CHAPTER IV

RESULTS

4.1 Characteristics of the Subjects

Forty–one subjects (17 males and 24 females) were enrolled in this study. The subjects were randomly divided into the treatment or control group. The treatment group comprised of 21 subjects (8 males and 13 females), and the control group comprised of 20 subjects (9 males and 11 females). Five subjects dropped out from the study because of loss to follow-up (1 subject in the treatment group and 1 subject in the control group), inflammation (1 subject in the control group), and non-compliance (2 subjects in the treatment group). Therefore, there were totally 36 subjects completed the study. The treatment group included 18 subjects (6 males and 12 females) and the control group included 18 subjects (8 males and 10 females).

4.1.1 General Data of the Subjects

The general demographic data of the subjects are presented in **Table 9**. In the present study, all demographic characteristics of the subjects were not different between groups. Most of the subjects were in the age group of $\geq$ 60 years old. Average age of the treatment and control groups were 62.6 and 59.7 years respectively. Fifty percent of the subjects in both groups had diabetic duration less than 5 years. Mean diabetic duration were 5.0 ± 0.9 and 7.0 ± 1.8 years in the treatment and the control groups respectively. There were 31 subjects (14 from the treatment group and 17 from the control group) who had diabetes concurrent with hypertension, dyslipidemia or both. The other remaining subjects had only diabetes.

All subjects in this study were treated with oral hypoglycemic drugs. Most of the subjects were taking both sulfonylureas and biguanides (12 and 17 subjects in the treatment and the control groups respectively). In the treatment group, there were 3 subjects taking sulfonylureas alone and 3 subjects taking biguanides alone. In the control group, there was one subject taking sulfonylureas alone. About 80-90% of the subjects in this study were taking either oral antihypertensive, antihyperlipidemic drugs or both. The other remaining (4 subjects from the treatment group and 1 subject from the control group) were taking only oral hypoglycemic drugs. All medications were held constantly throughout the course of the study. More than 80% of the subjects in both groups had diabetic knowledge prior to participation the study.

Focusing on obesity, approximately 50-60% of the subjects in both groups were obese, 20-30% were overweight, and 20% were normal. Abdominal obesity was found in majority of the subjects in both groups. Moreover, almost all of the subjects had metabolic syndrome. For the physical activity, the results showed that about 75% of the subjects had physical activity $\geq$ 3 hours/week. Most of the subjects were active (77.7% and 72.2% in the treatment and the control groups respectively). There was no significant difference in physical activity levels between groups.

Table 9 Characteristics of the subjects

Demographic data	Treatment Group (n = 18)	Control Group (n = 18)	Total (n = 36)	χ^2	df	p
	number (%)	number (%)	number (%)			
Gender						
Male	6 (33.3)	8 (44.4)	14 (38.9)	0.468	1	0.494
Female	12 (66.7)	10 (55.6)	22 (61.1)			
Age distribution (years)						
40-49	4 (22.2)	2 (11.1)	6 (16.6)	1.067	2	0.587
50-59	4 (22.2)	6 (33.3)	10 (27.8)			
≥ 60	10 (55.6)	10 (56.6)	20 (55.6)			
Mean ± SEM[1]	62.6 ± 2.5	59.7 ± 2.4	61.1 ± 1.7		34	0.412
Marital status						
Single	4 (22.2)	4 (22.2)	8 (22.2)	0.243	2	0.885
Married	11 (61.1)	12 (66.7)	23 (63.9)			
Divorce/separate	3 (16.7)	2 (11.1)	5 (13.9)			
Education						
Primary	8 (44.4)	8 (44.4)	16 (44.4)	3.543	3	0.315
Secondary	4 (22.2)	6 (33.4)	10 (27.9)			
Diploma	3 (16.7)	0 (0.0)	3 (8.3)			
Bachelor or higher education	3 (16.7)	4 (22.2)	7 (19.4)			
Occupation						
Housewife/Retiree	8 (44.4)	8 (44.4)	16 (44.4)	1.818	2	0.403
Employee	6 (33.4)	3 (16.7)	9 (25.0)			
Trading	4 (22.2)	7 (38.9)	11 (30.6)			

[1] Difference between groups was compared by independent sample t-test
df = degree of freedom; χ^2 = compare frequency between groups by Chi-square test

Table 9 Characteristics of the subjects (continued)

Demographic data	Treatment Group (n = 18) number (%)	Control Group (n = 18) number (%)	Total (n = 36) number (%)	χ^2	df	p
Diabetic duration range						
< 5 years	9 (50.0)	9 (50.0)	18 (50.0)	3.600	2	0.165
5 - <10 years	2 (11.1)	6 (33.3)	8 (22.2)			
≥ 10 years	7 (38.9)	3 (16.7)	10 (27.8)			
Mean ± SEM[1]	5.0 ± 0.9	7.0 ± 1.8	6.1 ± 1.0		3	0.329
Presence of co-existing diseases						
No	4 (22.2)	1 (5.6)	5 (13.9)	5.086	3	0.164
Hypertension	5 (27.8)	2 (11.1)	7 (19.4)			
Dyslipidemia	3 (16.7)	3 (16.7)	6 (16.7)			
Hypertension + dyslipidemia	6 (33.3)	12 (66.6)	18 (50.0)			
Use of oral antihyperglycemic drugs						
Sulfonylureas	3 (16.7)	1 (5.6)	4 (11.1)	4.862	2	0.088
Biguanides	3 (16.7)	0 (0.0)	3 (8.3)			
Sulfonylureas + Biguanides	12 (66.7)	17 (94.4)	29 (80.6)			
Use of antihypertensive drugs[2]						
No	4 (22.2)	6 (33.3)	10 (27.8)	0.554	1	0.457
Yes	14 (77.8)	12 (66.7)	26 (72.2)			
Use of antidyslipidemic drugs (Statins)						
No	3 (16.7)	8 (44.4)	11 (30.6)	3.273	1	0.070
Yes	15 (83.3)	10 (55.6)	25 (69.4)			
Having of diabetic knowledge (prior to this study)						
No	3 (16.7)	0 (0.0)	3 (8.3)	3.273	1	0.114
Yes	15 (83.3)	18 (100.0)	33 (91.7)			

[1] Difference between groups was compared by independent sample t-test
[2] Antihypertensives drugs = Moduretic, Beta blockers, Calcium blockers, or Angiotensin converting enzyme inhibitors
df = degree of freedom; χ^2= compare frequency between groups by Chi-square test

Table 9 Characteristics of the subjects (continued)

Demographic data	Treatment Group (n = 18)	Control Group (n = 18)	Total (n = 36)	χ^2	df	p
	number (%)	number (%)	number (%)			
Body mass index (kg/m^2)						
18.5-22.9 (normal)	4 (22.2)	3 (16.7)	7 (19.4)	0.454	2	0.797
23-24.9 (overweight)	5 (27.8)	4 (22.2)	9 (25.0)			
25-29.9 (obese)	9 (50.0)	11 (61.1)	20 (55.6)			
Presence of abdominal obesity[2]						
No	5 (27.8)	3 (16.7)	8 (22.2)	0.643	1	0.423
Yes	13 (72.2)	15 (83.3)	28 (78.8)			
Presence of metabolic syndrome[2]						
No	2 (11.1)	0 (0.0)	2 (5.6)	2.118	2	0.146
Yes	16 (88.9)	18 (100.0)	34 (94.4)			
Physical activity						
< 1 hour/week	0 (0.0)	2 (11.1)	2 (5.6)	0.370	2	0.831
1 - < 3 hours/week	4 (22.2)	3 (16.7)	7 (19.4)			
≥ 3 hours/week	14 (77.8)	13 (72.2)	27 (75.0)			
Physical activity index[3]						
Inactive	0 (0.0)	0 (0.0)	0 (0.0)	0.370	2	0.831
Moderately inactive	1 (5.6)	2 (11.1)	3 (8.3)			
Moderately active	3 (16.7)	3 (16.7)	6 (16.7)			
Active	14 (77.7)	13 (72.2)	27 (75.0)			

[1] Normal, overweight and obese were defined by the WHO Asia-Pacific guideline for Asian adults (International Obesity Task Force, 2000).

[2] Abdominal obesity was defined as WC ≥ 90 cm in men and ≥ 80 cm in women, and metabolic syndrome were defined by modified NCEP-ATP III (Grundy et al., 2005).

[3] Physical activity index was classified using NICE guideline (NICE, 2006).

df = degree of freedom; χ^2= compare frequency between groups by Chi-square test

4.1.2   Dietary Patterns of the Subjects

Dietary patterns of subjects in the treatment and the control groups were not significantly different (**Table 10**). Majority of the subjects in both groups consumed meat and meat products ≥ 5 days/week. It was found that about 80% of the subjects in both groups consumed food containing high saturated fatty acid < 3 days/week. For snacks and fast foods consumption, most of them never or rarely consumed snacks and fast foods. At least 15 subjects in each group consumed fresh fruits or vegetables ≥ 3 days/week. For sweetened or carbonated beverages, more than 50% of the subjects in both groups did not drink these types of beverages. About 30% of the subjects drank the beverages about 1-2 days/week. Approximately 80-90% of the subjects in both groups did not drink tea. The results showed that most of them drank coffee about 1-2 cups/day (data not shown). About 60% and 50% of the subjects in the treatment and control groups respectively drank water at least 8 glasses/day.

Table 10 Dietary patterns of the subjects

Dietary patterns	Treatment Group (n = 18)	Control Group (n = 18)	Total (n = 36)	χ^2	df	p
	number (%)	number (%)	number (%)			
Frequency of meat and meat products intake (days/week)						
None	0 (0.0)	1 (5.6)	1 (2.8)	1.111	3	0.774
1-2	3 (16.7)	3 (16.7)	6 (16.7)			
3-4	5 (27.8)	4 (22.2)	9 (25.0)			
≥ 5	10 (55.5)	10 (55.5)	20 (55.5)			
Frequency of high saturated fatty acid food intake (days/week)						
None	4 (22.2)	8 (44.4)	12 (33.3)	5.222	3	0.156
1-2	11 (61.1)	7 (38.9)	18 (50.0)			
3-4	0 (0.0)	2 (11.1)	2 (5.6)			
≥ 5	3 (16.7)	1 (5.6)	4 (11.1)			
Frequency of snacks intake (days/week)						
None	13 (72.2)	16 (88.8)	29 (80.5)	2.110	2	0.348
1-2	4 (22.2)	1 (5.6)	5 (13.8)			
3-4	1 (5.6)	1 (5.6)	2 (5.6)			
Frequency of fast foods intake (days/week)						
None	14 (77.8)	16 (88.9)	30 (83.3)	0.800	1	0.658
1-2	4 (22.2)	2 (11.1)	6 (16.7)			
Frequency of vegetables and fruits intake (days/week)						
None	1 (5.6)	0 (0.0)	1 (2.8)	2.000	3	0.572
1-2	2 (11.1)	1 (5.6)	3 (8.3)			
3-4	2 (11.1)	4 (22.2)	6 (16.7)			
≥ 5	13 (72.2)	13 (72.2)	26 (72.2)			
Frequency of preserved or canned fruits intake (days/week)						
None	15 (83.3)	14 (77.8)	29 (80.5)	1.701	2	0.427
1-2	2 (11.1)	4 (22.2)	6 (16.7)			
3-4	0 (0.0)	0 (0.0)	0 (0.0)			
≥ 5	1 (5.6)	0 (0.0)	1 (2.8)			

df = degree of freedom; χ^2= compare frequency between groups by Chi-square test

Table 10 Dietary patterns of the subjects (continued)

Dietary patterns	Treatment Group (n = 18)	Control Group (n = 18)	Total (n = 36)	χ^2	df	p
	number (%)	number (%)	number (%)			
Frequency of salty food intake (days/week)						
None	7 (38.8)	5 (27.7)	12 (33.2)	0.533	3	0.912
1-2	9 (50.0)	11 (61.1)	20 (55.6)			
3-4	1 (5.6)	1 (5.6)	2 (5.6)			
≥ 5	1 (5.6)	1 (5.6)	2 (5.6)			
Frequency of sweeten or carbonated beverages intake (days/week)						
None	11 (61.1)	9 (50.0)	20 (55.6)	0.624	3	0.891
1-2	5 (27.7)	6 (33.3)	11 (30.5)			
3-4	1 (5.6)	2 (11.1)	3 (8.3)			
≥ 5	1 (5.6)	1 (5.6)	2 (5.6)			
Drinking of tea						
Not drink	17 (94.4)	14 (77.8)	31 (86.1)	2.090	1	0.338
Drink	1 (5.6)	4 (22.2)	5 (13.9			
Drinking of coffee						
Not drink	8 (44.4)	5 (27.8)	13 (36.1)	1.084	1	0.489
Drink	10 (55.6)	13 (72.2)	23 (63.9)			
Amount of water intake (glasses/day)						
< 8	7 (38.9)	9 (50.0)	16 (44.4)	0.450	1	0.738
≥ 8	11 (61.1)	9 (50.0)	20 (55.6)			

df = degree of freedom; χ^2 = compare frequency between groups by Chi-square test

Table 11 Baseline clinical characteristics of the subjects[1]

Characteristics	Treatment Group (n = 18)	Control Group (n = 18)
Body weight (kg)	63.24 ± 1.92	63.11 ± 2.25
BMI (kg/m^2)	25.92 ± 0.60	25.18 ± 0.59
SBP (mmHg)	127.50 ± 3.19	123.67 ± 3.97
DBP(mmHg)	73.83 ± 1.84	75.56 ± 2.46
FPG (mg/dl)	123.39 ± 5.64	114.39 ± 5.51
HbA1c (%)	6.88 ± 0.21	7.26 ± 0.37
Serum insulin (μIU/ml)	6.33 ± 0.87	5.77 ± 1.03
HOMA-IR	1.88 ± 0.25	1.68 ± 0.34
HOMA-B%	43.26 ± 6.67	38.41 ± 6.44
Total-C (mg/dl)	187.78 ± 6.67	199.28 ± 6.05
HDL-C (mg/dl)	48.44 ± 2.13	52.06 ± 2.22
LDL-C (mg/dl)	111.11 ± 6.31	117.06 ± 6.86
TG (mg/dl)	141.89 ± 8.97	140.72 ± 10.86

[1] Values are expressed as mean ± SEM.
BMI = body mass index; SBP = systolic blood pressure; DBP = diastolic blood pressure; FPG = fasting plasma glucose; HbA1c = hemoglobin A1c; HOMA-IR = homeostasis model assessment of insulin resistance; HOMA-B% = homeostasis model assessment of beta-cell function; Total-C = total cholesterol; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; TG = triglyceride; kg/m^2 = kilogram per metre square, mmHg = millimetre of mercury, mg/dl= milligram/deciliter

4.1.3 Baseline Clinical Characteristics of the Subjects

The baseline clinical characteristics of the subjects in treatment and control groups are summarized in **Table 11**. None of the measured parameters differed between groups ($p > 0.05$). About 56% of subjects in each group could achieve the glycemic control (defined as HbA1c < 7.0% and FPG < 130 mg/dl). In addition, baseline serum insulin levels of all subjects were within the normal range (6.0-27.0 μIU/ml).

4.2   Dietary and Energy Intakes of the Subjects

In this study, dietary intakes of the subjects were assessed by 3-day food records. The records were analyzed in term of total energy, carbohydrate, protein, fat, cholesterol, sugar, dietary fiber, and water intakes per day. The average dietary intakes of the subjects at baseline and week 6 of the experiment period are presented in **Table 12**.

The result demonstrated that dietary and energy intakes of the subjects in the treatment and the control groups were not significantly different at baseline. Over the course of the study, total energy intakes of the subjects in both groups were about 1,400 kcal/day without significant differences within group and between groups. In the treatment group, the amount of carbohydrate intake at week 6 was significantly less than that at baseline. At week 6, the amount of total protein and animal protein intakes were greater in the treatment group, whereas vegetable protein intake was lower than those at baseline. In the control group, carbohydrate consumption at week 6 increased significantly from baseline ($p = 0.019$). When compared dietary intakes between groups at week 6, the amount of total protein and animal protein intakes were significantly greater in the treatment group than those in the control group. In contrast, the amount of carbohydrate and vegetable protein intakes in the treatment group were significantly less than those in the control group.

The intakes of fat, cholesterol, sugar, dietary fiber, and water did not change significantly from baseline and were also not different between groups. Sodium intake was assessed in this study because it may affect blood pressure. The results showed that the amounts of sodium intake in both groups were about 1,700-2,000 mg/day throughout the study without significant difference between groups.

Table 12 Dietary and energy intakes of the subjects at baseline and week 6 of the study

Dietary intake	Treatment Group (n = 18)		Control Group (n = 18)	
	Baseline	**Week 6**	**Baseline**	**Week 6**
Total energy (TE)				
kcal/day	1406.45 ± 46.02	1349.03 ± 47.56	1400.58 ± 42.70	1414.54 ± 49.61
Carbohydrate				
g/day	207.50 ± 8.55	171.13 ± 6.26*[†]	191.05 ± 6.93	201.22 ± 8.53*
kcal/day	830.02 ± 34.20	684.50 ± 25.04*[†]	723.87 ± 37.46	804.89 ± 34.10*
% TE	59.33 ± 2.20	51.02 ± 1.35*[†]	52.60 ± 2.54	57.81 ± 1.62*
Protein				
g/day	63.79 ± 4.83	81.59 ± 4.29*[#]	62.31 ± 3.67	60.77 ± 2.57
g/kg/day	1.03 ± 0.08	1.32 ± 0.08*[†]	1.00 ± 0.06	0.98 ± 0.05
kcal/day	255.17 ± 19.31	326.36 ± 17.14*[#]	249.24 ± 14.67	243.08 ± 10.29
% TE	17.93 ± 0.99	24.27 ± 0.98*[#]	17.50 ± 1.10	16.86 ± 0.45
From animal				
g/day	40.13 ± 4.93	61.30 ± 4.66*[#]	36.73 ± 4.36	32.74 ± 1.96
From vegetable				
g/day	16.90 ± 0.79	12.27 ± 0.72*[†]	16.35 ± 1.09	16.64 ± 1.46
Fat				
g/day	35.68 ± 2.82	37.46 ± 2.78	44.83 ± 2.75	39.57 ± 3.01
kcal/day	321.05 ± 25.37	337.10 ± 25.00	403.49 ± 24.77	356.14 ± 24.07
% TE	22.75 ± 1.67	24.61 ± 1.24	28.81 ± 1.54	24.75 ± 1.50
Cholesterol				
mg/day	181.15 ± 23.37	177.32 ± 30.14	202.09 ± 19.41	179.53 ± 18.13
Sugar				
g/day	21.66 ± 2.93	21.51 ± 2.52	20.29 ± 2.59	28.27 ± 5.04
Dietary fiber				
g/day	9.00 ± 0.86	7.56 ± 0.66	8.35 ± 0.83	8.68 ± 0.70
Sodium				
mg/day	1851.17 ± 315.27	1742.01 ± 224.50	1825.51 ± 164.43	2038.62 ± 248.28
Water				
	1730.10 ± 39.85	1672.74 ± 39.11	1743.68 ± 50.45	1802.83 ± 59.74
% Energy distribution (carbohydrate:protein:fat)				
	59:18:23	51:24:25	53:18:29	58:17:25

[1] Values are expressed as mean ± SEM.
kcal = kilocalorie; g = gram; mg = milligram; %TE = percentage of total energy
* Significant difference from baseline ($p < 0.05$)
[†] Significant difference between groups at week 6 ($p < 0.05$)
[#] Significant difference between groups at week 6 ($p < 0.001$)

Table 13 Effects of WPI supplementation on glycemic control and insulin resistance[1]

Parameters	Treatment Group (n = 18)		Control Group (n = 18)	
	Baseline	**Week 6**	**Baseline**	**Week 6**
FPG				
mg/dl	123.39 ± 5.64	125.89 ± 4.41	114.39 ± 5.51	124.11 ± 4.87
mmol/l	6.86 ± 0.31	6.99 ± 0.25	6.35 ± 0.31	6.89 ± 0.27
HbA1c (%)	6.88 ± 0.21	6.83 ± 0.17	7.26 ± 0.37	6.97 ± 0.27
Serum insulin (μIU/ml)	6.33 ± 0.87	5.78 ± 0.82	5.77 ± 1.03	6.10 ± 0.92
HOMA-IR	1.88 ± 0.25	1.87 ± 0.30	1.68 ± 0.34	1.76 ± 0.27
HOMA-B%	43.26 ± 6.67	33.06 ± 3.93	38.41 ± 6.44	39.28 ± 5.91

[1] Values are expressed as mean ± SEM.
FPG = fasting plasma glucose; HbA1c = hemoglobin A1c; HOMA-IR = homeostasis model assessment of insulin resistance; HOMA-B% = homeostasis model assessment of beta-cell function; mg/dl = milligram/deciliter; mmol/l = millimole/liter; μIU/ml = micro-international unit per milliliter

4.3 Effects of WPI Supplementation on Glycemic Control and Insulin Resistance

The levels of FPG, HbA1c, serum insulin, HOMA-IR and HOMA-B% at baseline and week 6 are presented in **Table 13**. At baseline, these parameters were comparable in both groups. After 6-week WPI supplementation, FPG, HbA1c, and serum insulin levels did not change from baseline in both groups. HOMA-IR and HOMA-B%, which were the indices of insulin resistance and β-cell function respectively did not change significantly from baseline in both groups. Additionally, there were no significant differences in FPG, HbA1c, serum insulin, HOMA-IR and HOMA-B% between groups at week 6.

4.4   Effects of WPI Supplementation on Serum Lipid Profile

Serum lipid profile of the subjects including total-C, HDL-C, LDL-C and TG are presented in **Table 14**. The levels of these parameters were comparable between groups at baseline. Total-C, HDL-C, and LDL-C levels at week 6 were not significantly different from baselines in both groups. Significant differences in total-C, HDL-C, and LDL-C levels were not observed between groups at week 6. Interestingly, a significant decline in TG level was found in the treatment group ($p = 0.043$) but not in the control group. Moreover, the TG level in the treatment group seemed to be lower than that in the control group at week 6 ($p = 0.064$).

To investigate whether the TG-lowering effect depended on baseline TG level or not, subgroup analysis was performed. The subjects were categorized into 4 groups including the treatment and control groups who achieved the treatment goal for TG (baseline TG < 150 mg/dl, n = 10 in each group) and the treatment and control groups who failed to achieve the treatment goal (baseline TG $\geq$ 150 mg/dl, n = 8 in each group) (ADA, 2010b). The results indicated that a significant decline in TG level was found in the treatment group with baseline TG $\geq$ 150 mg/dl (n = 8) but not in the group with baseline TG < 150 mg/dl (n = 10) (**Table 15**). For the control group, significant change in TG level was not found in both subjects with baseline TG < 150 mg/dl and $\geq$ 150 mg/dl.

Table 14 Effects of WPI supplementation on serum lipid profile[1]

Parameters	Treatment Group (n = 18)		Control Group (n = 18)	
	Baseline	Week 6	Baseline	Week 6
Total-C				
mg/dl	187.78 ± 6.67	183.39 ± 6.91	199.28 ± 6.05	199.61 ± 9.2
mmol/l	4.86 ± 0.17	4.74 ± 0.18	5.15 ± 0.16	5.16 ± 0.24
HDL-C				
mg/dl	48.44 ± 2.13	47.70 ± 2.02	52.06 ± 2.22	48.41 ± 2.86
mmol/l	1.25 ± 0.06	1.23 ± 0.05	1.35 ± 0.06	1.25 ± 0.07
LDL-C				
mg/dl	111.11 ± 6.31	113.21 ± 5.79	117.06 ± 6.86	118.80 ± 8.11
mmol/l	2.87 ± 0.16	2.93 ± 0.15	3.03 ± 0.18	3.07 ± 0.21
TG				
mg/dl	141.89 ± 8.97	124.17 ± 7.54*	140.72 ± 10.86	149.44 ± 10.84
mmol/l	1.60 ± 0.10	1.40 ± 0.09*	1.59 ± 0.12	1.69 ± 0.12

[1] Values are expressed as mean ± SEM.
Total-C = total cholesterol; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; TG = triglyceride; mg/dl = milligram/deciliter; mmol/l = millimole/liter
* Significant difference from baseline ($p < 0.05$)

Table 15 Effects of WPI supplementation on triglyceride level in the subjects with baseline triglyceride ≥ 150 mg/dl and < 150 mg/dl[1]

Parameters		Baseline TG ≥ 150 mg/ml		Baseline TG < 150 mg/ml	
		Treatment (n = 8)	Control (n = 8)	Treatment (n = 10)	Control (n = 10)
TG					
mg/dl	Baseline	178.38 ± 5.77	180.63 ± 10.14	112.70 ± 6.31	108.80 ± 10.88
	Week 6	140.00 ± 12.34*	172.13 ± 13.99	111.50 ± 7.64	131.30 ± 13.97
mmol/l	Baseline	2.01 ± 0.07	2.04 ± 0.08	1.27 ± 0.08	1.22 ± 0.12
	Week 6	1.58 ± 0.14*	1.94 ± 0.16	1.25 ± 0.09	1.48 ± 0.16

[1] Values are expressed as mean ± SEM.
TG = triglyceride; mg/dl = milligram/deciliter; mmol/l = millimole/liter; n = number of subjects
* Significant difference from baseline ($p < 0.05$)

4.5   Effects of WPI Supplementation on Other Biochemical Parameters

Albumin, uric acid, SCr, AST, ALT, ALP, BUN, and electrolyte concentrations of the subjects at baseline and week 6 of WPI supplementation period are presented in **Table 16**. At baseline, concentrations of these parameters in both groups were not different. After WPI supplementation for 6 weeks, there were no significant differences in albumin, uric acid, AST, ALT, SCr, and electrolyte concentrations within group and between groups. However, mean ALP level in the treatment group increased significantly from baseline ($p = 0.022$) while those for the control group did not change significantly. In addition, a significant increase in BUN level at week 6 was found in the treatment group ($p = 0.004$) but not in the control group. In this regard, BUN levels were higher than the normal clinical ranges (6.0-25.0 mg/dl) in 3 subjects in the treatment group (29.0-31.0 mg/dl). At week 6, mean BUN level was significant greater in the treatment group than that in the control group ($p = 0.019$). With the exception of BUN, all other blood biochemical parameters in both groups were not statistically different at week 6.

Table 16 Effects of WPI supplementation on other biochemical parameters[1]

Parameters	Treatment Group (n = 18)		Control Group (n = 18)	
	Baseline	Week 6	Baseline	Week 6
Albumin (g/dl)	4.58 ± 0.07	4.51 ± 0.06	4.56 ± 0.05	4.53 ± 0.06
Uric acid (mg/dl)	5.95 ± 0.28	5.74 ± 0.33	5.40 ± 0.33	5.38 ± 0.31
AST (U/L)	19.56 ± 1.17	17.24 ± 0.92	22.13 ± 1.14	20.63 ± 1.43
ALT (U/L)	19.65 ± 1.54	19.92 ± 1.45	26.22 ± 3.57	24.28 ± 2.22
ALP (U/L)	66.11 ± 3.96	68.82 ± 4.22*	63.78 ± 3.10	63.83 ± 2.92
BUN (mg/dl)	15.50 ± 0.92	19.13 ± 1.39*†	15.28 ± 1.00	14.44 ± 1.29
SCr (mg/dl)	0.96 ± 0.06	0.97 ± 0.06	0.86 ± 0.04	0.86 ± 0.06
Na (mmol/l)	140.94 ± 0.51	141.78 ± 0.38	142.11 ± 0.54	142.39 ± 0.47
K (mmol/l)	4.70 ± 0.07	4.57 ± 0.08	4.65 ± 0.08	4.54 ± 0.10
Cl (mmol/l)	101.94 ± 0.62	102.56 ± 0.63	102.28 ± 0.45	101.72 ± 0.58
CO_2 (mmol/l)	25.50 ± 0.64	26.39 ± 0.57	26.06 ± 0.46	26.78 ± 0.53

[1] Values are expressed as mean ± SEM.
SCr = serum creatinine; BUN = blood urea nitrogen; AST = aspartate aminotransferase; ALT = alanine aminotransferase; ALP = alkaline phosphatase; Na = sodium; K = potassium; Cl = chloride; CO_2 = carbondioxide; mg/dl = milligram/deciliter; g/dl = gram/deciliter; mmol/l = millimole/liter; U/L = international unit/liter
* Significant difference from baseline ($p < 0.05$)
† Significant difference between groups at week 6 ($p < 0.05$)

4.6 Effects of WPI Supplementation on Blood Pressure

Systolic and diastolic blood pressures of the subjects are shown in **Table 17**. At baseline, systolic and diastolic blood pressures were not significant different between groups. In the treatment group, there was a significant decrease in SBP at week 6 (p = 0.002), but not in DBP. In the control group, SBP and DBP did not change significantly from baselines. The reduction of SBP was significantly larger in the treatment group than that in the control group (-9.28 ± 2.51 and -1.33 ± 2.86 mmHg for the treatment and the control group respectively, p = 0.044). In the present study, significant differences between groups in SBP and DBP were not found.

4.7 Effects of WPI Supplementation on Anthropometric Parameters

The results of anthropometric measurements including body weight, height, WC, HC, WHR, MAC, MAMC, and TSF are shown in **Table 17**. At baseline, there were no significant differences between groups in any anthropometric parameters.

After 6 weeks of WPI supplementation, there were a significant decrease in body weight and BMI in the treatment group, whereas no significant changes in any parameters were observed in the control group. Indeed, the mean weight loss for the treatment group was about 0.52 ± 1.24 kg or 0.80 ± 0.36% of baseline body weight (p < 0.043). The mean reduction of BMI was about 0.2 kg/m^2 (p = 0.043). WC of the treatment group tended to reduce from baseline (p = 0.055). Nevertheless, there were no significant differences between groups in any anthropometric parameters at week 6.

Table 17 Effects of WPI supplementation on blood pressure and anthropometric parameters[1]

Parameters	Treatment Group (n = 18)		Control Group (n = 18)	
	Baseline	Week 6	Baseline	Week 6
SBP (mmHg)	127.50 ± 3.19	118.22 ± 2.24*	123.67 ± 3.97	122.33 ± 4.04
DBP (mmHg)	73.83 ± 1.84	77.11 ± 1.88	75.56 ± 2.46	74.44 ± 1.85
Weight (kg)	63.24 ± 1.92	62.73 ± 1.89*	63.11 ± 2.25	62.77 ± 2.31
Height (cm)	156.10 ± 0.02	156.10 ± 0.02	158.10 ± 0.02	158.10 ± 0.02
BMI (kg/m^2)	25.92 ± 0.60	25.71 ± 0.58*	25.18 ± 0.59	25.03 ± 0.60
WC (cm)	85.44 ± 1.00	84.94 ± 0.93	83.64 ± 1.96	83.62 ± 2.03
HC (cm)	96.79 ± 1.08	96.70 ± 1.13	95.16 ± 1.28	94.90 ± 1.26
WHR	0.89 ± 0.01	0.88 ± 0.00	0.88 ± 0.02	0.88 ± 0.02
TSF (mm)	16.97 ± 1.47	16.66 ± 1.43	16.27 ± 1.55	15.17 ± 1.18
MAC (cm)	30.01 ± 0.62	29.78 ± 0.57	30.24 ± 0.74	29.97 ± 0.60
MAMC (cm)	24.68 ± 0.39	24.55 ± 0.36	25.14 ± 0.66	25.21 ± 0.60

[1] Values are expressed as mean ± SEM.
SBP = systolic blood pressure; DBP = diastolic blood pressure; BMI = body mass index; WC = waist circumference; HC = hip circumference; WHR = waist to hip ratio; TSF = triceps skinfold thickness; MAC = mid-arm circumference; MAMC = mid-arm muscle circumference; mmHg = millimeter of mercury; kg = kilogram; cm = centimeter; m^2 = square meter; cm = centimeter; mm = millimeter
*Significant difference from baseline ($p < 0.05$)

4.8   Compliance and Adverse Effects of Whey Protein

Compliance of the treatment was assessed by calculation the eaten sachets of WPI supplement throughout the 6-week WPI supplementation. The results showed that compliance of WPI supplementation was excellent. The average percentage of compliance was 97.00 ± 0.98. According to the information obtained from the treatment subjects, tolerance and acceptability of whey protein isolate were good. No serious adverse effects were found throughout the study period. The minor adverse effect was flatulence. Three subjects (16.67%) reported transient flatulence. Flatulence was troublesome only at the beginning of the treatment and was improved or disappeared as they continued supplementing WPI or consumed WPI in divided doses (2-3 times/day). No subject dropped out from the study because of adverse effects caused by the whey protein supplementation.