceived stress (37.62%), along with a notable increase in HDL levels (16.55%). Significant improvements in digestive health and quality of life were also recorded, reinforcing the probiotic-fiber blend efficacy.

Conclusion: The findings provide robust evidence that the probiotic-fiber blend effectively improves anthropometric and biochemical markers in obesity. These results underscore the therapeutic potential of gut microbiome modulation in metabolic health. Further research should explore long-term effects, mechanistic pathways, and broader clinical applications.

Categories: Endocrinology/Diabetes/Metabolism, Nutrition, Quality Improvement

Keywords: fiber, gut microbiome, metabolic health, obesity, probiotics

Introduction

Obesity, affecting 37% of the global population, is a significant global health crisis, contributing to metabolic disorders and straining healthcare systems [1]. India, with a population of over 1.4 billion, faces an increasing obesity burden, with prevalence rates rising sharply in recent decades. A Lancet study tracking global obesity between 1990 and 2022 found that the prevalence of obesity among women in India increased from 1.2% to 9.8% and among men from 0.5% to 5.4% [2]. Even with body mass index (BMI) under normal, Indians have a tendency to have higher body fat% and disrupted metabolic health. Other estimates suggest obesity rates vary between 8% and 50%, with urban populations showing higher rates [3]. This growing public health challenge underscores the need for effective, safe, and sustainable interventions.

Conventional weight management strategies, including lifestyle modifications and pharmacological treatments, often present challenges in achieving long-term success. Emerging evidence suggests that gut microbiota plays a pivotal role in metabolic health and weight regulation [4]. The gut microbiome plays a crucial role in regulating glucagon-like peptide-1 (GLP-1) secretion, influencing metabolic health through fiber fermentation and probiotic interactions. Prebiotic fiber serves as a substrate for beneficial gut bacteria,

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enhancing microbial diversity and supporting short-chain fatty acid (SCFA) production, particularly butyrate [4]. Specific probiotic strains, including *Bifidobacterium* and *Lactobacillus*, can directly stimulate L-cells in the gut epithelium, promoting GLP-1 release [5]. The synergy between fiber and probiotics supports gut microbial composition, leading to enhanced SCFA production and promoting insulin sensitivity and satiety while modulating inflammation by regulating immune responses and gut barrier integrity [6]. These mechanisms highlight the gut microbiome's pivotal role in managing obesity and metabolic disorders. Dysbiosis, characterized by imbalances in microbial composition, is linked to obesity, insulin resistance, and inflammation [7,8]. Specifically, alterations in the *Firmicutes/Bacteroidetes* ratio and reduced microbial diversity contribute to metabolic dysfunction [9].

Prebiotics (such as fiber, fructooligosaccharides (FOS), and inulin) and probiotics (like *Lactobacillus* and *Bifidobacterium* strains) offer a promising approach to modulating gut microbiota and improving metabolic health [10]. Stress induces hyperactivation of the hypothalamic-pituitary-adrenal (HPA) axis, leading to elevated cortisol levels, which enhance appetite, promote adipogenesis, and contribute to excessive weight gain, necessitating targeted weight management interventions [11]. Stress also influences the gut microbiome via the gut-brain axis; conversely, gut microbes modulate stress responses and inflammation, creating a feedback loop that impacts weight gain and metabolic health [12,13].

This study investigates the efficacy and safety of probiotic-fiber blend formulation in obese adults, evaluating its impact on anthropometric measures (like weight, BMI, body fat%, and waist and hip circumference), metabolic markers, the MetS-Z score, and digestive health.

Materials And Methods

Study design

This 90-day randomized, double-blind, placebo-controlled, parallel-group, multicenter clinical trial evaluated the efficacy and safety of probiotic-fiber blend formulation in obese adults. The study was conducted at two sites-Lokmanya Medical Research Centre and Hospital, Pune, and Krishna Vishwa Vidyapeeth Deemed to be University, Karad, Satara. It was initiated only after written ethical approval was obtained from the Institutional Ethics Committee Lokmanya Medical Research Center, Pune (ECR/175/Inst/MH/2013/RR-19) and IEC Krishna Institute of Medical Sciences (KIMS) Deemed to be University, Karad, Satara (ECR/307/Inst/MH/2013/RR-20). The study was registered under the Clinical Trial Registry of India (CTRI/2024/07/070532). Clinical trial data were collected between August 20, 2024, and January 20, 2025.

Before enrollment, participants received a detailed explanation of the study design, expected benefits, and potential risks in a comprehensible format. They were informed of their right to withdraw at any time. Written informed consent was obtained from all participants after they were briefed on the study's objectives, methods, potential risks and benefits, confidentiality measures, and the contact details of the institutional ethics committee and study investigator. To ensure confidentiality, personal data and study records were securely stored and accessible only to authorized personnel. Participant anonymity was maintained in all study reports and publications. Study codes were securely stored with access restricted to the site investigator, with unblinding only permitted in case of adverse events (AEs) requiring treatment identification, though unblinding was not needed.

Intervention

A total of 106 participants were randomized 1:1 to receive either the probiotic-fiber blend or placebo intervention for 90 days. Both groups received lifestyle counseling at baseline, day 30, day 60, and day 90. Both the probiotic-fiber blend and placebo arm were given counseling on healthy eating and staying physically active for a minimum of 30 minutes.

The probiotic-fiber blend group received a supplement containing a probiotic blend of *Bifidobacterium animalis* subsp. *lactis*, *Lactobacillus gasseri*, *Bifidobacterium longum*, *Bifidobacterium bifidum*, *Bifidobacterium breve*, and *Lactobacillus reuteri*, providing a total of 16 billion colony-forming units (CFUs). Additionally, it includes metabolic enhancers L-carnitine and chromium picolinate and prebiotic fibers (soluble fiber-8 g) FOS, inulin, glucomannan, and wheat dextrin. The supplement was dissolved in 200 mL of water and consumed once daily. The placebo group received an identical placebo in appearance, weight, and texture, dissolved in 200 mL of water and administered once daily.

Study participants

One hundred and six patients were recruited in a double-blind, randomized, placebo-controlled multicenter clinical trial for weight management. The criteria listed below were used to enroll participants.

Inclusion Criteria

Participants included men and women aged 30 to 45 years with Class I (BMI 30 to <35 kg/m²) or Class II

(BMI 35 to <40 kg/m²) obesity based on the World Health Organization (WHO) criteria [14], who had experienced a significant weight gain of at least 10 kg over the past three years. Eligible participants met at least three metabolic syndrome criteria as per National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III), including serum triglycerides \geq 150 mg/dL, high-density lipoprotein (HDL) cholesterol \leq 40 mg/dL in men or \leq 50 mg/dL in women, blood pressure \geq 130 mmHg systolic or \geq 85 mmHg diastolic, fasting plasma glucose \geq 100 mg/dL, or abdominal obesity (waist circumference > 90 cm in men and >80 cm in women). Individuals with any dietary or medication history, particularly oral/intravenous antibiotics or probiotics within three months prior to recruitment, that could interfere with metabolic homeostasis and gut microbiota were excluded. All participants provided voluntary, written informed consent before enrollment.

Exclusion Criteria

The exclusion criteria included recent antibiotic use (within three months), major surgery in the past six months, pregnancy or lactation, type 1 diabetes mellitus, use of weight-loss medications or supplements affecting the gut microbiome, history of substance abuse, bowel disease, immunosuppressive conditions, participation in other weight reduction programs, and significant dietary changes or weight loss within two months before enrollment.

Objectives

The study aimed to evaluate the efficacy of probiotic-fiber blend formulation in obese individuals by assessing its effects on anthropometric parameters and metabolism compared to a placebo. Additionally, the study examined the impact of the probiotic-fiber blend on biochemical parameters, digestive health, quality of life, perceived stress levels, metabolic health, and overall improvement. Safety was assessed by monitoring AEs, vital signs, tolerability, and compliance throughout the study.

Clinical study procedure

This was a randomized, double-blind, parallel-group, placebo-controlled, multicentric, and comparative clinical trial evaluating the efficacy and safety of probiotic-fiber blend formulation in obese individuals compared to placebo.

In this study, obese individuals aged between 30 and 45 years with specific inclusion and exclusion criteria were enrolled. A total of 114 participants were screened, with eight screen failures. The remaining 106 participants were randomized in a 1:1 ratio using a computer-generated randomization sheet prepared by a qualified biostatistician to receive either probiotic-fiber blend formulation with nutritional counseling and tracking or placebo with nutritional counseling and tracking in a 1:1 ratio for 90 days, with 53 allocated to the probiotic-fiber blend group and 53 to the placebo group. During the study, two participants from the placebo group were lost to follow-up. Ultimately, 104 participants completed the study (53 in the probiotic-fiber blend and 51 in the placebo group). The CONSORT diagram is depicted below in Figure 1.

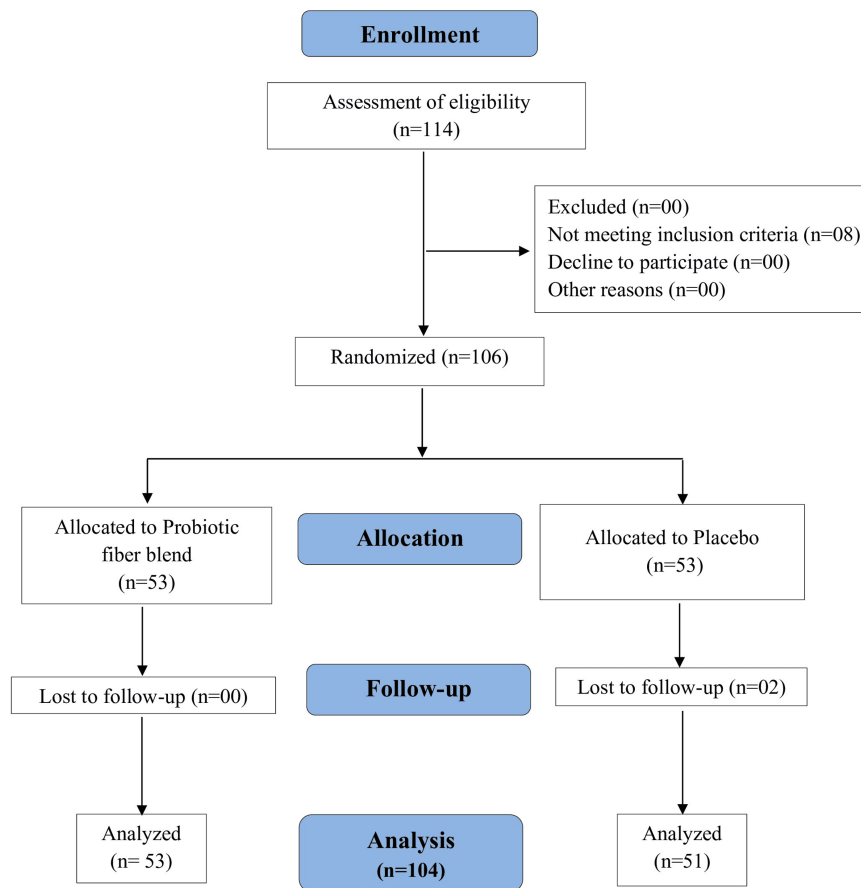


FIGURE 1: CONSORT diagram for the study.

Assessment of concomitant diseases and medications was evaluated at screening. The efficacy of the investigational products was compared between the groups. The following medications were not permitted during the study: any allopathic, nutritional supplements, ayurveda, homeopathy, siddha, and unani medication for weight management.

Body weight, BMI, and body fat percentage were assessed using a digital weighing scale from E.G. Kantawalla Pvt. Ltd. (Eagle, Model No. EEF2001A, India), employing bioelectrical impedance analysis (BIA). Height was measured with a stadiometer. Waist and hip circumference measurements were performed using a tailoring tape. Waist circumference was recorded at a horizontal level just above the iliac crest, while hip circumference was measured at the widest part of the buttocks with participants standing upright and feet together. Participants underwent all anthropometric assessments without shoes and in light, consistent clothing at each visit.

The assessment of biochemical parameters, including lipid profile and thyroid-stimulating hormone (TSH), was conducted at screening and the end of the study. Lipid profile assessments included total cholesterol (cholesterol oxidase-peroxidase (CHOD-PAP) method), triglycerides (glycerol phosphate oxidase-peroxidase (GPO-PAP) method), HDL (selective inhibition method), low-density lipoprotein (LDL) (enzymatic selective protection method), and very LDL (VLDL) (calculated formula), all analyzed using the Fully Bio CPC Machine. The MetS-Z score was calculated at screening and on day 90 using the online calculator available at <http://mets.health-outcomes-policy.ufl.edu/calculator/> [15]. Blood samples were collected by a trained phlebotomist at each study site during screening and on day 90 visits and processed at local National Accreditation Board for Testing and Calibration Laboratories (NABL)-accredited laboratories.

Digestive health symptoms were assessed using a self-assessment questionnaire score using a four-point ordinal scale (acidity, bloating, bowel movements, and cravings) and an 11-point numerical rating scale (hunger and satiety) at screening, day 30, day 60, and day 90. Additionally, subjective assessments included the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) score and the Perceived Stress Scale-10 (PSS-10) score recorded at baseline and day 90. The Clinical Global Impression-Improvement (CGI-I) scale was assessed at the end of the study to evaluate perceived overall improvement. Safety of the investigational

treatments in terms of vital signs, AEs, and serious AEs (SAEs) along with treatment compliance and tolerability was assessed from baseline to the end of the study.

Statistical analysis

Sample Size

The primary objective of this study was to assess the mean difference in body weight between the probiotic-fiber blend and placebo groups. Based on the sample size calculation (ClinicalCalc, 2023), the study was powered at 90% with a significance level of 5% to detect a minimum clinically meaningful difference in body weight (delta) of 4.65 kg with a standard deviation of 7.14 between groups. To achieve this, 100 completed cases were required, with an equal allocation of 50 participants to the probiotic-fiber blend and placebo groups (in a 1:1 ratio). In this study, a total of 114 participants were screened, 106 were enrolled and randomized, and 104 participants completed the study [16,17].

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) software (Version 10.0, SPSS Inc., Chicago, IL, US). The data's normality was assessed by using the Kolmogorov-Smirnov test. The primary and secondary endpoints were analyzed by using the Student t-test, Mann-Whitney U test, Wilcoxon signed-rank test, and chi-squared test. Compliance and tolerance were expressed in percentages and numbers, respectively. AE data is expressed as numbers and percentages. Statistical significance was set at $p < 0.05$.

Results

Demographics

A total of 106 participants were randomized and double-blinded, with 104 completing the study. The final analysis included 53 participants in the probiotic-fiber blend group (30 female and 23 male) and 51 in the placebo group (26 female and 25 male). No significant differences in age or sex were observed between the groups. The mean age was 37.87 ± 4.57 years in the probiotic-fiber blend group and 37.06 ± 4.68 years in the placebo group.

Anthropometric measurements

Both groups exhibited significant reductions in body weight, BMI, waist circumference, and hip circumference over time, with the probiotic-fiber blend group consistently demonstrating superior outcomes at each time point. Weight loss in the probiotic-fiber blend group ($n = 53$) was gradual yet statistically significant, with a reduction of 4.15 kg (4.84%) by day 30, 6.86 kg (7.99%) by day 60, and 10.31 kg (12.01%) by day 90, compared to 0.90 kg (1.05%), 1.78 kg (2.08%), and 3.01 kg (3.52%) in the placebo group ($n = 51$), respectively ($p < 0.001$ for all comparisons). Similarly, BMI reductions followed a progressive pattern, with a 12.14% decrease in the probiotic-fiber blend group by day 90, significantly exceeding the 3.53% reduction observed in the placebo group.

Waist circumference showed a continuous and statistically significant decline in the probiotic-fiber blend group, decreasing by 3.69% (3.89 cm) on day 30, 6.92% (7.29 cm) on day 60, and 9.64% (10.16 cm) on day 90, in contrast to the placebo group's reductions of only 2.74% (2.79 cm) on day 90 ($p < 0.001$ for all time points). Hip circumference followed a similar trend, with the probiotic-fiber blend group exhibiting a 9.63% reduction (10.48 cm) by day 90, markedly greater than the 2.86% (3.04 cm) reduction in the placebo group ($p < 0.001$).

All observed changes were statistically significant, highlighting the superior efficacy of the probiotic-fiber blend intervention in promoting weight loss and anthropometric improvements compared to the placebo. Changes in anthropometric measurements are presented in Table 1 and Figures 2, 3.

Visits	Probiotic-fiber blend group	Placebo group	p-value (within groups)		p-value (t-value/z-score) (between groups)
			Probiotic-fiber blend	Placebo group	
Body weight (kg)					
Baseline	85.85 ± 10.77	85.32 ± 9.42	-	-	0.792 (t-value = 0.264)
Day 30	81.69 ± 10.45	84.43 ± 9.21	<0.001 (t-value = -25.920)	<0.001 (t-value = -7.146)	<0.001 (t-value = 15.910)
% change	4.84%	1.05%	-	-	-
CFB	4.15 kg	0.90 kg	-	-	-

Day 60	78.99 ± 10.47	83.55 ± 8.93	<0.001 (t-value = -31.749)	<0.001 (t-value = -7.976)	<0.001 (t-value = 16.368)
% change	7.99%	2.08%	-	-	-
CFB	6.86 kg	1.78 kg	-	-	-
Day 90	75.54 ± 11.12	82.32 ± 9.40	<0.001 (t-value = -21.178)	<0.001 (t-value = 12.801)	<0.001 (t-value = 16.226)
% change	12.01%	3.52%	-	-	-
CFB	10.31 kg	3.01 kg	-	-	-
Body mass index (kg/m²)					
Baseline	33.21 ± 2.85	33.31 ± 2.84	-	-	0.857 (z-score = -0.175)
Day 30	31.60 ± 2.73	32.97 ± 2.85	<0.001 (z-score = -6.334)	<0.001 (t-value = -6.759)	<0.001 (z-score = 8.708)
% change	4.85%	1.03%	-	-	-
CFB	1.61 kg/m ²	0.34 kg/m ²	-	-	-
Day 60	30.54 ± 2.68	32.63 ± 2.76	<0.001 (z-score = -6.334)	<0.001 (t-value = -7.679)	<0.001 (z-score = 8.577)
% change	8.04%	2.05%	-	-	-
CFB	2.67 kg/m ²	0.68 kg/m ²	-	-	-
Day 90	29.18 ± 3.08	32.13 ± 2.88	<0.001 (z-score = -6.334)	<0.001 (t-value = -11.905)	<0.001 (t-value = 14.418)
% change	12.14%	3.53%	-	-	-
CFB	4.03 kg/m ²	1.18 kg/m ²	-	-	-
Waist circumference (cm)					
Baseline	105.40 ± 11.14	102.02 ± 9.05	-	-	0.093 (t-value = 1.698)
Day 30	101.52 ± 10.89	101.69 ± 8.89	<0.001 (t-value = -29.339)	0.033 (t-value = -2.191)	<0.001 (t-value = 17.918)
% change	3.69%	0.32%	-	-	-
CFB	3.89 cm	0.33 cm	-	-	-
Day 60	98.11 ± 10.87	100.40 ± 8.99	<0.001 (t-value = -37.512)	<0.001 (t-value = -4.867)	<0.001 (t-value = 14.844)
% change	6.92%	1.59%	-	-	-
CFB	7.29 cm	1.62 cm	-	-	-
Day 90	95.25 ± 10.75	99.22 ± 8.59	<0.001 (t-value = -41.009)	<0.001 (t-value = -7.789)	<0.001 (t-value = 16.999)
% change	9.64%	2.74%	-	-	-
CFB	10.16 cm	2.79 cm	-	-	-
Hip circumference (cm)					

Baseline	108.80 ± 12.93	106.58 ± 9.42	-	-	0.509 (z-score = 0.660)
Day 30	104.34 ± 12.49	106.38 ± 9.49	<0.001 (z-score = -6.325)	0.079 (t-value = -1.792)	<0.001 (t-value = 18.409)
% change	4.10%	0.19%	-	-	-
CFB	4.47 cm	0.20 cm	-	-	-
Day 60	100.93 ± 12.58	105.42 ± 9.59	<0.001 (z-score = -6.334)	<0.001 (t-value = -3.536)	<0.001 (t-value = 16.548)
% change	7.24%	1.09%	-	-	-
CFB	7.88 cm	1.16 cm	-	-	-
Day 90	98.32 ± 12.57	103.54 ± 9.67	<0.001 (z-score = -6.334)	<0.001 (t-value = -7.531)	<0.001 (t-value = 15.840)
% change	9.63%	2.86%	-	-	-
CFB	10.48 cm	3.04 cm	-	-	-

TABLE 1: Changes in anthropometric measurements from baseline to day 90.

Data are presented as the mean ± SD (percent change). Within-group comparisons were performed using the Student t-test (dependent) and Wilcoxon signed-rank test, and between-group comparisons were conducted using the Student t-test (independent) and Mann-Whitney U test. Statistical significance was set at $p < 0.05$. The t-value represents the results of dependent and independent Student t-tests, and the z-score represents Wilcoxon and Mann-Whitney U test results.

CFB: change from baseline; SD: standard deviation

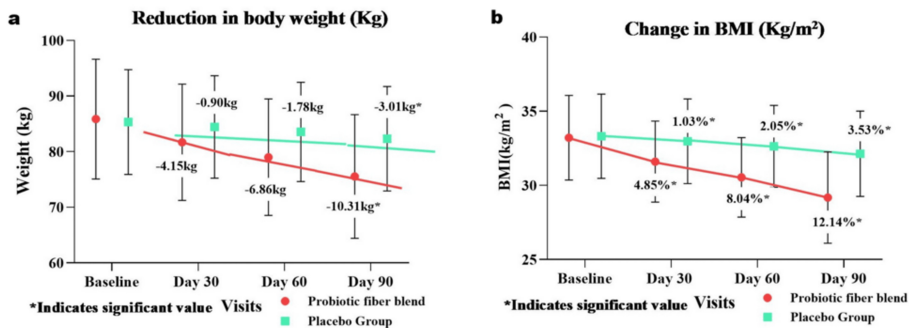


FIGURE 2: Reduction in (a) body weight and (b) BMI over 90 days.

BMI: body mass index

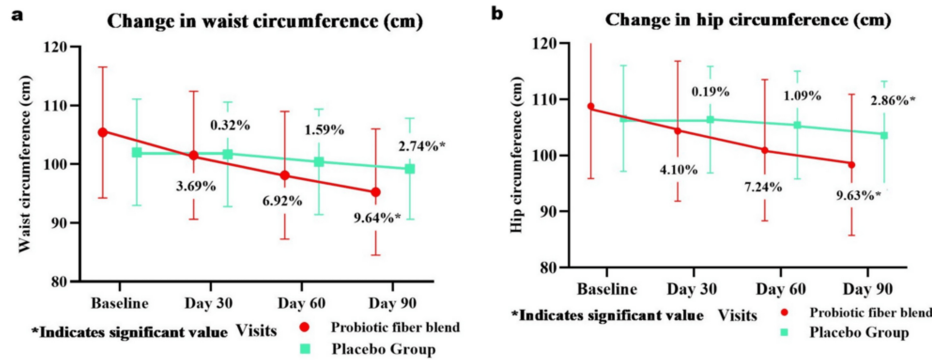


FIGURE 3: Effect of probiotic-fiber blend vs. placebo on (a) waist and (b) hip circumference over 90 days.

Body fat percentage

A statistically significant and progressive reduction in body fat percentage in the probiotic-fiber blend (n = 53) group compared to the placebo (n = 51) was observed. By day 30, body fat decreased by 11.13% in the probiotic-fiber blend group versus 2.88% in the placebo. The reduction continued at day 60, reaching 20.64% in the probiotic-fiber blend group compared to 5.04% in the placebo. By day 90, the probiotic-fiber blend group achieved a 26.73% reduction, significantly surpassing the 7.50% decrease in the placebo. Reductions in body fat percentage over time are illustrated in Figure 4. The probiotic-fiber blend group demonstrated a significantly greater reduction in body fat compared to the placebo group.

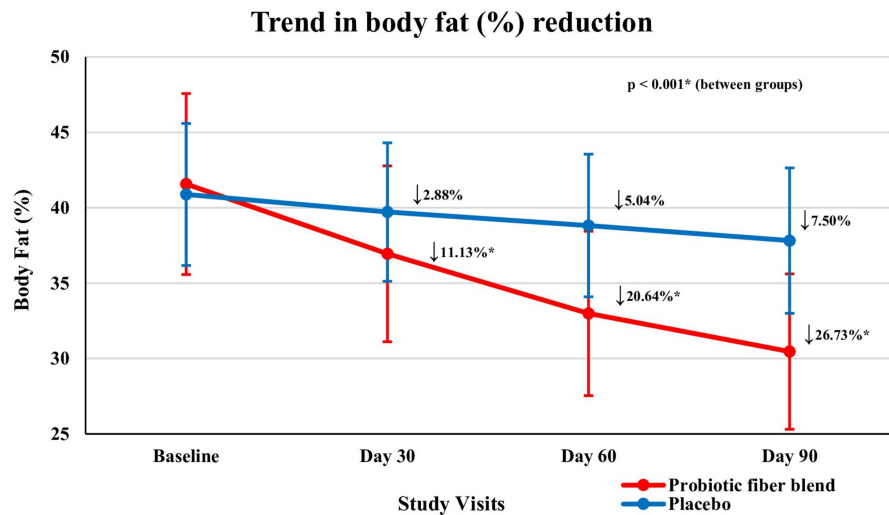


FIGURE 4: Reduction in body fat percentage from baseline to day 90.

MetS-Z score

The MetS-Z score is a composite index that quantifies metabolic health by integrating key parameters like waist circumference, triglycerides, HDL cholesterol, systolic blood pressure, and fasting plasma glucose, with a lower score indicating improved metabolic status. The MetS-Z score significantly improved in the probiotic-fiber blend group (n = 53), with a 54.02% reduction by day 90, compared to 18.88% in the placebo group (n = 51) ($p < 0.001$). Adherence to the diet and exercise diary was consistently higher in the probiotic-fiber blend group; however, the difference between groups was not statistically significant at day 90. Participants in both groups engaged in regular mild to moderate physical activity, which may have contributed to the observed weight reduction and metabolic benefits. Figure 5 demonstrates the changes in MetS-Z scores over the study period.

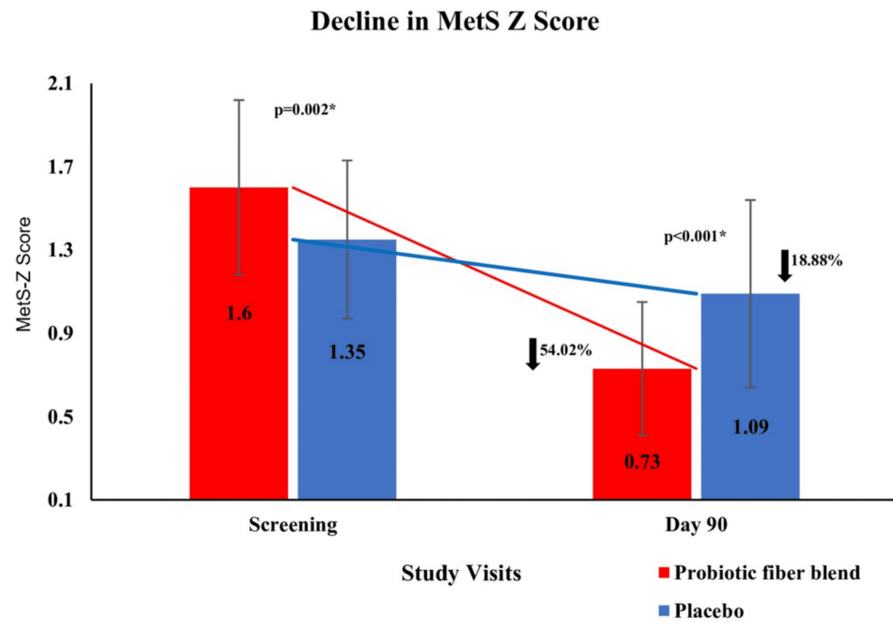


FIGURE 5: Graph depicting changes in the MetS-Z score over time.

Biochemical markers

Lipid parameters improved significantly by day 90 in the probiotic-fiber blend group (n = 55), with reductions in total cholesterol (15.26% vs. 6.62%, p = 0.002), triglycerides (25.75% vs. 6.65%, p < 0.001), and LDL (23.92% vs. 8.92%, p < 0.001), alongside a marked HDL increase (16.55% vs. 2.86%, p < 0.001). Table 2 summarizes the changes in key biochemical markers. These results highlight the probiotic-fiber blend intervention's strong potential in improving lipid profiles.

Parameters	Probiotic-fiber blend group		Placebo group		p-value (t-value/z-score) (within groups)		p-value (t-value/z-score) (between groups)	
	Screening	Day 90	Screening	Day 90	Probiotic-fiber blend	Placebo group	Screening	Day 90
Total cholesterol (mg/dL)	196.47 ± 25.69	166.49 ± 18.49	194.65 ± 25.19	181.77 ± 24.24	<0.001 (t-value = -7.424)	<0.001 (t-value = -3.785)	0.716 (t-value = 0.365)	0.002 (t-value = 3.226)
% change	15.26%		6.62%		-	-	-	-
Triglycerides (mg/dL)	211.43 ± 56.59	156.99 ± 40.09	194.21 ± 36.03	181.30 ± 38.90	<0.001 (z-score = -6.272)	0.004 (t-value = -3.009)	0.418 (z-score = 0.809)	<0.001 (t-value = 4.774)
% change	25.75%		6.65%		-	-	-	-
HDL (mg/dL)	39.78 ± 4.95	46.37 ± 8.19	38.02 ± 4.91	39.11 ± 6.54	<0.001 (t-value = 6.877)	0.240 (t-value = 1.189)	0.072 (t-value = 1.820)	<0.001 (t-value = -4.148)
% change	16.55%		2.86%		-	-	-	-
LDL (mg/dL)	117.63 ± 19.08	89.49 ± 14.75	118.47 ± 24.68	107.90 ± 24.41	<0.001 (t-value = -8.536)	0.004 (t-value = -2.975)	0.847 (t-value = -0.193)	<0.001 (t-value = 3.631)
% change	23.92%		8.92%		-	-	-	-

TABLE 2: Changes in biochemical markers from baseline to day 90.

Data are presented as the mean ± SD (percent change). Within-group comparisons were performed using the Student t-test (dependent) and Wilcoxon signed-rank test, and between-group comparisons were conducted using the Student t-test (independent) and Mann-Whitney U test. Statistical significance was set at $p < 0.05$. The t-value represents the results of dependent and independent Student t-tests, and the z-score represents Wilcoxon and Mann-Whitney U test results.

SD: standard deviation; HDL: high-density lipoprotein; LDL: low-density lipoprotein

Digestive health, quality of life, and stress

The probiotic-fiber blend group ($n = 53$) demonstrated significant improvements in digestive health and appetite compared to the placebo ($n = 51$) over 90 days. Acidity severity decreased by 91.67% in the probiotic-fiber blend group vs. 24.07% in the placebo ($p = 0.037$), with nearly 2.5 times more participants reporting complete symptom resolution (49 vs. 20). Bloating reduction was substantially greater in the probiotic-fiber blend group (92.19% vs. 39.39%, $p < 0.001$), while placebo participants showed inconsistent results with only five becoming symptom-free. Bowel movement normalization reached 90% in the probiotic-fiber blend group, compared to 37.84% in the placebo ($p < 0.001$).

Cravings declined significantly by 91.96% in the probiotic-fiber blend group ($n = 53$) vs. 8.80% in the placebo ($n = 51$) ($p < 0.001$), highlighting enhanced appetite regulation. Hunger scores dropped by 95.57% in the probiotic-fiber blend group vs. only 0.79% in the placebo ($p < 0.001$), while satiety improved by 386.60% in the probiotic-fiber blend group with no significant change in the placebo ($p < 0.001$).

The IWQOL-Lite assessment demonstrated statistically significant improvements in quality of life parameters in the probiotic-fiber blend group ($n = 53$) compared to the placebo group ($n = 51$) by day 90. Physical function scores improved by 79.97% vs. 16.16%, self-esteem by 81.59% vs. 12.81%, and sexual life by 27.40% vs. 0.55%, confirming the probiotic-fiber blend intervention's superiority. Public distress decreased by 44.33% vs. 11.14%, while the work-related quality of life improved significantly by 68.42% vs. 0.89%, further emphasizing the probiotic-fiber blend intervention's broad impact.

The PSS-10 evaluation indicated a statistically significant and greater stress reduction in the probiotic-fiber blend group ($n = 53$) (37.62%) compared to the placebo ($n = 51$) (17.80%), confirming the intervention's efficacy in alleviating perceived stress over 90 days.

Tables 3-5 present data on digestive health improvements, quality of life scores, and perceived stress levels, respectively. By day 90, significant ($p < 0.001$ for all comparisons) improvements were observed in the probiotic-fiber blend group ($n = 53$) across these measures and overall metabolic well-being, reinforcing its potential for effective weight management and enhanced quality of life.

Visits	Probiotic-fiber blend group	Placebo group	z-score (within groups)		p-value (z-score) (between groups)
			Probiotic-fiber blend group	Placebo group	
Acidity¹					
Screening	0.91 ± 0.86	1.06 ± 0.81	-	-	0.379 (z-score = -0.884)
Day 30	0.17 ± 0.38*	0.80 ± 0.75	z-score (-4.468)	z-score (-1.192)	0.101 (z-score = 1.642)
Day 60	0.11 ± 0.32*	0.98 ± 0.68	z-score (-4.503)	z-score (-0.678)	<0.001 (z-score = 3.596)
Day 90	0.08 ± 0.27*	0.80 ± 0.75	z-score (-4.537)	z-score (-1.192)	0.037 (z-score = 2.091)
Bloating²					
Screening	1.21 ± 0.88	1.29 ± 1.01	-	-	0.881 (z-score = 0.150)
Day 30	0.43 ± 0.54*	1.84 ± 0.86	z-score (-4.445)	z-score (-3.266)	<0.001 (z-score = 5.621)
Day 60	0.30 ± 0.46*	1.63 ± 0.72	z-score (-4.697)	z-score (-2.197)	<0.001 (z-score = 5.322)
Day 90	0.09 ± 0.30*	1.80 ± 0.85	z-score (-5.306)	z-score (-3.111)	<0.001 (z-score = 6.528)
Bowel movement³					
Screening	0.94 ± 0.72	0.73 ± 0.63	-	-	0.159 (z-score = 1.414)
Day 30	0.62 ± 0.71	0.86 ± 0.72	z-score (-1.882)	z-score (-0.879)	0.029 (z-score = 2.182)
Day 60	0.26 ± 0.45*	0.80 ± 0.60	z-score (-4.337)	z-score (-0.549)	<0.001 (z-score = 3.609)
Day 90	0.09 ± 0.30*	0.45 ± 0.58*	z-score (-5.092)	z-score (-2.403)	<0.001 (z-score = 3.521)
Cravings⁴					
Screening	2.11 ± 0.38	2.45 ± 0.61	-	-	0.009 (z-score = -2.617)
Day 30	0.87 ± 0.65*	2.24 ± 0.71	z-score (-5.968)	z-score (-1.425)	<0.001 (z-score = 4.922)
Day 60	0.32 ± 0.47*	2.20 ± 0.63*	z-score (-6.334)	z-score (-2.199)	<0.001 (z-score = 7.302)
Day 90	0.17 ± 0.38*	2.24 ± 0.71	z-score (-6.275)	z-score (-1.425)	<0.001 (z-score = 7.666)
Hunger⁵					
Screening	7.66 ± 0.98	7.49 ± 1.08	-	-	0.459 (z-score = 0.738)
Day 30	4.89 ± 0.75*	6.29 ± 0.67*	z-score (-6.275)	z-score (-4.987)	<0.001 (z-score = 5.751)
Day 60	2.36 ± 0.48*	7.29 ± 0.83	z-score (-6.334)	z-score (-0.821)	<0.001 (z-score = 8.664)
Day 90	0.34 ± 0.55*	7.43 ± 0.94	z-score (-6.334)	z-score (-0.203)	<0.001 (z-score = 8.785)
Satiety⁶					
Screening	1.83 ± 0.85	1.88 ± 0.84	-	-	0.741 (z-score = -0.335)

Day 30	4.49 ± 0.58*	2.53 ± 0.50*	z-score (-6.334)	z-score (-3.800)	<0.001 (z-score = -7.198)
Day 60	7.17 ± 0.75*	1.76 ± 0.68	z-score (-6.334)	z-score (-0.946)	<0.001 (z-score = -8.785)
Day 90	8.91 ± 0.56*	1.88 ± 0.77	z-score (-6.334)	z-score (-0.098)	<0.001 (z-score = -8.785)

TABLE 3: Digestive health improvements.

Data are presented as the mean ± SD. Within-group comparisons were performed using the Wilcoxon signed-rank test, and between-group comparisons were conducted using the Mann-Whitney U test. Statistical significance was set at $p < 0.05$. Symptoms 1, 2, 3, and 4 were assessed using a four-point ordinal scale, while symptoms 5 and 6 were assessed using an 11-point numerical rating scale. * represents significant values. The z-score represents Wilcoxon and Mann-Whitney U test results.

SD: standard deviation

Parameters	Probiotic-fiber blend group		Placebo group		p-value (t-value/z-score) (within groups)		p-value (t-value/z-score) (between groups)	
	Screening	Day 90	Screening	Day 90	Probiotic-fiber blend group	Placebo group	Screening	Day 90
Physical function	41.74 ± 1.98	8.36 ± 0.88	41.86 ± 3.08	35.10 ± 1.94	<0.001 (z-score = 6.334)	<0.001 (t-value = 14.550)	0.802 (t-value = 0.251)	<0.001 (z-score = 8.785)
Self-esteem	26.34 ± 1.72	4.85 ± 1.01	26.02 ± 1.30	22.69 ± 1.26	<0.001 (z-score = 6.334)	<0.001 (z-score = -6.073)	0.159 (z-score = 1.414)	<0.001 (z-score = 8.785)
Sexual life	23.96 ± 1.74	17.40 ± 1.35	28.67 ± 1.60	28.51 ± 1.63	<0.001 (z-score = 6.334)	0.547 (t-value = -0.606)	<0.001 (t-value = 14.341)	<0.001 (z-score = 8.525)
Public distress	7.15 ± 0.69	3.98 ± 1.05	7.39 ± 0.72	6.57 ± 0.50	<0.001 (z-score = 6.334)	<0.001 (z-score = -4.509)	0.136 (z-score = -1.486)	<0.001 (z-score = 7.257)
Work	11.11 ± 0.78	3.51 ± 1.19	10.96 ± 0.89	10.86 ± 0.83	<0.001 (z-score = 6.334)	0.024 (t-value = -2.331)	0.401 (z-score = 0.842)	<0.001 (z-score = 8.785)

TABLE 4: IWQOL-Lite scores.

Data are presented as the mean ± SD. Within-group comparisons were performed using the Student t-test (dependent) and Wilcoxon signed-rank test, while between-group comparisons were conducted using the Student t-test (independent) and Mann-Whitney U test. Statistical significance was set at $p < 0.05$. The t-value represents the results of dependent and independent Student t-tests, and the z-score represents Wilcoxon and Mann-Whitney U test results.

IWQOL-Lite: Impact of Weight on Quality of Life-Lite; SD: standard deviation

Visits	Probiotic-fiber blend group	Placebo group	p-value (t-value/z-score) (within groups)		p-value (t-value/z-score) (between groups)	
			Probiotic-fiber blend group	Placebo group	Screening	Day 90
Screening	12.19 ± 2.14	12.45 ± 2.60	<0.001 (z-score = 6.156)	<0.001 (t-value = 6.563)	0.575 (t-value = -0.562)	<0.001 (z-score = -4.535)
Day 90	7.60 ± 2.33	10.24 ± 1.93				
% change	37.62%	17.80%	-		-	

TABLE 5: Assessment of changes in the Perceived Stress Scale-10 score.

Data are presented as the mean ± SD (percent change). Within-group comparisons were performed using the Student t-test (dependent) and Wilcoxon signed-rank test, while between-group comparisons were conducted using the Student t-test (independent) and Mann-Whitney U test. Statistical significance was set at $p < 0.05$. The t-value represents the results of dependent and independent Student t-tests, and the z-score represents Wilcoxon and Mann-Whitney U test results.

SD: standard deviation

Clinical Global Impression-Improvement

The CGI-I scale, a four-point Likert scale, evaluates the investigator’s perception of participants’ overall clinical improvement, ranging from 0 (worsened) to 3 (much improved). At day 90, the probiotic-fiber blend group (n = 53) exhibited significantly greater clinical improvement, with a CGI-I score of 2.49 ± 0.50 , indicating that most participants were categorized as improved to much improved. In contrast, the placebo group (n = 51) had a significantly lower score of 0.80 ± 0.41 , suggesting that the majority remained in the not improved to worsened category.

Vital signs

The probiotic-fiber blend group demonstrated a progressive and statistically significant reduction in systolic and diastolic blood pressure, with values remaining within physiological limits. Heart rate and respiratory rate exhibited minor changes with no clinically significant variations observed across the study. These findings reflect changes in vital signs from baseline to day 90.

AEs, tolerability, and compliance

AEs were mild and infrequent in both groups. Two participants (3.77%) in the probiotic-fiber blend group (n = 53) reported mild diarrhea, while one participant (1.96%) in the placebo group (n = 51) experienced mild constipation and another (1.96%) reported mild fever. All events resolved without intervention.

Tolerability was assessed using a predefined scoring system: 0: poor tolerability: severe AEs or SAE(s) requiring discontinuation of the study; 1: fair tolerability: moderate to severe AE(s) that subsided with or without medication but did not necessitate study discontinuation; 2: good tolerability: mild AEs related to the investigational product that subsided with or without medication; and 3: excellent tolerability: no AEs related to the investigational product.

All participants consistently reported good to excellent tolerability throughout the study period ($p < 0.001$). Compliance with the intervention was 100% (n = 104) among all participants.

These findings confirm the probiotic-fiber blend intervention’s efficacy and safety in weight reduction, metabolic health, digestive function, and quality of life improvements, supporting its potential as a strategy for obesity management.

Discussion

Summary of key findings

This randomized, double-blind, placebo-controlled clinical trial investigated the efficacy and safety of a combined probiotic and prebiotic probiotic-fiber blend formulation in obese adults compared to placebo over 90 days. The results demonstrated that daily supplementation significantly and progressively improved anthropometric measures, with reductions of 10.31 kg in body weight, 12.14% in BMI, 9.64% in waist circumference, and 26.73% in body fat percentage. Additionally, significant improvements were observed in

metabolic health markers and lipid profile, digestive function, perceived stress, and quality of life compared to the placebo group. On day 90, the probiotic-fiber blend group demonstrated significantly greater clinical improvement, with most participants categorized as improved to much improved, whereas the placebo group mostly remained not improved or worsened. These findings underscore the clinical potential of microbiome-targeted interventions as effective adjuncts to conventional obesity management strategies [8,9], reinforcing their role in metabolic and systemic health improvements.

Impact on anthropometric measures and obesity

Obesity is a complex, multifactorial condition influenced by metabolic, dietary, and microbiota-related factors. The significant reductions in body weight, BMI, waist and hip circumference, and body fat percentage observed in the probiotic-fiber blend group underscore the role of gut microbiota modulation in adiposity regulation [18].

Emerging evidence globally suggests that probiotic and prebiotic dietary fiber blends may positively influence metabolic outcomes through the modulation of the gut microbiome; however, definitive data, particularly in Indian populations, remains limited [19] and inconclusive [20,21], underscoring the need for further research in this demographic.

A double-blind, placebo-controlled trial in 180 individuals with abdominal overweight evaluated the effects of *Lactobacillus fermentum* strains K7-Lb1, K8-Lb1, and K11-Lb3, with or without acacia gum. The probiotic group demonstrated significant reductions in body weight, BMI, waist circumference, visceral adipose tissue, and liver steatosis grade (LSG), while the synbiotic further enhanced visceral fat reduction and improved constipation scores [22]. Similarly, a study on *B. breve* B-5 in overweight adults reported significant reductions in body fat mass and percentage by weeks eight and 12, alongside slight improvements in triglyceride and HDL cholesterol levels [23]. Furthermore, a 12-week trial of *L. gasseri* BNR17 in obese individuals showed significant decreases in waist and hip circumference, even in the absence of dietary modifications, reinforcing the role of probiotics in body composition improvements [24].

The observed metabolic benefits in our study may be attributed to the synergistic effects of probiotics and prebiotics in modulating gut microbiota composition, particularly by promoting beneficial bacteria such as *Bifidobacterium* and *Lactobacillus* and enhancing SCFA production [4]. SCFAs, particularly butyrate and propionate, play a pivotal role in regulating lipid metabolism, improving insulin sensitivity, and stimulating gut-derived satiety hormones such as GLP-1, glucose-dependent insulinotropic polypeptide (GIP), and peptide YY (PYY) [25-27]. These mechanisms align with the significant reductions in LDL cholesterol, triglycerides, and MetS-Z scores observed in the probiotic-fiber blend group, further supporting the role of gut microbiota-targeted interventions in metabolic health.

Overall, the findings of this study, along with supporting evidence from previous clinical trials, reinforce the growing recognition of probiotics in combination with prebiotics as promising strategies for improving body composition and metabolic parameters. By harnessing the gut microbiota's influence on adiposity regulation, these interventions offer a potential approach to obesity and metabolic syndrome management.

Effects on digestive health and appetite regulation

Gut microbiota modulation plays a critical role in digestive health and appetite regulation, as reflected in the significant improvements observed in bloating, acidity, and bowel movement frequency in the probiotic-fiber blend group. Probiotic supplementation has been shown to enhance gastrointestinal motility, strengthen gut barrier function, and promote microbiota diversity. Specific strains, such as *Bifidobacterium lactis* and *L. gasseri*, have been reported to improve gut motility and barrier integrity by modulating tight junction proteins and reducing gut permeability [28,29]. Additionally, *L. reuteri* has been linked to increased gut serotonin production, a key regulator of intestinal peristalsis and motility [30]. These mechanisms may have contributed to the enhanced digestive function observed in our study.

Beyond digestive health, the probiotic-fiber blend group exhibited increased satiety and reduced hunger scores, suggesting that gut microbiota modulation influenced appetite regulation via SCFA signaling and gut-derived peptides such as GLP-1 and PYY [25]. The increased prevalence of *Bifidobacterium* and *Lactobacillus* strains, known for their anti-inflammatory and gut-protective effects, may have played a pivotal role in these benefits [31].

Prebiotic fibers such as glucomannan and oligofructose further support appetite regulation by influencing satiety and systemic inflammation. Glucomannan, a water-soluble dietary fiber, expands in the stomach, inducing a prolonged feeling of fullness, while chromium has been shown to regulate insulin response and glucose metabolism.

Previous research supports our findings, demonstrating that fiber supplements and multistrain probiotics positively impact anthropometric measures, lipid profiles, and appetite regulation, reinforcing the metabolic and weight management benefits observed in the current study [32-34]. These findings align with existing evidence, emphasizing the role of microbiota-targeted interventions like probiotics and prebiotics

in optimizing gastrointestinal function and appetite control.

Quality of life and gut-brain axis connection

The significant improvements in perceived stress and quality of life scores observed in this study underscore the pivotal role of the gut-brain axis in both metabolic and psychological well-being. The gut microbiome plays a crucial role in modulating neurotransmitter production, stress response, and cognitive function, primarily via interactions with the HPA axis [35]. Probiotic strains, particularly from the *Lactobacillus* and *Bifidobacterium* genera, have demonstrated anxiolytic and antidepressant-like effects by reducing cortisol levels and modulating neuroinflammatory pathways [36]. These findings align with the growing body of evidence supporting the therapeutic potential of psychobiotics probiotics that positively influence mental well-being through microbiota modulation.

The current study highlights the integral link between gut microbiota, metabolic health, and psychological well-being. Probiotic supplementation has been shown to enhance stress resilience and mood regulation, reinforcing the gut-brain axis's role in mental health. In our study, improvements in IWQOL-Lite scores across multiple domains—physical function (79.97%), self-esteem (81.59%), sexual life (27.40%), public distress (44.33%), and work-related quality of life (68.42%)—demonstrate the broad-ranging benefits of gut microbiota modulation. Additionally, the significant reduction in perceived stress scores, alongside improvements in metabolic health and digestive function, further supports the efficacy of this intervention.

These findings reinforce the critical interplay between the gut and brain in regulating stress, mood, and overall well-being. By enhancing both metabolic function and psychological resilience, microbiota-targeted interventions offer a promising approach to holistic health optimization.

Strengths and limitations

A major strength of this study is its rigorous randomized, double-blind, placebo-controlled design, ensuring high internal validity. The comprehensive assessment of anthropometric, metabolic, digestive, and quality of life parameters offers a holistic evaluation of the intervention's impact. Additionally, the high compliance rate and excellent tolerability reinforce the feasibility and safety of microbiome-based interventions in obesity management.

While this 90-day study demonstrated promising metabolic and weight-related improvements, further research could strengthen these findings by exploring long-term sustainability. Future studies should extend the follow-up period to 6–12 months to evaluate long-term sustainability, as previous research has shown that microbiota composition and metabolic benefits can take several months to stabilize post-intervention. Such extended follow-up periods would offer valuable insights into the persistence and stabilization of these health benefits over time, enhancing the overall understanding of long-term efficacy [37,38].

Future research directions

To expand on these findings, ongoing research is exploring the effects of post-intervention discontinuation and conducting a six-month intervention trial to evaluate gut microbiome composition and GLP-1 levels. The methodology will include microbiome sequencing, biomarker analysis, and extended follow-ups to assess the persistence of intervention benefits, the persistence of benefits post-supplementation, and the role of specific microbial taxa in energy homeostasis and metabolic regulation.

Conclusions

This clinical trial demonstrates the significant efficacy and safety of probiotic-fiber blend in promoting weight loss and other anthropometric measures, enhancing metabolic health and lipid metabolism, digestive function, and quality of life in obese individuals. These findings suggest that microbiota-targeted interventions offer a promising strategy for obesity and metabolic syndrome management, reinforcing the gut-brain axis's role in metabolic and mental health. By modulating gut microbiota, probiotics and prebiotics not only enhance digestion but also influence neuroendocrine pathways regulating stress, satiety, and metabolic balance. The intervention was well-tolerated, with excellent compliance and minimal AEs, supporting its safety and clinical relevance.

This study provides compelling evidence that targeted gut modulation offers an effective, integrative approach to sustainable weight management and metabolic optimization. Future research should explore long-term efficacy, microbiome profiling, and precision nutrition to enhance personalized treatment strategies, paving the way for microbiota-driven solutions in combating obesity and metabolic disorders.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the

work.

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Disclosures

Human subjects: Consent for treatment and open access publication was obtained or waived by all participants in this study. Institutional Ethics Committees of Lokmanya Medical Research Center, Pune, and KIMS Deemed to be University, Karad issued approval ECR/175/Inst/MH/2013/RR-19 and ECR/307/Inst/MH/2013/RR-20, respectively. The study was registered under the Clinical Trial Registry of India (CTRI/2024/07/070532). **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All the trial-related expenses and investigational product expenses were borne by Seven Turns Pvt. Ltd. We would like to acknowledge the support of Mprex Healthcare Pvt. Ltd., Pune, as a clinical research organization for this trial. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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