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Original article

The Effect of Probiotic Use on Some Blood Parameters in Overweight and Obese Women Who Follow a Weight-Loss Diet

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Abstract. *Background and aim:* This study was conducted to determine the effect of 8-week probiotic use on body composition and blood parameters in overweight and obese women who are on a weight loss diet *Methods:* 34 women with a BMI value above 25 kg/m^2 participated. The individuals participating in the research were divided into two groups. For eight weeks, the experimental group was given a weight loss diet program, exercise program and oral probiotic nutritional supplement containing various probiotic strains in the amount of 1.5x10^9 cfu/g in each capsule twice a day; The control group was given a weight loss diet program and an exercise program without probiotic supplementation. Anthropometric measurements of the individuals (height baseline, body weight, waist, hip and neck circumference, body mass index, waist/hip circumference and waist-height ratio) in both groups were evaluated statistically at the initial, 4th and 8th weeks. Some biochemical parameters were measured at the beginning of the study and the end of the 8th week. *Results:* A significant difference was found between body weight, body mass index, waist circumference, hip circumference, waist-height ratio, body fat percentage, and body fat mass measurements (p<0,001). Significant improvements were found in LDL-C, fasting insulin, AST and TSH values in both groups (p<0.05). While the HOMA-IR values were significantly lower, HDL-C values were found to be significantly higher at the end of the study in the experimental group (p<0.05). *Conclusions:* Balanced hypocaloric diet caused significant improvements in anthropometric measurements and blood parameters in experimental and control groups. The use of probiotics has positive effects on HOMA-IR and HDL-C values in the experimental group.

Key words: weight-loss diet, overweight, obesity, probiotic, body composition

Introduction

World Health Organization (WHO) defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". However, despite the efforts to improve or preserve health, overweight or obesity is a growing epidemic worldwide. The body mass index (BMI) is the metric currently in use for defining anthropometric height/weight characteristics in adults and for classifying them. Body weight (kilograms) divided by height squared (meters) = BMI. The common interpretation is that it represents an index of an individual's fatness. It is widely used in determining public health policies. A BMI of greater than or equal to 18.5 to 24.9 is normal weight, 25 to 29.9 is overweight, a BMI of 30 to 34.9 is class I obesity, 34.9 to 39.9 is class II obesity, and a BMI of 40 or greater is class III obesity. Obesity and overweight occur when excess fat accumulation (regionally, globally, or both) increases the risk to health, an imbalance between energy intake and energy expenditure (1-3). The main causes of obesity and overweight are

genetic, hormonal, environmental, socio-cultural, and behavioral factors. Obesity and overweight prevalence area around 650 million among the adult population, affirmed by WHO. Global age-standardized mean BMI in men increased from 21.7 kg/m² in 1975 to 24.2 kg/m² in 2014, and in women from 22.1 kg/m² in 1975 to 24.4 kg/m² in 2014. The collection of bacteria, archaea and eukarya colonizing the gastrointestinal tract is termed the 'gut microbiota' and has co-evolved with the host over thousands of years to form an intricate and mutually beneficial relationship. Based on findings from human and animal studies, the intestinal microbiota is involved in the development of obesity and overweight. Early in life, the GI tract is quickly colonized by microbes, and the gut microbiota is purported to reach an adult state at around 3 years of age. The structure of the gut microbiota varies spatially along the intestinal tract and cross-sectionally. The bacteria that reside close to the mucosal surface interact with the immune system, whereas bacteria that reside in the lumen may be more closely associated with homoeostasis by controlling metabolic pathways, nutrient metabolism, and the production of vitamins (4-11). Humans have been proposed to be "meta-organisms" consisting of 10-fold greater numbers of bacterial than animal cells that are metabolically and immunologically integrated. The human meta-organism includes approximately 10^{14} prokaryotic organisms, with a biomass of >1 kg. It has been demonstrated for the first time by animal studies that bacteria in our intestines may be related to body composition. It has been determined that the balance of the sections in the intestinal microbial system in *ob/ob mice*, which are genetically obese, the increased ratio of *Firmicutes* to *Bacteroidetes* in mice may help promote adiposity. The component of the individual's gut microbiota and the effect of these bacteria on energy conversion is thought to predispose the individual to obesity. The word "probiotic" comes from Greek, and it means "for life". In 2002 FAO (Food and Agriculture Organization of the United Nations) and WHO working group experts, states that probiotics are "live strains of strictly selected microorganisms which, when administered in adequate amounts, confer a health benefit on the host". On the other hand, prebiotics was defined as non-digested food components that, through the stimulation of growth and/or activity of a single type or a limited number of microorganisms in the gastrointestinal tract, improve the health condition of a host. Prebiotics may be used as an alternative to probiotics or as additional support for them. In 2007, FAO/WHO experts described prebiotics as a nonviable food component that confers a health benefit on the host associated with modulation of the microbiota (12-15). Alteration in the composition of the gut microbiota is called dysbiosis which is related to the development of several diseases including type II diabetes, allergies, fatty liver disease, and obesity. Current studies on probiotics, as a food supplement, showed that probiotics change the composition of the microbiota, thus allowing the return to eubiosis. Also, prebiotic foods, which contain soluble fibers, help maintaining intestinal eubiosis (16). In recent years, many experimental and clinical studies have been carried out to investigate the effect of prebiotics and probiotic bacteria (especially *lactobacillus* and *bifidobacterium*) on body weight loss and in the treatment of obesity. Convincing evidence from animal studies suggests that probiotic administration reduces, at least in part, the amount of weight gained in response to a high-fat diet. Probiotics like *Bifidobacterium, Lactobacillus and Streptococcus* are of interest because they have been shown to alter the composition of gut microbiota and to affect food intake and appetite, body weight and metabolic functions through gastrointestinal pathways and modulation of the gut bacterial community (17-21).

To the best of our knowledge, there is no data about the effect of probiotics on overweight and obese individuals who follow a weight-loss diet in Turkiye. This study aims to examine the effect of probiotic use on body composition and some blood parameters for 8 weeks in overweight and obese women who follow a weight-loss diet.

Material and Methods

Study design

This was a randomized controlled trial conducted at Özel Gaziantep Emek Hospital in Gaziantep, Turkiye between December 2020, and June 2021.

The protocol for this trial and CONSORT checklist are available as supporting information (Figure 1). 40 women who were followed up in the Nutrition and Diet Clinic of Özel Gaziantep Emek Hospital were assessed for eligibility. Participants who are between the ages of 19-50, not in the period of pregnancy, lactation and menopause who have a BMI of 25 kg/m^2 or above, absence of any chronic or inflammatory disease except obesity, who does not smoke, use alcohol, any antidiabetic agent and nutritional supplements in the last 3

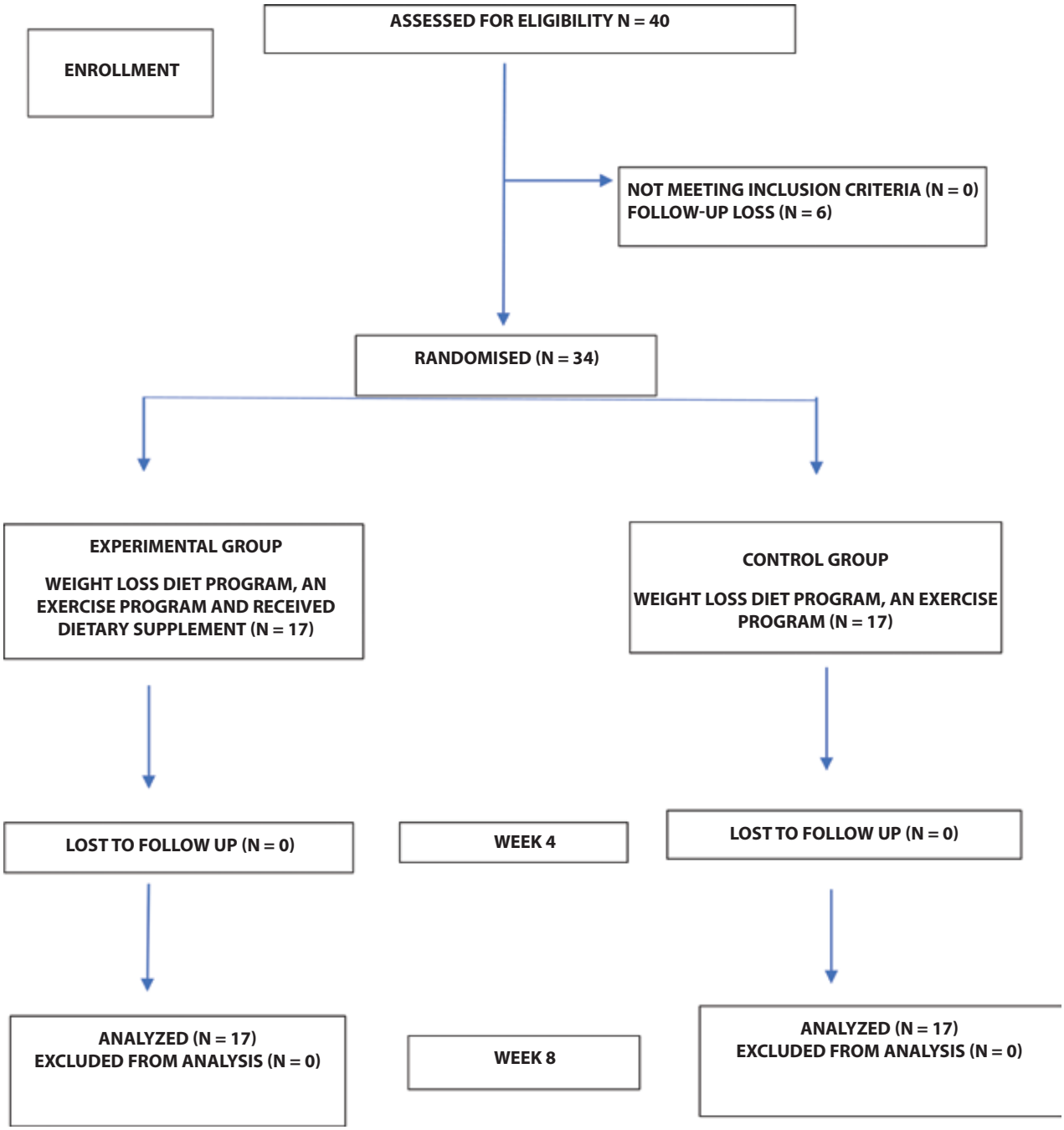

Figure 1. Participant flow in CONSORT-recommended form.

months were included in the research. Insulin resistance is not an exclusion criterion. Individuals who accepted to participate in the study were selected randomly into experimental and control groups. However, the study was completed with a total of 34 people, due to the pandemic process that emerged after the beginning of the study, failure to attend face-to-face interviews with the dietitian or failure to obtain the necessary blood sample for biochemical parameters. All women received oral and written information and signed informed consent before entering the study. For eight weeks, the experimental group (n=17) was given a weight loss diet program, exercise program and probiotic dietary supplements; The control group (n=17) was given a weight loss diet program and an exercise program without probiotic dietary supplements (Figure 1). Participants in both groups were advised brisk walking for 30-50 minutes 3-5 days a week. The nutritional instructions were developed based on the Dietary Reference Intakes published by The Turkish Ministry of Health. The participants in the experimental group were given an oral probiotic nutritional supplement containing various probiotic strains in the amount of $1.5x10^9$ cfu/g in each capsule, twice a day. Anthropometric measurements of the individuals (height baseline, body weight, waist, hip and neck circumference, body mass index, waist/hip circumference and waist-height ratio) in both groups were evaluated statistically at the initial, 4th and 8th weeks. Also, biochemical findings in both groups were determined. The personalized diet planning of the women participating in the study was arranged according to their daily energy needs. Basal metabolic rates of individuals participating in the study were calculated using the Mifflin-St Jeor equation (22). When calculating the total energy requirement of individuals, first, physical activity level (PAL) values were calculated (23). The total energy requirement of the individual was calculated by multiplying the PAL value found with the basal metabolic rate value (24). Control sessions were planned to monitor the participants' compliance with diet and exercise programs and to monitor the regular use of probiotic supplements.

The study was approved by the Sanko University Medical Faculty Ethics Committee. Informed consent was obtained before the blood samples were taken. The study was carried out in compliance with the Helsinki Declaration.

Probiotic Dietary Supplement

The probiotic nutritional supplement preferred and used within the scope of the research was obtained from the pharmacy and given to the participants by the researcher. The probiotic nutritional supplement used (NBL Probiotic Optima) contains 6 different bacterial strains in a total amount of $1.5x10^9$ cfu/g for each tablet. The strain codes in the probiotic capsule are specified as *Enterococcus faecium CBT EF4*, *Lactobacillus plantarum CBT LP3, Streptococcus thermophilus CBT ST3, Bifidobacterium lactis CBT BL3, Lactobacillus acidophilus CBT LA1 and Bifidobacterium longum CBT BG7*. In addition, each capsule contains fructooligosaccharides (225 mg). In addition, this oral probiotic contains 30 mg of vitamin C in each tablet. The factors in choosing this probiotic are that it is highly accessible in Turkiye and it contains prebiotics. Prebiotics are also a factor that increases the growth and proliferation of probiotics. Participants who used probiotic nutritional supplement tablets twice a day, in the morning and the evening, for 8 weeks (56 days), considering the information obtained from the literature.

Analysis

The blood samples required for biochemical tests were taken from the participants twice, at the beginning of the study and the end of the 8th week. The participants were informed by the researcher that they should be in the fasting process for at least 8 hours in the morning after the night before blood samples were taken. Physician-controlled routinely fasting blood glucose (mg/dL), fasting insulin level (mIU/mL), total cholesterol (mg/dL), LDL-cholesterol (mg/dL), HDL-cholesterol (mg/dL), triglyceride (mg/dL), TSH (mIU/L), T3 (pg/mL), T4 (ng/dL), AST (IU/L), ALT (IU/L) and HOMA-IR values were analyzed. Blood samples were placed in blood collection tubes and analyzed in the Department of Clinical Biochemistry Özel Emek Hastanesi.

Statistics

Statistical analysis was performed with SPSS version 22.0 (SPSS Inc., Chicago, IL, USA). Clinical and anthropometrical data of the study populations

are given as means ± SD. Differences in the means of variables were tested using both parametric and non-parametric tests depending on the distribution of the variables. To check the normality of the data distribution Shapiro-Wilk test was performed. The student's t-test was used to compare two independent measurements with normal distribution, and the Mann Whitney U test was used to compare two independent measurements that were not normally distributed. Wilcoxon's test was used to compare two dependent measures of non-normally distributed variables. Friedman's test is used to compare the distributions of the two or more quantitative variables. For all statistical analyses $p<0.05$ was considered significant.

Results

The mean age of women using probiotics was 32.41 ± 7.25, while the mean age of women who do not use probiotics was 31.76 ± 8.86 years, and the difference between the two groups was not statistically significant (p=0.819; p>0.05). The distribution of the women according to their socio-demographic characteristics were given in Table 1. Of the women participating in the study, 52.9% of them were undergraduates 29,5% of the women were high school graduates, 5.9% of women were postgraduates and, 2.9% of them were illiterates. There was no statistical significance between the two groups in terms of educational status (p=0.085; p>0.05). It has been shown that the women participating in our study were housewives (41.2%), public servants (29.4%), students (17.6%) and others (2.9%). There is no difference between the groups that used probiotics and those that did not, in terms of occupation (p=0.414; p>0.05).

Anthropometric measurements were given in Table 2. In terms of body weight, the measurements of women using probiotics at the beginning of the study at the 4th and 8th weeks were statistically significant respectively (85.24 ± 10.05; 81.33 ± 10.08; 79.25 ± 9.99 (p=0.001)). Also, the body weight measurements of women not using probiotics at the beginning of the study (83.48 ± 12.67) at the 4th (78.83 ± 12.07) and 8th (76.24 ± 11.9) weeks were statistically significant (p=0.001). The BMI values of the women using probiotics at the beginning of the study at the 4th and 8th weeks were statistically significant respectively (33.04 ± 3.2; 31.28 ± 3.31; 30.52 ± 3.23 (p=0.001)). Besides, the BMI values of the women not using probiotics at the beginning of the study (32.07 ± 4.57) at the 4th (30.43 ± 4.63) and 8th (29.43 ± 4.55) weeks were statistically significant (p=0.001). There were significant differences between waist circumference measurements of women using probiotics at the beginning of the study, at the 4th and 8th weeks respectively (103.68 ± 9.87; 99.41 ± 9.68; 95.85 ± 9.48 (p=0.001)). In addition to this, waist circumference measurements of the women not using probiotics at the beginning of the study (102.53 ± 12.16), at the 4th (97.26 ± 12.5) and

Table 1. Distribution of the women according to their socio-demographic characteristics

		Experimental		Control		Total		p values
		n	%	n	%	n	%	
Educational status	Illiterate	1	5.9	0	0.0	1	2.9	0.085
	Primary education	1	5.9	2	11.8	3	8.8	
	High school	7	41.2	3	17.6	10	29.5	
	Undergraduate	6	35.3	12	70.6	18	52.9	
	Postgraduate	2	11.8	0	0.0	2	5.9	
Occupational status	Housewive	9	52.9	5	29.4	14	41.2	0.414
	Self-employed	1	5.9	1	5.9	2	5.9	
	Public servant	4	23.5	6	35.3	10	29.4	
	Wage-earner	0	0.0	1	5.9	1	2.9	
	Student	2	11.8	4	23.5	6	17.6	
	Others	1	5.9	0	0.0	1	2.9	

Table 2. Distribution of anthropometric measurements of women by groups at the beginning of the study, at 4 weeks and the end of 8 weeks.

Anthropometric measurements	Phase	Experimental		Control		Total		
		$\bar{x} \pm S$	Median	$\bar{x} \pm S$	Median	$\bar{x} \pm S$	Median	p values
Body weight (kg)	Initial	85.24±10,05^{C}	83.4	83.48±12.67^{C}	81.1	84.36±11.3^{C}	83.25	0.375
	4th week	81.33±10,08^{B}	80.2	78.83±12.07^{B}	75.5	80.08±11.02^{B}	79.85	0.357
	8th week	79.25±9,99^{A}	78.3	76.24±11.9^{A}	72.8	77.74±10.93^{A}	77.6	0.274
	p value	0.001*		0.001*		0.001*		
BMI (kg/m^2)	Initial	33.04±3.2^{C}	32.9	32.07±4.57^{C}	31.5	32.56±3.92^{C}	32.2	0.479
	4th week	31.28±3.31^{B}	30.8	30.43±4.63^{B}	29.4	30.86±3.99^{B}	30.4	0.541
	8th week	30.52±3.23^{A}	30.3	29.43±4.55^{A}	28.7	29.98±3.92^{A}	29.3	0.425
	p value	0.001*		0.001*		0.001*		
Waist Circumference (cm)	Initial	103.68±9.87^{C}	103.0	102.53±12.16^{C}	102.0	103.1±10.92^{C}	102.5	0.765
	4th week	99.41±9.68^{B}	97.0	97.26±12.5^{B}	97.0	98.34±11.06^{B}	97.0	0.579
	8th week	95.85±9.48^{A}	94.0	94±12.54^{A}	96.0	94.93±10.98^{A}	94.5	0.630
	p value	0.001*		0.001*		0.001*		
Hip Circumference (cm)	Initial	116.88±7.05^{C}	118.0	110.94±8.79^{C}	112.0	113.91±8.4^{C}	114.0	0.037*
	4th week	112.41±7.05^{B}	113.0	107.68±8.41^{B}	108.0	110.04±8.01^{B}	109.75	0.085
	8th week	109.62±7.04^{A}	109.0	104.97±8.52^{A}	106.0	107.29±8.05^{A}	107.0	0.092
	p value	0.001*		0.001*		0.001*		
Waist/Hip (cm)	Initial	0.88±0.07	0.88	0.9±0.1	0.91	0.89±0.09^{B}	0.91	0.509
	4th week	0.88±0.07	0.88	0.9±0.1	0.91	0.89±0.09^{B}	0.91	0.518
	8th week	0.88±0.08	0.86	0.9±0.1	0.9	0.89±0.09^{A}	0.90	0.484
	p value	0.068		0.056		0.004*		
Waist/Height (cm)	Initial	0.62±0.06^{B}	0.63	0.6±0.08^{B}	0.61	0.61±0.07^{B}	0.62	0.603
	4th week	0.62±0.06^{B}	0.63	0.6±0.08^{B}	0.61	0.61±0.07^{B}	0.62	0.603
	8th week	0.6±0.06^{A}	0.61	0.58±0.08^{A}	0.59	0.59±0.07^{A}	0.6	0.654
	p value	0.001*		0.001*		0.001*		
Neck Circumference (cm)	Initial	36.32±2.47^{C}	36.0	35.85±2.58^{C}	35.5	36.09±2.5^{C}	36.0	0.433
	4th week	35.26±2.37^{B}	35.0	37.35±10.04^{B}	35.0	36.31±7.26^{B}	35.0	0.786
	8th week	34.62±2.23^{A}	34.5	34.29±2.6^{A}	34	34.46±2.39^{A}	34	0.413
	p value	0.001*		0.001*		0.001*		

[ŧ]Student's t-test and repeated measure analysis of variance, ₮Mann Whitney U test and Friedman two-way analysis of variance, A, B, C are significantly different from each other, *p<0.05

8th (94 ± 12.54) weeks were significant (p=0.001). The hip circumference values of women using probiotics at the beginning of the study at the 4th and 8th weeks were statistically significant respectively (116.88 ± 7.05; 112.41 ± 7.05; 109.62 ± 7.04 ((p=0.001)). Moreover, the hip circumference values of women not using probiotics at the beginning of the study (110.94 ± 8.79) at the 4th (107.68 ± 8.41) and 8th (104.97 ± 8.52) weeks were statistically significant. The waist/hip ratio measurements of women using probiotics at the beginning of the study, at the 4th and 8th weeks were not statistically significant respectively (0.88 ± 0.07; 0.88 ± 0.07; 0.8 8± 0.08 (p>0.05)). Even, the waist/hip ratio measurements of women not using probiotics at the beginning of the

study (0.9 ± 0.1), at the 4th (0.9 ± 0.1) and 8th (0.9 ± 0.1) weeks were not statistically significant (p>0.05). The waist/height ratio measurements of women using probiotics at week 4 (0.62 ± 0.06), and at week 8 (0.6 ± 0.06) were statistically significant (p=0.001). Similarly, the waist/height ratio measurements of women not using probiotics at week 4, and at week 8 were statistically significant respectively (0.6 ± 0.08; 0.58 ± 0.08 (p=0.001)). The difference between neck circumference measurements of women using probiotics at week 4 (35.26 ± 2.37), and at week 8 (34.62 ± 2.23) was statistically significant (p=0.001). By the same token, the difference between neck circumference measurements of women not using probiotics at week 4, and week 8 was statistically significant respectively (37.35 ± 10.04; 34.29 ± 2.6 (p=0.001)).

The comparison of the biochemical parameters of the women according to the groups at the beginning and end of the study according to the mean, standard deviation and median values were given in Table 3.

Table 3. Comparison of women's biochemical parameters at the beginning and end of the study according to mean (X), standard deviation (SD) and median values.

Groups		Initial		End of study		P[Ŧ]
		$\bar{x}$ ± S	Median	$\bar{x}$ ± S	Median	
Fasting blood glucose (mg/dl)	Experimental	92.47±16.56	91.00	93.24±8.44	93	0.652
	Control	88.94±9.36	90.00	91.94±5.33	92	0.355
	p values	0.496		0.658		
Triglyceride (mg/dl)	Experimental	123.35±63.75	115.00	100.47±43.25	88	0.113
	Control	81.24±31.22	80.00	80±30.47	72	0.877
	p values	0.014*		0.193		
Total cholesterol (mg/dl)	Experimental	190.71±40.48	184.00	181.47±40.07	163	0.078
	Control	178.12±36.57	180.00	169.76±38.98	168	0.098
	p values	0.433		0.518		
LDL-C (mg/dl)	Experimental	119.89±37.07	108.80	112.16±35.05	98.4	0.004*
	Control	113.41±29.62	119.60	104.67±35.13	106.6	0.025*
	p values	0.838		0.563		
HDL-C (mg/dl)	Experimental	44.12±10.29	42.00	49.65±16.48	48	0.023*
	Control	49.78±11.34	50.00	49.18±12.03	48	0.622
	p values	0.170		0.838		
Fasting insulin (mg/dl)	Experimental	15.99±7.26	15.09	10.6±4.89	9.37	0.002*
	Control	15±9.58	10.70	12.16±7.68	10.1	0.039*
	p values	0.413		0.892		
AST (u/l)	Experimental	15.76±5.15	14.00	12.71±2.8	13	0.013*
	Control	17.94±7.85	17.00	13.88±4.55	14	0.007*
	p values	0.394		0.634		
ALT (u/l)	Experimental	26±12.64	24.00	25.94±12.05	23	0.887
	Control	31.12±21.46	27.00	28.18±10.32	23	0.981
	p values	0.413		0.563		
TSH (mIU/ml)	Experimental	1.96±0.98	1.73	1.53±0.68	1.27	0.005*
	Control	1.86±0.77	1.73	1.59±0.69	1.66	0.009*
	p values	1.000		0.734		

Table3. (Continued)

Groups		Initial		End of study		P[Ŧ]
		$\bar{x} \pm S$	Median	$\bar{x} \pm S$	Median	
T3 (pg/ml)	Experimental	3.04±0.55	3.10	2.98±0.29	2.96	0.449
	Control	3.04±0.28	2.94	2.89±0.3	2.95	0.169
	p values	0.786		0.563		
T4 (ng/dl)	Experimental	1.12±0.14	1.11	1.13±0.13	1.16	0.737
	Control	1.15±0.18	1.10	1.18±0.14	1.17	0.355
	p values	0.946		0.413		
Homa-IR (mg/dl)	Experimental	3.80±2.51	3.34	2.50±1.35	2.17	0.004*
	Control	3.37±2.21	2.30	2.78±1.74	2.37	0.084
	p values	0.413		0.892		

[ł]Mann Whitney U test, Ŧ Wilcoxon test, statistically significant as *p < 0.05

While the difference between the triglyceride values of women using and not using probiotics at the beginning of the study was statistically significant (p=0.014); The difference between triglyceride values at the end of the study (p=0.193) was not statistically significant. The difference between the LDL-C values at the beginning and end of the study of both probiotic users and non-users was statistically significant (p=0.04; p=0.025). The difference between HDL-C values at the beginning and the end of the study of women using probiotics was statistically significant (p=0.023); The difference between HDL-C values at the beginning and at the end of the study of women who did not use probiotics was statistically significant (p=0.622). Besides, the difference between fasting insulin values at the beginning and the end of the study in both groups was statistically significant (p=0.02; p=0.039). AST and TSH values of both groups at the beginning and end of the study were statistically significant (p=0.013; p=0.007), (p =0.05; p=0.09) respectively. The difference between the Homa-IR values at the beginning and the end of the study in the experimental group was statistically significant (p=0.004). On the other hand, the difference between the Homa-IR values at the beginning and the end of the study in the control group was not statistically significant (p=0.084).

Discussion

Obesity is one of the most prevalent human health problems. Studies have clarified the role of the imbalance between energy intake and expenditure, unhealthy lifestyle, and genetic variability in the development of obesity. The intestinal microbiota can constitute a relevant environmental factor in the pathogenesis of obesity has led to the investigation of gut microbial communities in overweight individuals (25). As both probiotics and prebiotics are thought to exert their beneficial effects on bowel movement through modulation of the gut microflora (26). According to the TURDEP-II study, which is another large-scale study in our country, the prevalence of obesity in Turkiye was 31.2% in total, 44% in women and 27% in men (27). In the present paper, we investigated whether probiotic use has a role in body composition and some blood parameters for 8 weeks in overweight and obese women who follow a weight-loss diet. We found a significant difference between body weight, body mass index, waist circumference, hip circumference, and the waist-height ratio at the initial, 4th and 8th weeks in both groups. While the HOMA-IR values were significantly lower, HDL-C values were found to be significantly higher at the end of the study in the experimental group. Sanchez et al. investigated the impact of a *Lactobacillus rhamnosus CGMCC1.3724 (LPR)* supplementation on weight loss and maintenance in obese men and women over 24 weeks. They found that the mean weight loss in women in the *LPR* group was significantly higher than that in women in the placebo group after the first 12 weeks. In addition to this, women in the *LPR* group continued to lose body weight and fat mass during the weight-maintenance period (28). In contrast, we found a significant

difference between body weight measurements at the 4th and 8th weeks in both groups. Sharafedtinov et al. conducted a study to observe probiotic *Lactobacillus plantarum TENSIA (Deutsche Sammlung für Mikroorganismen, DSM 21380)* effects on 25 Russian adults with obesity and hypertension. They found that a hypocaloric diet supplemented with a probiotic helped to reduce BMI values in the probiotic group versus the control group (29). Rahayu et al. aimed to determine the effect of the consumption of indigenous probiotic *Lactobacillus plantarum Dad-13* powder in 60 overweight adults. They observed no significant differences in both the probiotic and placebo groups as well as in the lipid profile of both cholesterol and triglyceride, HDL, and LDL. But interestingly, they found a significant decrease in body weight and BMI in the experimental group (30). Conversely, our data indicated significant improvements in LDL-C in both groups and HDL-C values in the experimental group. In another study, Sohn et al. aimed to determine the efficacy and safety of an intake of *Lactobacillus plantarum K50 (LPK)* on body fat and lipid profiles in 81 adult people with obesity. They conducted a double-blind, placebo-controlled, clinical trial. After 12 weeks of treatment, body weight, fat mass, and the abdominal fat area did not change significantly in the two groups. However, total cholesterol and leptin levels decreased in the experimental group (31). Majewska et al. assessed the effects of a 12-week supplementation with a multispecies probiotic on homocysteine levels, oxidative stress, inflammation, and lipid profile in obese patients. A randomized double-blind placebo-controlled trial was performed on 50 obese women (aged 45–70 years). At the end of their study, a significant decrease in homocysteine, tumor necrosis factor α, total cholesterol, low-density lipoprotein cholesterol and triglyceride levels were observed in the probiotic group (32). Rajkumar et al. evaluated the effects of probiotic (*VSL#3*) and omega-3 fatty acid on insulin sensitivity, blood lipids, and inflammation, they conducted a clinical trial in 60 overweight, healthy adults, aged 40–60 years. The four groups received, respectively, placebo, omega-3 fatty acid, probiotic *VSL#3*, or both omega-3 and probiotic, for 6 weeks. They showed that fasting blood glucose rose slightly in the placebo group but reduced significantly in the probiotic, omega-3, and probiotic + omega-3 combination groups. Similarly, the insulin levels reduced significantly in the probiotic, omega-3, and probiotic + omega-3 combination groups (33). Shavakhi et al. demonstrated that probiotic combination with metformin improves liver aminotransferases better than metformin alone in patients with non-alcoholic steatohepatitis (34). Spaggiari et al. assessed whether a mixture of highly charged *Lactobacilli* and *Bifidobacteria (VSL#3®)* can influence levothyroxine (LT4) metabolism acting on the gut microbiota. They stated that probiotics influence the activities of the deiodinases and temporarily reduce the feedback. Since probiotics supplementation could be able to influence thyroid hormones homeostasis and prevent serum hormonal fluctuations (35). These results are consistent with the findings of our study. We found significant improvements in the fasting insulin, AST and TSH values in both groups, HDL-C and HOMA-IR values in the experimental group. The novelty of this work was based on the studied population and probiotics used in this trial for the first time in our country.

Strengths of the study include timely collection, processing of specimens, quality biochemical assays and accurate anthropometric measurements.

There were several limitations to the current study that should be noted. The relatively small sample size, besides cultural factors among the women, were not considered in both groups.

Conclusion

In summary, the beneficial effects of probiotic supplementation on anthropometric measurements and some blood parameters were demonstrated in the present study. These findings suggest that a hypocaloric diet and probiotic supplementation have positive effects on anthropometric measurements and blood parameters in overweight and obese women. Therefore, it is aimed that the data obtained from this study on probiotics will make an important contribution to the literature.

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for submission. S.B. is the guarantor of this work and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Ethics Statement: The study involving human participants was reviewed and approved by the Sanko University Medical Faculty Ethics Committee. The participants provided their written informed consent to participate in this study.

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Conflict of Interest: Each author declares that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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