Turk J Public Health
Available online at: http://dergipark.org.tr/tjph/
Doi: 10.20518/tjph.1512683

TURKISH JOURNAL OF PUBLIC HEALTH

ORIGINAL ARTICLE

Effect of green tea and wheat bran on professional drivers with metabolic syndrome: A controlled clinical trial

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Received: 29.07.2024, **Accepted:** 13.03.2025

Abstract

Objective: The present study aims to investigate the effect of Green Tea (GT) and Wheat Bran (WB) on Metabolic Syndrome in male drivers.

Methods: A controlled clinical trial was conducted with two intervention groups (GT and WB) and a control group on ninety male drivers with metabolic syndrome. Random allocation was done using permuted block randomization. Before the intervention, parametric measurements (height, weight, systolic and diastolic blood pressure, and abdominal circumference) and blood tests (fasting blood sugar (FBS), triglycerides (TG), high-density lipoprotein (HDL)) were checked. The GT group consumed three cups of GT tea bags (1gr) daily, and the WB group received 3.5 grams of WB powder daily. After two months, measurements and tests were repeated.

Results: There were no significant differences in blood pressure among the groups ($p>0.05$). The GT group showed a decrease in weight, FBS, and TG, as well as an increase in HDL. The WB group also exhibited a decrease in FBS and TG and an increase in HDL. A significant increase was found in the HDL level in the GT group before and after the intervention ($p<0.05$).

Conclusion: Consumption of green tea has been effective in reducing the number of patients with metabolic syndrome, and consumption of green tea and wheat bran can positively increase HDL. Also, green tea can be effective in reducing weight, FBS, and TG in male drivers suffering from metabolic syndrome.

Keywords: Metabolic Syndrome, Clinical Trial, Green Tea, Wheat Bran

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Cite This Article: Behboudi MR, Ebrahimi MH, Mirmohammadkhani M, Pour MA, Basati R, Shayestefar M. Effect of green tea and wheat bran on professional drivers with metabolic syndrome: A controlled clinical trial. Turk J Public Health 2024;22(3): 25-34.

INTRODUCTION

Metabolic Syndrome (MetS) is a multifactorial metabolic disorder characterized by hypertension, insulin resistance, dyslipidemia, and impaired glucose homeostasis [1]. MetS is a set of physiological and biochemical abnormalities that affects about 20-25% of adults in developing countries [2]. MetS and its components are the most important health problems in the 21st century and have a growing trend in developed and developing countries [3]. MetS is estimated to affect 27.46% to 33.7% of Iranian adults [4]. This syndrome directly increases atherosclerotic cardiovascular diseases [5]. Based on the ATP III definition, cardiovascular diseases are the first consequence of MetS [3].

MetS based on the ATP III and IDF definitions is shown in the following table.

Table 1. Definitions of metabolic syndrome

	Modified NCEP ATP III [27, 28, 29]	IDF [26]
Absolutely required	None	Central obesity (waist circumference) ≥ 94 cm
Criteria	Any three of the five criteria below	Obesity, plus two of the four criteria below
Obesity	Waist circumference: >40 inches (102 cm)	Central obesity already required
Hyperglycemia	Fasting glucose≥ 100 mg/dl or Rx*	Fasting glucose≥ 100 mg/dl or Rx
Plasma triglycerides	TG ≥150 mg/dl or Rx	TG ≥150 mg/dl or Rx
HDL cholesterol	<40 mg/dl or Rx	<40 mg/dl or Rx
Hypertension	>130 mmHg systolic or >85 mmHg diastolic or Rx	>130 mmHg systolic or >85 mmHg diastolic or Rx

NCEP: ATP III: National Cholesterol Education Program's Adult Treatment Panel III.

IDF: International Diabetes Federation.

* Rx, pharmacologic treatment.

Most people with MetS are elderly, inactive, obese, and have some degree of insulin resistance. The most important risk factors include genetic history, obesity, especially abdominal obesity, lifestyle, inactivity, stress, smoking, etc. [3].

Obesity is one of the factors that can cause MetS and is rapidly becoming a major threat in developing countries [6]. In the cohort study of 10,086 people aged 35 to 65 in western Iran, Najafi et al. (2018) reported that 26.7% of the study population was obese [7] Also, in a study of 2818 citizens of East Azerbaijan, Tabrizi et al. (2018) reported the prevalence of overweight, obesity, and abdominal obesity at 39.6%, 24%, and 76.4%, respectively [8].

Green tea (GT) (Camellia sinensis) is one of the oldest beverages in the world and also one of the most studied beverages, especially its role in the prevention of coronary heart disease. Clinical and epidemiological evidence shows that GT consumption is associated with an improved lipid profile and body weight loss [9, 10, 11]. Due to the presence of its catechins, GT is effective in breaking down fats into triglycerides, suppressing adipogenesis, increasing metabolism through thermogenesis, and excreting fecal lipids [12].

Wheat bran (WB) (residue of milled wheat grain[13]) is also associated with improved gastrointestinal health and reduced risk of colorectal cancer, cardiovascular disease, and metabolic disorders.

These benefits are likely mediated by a combination of mechanisms, including colonic fermentation of WB fiber, stool

bulking, and prevention of oxidative damage due to its antioxidant capacities [14]. Short-term consumption of breakfasts containing insoluble WB improves health, digestive feeling status, and intestinal function [15]. The distribution of WB components as measured by dry matter is 55-60% non-starch carbohydrates, 14-25% starch, 13-18% protein, 3-8% minerals, and 3-4% fat [16].

WB and GT are two accessible substances with different beneficial effects on body systems, which can be a suitable choice for research on metabolic syndrome. Today, considering the effects of MetS on the cardiovascular system, the high prevalence of this syndrome, and the importance of the health of drivers on the individual and society, as well as the few studies of the effects of consuming GT and WB to control it, researchers decided to investigate impacts of GT and WB in controlling this MetS in drivers based on the ATP III definition due to the nature of the driving job.

METHODS

The current study is a controlled clinical trial with two intervention groups of GT, WT, and one control group, implemented from March to November 2023. Of all the male professional drivers with MetS in Shahroud who had electronic health records at Kasra Specialized Center for Occupational Medicine, 90 patients in the age group of 40-50 years old due to the higher probability of onset of MetS in middle age, higher cooperation and the possibility of better education were selected. A total of 30 participants were allocated to each of the three groups (intervention group 1, intervention group 2, and control group), resulting in 90 participants in total. This sample size was chosen to ensure adequate statistical power (80%) to detect meaningful differences between groups, considering an alpha level of 0.05 and a medium effect size. The sample size for each group (considering three groups in total) was calculated using appropriate statistical software, such as G*Power.

Drivers who had 3 out of 5 indicators for MetS based on the ATP III definition were considered to have metabolic syndrome. The total number of drivers was 948, and based on this definition of metabolic syndrome, 392 drivers were affected. A total of 90 people from all patients were selected to participate in the study using convenience sampling. Inclusion criteria included age 40-50 years, good cooperation, and easy accessibility. Exclusion criteria also included drivers with a history of gastrointestinal disease, a history of gastrointestinal liver disease, being treated with corticosteroid drugs (which causes excess weight due to peripheral edema), and unwillingness to continue participation in the study.

Then, the random allocation was carried out using permuted block randomization, and the participants were entered into two intervention groups; GT and WB (n=30, in each group) and one control group (n=30).

Before the study, written informed consent was obtained from participants. The study objectives and methodology were clarified for each participant, and they were assured that if they requested, they would be accepted to withdraw from the research project. After explaining the contents of the informed consent and obtaining it, the active participation of the participants during the study was requested. All participants were assured that all the information provided by them would be kept confidential by

the researcher. The participants were also reminded that participation in the study is completely voluntary and they are allowed to decide whether to continue or stop cooperating with the researcher at any stage of the study.

To participate in the study, the participants completed the demographic information questionnaire. Before the intervention, parametric measurements (height, weight, systolic, diastolic blood pressure, and abdominal circumference) and blood tests (FBS, TG, HDL) were checked by two nurses.

A calibrated digital weighing scale (10-gram precision) and a wall-mounted height rod were used. Also, blood pressure measurements for all participants were conducted on the right arm using a validated oscillometric sphygmomanometer (Brisk Model PG-800B16, Germany). Each participant's blood pressure was recorded at least twice, with a minimum five-minute interval between measurements, while seated and after a rest period of at least five minutes. To ensure accurate readings, the procedure followed the American Heart Association guidelines, which recommend that participants remain seated and relaxed for at least five minutes before measurement, avoid smoking, coffee, or tea consumption, use a cuff that fits the arm circumference properly, and refrain from speaking during the measurement process. The tests were performed using the microplate ELISA reader and the kits of Parsazmun company and with the specificity, and sensitivity values specified in the table below.

Table 2. Specifications of blood tests and laboratory kits

Test	Unit	Sensitivity	Normal range	company	Year	Method
HDL-C	mg/dL	1 mg/dL	≥35 mg/dL	Parsazmun kit	2023	600 nm
TG	mg/dL	1 mg/dL	<200 mg/dL	Parsazmun kit	2023	546 nm
FBS	mg/dL	5 mg/dL	70-115 mg/dL	Parsazmun kit	2023	546 nm

The GT group received three cups of sugar-free or milk-free GT bags (1gr) daily [17], and the WB group also received 3.5 grams of WB powder [15] daily orally and according to the individual's taste in combination with yogurt or rice with hygienic packaging and standard logo. Daily consumption of 3 cups of water was suggested for the control group. The literature review showed no side effects for these two substances at these two suggested amounts. There were also two similar articles suggesting 3 cups and 4 cups of GT, which due to the prevention of possible harmful effects, the lower amount (3 cups) was chosen [17]. The control group received their previous dietary regimen but without both green tea and wheat bran, allowing for a clearer comparison of the specific effects of each intervention. Also, it was mentioned to all the participants that if any new dietary or treatment regimens started, it should be informed to the researchers.

To ensure participants' adherence to the study protocol or monitor probability digestive problems, they were called every two weeks.

After the completion of the present study (two months), tests and parametric measurements were repeated. Throughout the study period, all samples were monitored and followed up by the project executive. Then, the changes in the definition items of MetS based on ATP were measured again.

Before the study, the code of ethics was

received from Semnan University of Medical Sciences (IR.SEMUMS.REC.1398.274) and the present research project was registered in the Iranian Registry of Clinical Trials with the code IRCT20200217046524N1. Then permission to conduct the study was obtained from Semnan University of Medical Sciences. Finally, the collected data were analyzed using descriptive statistics (mean, standard deviation) and inferential statistical tests (correlation, t-student, ANOVA, and regression) in SPSS ver. 23. Values of $p < 0.05$ were considered statistically significant.

RESULTS

There were 25 individuals in the GT group, 23 in the WB group, and 26 in the control group. Dropout reasons were participants' withdrawal and digestive problems during the study. The mean ± SD age of each group was 49.04 ±7.62, 48.52 ± 7.72, and 47.26 ± 8.36, respectively, and the overall age range was 48.25 ± 7.85 years.

Initially, all the participants in all three groups had metabolic syndrome, but after the intervention, this syndrome was not reported in 7 cases from the GT group and 3 from the WB group based on the ATP III definition, and this reduction in the GT group was statistically significant ($p<0.05$).

The mean ± SD of metabolic syndrome variables before and after the intervention in all groups is shown in Table 3.

Table 3. Mean ±SD of Metabolic syndrome variables before and after the intervention in three groups

Variable	Group	Mean ±SD	
		Before the intervention	After the intervention
Systolic blood pressure (mmHg)	Green tea	131.64±10.72	129.20±10.91
	Wheat bran	135.34±11.89	136.78±16.56
	Control	138.42±16.68	133.84±16.31
Diastolic blood pressure (mmHg)	Green tea	82.68±7.56	80.60±7.68
	Wheat bran	81.17±9.06	85.17±12.61
	Control	84.19±10.29	83.50±7.42
FBS (mg/dL)	Green tea	113.20±41.01	116.28±42.64
	Wheat bran	118.56±40.56	116.56±39.13
	Control	117.38±42.51	116.03±37.04
TG (mg/dL)	Green tea	243.60±69.43	233.24±122.16
	Wheat bran	237.04±108.78	204.30±62.00
	Control	219.38±66.36	199.46±63.75
HDL (mg/dL)	Green tea	35.84±2.85	37.84±5.01
	Wheat bran	36.82±2.05	38.13±2.78
	Control	36.00±2.48	37.11±3.43
Abdominal circumference (cm)	Green tea	105.08±11.20	105.24±9.72
	Wheat bran	103.73±10.01	101.82±10.34
	Control	104.26±12.13	102.50±12.42

It was found that there was no significant difference between the interventions in terms of their effectiveness on the Systolic and Diastolic blood pressure, FBS, TG, HDL, and abdominal circumference of the participants in all three groups (p>0.05) (Table 4).

Table 4. Comparison of mean variables (after the interventions) across three groups

Variable		Sum of Squares	df	Mean Square	F	p-value
Systolic blood pressure (mmHg)	Between Groups	706.05	2	353.02	1.61	0.20
	Within Groups	15555.29	71	219.08		
	Total	16261.35	73			
Diastolic blood pressure (mmHg)	Between Groups	259.07	2	129.53	1.46	0.23
	Within Groups	6297.80	71	88.70		
	Total	6556.87	73			
FBS (mg/dL)	Between Groups	3.38	2	1.69	0.01	0.99
	Within Groups	111653.65	71	1572.58		
	Total	111657.04	73			
TG (mg/dL)	Between Groups	16717.51	2	8358.75	1.09	0.34
	Within Groups	544421.89	71	7667.91		
	Total	561139.40	73			
HDL (mg/dL)	Between Groups	13.59	2	6.79	0.45	0.63
	Within Groups	1068.62	71	15.05		
	Total	1082.21	73			
Abdominal circumference (cm)	Between Groups	160.17	2	80.08	0.67	0.51
	Within Groups	8480.36	71	119.44		
	Total	8640.54	73			

The comparisons of variables in the green tea group before and after the interventions are shown in the table below. The results revealed significant changes in the HDL levels of the participants in the GT group before and after the intervention (p<0.05).

Table 5. Comparison of variables in the green tea group after vs before the intervention

Paired variables	Paired Differences					t	df	p-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
HDL (mg/dL)	2.00	4.28	0.85	0.23	3.76	2.33	24	0.02
Diastolic blood pressure (mmHg)	-2.08	10.02	2.00	-6.21	2.05	-1.03	24	0.31
Systolic blood pressure (mmHg)	-2.44	10.54	2.10	-6.79	1.91	-1.15	24	0.25
FBS (mg/dL)	3.08	41.93	8.38	-14.22	20.38	0.36	24	0.71
TG (mg/dL)	-10.36	103.23	20.64	-52.97	32.25	-0.50	24	0.62
Abdominal circumference (cm)	0.16	5.30	1.06	-2.02	2.34	0.15	24	0.88

Also, the comparisons of variables in the wheat bran group before and after the interventions are shown in the table below. The results revealed no significant changes (p>0.05).

Table 6. Comparison of variables in the wheat bran group before and after the intervention

Paired variables	Paired Differences					t	df	p-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
HDL (mg/dL)	1.30	3.21	0.66	-0.08	2.69	1.94	22	0.06
Diastolic blood pressure (mmHg)	4.00	12.42	2.59	-1.37	9.37	1.54	22	0.13
Systolic blood pressure (mmHg)	1.43	14.89	3.10	-5.00	7.87	0.46	22	0.64
FBS (mg/dL)	-2.00	28.30	5.90	-14.24	10.24	-0.33	22	0.73
TG (mg/dL)	-32.73	85.79	17.88	-69.83	4.36	-1.83	22	0.08
Abdominal circumference (cm)	-1.91	5.17	1.07	-4.15	0.32	-1.77	22	0.09

Based on the regression analysis, HDL level Changes have a significant effect on being affected by Metabolic Syndrome (β=0.33, p<0.05).

Table 7. Relationship between changes in Metabolic Syndrome variables and post-intervention Metabolic Syndrome

Variable	Unstandardized Coefficients		Standardized Coefficients	t	p-value
	B	Std. Error	β		
Systolic blood pressure.Changes	-0.006	0.003	-0.23	-1.85	0.06
Diastolic blood pressure.Changes	-0.003	0.004	-0.09	-0.78	0.43
FBS.Changes	<0.001	0.001	0.03	0.36	0.72
TG.Changes	-0.001	0.000	-0.21	-1.93	0.05
Abdominal.circumference.Changes	0.01	0.008	0.13	1.24	0.21
HDL.Changes	0.02	0.009	0.33	3.18	<0.01

DISCUSSION

There was no significant difference between WB and GT interventions in terms of their effect on the systolic and diastolic blood pressure of the participants in all three groups. Also, in a randomized controlled trial (RCT) by Rasmus Fuglsang-Nielsen et al. (2020), it was found that WB dietary fiber did not affect 24-hour blood pressure (BP) compared to low dietary fiber [18], which may require higher WB level or a longer intervention.

A decrease in FBS and TG and an increase in HDL were observed in the GT and WB groups. In this regard, Li et al. (2023) performed a systematic review and meta-analysis of randomized controlled trials regarding the effect of green tea on the lipid profile of obese women. It was concluded that GT reduces the concentration of LDL-C and total cholesterol. The decrease in TG level was significant especially in overweight patients with hypertriglyceridemia at baseline beginning. Besides, a significant increase in HDL-C was observed in obese subjects following GT consumption [19]. In a review study by Budhwar et al. (2020), it was stated that wheat bran and rice can be used to control chronic diseases, especially diabetes [20].

A reduction in body weight was observed in the GT group with metabolic syndrome. Similarly, a series of RCTs on GT (4 cups/day)

and GTE (2 capsules/day) drinks for 8 weeks in 35 obese subjects with MetS, serum plasma amyloid alpha (an independent risk factor for cardiovascular diseases), BW, BMI, and lipid peroxidation were significantly reduced [21, 22, 23]. In another interventional study, Sanger et al. concluded that a 60-day consumption of three cups of GT (as 1-gram bags) reduced weight, BMI, and waist circumference in 45 elderly people with metabolic syndrome. However, it did not change their lipid profile and glycemia [17].

Overall, GT had a significant effect on the reduction of people with metabolic syndrome, and it was also effective on four variables of metabolic syndrome, including body weight, FBS, TG, and HDL, which can indicate a favorable effect on these people. Similarly, in an epidemiological study of 15,568 Korean population aged 19–65, Kim et al. (2016) showed that regular GT consumption was inversely associated with metabolic syndrome [24]. Also, in another RCT of 70 women with a confirmed MetS, Mortazavi et al. (2019) found a significant improvement in anthropometric indices, i.e., BP, BG, and lipid profile after drinking 200 ml of GT 3 times a day for eight weeks [25].

Study Strengths

The present study is a clinical trial on participants with Metabolic syndrome which is a common problem. Also, two intervention groups consumed wheat bran and green tea which are two accessible substances. The objective, inclusion, and exclusion criteria were clearly stated. The authors stated that there was no conflict of interest.

Study limitations

During the implementation phase, green tea and wheat bran produce some digestive problems, leading to the participants dropping out. Also, the potential effects of concomitant medications and comorbidities cannot be excluded. In addition, blood pressure was measured in an occupational medicine clinic, where anxiety could have led to an increase in the readings.

CONCLUSION

Consumption of green tea has effectively reduced the number of patients with metabolic syndrome, and consumption of green tea and wheat bran can positively increase HDL. Also, green tea can be effective in reducing weight, FBS, and TG in male drivers suffering from metabolic syndrome. Considering their impact on HDL and some variables of metabolic syndrome, green tea can replace black tea as a drink during the day, especially in these groups, and wheat bran can also be added to their diet, which of course requires more information about MetS and to make changes in lifestyle and benefit from the beneficial effects of green tea and wheat bran on the cardiovascular system.

ACKNOWLEDGMENT

Conflict of interest: The authors of this article declare no conflict of interest in writing and publishing this article.

Financial Support: The study did not receive any financial support.

Ethical considerations: This article is the result of a research project with the ethics code IR.SEMUMS.REC.1398.274 in the Vice Chancellor for Research of Semnan University of Medical Sciences. Also, this study has been approved by Iranian Registry of Clinical Trials (IRCT) with registration reference IRCT20200217046524N1.

The authors would like to appreciate the Deputy for Research and Technology of Semnan University of Medical Sciences who sponsored the study and also the participants in this study. We are grateful to the Kasra Occupational Medicine Specialist Center for providing data and their continuing commitment to the study.

Authors Contributions: Concept: PD, APSN, MT, Data collection: NC, MT, APSN, SS, Supervision: PD, SM, MT, APSN, Analysis and interpretation: NC, PD, Literature search: NC, PD, Manuscript writing: NC, PD, SM, Critical review: PD, MT. All authors have approved final manuscript.

Data availability statement

The datasets generated during and analyzed during the current study are available from the corresponding author upon reasonable request.

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