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EVALUTATING THE EFFICACY OF PROBIOTIC-ENRICHED NUTRITIONAL SUPPELEMENTS ON GUT HEALTH AND WEIGHT MANAGEMENT IN OBESE ADULT: A RANDOMIZED CONTROLLED TRIAL

Muhammad Tahir Habib[1], Afaq Ahmad[2], Khurram Saeed[3], Asma Qurban[4], Rida Chaudhry[5], Areej Badar[*6], Uswa Afzal[7]

[1]*Department of Nutrition and Food Services, Multan Institute of Kidney Diseases, Indus Hospital and Health Network*
[2]*Institute of Food Science and Nutrition, University of Sargodha*
[3]*Kohat University of Science & Technology, Department of Human Nutrition and Dietetics*
[4]*Department of Food and Nutrition, University of The Punjab (College of Home Economics)*
[5]*Dnstitute of Home Sciences, Faculty of Food, Nutrition and Home Sciences, University of Agriculture Faisalabad*
[*6]*Department of Food Science & Technology, National University of Medical Sciences*
[7]*Institute of Food and Nutritional Sciences, Pir Mehr Ali Shah Arid Agriculture University Rawalpindi*

[1]mrtahirhabib@gmail.com, [2]afaqfoodtechnologist300@gmail.com, [3]khurramktk22@gmail.com, [4]asmaqurbanali@gmail.com, [5]rida.ch161@gmail.com, [*6]areejbadar99@gmail.com, [7]uswaafzal24@gmail.com

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Corresponding Author: *
Areej Badar

Abstract

Background: *Obesity is a serious worldwide health issue, directly associated with changes in gut microbiota and higher rates of metabolic disorders.*

Objective: *The aim of this research was to assess the effectiveness of probiotic-supplemented nutritional supplements in enhancing gut health and weight management among obese adults.*

Methodology: *A randomized controlled trial for 12 weeks was carried out among 100 obese adults, aged 25–55 years, who were randomized to be given either a probiotic or a placebo supplement, with measurements of gut microbiota, anthropometric parameters, and metabolic indices before and after intervention.*

Results: *Members of the probiotic group experienced marked reductions in body weight, BMI, and fat mass, with better blood glucose and lipid profiles; analysis of gut contents demonstrated higher levels of Lactobacillus and Bifidobacterium species.*

Conclusion: *Probiotic supplementation could be an effective and safe addition to standard obesity management by promoting gut microbiota and metabolic health.*

INTRODUCTION

Obesity is now an international health crisis where more than a billion individuals are obese as of 2022, and estimates suggest that this figure can increase exponentially up to 2050 (NCD Risk Factor Collaboration, 2024). The illness is deeply associated with various chronic conditions, such as cardiovascular disease, type 2 diabetes, and cancer (Hruby & Hu, 2015). Old diagnostic criteria, e.g., BMI, are now complemented with others such as waist circumference and the presence of metabolic complications (Guh et al., 2009). Central to all debates regarding obesity is the function

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of the gut microbiota. The human intestine harbors trillions of microbes that play roles in metabolic homeostasis, immune regulation, and energy harvesting (Turnbaugh et al., 2006). Dysbiosis—an imbalance of such microbial communities—has been shown to contribute to the pathogenesis of obesity (Ley et al., 2006). Short-chain fatty acids (SCFAs), specifically acetate, propionate, and butyrate, are metabolic byproducts of microbial fermentation and have important functions in energy metabolism and appetite control (Delzenne et al., 2011).

As such a microbial-metabolic interaction, probiotics then present as an interesting intervention into obesity treatment. Probiotics are simply defined as "live microorganisms which, when consumed in sufficient numbers, have health benefits" (Hill et al., 2014). Various randomized controlled trials have shown the promise of certain strains like Lactobacillus gasseri and Lactobacillus rhamnosus in lowering adiposity and enhancing metabolic well-being (Kadooka et al., 2010; Sanchez et al., 2014). Nevertheless, heterogeneity in study design, probiotic strain, dosing, and population is still curbing definitive conclusions (Borgeraas et al., 2018). Recent meta-analyses also substantiate the beneficial role of probiotics in body weight modulation, albeit not entirely consistent in results (Zhang et al., 2016; John et al., 2018). Furthermore, contemporary clinical recommendations advise against the use of probiotics in an indiscriminate manner, with the necessity for specific interventions backed by solid evidence (Walters et al., 2014).

The purpose of this study is to assess the effectiveness of a probiotic-fortified dietary supplement in enhancing gut microbiota profile and weight loss in obese adults. It is expected that participants who take the probiotic supplement will show substantial gut health parameter improvements and quantifiable decreases in BMI and fat mass compared to those taking a placebo.

Aims and Objectives:

1. Determine alterations in gut microbiota composition in the probiotic versus placebo groups at 12 weeks.
2. Compare the effect of probiotic supplementation on body weight, BMI, and fat mass.
3. Assess improvements in metabolic indices, including fasting blood glucose and lipid profile (HDL, LDL, triglycerides).
4. Monitor gastrointestinal well-being for side effects or tolerability problems during the intervention.
5. Investigate the relationship between changes in gut microbiota and clinical outcomes (e.g., weight loss, metabolic improvement).

Literature Review

Global Impact of obesity

Obesity has been recognized as an international epidemic with major public health implications. Obesity is a BMI of 30 or higher according to the World Health Organization (WHO), and it carries increased risk of several chronic conditions, such as type 2 diabetes, cardiovascular disease, and cancer (Hruby & Hu, 2015). Prevalence of obesity is still growing globally, and recent figures show that over 1.9 billion adults are overweight and over 650 million are obese (NCD Risk Factor Collaboration, 2024). Growing levels of obesity have led to increased research in looking for interventions, particularly for addressing metabolic dysfunction secondary to obesity (Guh et al., 2009).

Metabolic Regulation and Gut Microbiota

Human gut microbiota consisting of trillions of microbes are involved in keeping the metabolic homeostasis in place and governing the energy balance. The past research has identified that the composition and diversity of gut microbiota strongly determine the metabolism of the host, which comprises energy harvesting, fat accumulation, and sensitivity to insulin (Turnbaugh et al., 2006; Ley et al., 2006). Disruption of the gut microbiota or dysbiosis is implicated in multiple metabolic disorders, such as obesity (Cani et al., 2007). Gut microbes enable the fermentation of dietary fiber to short-chain fatty acids (SCFAs), which stimulate fat oxidation and inhibit fat storage (den Besten et al., 2013). Thus, the restoration of a stable gut microbiota can provide a novel intervention for obesity and associated metabolic disorders.

Gut Health and Probiotics

Probiotics, which are live microorganisms that provide health benefits when ingested in sufficient

Frontier in Medical & Health Research

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amounts, have come into the spotlight for their potential to enhance gut health. Some of these probiotic strains, especially from the genera Lactobacillus and Bifidobacterium, have shown capability to restore the microbial equilibrium within the gut and encourage digestive well-being (Hill et al., 2014). In clinical trials, probiotics improved symptoms of irritable bowel syndrome, inflammatory bowel disease, and other gastrointestinal conditions (Maggio et al., 2020). Probiotics can also increase gut barrier integrity, decrease intestinal permeability, and regulate the immune system (Kim et al., 2017).

Probiotics in Obesity Management

Previous investigated the putative role of probiotics for weight management. Numerous randomized controlled trials (RCTs) reported that probiotic intake can achieve moderate weight and fat mass decreases. For instance, Kadooka et al. (2010) established that Lactobacillus gasseri SBT2055 supplementation led to decreased abdominal fat in obesity. In a similar manner, other research by Sanchez et al. (2014) revealed that Lactobacillus rhamnosus, if supplemented, resulted in notable weight loss among overweight and obese women. The processes behind such impacts are thought to comprise alterations in the gut microbiota population, increased energy expenditure, and suppression of inflammation (Koh et al., 2018).

In addition, a meta-analysis and systematic review by Zhang et al. (2016) reported that probiotics, especially those with Lactobacillus species, were linked to a decrease in BMI and fat mass. The findings of these studies have, however, been inconsistent, with some trials reporting no influence on metabolic parameters or body weight (John et al., 2018). This is due to heterogeneity in the types of probiotic strains, dosages, and study designs

Weight Loss and Gut Microbiota

Experiments examining the link between gut microbiota and weight loss have established that weight loss programs, such as dietary adjustment and probiotic supplementation, may result in alterations in microbial composition. For example, Ley et al. (2006) discovered that obese subjects had less gut bacterial diversity than lean subjects. After weight loss, however, this bacterial diversity improved, indicating that changes in microbes can contribute to weight control. Moreover, research by Cani et al. (2007) suggested that alterations in the composition of gut microbiota might have an impact on the host's metabolic reaction to obesity.

Other studies have also explored the relationship between the weight loss properties of certain probiotic strains. For instance, Lactobacillus gasseri decreased abdominal fat in human and animal models (Kadooka et al., 2010). Other researchers have reported that probiotics might modify the fat metabolism gene expression, increase the oxidation of fats, and inhibit adipogenesis (Sartor, 2008).

Tolerability of Probiotics and Safety

Although probiotics are regarded as safe, their administration should be strictly monitored in susceptible populations. The majority of studies have indicated negligible side effects with probiotic supplementation, such as transient gastrointestinal upset in the form of bloating or gas (Lemke et al., 2018). It is still unclear, however, about the long-term safety of probiotic supplementation, particularly at higher levels or in combination with other supplements. The American Gastroenterological Association (2019) recommends the cautious application of probiotics in immunocompromised patients or those with serious underlying health conditions

Methodology

Study Design

This study used a randomized controlled trial (RCT) design, which is deemed as the gold standard for assessing the effectiveness of interventions. The study was double-blinded, such that neither the participants nor the researchers were aware of the group to which the participants had been allocated (probiotic or placebo). This design reduced bias and ensured the reliability and validity of the findings. The trial was 12 weeks long.

Study Population

The population targeted in this study was obese adults between the ages of 18 and 50 years with a Body Mass Index (BMI) of 30 or higher. Participants were drawn from local health clinics and by community

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advertisements. Informed consent was received from all participants before enrollment.

Criteria

Inclusion Criteria	Exclusion Criteria
Adults between 18 and 50 years	Pregnant or lactating women
Body Mass Index (BMI) ≥ 30 kg/m²	Patients who were taking probiotics or prebiotics at recruitment
No history of gastrointestinal diseases, chronic illnesses, or use of medications that impact weight or gut microbiota (e.g., antibiotics, antidiabetics, or anti-obesity drugs)	Patients with severe gastrointestinal diseases (e.g., inflammatory bowel disease, celiac disease)
Willingness to participate and follow the study protocol	Those with serious metabolic disorders, such as uncontrolled diabetes or cardiovascular diseases

Intervention and Control Groups

The participants were randomly divided into either of two groups:

Probiotic Group:

Participants took a daily dose of a probiotic-fortified nutritional supplement with a particular strain or blend of strains (e.g., Lactobacillus gasseri, Lactobacillus plantarum, and Bifidobacterium bifidum). The probiotic supplement was chosen based on existing evidence that it may be effective in modulating gut microbiota and inducing weight loss. The daily dose was derived from the recommended therapeutic range for each strain, usually between 10^9 and 10^{10} CFU (colony-forming units).

Placebo Group:

The participants took a placebo supplement that was similar in packaging and appearance to the probiotic supplement but had no active ingredients. The placebo consisted of inactive products like maltodextrin.

Both intervention and placebo groups took their respective supplements for 12 weeks, with one capsule per day.

Primary Outcome Measures

The primary outcomes of this study included:

Gut Microbiota Composition Changes:

Stool samples taken at baseline (week 0) and completion of the intervention (week 12). The samples were examined using 16S rRNA gene sequencing to determine the diversity and relative abundance of microbial species in the gut. Emphasis is given to the abundance of Lactobacillus and Bifidobacterium species, which are frequently used in probiotic supplements.

Changes in Body Weight and BMI:

Weight and BMI assessed at baseline and at 12 weeks of intervention. Weight was obtained using a calibrated digital scale, and height was measured with a stadiometer to calculate BMI (kg/m²).

Alteration in Fat Mass:

Body composition, such as fat mass, was determined through bioelectrical impedance analysis (BIA). This method is not invasive and was carried out at baseline and during the intervention duration.

Secondary Outcome Measures

The secondary outcomes were:

Metabolic Parameters:

Blood drawn to measure metabolic parameters, such as:

Blood Glucose Levels:

Fasting blood glucose assessed with a regular glucometer.

Lipid Profile:

Total cholesterol, LDL cholesterol, HDL cholesterol, and triglyceride levels in the serum were determined by using automated blood chemistry analyzers.

Appetite Regulation:

At baseline and each week during the intervention, participants fill out a visual analogue scale (VAS) for

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appetite. The scale measured subjective hunger, satiety, and fullness.

Gut Health Symptoms:
A questionnaire filled out by participants to measure symptoms of gut health, like bloating, constipation, and diarrhea, using a proven tool such as the Gastrointestinal Symptom Rating Scale (GSRS) at baseline and after the intervention.

Safety and Tolerability
The safety and tolerability of probiotic supplementation were evaluated through:

Adverse Event Monitoring:
Participants were asked to report any adverse events (e.g., gastrointestinal discomfort, bloating, nausea) throughout the study. These were recorded and categorized as mild, moderate, or severe.

Dropout Rate:
The number of subjects who dropped out of the study because of side effects or non-compliance was tracked. The high dropout rate was inspected for possible reasons, and any side effect trends were examined.

Data Collection and Analysis
Data were obtained at baseline (week 0), at 6 weeks, and at week 12, the end of the intervention. Descriptive statistics (mean, standard deviation, and frequency distributions) were applied to present the baseline characteristics.

Statistical Analysis:
Between-group comparisons of the primary and secondary outcomes were done using independent t-tests (for normally distributed data) or Mann-Whitney U tests (for non-normally distributed data). Within-group comparisons were assessed with paired t-tests or Wilcoxon signed-rank tests. The significance level of the tests was $p < 0.05$. Statistical analysis was carried out with statistical software

Results

Participant Demographics

Characteristic	Probiotic Group (n = 50)	Placebo Group (n = 50)
Age (years)	38.5 ± 6.2	39.1 ± 7.4
Gender (% female)	70%	70%
Baseline BMI (kg/m²)	32.8 ± 3.2	33.0 ± 3.5
Significant baseline differences	No ($p > 0.05$)	No ($p > 0.05$)
Dropouts	8	9
Final Sample Size	42	41

Changes in Gut Microbiota Composition

Microbial Group	Change in Probiotic Group	Change in Placebo Group	p-value
Lactobacillus spp.	↑ 60%	No significant change	$p < 0.001$ / $p = 0.90$
Bifidobacterium spp.	↑ 50%	No significant change	$p < 0.01$ / $p = 0.80$
Firmicutes/Bacteroidetes Ratio	Significant reduction	No significant change	$p = 0.03$ / $p = 0.95$
Summary	Probiotic supplementation significantly enhanced beneficial bacteria and reduced the Firmicutes/Bacteroidetes ratio.		-

Changes in Body Weight and BMI

Group	Body Weight Change (kg)	BMI Change (kg/m²)	Significance (p-value)
Probiotic	−3.8 ± 2.5	−1.3 ± 0.9	$p < 0.001$
Placebo	−1.0 ± 1.8	−0.4 ± 0.6	$p = 0.14$ (weight), $p = 0.10$ (BMI)
Summary	The probiotic group showed significant weight and BMI reduction compared to the placebo.		-

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Reduction in Fat Mass

Group	Fat Mass Change (kg)	Significance (p-value)
Probiotic	−2.5 ± 1.6	$p < 0.01$
Placebo	−0.5 ± 1.2	$p = 0.21$

Changes in Metabolic Parameters

Group	Change in Fasting Blood Glucose (mg/dL)	Significance (p-value)
Probiotic	−12.7 ± 9.3	$p < 0.01$
Placebo	−2.3 ± 4.6	$p = 0.28$

Lipid Profile

Parameter	Probiotic Group (Mean ± SD)	p-value	Placebo Group (Mean ± SD) p-value
Total Cholesterol	−12.4 ± 10.1 mg/dL	$p < 0.05$	−1.1 ± 5.3 mg/dL $p = 0.68$
LDL Cholesterol	−9.5 ± 7.2 mg/dL	$p < 0.05$	−0.7 ± 3.8 mg/dL $p = 0.72$
HDL Cholesterol	+3.6 ± 2.9 mg/dL	$p < 0.05$	+0.5 ± 1.6 mg/dL $p = 0.56$
Triglycerides	−22.9 ± 14.2 mg/dL	$p < 0.01$	−5.1 ± 8.3 mg/dL $p = 0.25$

The results discovered that the consumption of probiotics had a beneficial impact on blood fat and cholesterol levels:

Total Cholesterol:
Individuals who consumed probiotics experienced their total cholesterol by approximately 12 mg/dL, a remarkable improvement. The placebo group experienced only a minimal and non-significant reduction.

LDL (bad cholesterol):
The group taking probiotics experienced a significant reduction of approximately 9.5 mg/dL, while the placebo group experienced no significant change.

HDL (good cholesterol):
The probiotic group experienced a slight rise in their HDL cholesterol (around 3.6 mg/dL), which is good, whereas the placebo group experienced only a very small rise.

Triglycerides:
There was a significant decrease (around 23 mg/dL) in triglycerides in the group that took probiotics, which is extremely good for cardiovascular health. The placebo group experienced only a small drop that was not statistically significant.

Changes in Hunger and Fullness Scores (VAS)

Group	Hunger Score Change	Fullness Score Change	p-value
Probiotic	↓ 30%	↑ 25%	$p < 0.01$ (hunger), $p < 0.05$ (fullness)
Placebo	No significant change	No significant change	$p > 0.05$

Individuals who received probiotics experienced reduced hunger (a reduction in hunger of 30%) and increased feelings of fullness (an increase in fullness of 25%).

Frontier in Medical & Health Research

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Individuals who received a placebo did not perceive much variation in their level of hunger or fullness. Therefore, it seems that probiotics can curb appetite, something which can support weight loss.

Changes in Gastrointestinal Symptoms (GSRS)

Symptom	Probiotic Group	Placebo Group	p-value
Bloating	↓ 28% (significant improvement)	Minimal change	$p < 0.01$ (probiotic)
Constipation	↓ 24% (significant improvement)	Minimal change	$p < 0.05$ (probiotic)
Diarrhea	↓ 18% (not statistically significant)	Minimal change	$p = 0.12$ (probiotic)

Individuals who received probiotics reported feeling less bloated and had better bowel movements (less constipation).

Their diarrhea symptoms also became better, but this difference wasn't large enough to be deemed statistically significant.

The placebo group improved very little in all of the symptoms.

Conclusion: Probiotics are able to alleviate stomach discomfort and enhance overall gut health, particularly in symptoms such as bloating and constipation.

Tolerability and safety

Both the probiotic and placebo groups experienced mild stomach problems such as bloating and gas at the beginning of the study. These were not severe and generally resolved within two weeks. In the probiotic group, approximately 10% of participants experienced mild stomach discomfort. In the placebo group, approximately 8% of participants experienced similar symptoms. There was no large difference between the two groups according to these minor side effects ($p = 0.79$). The probiotic was safe and tolerated with minor and transient side effects.

Discussion

This randomized controlled trial sought to assess the effects of probiotic-fortified nutritional supplements on gut health and weight loss among obese adults. The results of this research confirm that probiotic supplementation is superior in enhancing the composition of gut microbiota, lowering body weight and BMI, decreasing fat mass, and improving metabolic parameters such as blood glucose and lipid profile. These findings accord with an increasing body of evidence for the health benefits of probiotics for obesity control and metabolic well-being.

Obesity and Gut Microbiota

The changes in composition of gut microbiota in the present study agree with the newer studies pointing toward dysbiosis, an imbalance in microbial gut communities, having a critical function in obesity (Zhang et al., 2019). The high levels of Lactobacillus and Bifidobacterium in the probiotic group are in agreement with the results of previous research that have proven the efficacy of these health-promoting bacteria in influencing gut health and metabolic improvements in obese individuals (Kalliomaki et al., 2019; Lee et al., 2020). In particular, Lactobacillus and Bifidobacterium have been found to stimulate gut barrier function and reduce inflammation, both of which are important for controlling energy metabolism (Xiao et al., 2020). In addition, the decrease in the Firmicutes/Bacteroidetes ratio in the probiotic group is consistent with the results of earlier work, which indicated that a low ratio of Firmicutes to Bacteroidetes is linked to better metabolic health (Zhang et al., 2020).

BMI Reduction and Weight Loss

The decrease in body weight and BMI among the probiotic group is in line with various studies on the impact of probiotics on obesity. A systematic review and meta-analysis conducted by Cheng et al. (2021) concluded that supplementation with probiotics was linked with a significant decrease in body weight and BMI among overweight and obese populations. Comparable findings were reported in research by Cani et al. (2018) and Lim et al. (2019), who found that particular probiotic strains resulted in weight loss through modulating the gut microbiota and increasing energy expenditure. Our research's identification of a 3.8 kg weight loss in the probiotic group after 12 weeks is similar to those findings in these studies, providing further evidence of the positive role of probiotics in weight control.

Frontier in Medical & Health Research

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Body Composition and Fat Mass

Besides weight loss, the probiotic group had noteworthy decreases in fat mass. This finding is in line with research that has shown the capability of probiotics to inhibit fat mass by increasing fat oxidation and enhancing energy metabolism (Fu et al., 2020). Specifically, Lactobacillus strains, including Lactobacillus gasseri, have been proven to lower visceral fat in clinical studies (Kondo et al., 2020). The results of this work contribute to the emerging evidence that probiotics, particularly those that modulate gut microbiota composition, have an important role to play in fat mass loss, which is one of the most vital components of obesity control.

Parameters of Metabolic

The significant reductions in blood glucose, lipid profile, and appetite observed in the probiotic group are in agreement with existing studies that have associated probiotic supplementation with enhanced metabolic well-being among obese subjects. The decreases in fasting blood glucose values are consistent with the findings of Zhang et al. (2021), who observed that probiotics enhance insulin sensitivity and decrease blood glucose in patients with metabolic disorders. In addition, the decrease in total cholesterol and LDL cholesterol in the probiotic group is in line with the findings of earlier studies that have demonstrated the cholesterol-lowering action of probiotics (Park et al., 2019; Tufan et al., 2020). The reduction in triglycerides and elevation in HDL cholesterol are also in agreement with studies conducted by Guo et al. (2019), who proved that specific probiotic strains have the ability to modulate lipid metabolism and reduce lipid profiles in obese subjects.

The enhancement of appetite control seen in the probiotic group is significant. The decrease in hunger scores and the increase in fullness scores in the probiotic group indicate that probiotics could have a role to play in appetite modulation, which is essential in weight management (Niv et al., 2020). This corroborates the research of Di Pierro et al. (2021), wherein it was concluded that probiotics can modulate appetite-regulatory hormones like ghrelin and leptin.

Tolerability and Safety

Safety and tolerability-wise, our research discovered that probiotics were well absorbed by the volunteers with minimal side effects, such as mild gastrointestinal symptoms, experienced during the first period of supplementation. The results concur with findings in earlier studies, which have proven that probiotics are safe for prolonged supplementation with no significant adverse effects (Gibson et al., 2020; Vinderola et al., 2021). Nonetheless, note that certain people will have some temporary gastrointestinal discomfort at the beginning of probiotic supplementation, which normally settles as the body acclimatizes (Castro et al., 2021).

Future Directions and Limitations

Although the findings of this trial are encouraging, there are a number of limitations that need to be taken into account. Firstly, the trial was of relatively short duration (12 weeks), and longer-term trials are required in order to determine the sustainability of the influence of probiotics on weight and metabolic health. Secondly, the trial only included a single intervention with probiotics, and it is unknown whether different strains or a mixture of probiotics might provide different outcomes. Future studies should examine the synergistic effects of multi-strain probiotic products and their long-term effects on obesity and metabolic diseases. Third, the absence of dietary control in this study may have affected the results, and future studies should incorporate more rigid dietary monitoring to control for possible confounding factors.

Conclusion

This research assessed the impact of probiotic-fortified nutritional supplements on gut health and weight control in obese adults using a randomized controlled trial. The results present strong evidence that probiotics have a significant impact on gut microbiota composition, facilitate weight loss, decrease fat mass, and improve metabolic parameters, such as blood glucose and lipid profile. The probiotics in this study resulted in a significant increase in beneficial gut bacteria, including Lactobacillus and Bifidobacterium, that are important for supporting gut health and energy metabolism.

Frontier in Medical & Health Research

ISSN: (e) 3007-1607 (p) 3007-1593

The decrease in body weight, BMI, and fat mass in the probiotic group also confirms the use of probiotics as a possible adjunctive treatment for obesity. Additionally, the improvement in metabolic health, such as reduced blood glucose and beneficial alterations in lipid profiles, indicates that probiotics can have an important function in improving overall metabolic function in obese subjects. These observations are in agreement with the literature, which points to the ability of probiotics to influence gut microbiota and enhance metabolic factors associated with obesity.

Also, the tolerability and safety data from the trial suggest that probiotics are well-tolerated overall, with very few side effects reported, further endorsing their use over the longer term in obesity control.

Yet, although the findings of the study are encouraging, more long-term studies are required to establish the sustainability of the benefits that were seen. Additional research is required to examine the impact of various probiotic strains and their possible synergies when taken together. The potential of probiotics as an effective and safe treatment for obesity and metabolic disorders should be pursued further, especially in diverse groups and over the longer term.

In summary, the current work provides useful evidence for the mounting body of research affirming the utility of using probiotics for enhanced gut health, weight reduction, and treating metabolic disorders. Probiotics potentially provide an alternative and additional therapeutic option for traditional obesity interventions, especially among individuals looking to enhance both gut and metabolic states.

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