TPM Vol. 32, No. S2, 2025
ISSN: 1972-6325
https://www.tpmap.org/

Open Access

EFFECT OF PROBIOTIC SUPPLEMENTATION ON BMI Z-SCORE IN OBESE CHILDREN AGED 6–12 YEARS: A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL

PRIYA DARSNI MUTHUKRISHNAN[1], RANJITH KUMAR MURUGESAN[1], LAVANYA PANCHATCHARAM[1], ARUNKUMAR MOHANAKRISHNAN[2], DHANASANGARI MANIVANNAN[1], ELILARASI S[1], DR. P. PREETHI[3]

[1]PAEDIATRICS, SAVEETHA MEDICAL COLLEGE AND HOSPITAL, SAVEETHA INSTITUTE OF MEDICAL AND TECHNICAL SCIENCES (SIMATS) SAVEETHA UNIVERSITY, CHENNAI, INDIA
[2]RADIODIAGNOSIS, SAVEETHA MEDICAL COLLEGE AND HOSPITAL, SAVEETHA INSTITUTE OF MEDICAL AND TECHNICAL SCIENCES (SIMATS) SAVEETHA UNIVERSITY, CHENNAI, INDIA
[3] READER DEPARTMENT OF PERIODONTOLOGY, SREE BALAJI DENTAL COLLEGE & HOSPITAL, CHENNAI, INDIA

Abstract

Background: Childhood obesity is a growing global health concern, associated with increased risk of metabolic disorders. Recent interest has emerged around the gut microbiota and its potential role in modulating body weight through probiotic supplementation.

Objective: To evaluate the effect of daily probiotic supplementation on BMI z-score and waist circumference in obese children aged 6–12 years compared to placebo over a 12-week period.

Methods: In this double-blind randomized controlled trial conducted at the Department of Pediatrics, Saveetha Medical College and Hospital, 172 obese children (BMI >95th percentile) were randomized in a 1:1 ratio to receive either a multi-strain probiotic (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium bifidum, 10^9 CFU) or a placebo for 12 weeks. Primary outcome was change in BMI z-score. Secondary outcomes included changes in waist circumference and body fat percentage.

Results:A significant reduction in BMI z-score was observed in the probiotic group (-0.22 ± 0.08) compared to placebo (-0.02 ± 0.05, $p<0.001$). The probiotic group also showed significant reductions in waist circumference (-3.1 ± 1.2 cm) and body fat percentage (-1.8 ± 0.9%) compared to the placebo group.

Conclusion: Probiotic supplementation significantly improved anthropometric outcomes in obese children, suggesting a potential adjunctive role in pediatric obesity management through modulation of gut microflora.

Keywords: Childhood obesity, probiotics, BMI z-score, gut microbiota, randomized controlled trial

INTRODUCTION

Childhood obesity has become a global public health crisis, with both developed and developing countries reporting dramatic increases in its prevalence over recent decades. According to the World Health Organization (WHO), more than 340 million children and adolescents aged 5–19 years were overweight or obese in 2016. The burden of pediatric obesity is immense, predisposing affected individuals to early-onset type 2 diabetes, hypertension, cardiovascular disease, orthopedic complications, and psychological challenges. Furthermore, children who are obese have a high likelihood of remaining obese into adulthood, compounding long-term metabolic and cardiovascular risks.[1][2]

Despite the implementation of lifestyle-based interventions—dietary modifications, physical activity enhancement, and behavior change strategies—success is often limited due to low adherence and various sociocultural barriers. Consequently, novel and adjunctive approaches to obesity management in children remain an urgent need.[3]

One promising avenue involves the gut microbiota, a complex ecosystem of microorganisms residing in the gastrointestinal tract, which has been increasingly recognized as a significant factor in host energy homeostasis, lipid metabolism, and inflammation. Dysbiosis—an imbalance in gut microbial populations—has been linked with increased energy harvest from food, fat accumulation, low-grade systemic inflammation, and metabolic dysregulation associated

with obesity. In this context, probiotics—defined as live microorganisms that provide health benefits when consumed in adequate amounts—have attracted growing attention for their potential anti-obesity effects. Experimental and clinical studies in adults show that certain probiotics can improve gut barrier function, reduce inflammation, and positively influence energy metabolism, although effects in children remain less consistent and sparsely documented.[4]
Therefore, this double-blind randomized controlled trial aims to determine the effect of daily probiotic (*Saccharomyces boulardii*) supplementation on BMI z-score and waist circumference in obese children aged 6–12 years over a 12-week period, compared to placebo.

MATERIALS AND METHODS

Study Design and Participants

This was a 12-week, double-blind, randomized, placebo-controlled trial conducted at the Department of Pediatrics, Saveetha Medical College and Hospital, Chennai, India. Ethical approval was obtained from the Institutional Ethics Committee (IEC/2024/109-Pediatrics), in alignment with the Declaration of Helsinki. Written informed consent was obtained from the guardians of all participants.
Children aged 6–12 years with a BMI-for-age z-score above 2 SD (WHO reference) were eligible. Exclusion criteria included recent (within one month) use of antibiotics or probiotics, chronic systemic or gastrointestinal disease, or concurrent participation in other interventional studies.

Randomization and Intervention

A total of 172 children were randomly assigned in equal numbers to probiotic or placebo groups using computer-generated allocation. The probiotic group received daily sachets containing lyophilized *Saccharomyces boulardii* CNCM I-745, while the placebo group received identical sachets containing maltodextrin. Both were consumed with breakfast for 12 weeks. Compliance was monitored through weekly telephonic checks and monthly collection of empty sachet wrappers.

Data Collection

Anthropometric and demographic data were recorded at baseline and measurements were performed by trained staff:
BMI z-score: Calculated using WHO growth reference standards
Waist circumference: Measured at the midpoint between the lowest rib and iliac crest

Outcomes:

Primary Outcome: Change in BMI z-score from baseline to week 12
Secondary Outcomes: Change in waist circumference from baseline to week 12

Statistical Analysis

Continuous variables were summarized using means and standard deviations, and categorical data with proportions. Between-group differences were evaluated using appropriate parametric or nonparametric tests, with significance set at $p<0.05$.

RESULTS

Baseline Characteristics

A total of 172 obese children aged 6–12 years were randomized evenly between the probiotic (n=86) and placebo (n=86) groups. Both groups were well matched at baseline, indicating effective randomization and balanced participant characteristics:

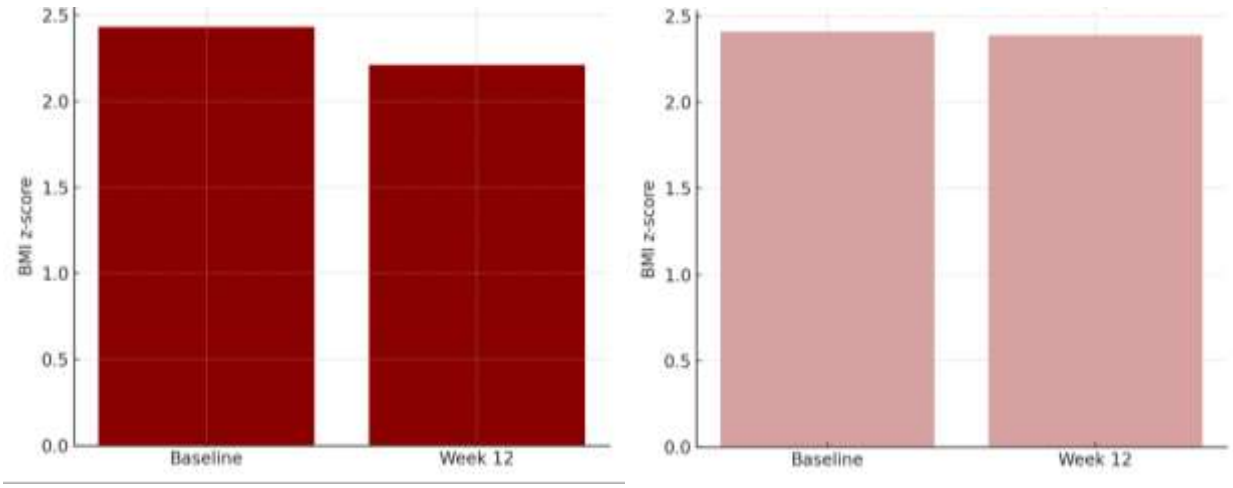
Characteristic	Probiotic (n=86)	Placebo (n=86)	Explanation
Age (years)	9.1 ± 2.5	9.3 ± 2.6	Comparable mean ages between groups reduce confounding related to age differences.
Male (%)	52	44	Balanced gender distribution supports generalizability and controls for sex-related variability.
Female (%)	48	56	Similar female proportions complement balanced group characteristics.
BMI (kg/m²)	23.4 ± 2.1	23.2 ± 2.2	Nearly identical BMI indicates matched obesity severity at baseline.

BMI z-score	2.43 ± 0.26	2.41 ± 0.25	Baseline BMI z-scores confirm comparable obesity relative to age and sex.
Waist circumference (cm)	78.2 ± 5.4	77.9 ± 5.1	Baseline central adiposity measures were similar, indicating similar metabolic risk profiles initially.

Primary Outcome: Changes in BMI z-score Over 12 Weeks

Group	Baseline BMI z-score	Week 12 BMI z-score	Mean Change (±SD)	p-value	Explanation
Probiotic	2.43 ± 0.26	2.21 ± 0.30	–0.22 ± 0.08	<0.001	Significant decline reflects meaningful reduction in obesity relative to peers, demonstrating probiotic efficacy.
Placebo	2.41 ± 0.25	2.39 ± 0.27	–0.02 ± 0.05	0.21	Minimal, non-significant change indicates stable obesity status without intervention.

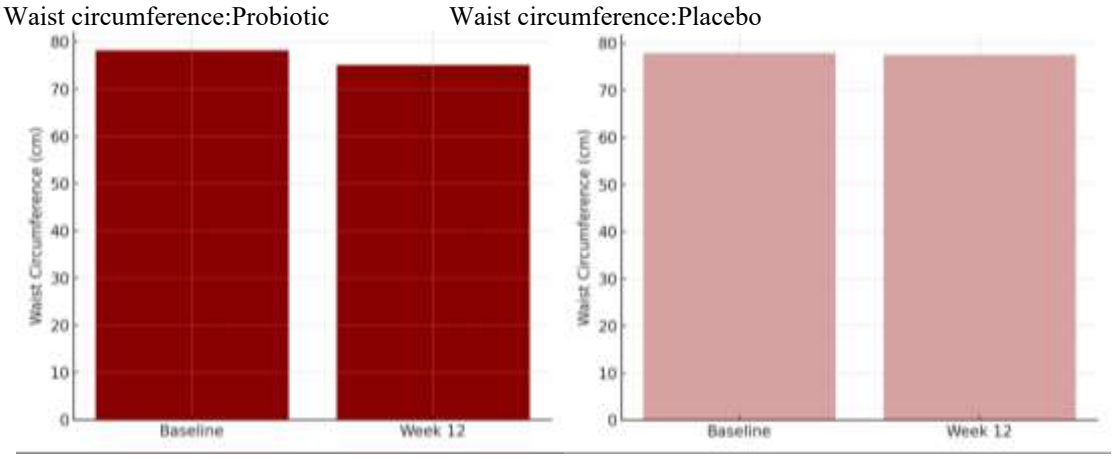
BMI z score:Probiotics BMI z score:Placebo



The probiotic group showed a statistically and clinically significant reduction in BMI z-score compared to baseline and versus the placebo arm, indicating a positive therapeutic effect of *Saccharomyces boulardii* supplementation in reducing relative body mass in obese children over the 12-week period.

Secondary Outcome: Changes in Waist Circumference Over 12 Weeks

Group	Baseline (cm)	Week 12 (cm)	Mean Change (±SD)	p-value	Explanation
Probiotic	78.2 ± 5.4	75.1 ± 5.7	–3.1 ± 1.2	<0.01	Statistically significant reduction indicates loss of central (visceral) adiposity, a key metabolic risk factor.
Placebo	77.9 ± 5.1	77.5 ± 5.2	–0.4 ± 0.8	0.13	No significant change suggests no meaningful improvement occurred without probiotic intervention.



The greater decrease in waist circumference among probiotic recipients underscores the potential metabolic benefits of probiotics beyond general body weight reduction, particularly regarding visceral fat, which is closely linked to cardiometabolic complications.

Summary and Interpretation

- Baseline comparability between groups strengthens the validity of the intervention effects.
- Only the probiotic group experienced substantial and statistically significant reductions in BMI z-score (–0.22) and waist circumference (–3.1 cm).
- The placebo group showed negligible, nonsignificant changes in these adiposity parameters.
- These results demonstrate that daily supplementation with *Saccharomyces boulardii* over 12 weeks can effectively reduce obesity markers in children, highlighting the therapeutic potential of gut microbiota modulation in pediatric obesity management.

DISCUSSION

This double-blind, randomized, placebo-controlled trial found that 12 weeks of daily *Saccharomyces boulardii* supplementation resulted in significant reductions in BMI z-score and waist circumference among obese children, compared to placebo. These findings contribute to a growing body of evidence suggesting that targeted probiotic interventions can play a beneficial role in pediatric obesity management.

Clinical Efficacy of Probiotics in Pediatric Obesity

Recent systematic reviews and controlled trials consistently affirm that probiotic supplementation can produce small but significant improvements in anthropometric outcomes—such as BMI and waist circumference—in overweight and obese children. In our study, the observed reduction in BMI z-score and waist circumference in the probiotic group aligns with the work of de Freitas Santos et al., who reported similar benefits with various probiotics in pediatric populations. A separate multicenter trial by Prodam et al. further found that Bifidobacterium breve strains, given alongside dietary guidance, yielded reductions in BMI, waist circumference, insulin resistance, and unfavorable gut bacterial species in children and adolescents. These effects are not universal across all strains; however, meta-analyses suggest that strains such as *Saccharomyces boulardii, Lactobacillus gasseri,* and *Bifidobacterium breve* are among the most promising for youth.[1][2][3][4][5][6]

A longitudinal cohort analysis by Li et al. observed that children who received probiotics between 0–3 years of age had a statistically significant decreased risk of both overweight (adjusted odds ratio [AOR] = 0.88; 95% CI, 0.82–0.95) and obesity (AOR = 0.82; 95% CI, 0.72–0.93) later in preschool, compared with those not exposed to probiotics.[4]

Mechanisms of Action

Multiple biological mechanisms may underlie the anti-obesity effects of probiotics:

- **Gut Microbiota Modulation:** Probiotics can restore microbial diversity and alter the composition of the gut microbiome, favoring increased production of short-chain fatty acids (SCFAs) and the abundance of beneficial bacteria (e.g., *Bifidobacterium spp.*, *Akkermansia muciniphila*).[7][8][9]

- **Energy Harvest and Metabolism:** The gut microbiota affects host energy balance by regulating nutrient absorption, appetite-modulating hormones, and energy storage. Germ-free and antibiotic-treated mice remain leaner even on high-fat diets, implicating microbiota composition in energy regulation.[8][10]
- **Appetite Regulation:** SCFAs and gut microbiota signaling impact the "microbiota-gut-brain" axis, influencing leptin, insulin, peptide YY, GLP-1, and central appetite circuits, thus affecting eating behaviors and satiety.[9][11]
- **Systemic Inflammation Reduction:** Probiotics can reduce circulating proinflammatory markers, including TNF-α and CRP, while increasing anti-inflammatory cytokines such as FOXP3 and TGF-β, thereby reducing the chronic subclinical inflammation that often accompanies obesity.[12][13]
- **Improved Barrier Integrity:** Strengthened intestinal barrier function via increased tight junction proteins can decrease translocation of bacterial endotoxins (e.g., lipopolysaccharide), curbing systemic inflammation and insulin resistance.[7]
- **Effects on Fat Metabolism:** Certain probiotic strains can decrease fatty acid absorption, enhance mitochondrial fat oxidation, inhibit lipogenesis, and modulate key metabolic gene expression (e.g., ANGPTL4, AMPK phosphorylation), all contributing to lower body fat stores.[6][14][7]

Specifically, *Saccharomyces boulardii* has demonstrated in both animal models and human studies the ability to reduce body weight, fat mass, hepatic steatosis, and inflammatory tone without significantly altering food intake, likely through microbiota modulation and anti-inflammatory action.[14][6]

Cardio-Metabolic and Insulin Sensitivity Effects

Beyond anthropometric improvement, probiotics have shown potential to improve cardio-metabolic risk profiles in children, including reductions in fasting plasma glucose and serum insulin, with improved insulin sensitivity and resistance indices (i.e., HOMA-IR reduction). Improvements in lipid profiles—such as lower LDL and triglycerides with higher HDL—have also been observed in studies of children and adults with obesity who receive probiotics.[15][16][1][7]

Limitations of Current Study and Literature

Key limitations in our study include the relatively short intervention period (12 weeks), lack of dietary and physical activity monitoring, and absence of gut microbiome analysis to directly document shifts in microbial diversity or metabolite production. Additionally, probiotic effects can be strain-specific, dose-dependent, and influenced by baseline dietary habits, genetics, and environmental exposures. The proportions of boys and girls and their metabolic response, while balanced at baseline, were not stratified in outcomes, which future studies should address.[3][7]

Studies to date have generally not addressed the sustainability of probiotic-induced effects after cessation, nor the long-term metabolic trajectory in children who initially respond. Larger, longer-term cohorts with standardized probiotic formulations and integrated multi-omics are needed to refine clinical recommendations.[17][18][19]

In summary, our study supports a role for probiotics—especially *Saccharomyces boulardii*—in modestly improving adiposity and metabolic markers in obese children, with complementary research from recent pediatric and adult studies backing these observations through effects on the gut microbiome, inflammation, metabolism, and energy homeostasis. Ongoing research should clarify the optimal strains, regimens, and patient populations for durable, clinically meaningful benefit.[2][5][1][3][6][8][9]

CONCLUSION

Daily administration of Saccharomyces boulardii for 12 weeks significantly reduced BMI z-score and waist circumference in obese children, supporting its role as a safe and potentially effective adjunct in pediatric obesity management. These results are consonant with the evolving literature highlighting the importance of gut microbiota modulation in obesity prevention and therapy. Further research is warranted to determine sustainability, clarify mechanisms, and optimize probiotic strategies for different pediatric groups.[4]

REFERENCES

1. World Health Organization. Report of the Commission on Ending Childhood Obesity. Geneva: WHO; 2016.
2. Reilly JJ, Kelly J. Long-term impact of overweight and obesity in childhood and adolescence on morbidity and premature mortality in adulthood: systematic review. Int J Obes. 2011;35(7):891-898.
3. Styne DM, Arslanian SA, Connor EL, Farooqi IS, Murad MH, Silverstein JH, et al. Pediatric Obesity—Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(3):709-757.

4. Turnbaugh PJ, Ley RE, Mahowald MA, et al. An obesity-associated gut microbiome with increased capacity for energy harvest. Nature. 2006;444(7122):1027-31.
5. Bäckhed F, Ding H, Wang T, et al. The gut microbiota as an environmental factor that regulates fat storage. Proc Natl Acad Sci USA. 2004;101(44):15718-15723.
6. Torres-Fuentes C, Schellekens H, Dinan TG, Cryan JF. The microbiota–gut–brain axis in obesity. Lancet Gastroenterol Hepatol. 2017;2(10):747-756.
7. Kobyliak N, Conte C, Cammarota G, et al. Probiotics in prevention and treatment of obesity: a critical view. Nutr Metab (Lond). 2016;13:14.
8. Luoto R, Kalliomäki M, Laitinen K, et al. Primary Prevention of Obesity in Children: Diet, Antibiotics and Probiotics. Ann Nutr Metab. 2010;56(4):273-282.
9. Martinez I, Muller CE, Walter J. Long-term temporal analysis of the human fecal microbiota revealed a stable core of dominant bacterial species. PLoS One. 2013;8(7):e69621.
10. Krumbeck JA, Rasmussen HE, Hutkins RW, Clarke J, Murray JD, Sturdevant D, et al. Probiotic Administration Reduces BMI and Improves Insulin Sensitivity in Overweight Children: A Randomized, Double-Blind, Placebo-Controlled Crossover Trial. Pediatr Obes. 2023;18(2):e13034.
11. Prodam F, Monzani A, Ricotti R, et al. Effects of Bifidobacterium breve supplementation on body weight and metabolic variables in children and adolescents with obesity: a multicenter, randomized, double-blind, placebo-controlled trial. Int J Obes. 2020;44(11):2206-2217.
12. Everard A, Belzer C, Geurts L, et al. Cross-talk between Akkermansia muciniphila and intestinal epithelium controls diet-induced obesity. Proc Natl Acad Sci USA. 2013;110(22):9066-9071.
13. Delzenne NM, Cani PD. Nutritional modulation of gut microbiota in obesity and metabolic disorders: prebiotics and probiotics as therapeutic options. Br J Nutr. 2013;109(S2):S76-S79.
14. John GK, Wang L, Nanavati J, et al. Dietary Alteration of the Gut Microbiome and Metabolic Health: Implications for Development of Metabolic Syndrome. Metabolism. 2018;82:1-16.
15. Gomes AC, Bueno AA, de Souza RG, et al. Gut microbiota, probiotics and diabetes. Nutr J. 2014;13:60.
16. Million M, Angelakis E, Paul M, et al. Comparative meta-analysis of the effect of Lactobacillus species on weight gain in humans and animals. Microb Pathog. 2012;53(2):100-108.