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Anti-obesity Effect of Burdock Tea in Healthy Japanese: A Randomized, Double-blind, Placebo-controlled Study

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● **Abstract**

Objectives: The objective of this study is to examine how the ingestion of Burdock (*Arctium lappa* L.) tea, "Baisen-GOBOUCHA" ("BG") containing inulin and chlorogenic acid contributes to an anti-obesity effect.
Methods: A randomized, placebo-controlled, double-blind study was conducted to elucidate an anti-obesity effect of the tea containing inulin and chlorogenic acid. In this study we measured the visceral fat area, subcutaneous fat area, Body mass index (BMI), body weight, and body fat percentage as the primary outcome. We also evaluated the circumference of body parts (the waist, hip, upper arm, and upper leg) as a secondary endpoint. Furthermore, adverse effects were collected by means of a written questionnaire during the study.
Results: From all of 72 applicants, 29 were eliminated due to not meeting inclusion criteria. The 43 subjects were randomly assigned to an intervention group and made a start with ingestion. 5 subjects were withdrawn due to business or fever, and the remaining 38 subjects completed the study. Thus, data obtained with 38 subjects (BG: 18, <M; 8, F; 10>, Placebo: 20 <M; 8, F; 12>) was used for the analysis of efficacy. After 12-weeks of ingestion, BG showed significant differences in BMI (⊿ 0-8w and ⊿ 0-12w) and body weight (⊿ 0-8 and ⊿ 0-12w) compared to the Placebo. As for the circumference of body parts, BG decreased more significantly than Placebo in ⊿ 0-4w, ⊿ 0-8w, and ⊿ 0-12w. Excluding 12 subjects (M; 8, F; 4) with BMI ≧ 25.0kg/m^2 as well as visceral fat area ≧ 100 cm^2, stratified analysis was applied with 26 subjects. As a result of the stratified analysis, the intergroup analysis also showed a significant difference in "BMI", "body weight", "waist circumference", "hip circumference", "upper arm circumference", and "upper leg circumference" in the BG. No adverse effects were observed after the ingestion of the test product.
Conclusion: We found out that the ingestion of Burdock tea containing inulin and chlorogenic acid for 12 weeks contributed to the prevention of obesity which is explained by the decrease of BMI, body weight, and the circumference of the waist, hip, upper arm, and upper leg. In addition, no safety-related matter occurred during the 12-week test period.

Key Words: Burdock tea, inulin, chlorogenic acid, polyphenols, anti-obesity, BMI

1. INTRODUCTION

Recently, advanced countries such as Japan are abundant with various foods. The dietary proclivity has shifted from foods with plenty of fiber such as vegetables to meals consisting of meat and fat, and as a result, more and more people are suffering from obesity caused by overeating. In addition, in recent years people tend to fall into the obese category due to lack of sleep, lack of activity caused by the development of transportation such as elevators or transport facilities, malfunction of metabolism due to the development of air-conditioning technology or disturbance of the autonomic nervous system caused by a stress-sick society. Obesity can cause lifestyle-related diseases such as diabetes, hypertension or dyslipidemia[1]. As a result, the Japanese government launched "A Basic Direction for Comprehensive Implementation of National Health Promotion" which set goals of nutrition, dietary habit, physical activity and recreation, and implemented it as "Health Japan 21" from 2013 in order to promote public health[2]. Therefore, prevention of obesity plays an important role in maintaining good health. For the prevention and treatment of obesity, it is necessary to improve the balance between appropriate energy intake (diet) and appropriate energy consumption (exercise). Or, we can also boost energy consumption by stimulating energy metabolism inside of the body[3].

In the current Japanese market, people wish to achieve obesity prevention while minimizing the extent of the

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change in their current living habit or avoiding strict diet restriction and exercise. For achieving the above goals, there are a variety of supplements or weight-loss methods which stimulate energy metabolism, diminish appetite or improve bowel movement. Among them, Japanese people can choose the appropriate supplements or methods suitable for their own lifestyle or preference, and make good use of them for preventing obesity. Obtaining dietary fiber is one of the well-known methods for achieving the above- explained goals since it can improve the condition of bowel lipid movement[4]. On the other hand, it is reported that polyphenols have a function of improving metabolism[5]. Burdock (*Arctium lappa* L.) is a plant rich with those two ingredients, dietary fiber and polyphenols[6][7], and has been enjoyed as a popular, healthy food by Japanese. However, it also needs some burdensome preparations (such as removing soil on the surface or skimming off the scum) for eating, and these preparations make it difficult for "busy" contemporary people to easily ingest it. One of the solutions for this hurdle is to ingest Burdock as "Burdock tea", which consists of its extracted ingredients. It enables us to easily ingest Burdock in everyday life.

In this study, we conducted a randomized, placebo-controlled, double-blind study to verify the efficacy of Burdock tea for anti-obesity means, by using healthy Japanese people as the test subject. At the same time, we also examined the safety of ingesting the tea.

2. METHODS

2.1. Trial design

A randomized, placebo-controlled, double-blind study was conducted with the aid of a fund AHJIKAN CO., LTD. (Hiroshima) at Japan Clinical Trial Association (JACTA, Tokyo). The study period was 12 weeks, from November 12th, 2016 to February 5th, 2017. This study was conducted in accordance with the ethical principles of the declaration of Helsinki. The study protocol was approved by the Institutional Review Board of Pharmaceutical Law Wisdoms (Tokyo). Written informed consent was obtained from all Subjects. This trial was registered at UMIN Clinical Trial Registry (Trial ID: UMIN 000024779).

The allocation of the test product to the subjects was carried out by the person in charge of allocation. The allocation list was sealed and strictly controlled in a safe deposit box of JACTA until the end of the study.

2.2. Subject

Healthy subjects participated in the present study. All of the subjects in this study were public volunteers who had enrolled in the monitor bank of CROee Inc. (Tokyo), recruited from October through November, 2016.

2.2.1. Inclusion criteria

(1) Healthy Japanese males and females aged between 30 and 59 years;

(2) Individuals with Body mass index (BMI) ≧ 20.0 and < 30.0 kg/m^2.

2.2.2. Exclusion criteria

(1) Subjects with food allergies;

(2) Subjects who are pregnant or lactating;

(3) Subjects who consume medicinal product which may influence the outcome of the study;

(4) Subjects who consume food which may influence the outcome of the study;

(5) Subjects who are judged as unsuitable for the study by the principle investigator.

2.3. Randomization

From all 72 applicants, 29 were eliminated according to the exclusion criteria. The inclusion criteria was judged by the principle investigator. All subjects were sequentially allocated to Group A (n=21, M; 11, F; 10) and Group B (n=22, M; 8, F; 14) using a random number table. In the process of subject assignment, background factors such as gender, age, body height, body weight, and BMI were taken into consideration to avoid biased distribution. Subjects in Group A ingested the test sample and subjects in Group B ingested placebo for 12 weeks.

2.4. Description of test foods and blinding

The test product was "Baisen- GOBOUCHA" ("BG") containing inulin and chlorogenic acid, prepared by AHJIKAN CO., LTD. The method of making the tea includes steeping a teabag (dried burdock root 2g) in a kettle filled with hot water (1L), and bringing to the boil for a few minutes. The subjects were asked to drink the tea every day once in the morning, afternoon, and evening (3 times a day). The placebo ("Placebo") was also burdock tea but it is from the dried burdock root which has been boiled. **Table 1**. shows the nutritional content of BG and Placebo (100ml of tea). BG and Placebo were indistinguishable in viscosity, color, flavor or taste. Teas were managed by an identification symbol. All involved were blinded.

Table 1　Nutritional content of the sample

Item	Quantity (per 100 ml of tea)	
	BG	Placebo
Moisture	100 g	99.9 g
Protein	—	—
Lipid	—	—
Ash	—	—
Available carbohydrate	0.1 g	0.1 g
Energy	0 kcal	0 kcal

2.5. Experimental procedures

2.5.1. Experimental protocol

Subjects consumed almost 1L of boiled tea every day for 12 weeks. Subjects were instructed as follows: to take the assigned tea; to maintain their usual lifestyles and habits; to avoid excessive amounts of food, drink, and alcohol; to maintain a daily record of every meal eaten

Table 2 Schedule for the study

Item \ Term	Screening	Pretrial test	Test period		
			4 w	8 w	12 w
Informed consent	●				
Selection and/or allocation	●				
Abdominal fat level	●	●			●
Anthropometric measurements	●	●	●	●	●
Ingestion of test foods			↔	↔	↔
Log			↔	↔	↔

● : Implementation
↔ : Daily practice during the test period

during the test period; and to send the diary to the study coordinator.

2.5.2. Outcome

The objective of this study is to elucidate the anti-obesity effect of the burdock tea containing inulin and chlorogenic acid. To evaluate this objective, the visceral fat area, subcutaneous fat area, BMI, body weight, and body fat percentage were measured as the primary outcome. Moreover, the circumference of body parts (the waist, hip, upper arm, and upper leg) were evaluated as the secondary endpoint. Furthermore, adverse events were collected by means of a written questionnaire during the study.

According to the schedule shown in **Table 2**, we measured parameters on efficacy and safety. These assessments were conducted upon pre-intervention and post-intervention.

2.5.2.1. The abdominal fat level

The abdominal fat level was obtained via the use of CT images captured by SOMATOM Emotion 16-Slice (Siemens healthineers Japan, Tokyo) at week 0 and 12. Several CT images around the umbilicus were obtained and single scan images at the precise point of the umbilicus were used for analysis. The visceral fat area and subcutaneous fat area were calculated from CT images using Power View Fat software (Vigoment Software Corp., Tokyo).

2.5.2.2. Anthropometric measurements

At week 0, 4, 8 and 12, BMI, body weight, and body fat percentage were scaled by a body composition analyzer, DF-860 (Yamato Scale Co., Ltd., Hyogo). Furthermore, the circumference of the waist (at the umbilical level), hip (at the coccyx), upper arm (at the midpoint of right side), and upper leg (at the midpoint of right side) were measured using a non-elastic anthropometric tape measure.

2.6. Data analysis

A full analysis set (FAS) was adopted in the study and no sample size design was used. All statistics were expressed as mean ± standard deviation (SD). For the abdominal fat level, anthropometric measurements, Student's t-test was used for intergroup comparisons of changes from the baseline. Changes from the baseline in the same group were assessed using paired t-test. A chi-square test and Student's t-test were used to compare subject backgrounds between groups. Stratified analysis was performed with subjects excluding BMI ≧ 25.0 kg/m^2 as well as visceral fat area ≧ 100 cm^2.

Multiplicity according to the occasions was not adjusted. Any subjects with missing values were eliminated from the analysis. Statistical analyses were performed using Statcel 4 (Yanai, 2015) and Excel Tokei 2015 (SSRI). The results were considered significant at a <5% level in the two-sided test.

3. RESULTS

3.1. Participant demographics

The 43 subjects were randomly assigned to an intervention group and made a start with ingestion. 5 subjects were withdrawn due to business or fever, and the remaining 38 subjects completed the study. Thus, data obtained with 38 subjects (BG: 18 <M; 8, F; 10>, Placebo: 20 <M; 8, F; 12>) was used for the analysis of efficacy (**Figure 1**). There was no significant difference in gender, age, body height, body weight, or BMI between groups (**Table 3**). The daily diet and amount of exercise just one week prior to the test were surveyed. Regarding those factors, there were no significant differences between two groups at the baseline (data not shown). This monitoring was continued during the study. That means that BG group did not differ in daily diet or amount of exercise during the study.

3.2. Visceral fat area, subcutaneous fat area, BMI, body weight, and body fat percentage

Table 4 shows the results of test analyses. Significant differences were observed between the two groups of the change in BMI (⊿ 0-8w and ⊿ 0-12w) and body weight (⊿ 0-8 and ⊿ 0-12w), whereas visceral fat area, subcutaneous fat area, and body fat percentage did not differ significantly between the groups. As for the intragroup comparison, BMI (8 and 12w), body weight (8 and 12w), and body fat percentage (12w) indicated

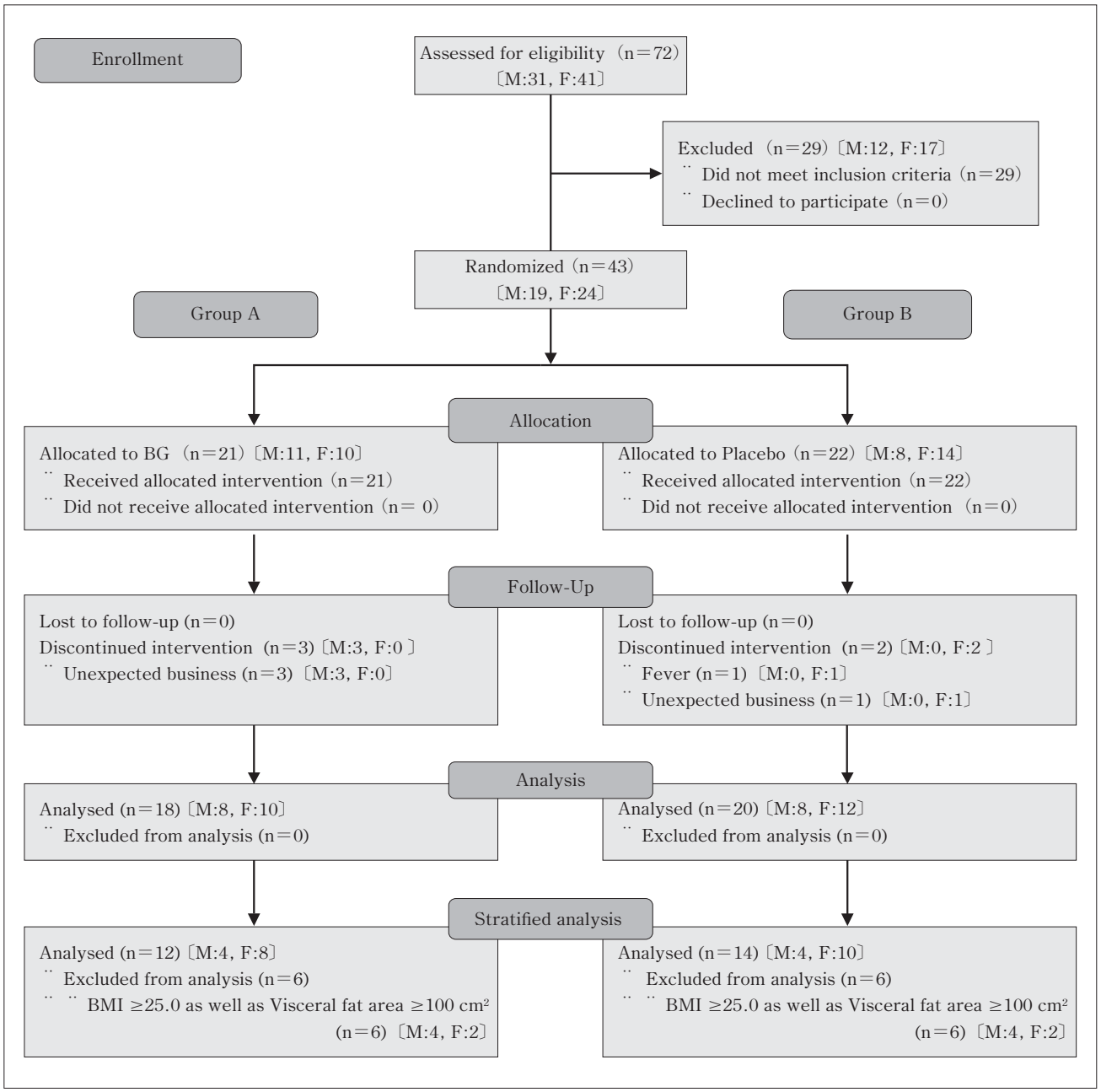

Figure 1　Flow diagram of subject disposition

Table 3　Subject demographics

Item	Unit	BG	Placebo
Subjects	numbers	18	20
Male: Female *	numbers	8:10	8:12
Age *	years	46.6 ± 7.6	45.1±7.9
Body height *	cm	165.6 ± 8.2	163.2±7.8
Body weight *	kg	70.9 ± 9.4	69.4±7.9
BMI *	kg/m²	25.8 ± 1.8	26.0±1.7

mean ± SD

* No significant difference

Table 4 Abdominal fat level and anthropometric measurements

Item	Unit	Time points	Values [1]		P-value [2]
			BG (n = 18)	Placebo (n = 20)	
Visceral fat area	cm^2	Baseline	106.8 ± 49.8	104.8 ± 47.9	
		12-week	98.1 ± 45.7	95.4 ± 45.8*	
		⊿ 0-12 w	− 8.8 ± 21.9	− 9.4 ± 15.6	0.920
Subcutaneous fat area	cm^2	Baseline	216.8 ± 65.2	213.9 ± 48.2	
		12-week	218.3 ± 63.3	207.7 ± 41.1	
		⊿ 0-12 w	1.5 ± 16.2	− 6.2 ± 21.4	0.224
BMI	kg/m^2	Baseline	25.8 ± 1.8	26.0 ± 1.7	
		4-week	25.8 ± 1.9	26.0 ± 1.7	
		⊿ 0-4 w	0.0 ± 0.2	0.0 ± 0.3	0.833
		8-week	25.3 ± 1.9**	26.1 ± 1.6	
		⊿ 0-8 w	− 0.5 ± 0.3	0.1 ± 0.5	< 0.001 ##
		12-week	25.0 ± 1.9**	26.0 ± 1.6	
		⊿ 0-12 w	− 0.8 ± 0.3	0.1 ± 0.4	< 0.001 ##
Body weight	kg	Baseline	70.91 ± 9.43	69.36 ± 7.94	
		4-week	70.90 ± 9.46	69.45 ± 8.15	
		⊿ 0-4 w	0.01 ± 0.58	0.10 ± 0.90	0.657
		8-week	69.56 ± 9.45**	69.74 ± 7.79	
		⊿ 0-8 w	− 1.35 ± 0.70	0.38 ± 1.19	< 0.001 ##
		12-week	68.90 ± 9.35**	69.55 ± 7.89	
		⊿ 0-12 w	− 2.02 ± 0.89	0.19 ± 1.06	< 0.001 ##
Body fat percentage	%	Baseline	33.2 ± 6.7	34.8 ± 6.4	
		4-week	33.7 ± 6.5	34.7 ± 6.3	
		⊿ 0-4 w	0.5 ± 1.5	− 0.1 ± 0.6	0.092 ‡
		8-week	33.6 ± 6.6	34.8 ± 6.1	
		⊿ 0-8 w	0.4 ± 1.6	− 0.0 ± 0.9	0.321
		12-week	32.8 ± 6.6*	34.4 ± 6.4*	
		⊿ 0-12 w	− 0.4 ± 0.7	− 0.5 ± 0.9	0.810

Values are expressed as the mean ± SD.

1) † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$ against baseline.

2) ‡ $p < 0.1$, ## $p < 0.01$ between-group difference in change from baseline.

significant differences from baseline in BG. In Placebo, Visceral fat area (12w) and body fat percentage (12w) showed significant differences from baseline values.

3.3. The circumference of body parts

Table 5 depicts the results of the circumference of the waist, hip, upper arm, and upper leg. As for the circumference of body parts, BG decreased more significantly than Placebo in ⊿ 0-4w, ⊿ 0-8w, and ⊿ 0-12w.

3.4. Stratified analysis

Excluding 12 subjects (M; 8, F; 4) with BMI ≧ 25.0 kg/m^2 as well as visceral fat area ≧ 100 cm^2, stratified analysis was applied with the remaining 26 subjects. **Table 6** depicts the results of the stratified analysis of the visceral fat area, subcutaneous fat area, BMI, body weight, and body fat percentage. Significant differences were observed between the two groups of changes in BMI (⊿ 0-8w and ⊿ 0-12w) and body weight (⊿ 0-8 and ⊿ 0-12w). The results of the stratified analysis of the circumference of body parts are indicated in **Table 7**. As for the circumference of waist, hip, upper arm, and upper leg, BG changed more significantly than Placebo in all time points.

3.5. Safety

No adverse effects associated with the test product were observed in the course of the reporting.

4. DISCUSSION

We conducted a randomized, placebo-controlled, double-blind study for examining the anti-obesity effect of

Table 5　The circumference of body parts

Item	Unit	Time points	Values [1]		P-value [2]
			BG（n = 18）	Placebo（n = 20）	
Waist	cm	Baseline	91.5 ± 6.5	88.9 ± 6.6	
		4-week	90.1 ± 6.3**	89.1 ± 6.5 †	
		⊿ 0-4 w	− 1.4 ± 0.5	0.2 ± 0.6	< 0.001##
		8-week	89.9 ± 6.4**	89.5 ± 6.6**	
		⊿ 0-8 w	− 1.5 ± 0.4	0.6 ± 0.5	< 0.001##
		12-week	89.7 ± 6.3**	89.5 ± 6.6**	
		⊿ 0-12 w	− 1.8 ± 0.5	0.6 ± 0.5	< 0.001##
Hip	cm	Baseline	100.6 ± 3.5	99.8 ± 3.7	
		4-week	99.4 ± 3.4**	99.9 ± 3.8*	
		⊿ 0-4 w	− 1.2 ± 0.4	0.2 ± 0.3	< 0.001##
		8-week	99.3 ± 3.5**	100.0 ± 3.8**	
		⊿ 0-8 w	− 1.3 ± 0.5	0.2 ± 0.3	< 0.001##
		12-week	99.1 ± 3.5**	100.0 ± 3.8**	
		⊿ 0-12 w	− 1.5 ± 0.5	0.2 ± 0.3	< 0.001##
Upper arm	cm	Baseline	30.8 ± 2.1	29.6 ± 2.4	
		4-week	29.6 ± 2.1**	29.7 ± 2.4	
		⊿ 0-4 w	− 1.2 ± 0.5	0.1 ± 0.3	< 0.001##
		8-week	29.6 ± 2.1**	29.8 ± 2.4 †	
		⊿ 0-8 w	− 1.3 ± 0.5	0.1 ± 0.3	< 0.001##
		12-week	29.2 ± 2.0**	29.9 ± 2.4**	
		⊿ 0-12 w	− 1.5 ± 0.4	0.2 ± 0.3	< 0.001##
Upper leg	cm	Baseline	49.3 ± 3.0	49.2 ± 2.7	
		4-week	48.1 ± 3.0**	49.5 ± 2.8**	
		⊿ 0-4 w	− 1.2 ± 0.4	0.3 ± 0.4	< 0.001##
		8-week	48.0 ± 3.0**	49.6 ± 2.7**	
		⊿ 0-8 w	− 1.3 ± 0.4	0.3 ± 0.5	< 0.001##
		12-week	47.8 ± 3.0**	49.6 ± 2.7**	
		⊿ 0-12 w	− 1.5 ± 0.4	0.4 ± 0.5	< 0.001##

Values are expressed as the mean ± SD.

1) † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$ against baseline.

2) ## $p < 0.01$ between-group difference in change from baseline.

Burdock tea (Baisen-GOBOUCHA: Burdock tea) containing inulin and chlorogenic acid. As the primary outcome, after 12-weeks of ingestion of the test product, the intergroup analysis showed significant differences in "BMI", "body weight", "waist circumference", "hip circumference", "upper arm circumference", and "upper leg circumference" in the BG, compared to the Placebo. In addition, as a result of the stratified analysis that excluded the criteria for obesity in Japan[8] (BMI ≧ 25 kg/m^2, as well as visceral fat area ≧ 100 cm^2), the intergroup analysis also showed a significant difference in "BMI", "body weight", "waist circumference", "hip circumference", "upper arm circumference", and "upper leg circumference" in BG. Moreover, no adverse effect associated with the test product was observed during the 12-week test period.

Main Findings

This study examined the efficacy of ingesting Burdock tea containing inulin, a type of water soluble dietary fiber, and chlorogenic acid, a type of polyphenols. After 12-weeks of ingestion, the BG showed a significant difference in BMI, body weight and the circumference of several body parts, compared to Placebo. The stratified analysis excluding the criteria for obesity in Japan[8] showed the same results.

The Burdock tea used in this study is an extract of Burdock (*Arctium lappa* L.) which is washed, shredded finely (including its skin) and then roasted. It is well

Table 6 Abdominal fat level and BMI (stratified analysis)

Item	Unit	Time points	Values [1]		P-value [2]
			BG (n = 12)	Placebo (n = 14)	
Visceral fat area	cm^2	Baseline	82.9 ± 39.3	80.9 ± 30.4	
		12-week	83.3 ± 41.2	73.3 ± 33.3 *	
		⊿ 0-12 w	0.4 ± 12.2	− 7.6 ± 12.9	0.120
Subcutaneous fat area	cm^2	Baseline	211.3 ± 37.7	219.3 ± 54.0	
		12-week	214.9 ± 39.6	214.7 ± 43.8	
		⊿ 0-12 w	3.6 ± 16.3	− 4.6 ± 22.7	0.306
BMI	kg/m^2	Baseline	24.9 ± 1.2	25.3 ± 1.2	
		4-week	24.9 ± 1.2	25.4 ± 1.4	
		⊿ 0-4 w	0.0 ± 0.2	0.1 ± 0.3	0.451
		8-week	24.5 ± 1.3 **	25.6 ± 1.4 *	
		⊿ 0-8 w	− 0.5 ± 0.3	0.3 ± 0.5	< 0.001 ##
		12-week	24.2 ± 1.3 **	25.5 ± 1.3 †	
		⊿ 0-12 w	− 0.8 ± 0.4	0.2 ± 0.4	< 0.001 ##
Body weight	kg	Baseline	66.96 ± 6.62	66.78 ± 6.74	
		4-week	66.92 ± 6.64	67.05 ± 7.25	
		⊿ 0-4 w	− 0.05 ± 0.67	0.27 ± 0.88	0.324
		8-week	65.63 ± 6.8 **	67.49 ± 7.11 *	
		⊿ 0-8 w	− 1.33 ± 0.81	0.71 ± 1.15	< 0.001 ##
		12-week	64.91 ± 6.92 **	67.31 ± 6.90 †	
		⊿ 0-12 w	− 2.05 ± 0.84	0.53 ± 0.99	< 0.001 ##
Body fat percentage	%	Baseline	33.0 ± 6.1	34.8 ± 6.6	
		4-week	33.8 ± 5.6	34.8 ± 6.6	
		⊿ 0-4 w	0.7 ± 1.8	0.0 ± 0.5	0.191
		8-week	33.5 ± 5.5	35.0 ± 6.3	
		⊿ 0-8 w	0.5 ± 1.9	0.2 ± 0.9	0.630
		12-week	32.7 ± 5.7	34.4 ± 6.7	
		⊿ 0-12 w	− 0.4 ± 0.9	− 0.4 ± 0.9	0.986

Values are expressed as the mean ± SD.

1) † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$ against baseline.

2) ## $p < 0.01$ between-group difference in change from baseline.

known that Burdock contains ingredients with a wide variety of health functions, such as dietary fibers, polyphenols or oligosaccharide[9]. Among them, inulin[10] (a type of water soluble dietary fiber) and chlorogenic acid[11] (a type of polyphenols) are easily eluted in hot water, therefore it is highly possible that the Burdock tea extracted with hot water has an abundance of these two ingredients. Placebo is also the same burdock tea but it is from the dried burdock root without the addition of inulin and chlorogenic acid, which are both removed after decocting the test product.

Obesity is caused by the accumulation of triglycerides in the human body. The triglycerides are originally fat and carbohydrates, which are ingested as foods but not sufficiently digested. Carbohydrates are broken down into monosaccharides and then absorbed in the course of digestion and absorption. However, if there are excess carbohydrates such as glucose, they either transform to glycogen by the glycogenesis, or change from fatty acid to triglycerides by the lipogenesis and accumulate in the body[9]. Triglycerides are a superior energy source, and therefore the human body can store any amount of them to prepare for starvation. Also, although fat is accumulated in the adipose tissue, the excess ingestion of it causes the accumulation ectopically in other tissues[10]. After all, this repetition of accumulation is a trigger for obesity. On the other hand, since the decomposition of triglycerides is also taken place in the adipocyte, the promotion of this decomposition is related to the prevention of obesity. For this promotion, it is important

Table 7　The circumference of body parts（stratified analysis）

Item	Unit	Time points	Values [1]		P-value [2]
			BG（n = 12）	Placebo（n = 14）	
Waist	cm	Baseline	89.0 ± 4.3	86.3 ± 5.5	
		4-week	87.8 ± 4.2**	86.5 ± 5.3	
		⊿ 0-4 w	− 1.3 ± 0.4	0.2 ± 0.6	< 0.001##
		8-week	87.6 ± 4.3**	86.8 ± 5.4**	
		⊿ 0-8 w	− 1.4 ± 0.4	0.5 ± 0.4	< 0.001##
		12-week	87.4 ± 4.2**	86.8 ± 5.4**	
		⊿ 0-12 w	− 1.7 ± 0.5	0.5 ± 0.4	< 0.001##
Hip	cm	Baseline	98.9 ± 2.4	99.2 ± 3.8	
		4-week	97.8 ± 2.3**	99.4 ± 3.9†	
		⊿ 0-4 w	− 1.1 ± 0.3	0.2 ± 0.3	< 0.001##
		8-week	97.6 ± 2.4**	99.4 ± 3.9*	
		⊿ 0-8 w	− 1.3 ± 0.5	0.2 ± 0.3	< 0.001##
		12-week	97.5 ± 2.5**	99.4 ± 3.8*	
		⊿ 0-12 w	− 1.5 ± 0.5	0.2 ± 0.3	< 0.001##
Upper arm	cm	Baseline	30.0 ± 1.9	29.0 ± 2.2	
		4-week	28.8 ± 1.8**	29.1 ± 2.3	
		⊿ 0-4 w	− 1.2 ± 0.4	0.0 ± 0.3	< 0.001##
		8-week	28.7 ± 1.7**	29.1 ± 2.3	
		⊿ 0-8 w	− 1.3 ± 0.4	0.1 ± 0.3	< 0.001##
		12-week	28.6 ± 1.7**	29.2 ± 2.3*	
		⊿ 0-12 w	− 1.5 ± 0.5	0.2 ± 0.3	< 0.001##
Upper leg	cm	Baseline	48.7 ± 3.1	48.9 ± 2.3	
		4-week	47.4 ± 2.9**	49.0 ± 2.4†	
		⊿ 0-4 w	− 1.2 ± 0.5	0.2 ± 0.3	< 0.001##
		8-week	47.3 ± 2.9**	49.1 ± 2.4*	
		⊿ 0-8 w	− 1.4 ± 0.5	0.2 ± 0.4	< 0.001##
		12-week	47.1 ± 2.9**	49.2 ± 2.4*	
		⊿ 0-12 w	− 1.5 ± 0.4	0.3 ± 0.4	< 0.001##

Values are expressed as the mean ± SD.

1) † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$ against baseline.

2) ## $p < 0.01$ between-group difference in change from baseline.

not only to reduce the amount of ingestion of carbohydrates and fat and/or to increase the consumption of energy by exercise, but also to stimulate the energy metabolism, such as the decomposition cycle of triglycerides.

The fresh roots of burdock contain 0.78% of polyphenols with antioxidant activity, and they mainly consist of chlorogenic acid and caffeic acid[11]. They are also included in coffee, and are widely known to have functions of inhibiting the elevation of blood sugar level and/or accumulation of fat[12)13)]. Triglycerides are decomposed into glycerol and fatty acid by the function of lipase. Then, the decomposition of the fatty acid is used for the gluconeogenesis in the liver or ATP synthesis of the muscles. The decomposition or synthesis of fatty acids in the liver have a close relationship with the rate-limiting enzyme called acetyl-CoA carboxylase (ACC) which synthesizes malonyl-CoA from acetyl-CoA. The synthesis of fatty acids are stimulated by the action of ACC. The ingestion of chlorogenic acid inhibits the activity of ACC, decreases the amount of malonyl-CoA and increases the activity of carnitine O-palmitoyltransferase I (CPT1). Eventually, the above-explained mechanism inhibits the synthesis of fatty acid and enhances energy metabolism[12)13)]. As for chlorogenic acid, it is reported that the chlorogenic acid activates AMP-activated protein kinase (AMPK) which controls glycogenesis[14)], stimulates glucose transportation and

inhibits gluconeogenesis[14]. Therefore, it is considered that the chlorogenic acid contained in the test product (Burdock tea) hindered the synthesis of fatty acid, promoted the decomposition of fatty acid, controlled the increase of the postprandial glucose level by suppressing the new formation of carbohydrates and eventually inhibited the accumulation of fat which is transformed from carbohydrates. On the other hand, Inulin included in the Burdock tea is treated as the water soluble dietary fiber under nutriology. Inulin is a type of fructan of the polysaccharide, which is a polymer of fructose. It cannot be decomposed in human digestive capacity, but is firstly metabolized in the microflora of the human large bowel[15]. Inulin has a relatively high water retention capacity, swelling capacity and oil-holding capacity[16].It also wraps around the carbohydrates or fats ingested at the same time and moves from stomach to small intestine[17]. Eventually, it slows down the speed of absorbing carbohydrates and suppresses the increase of the postprandial glucose level[18]. In addition, inulin has the function of normalizing the condition of the microflora, stimulating the growth of the bifidobacteria population and/or inducing a stool bulking effect[19]. The deterioration of the intestinal environment may lead to the production of endotoxins and trigger a disorder of energy metabolism[20]. There is also a report that the short-chain fatty acid produced in the microflora can improve on lipid metabolism[21]. According to the clinical report, the ingestion of inulin decreased the amount of serum cholesterol and triglycerides[22], and this report supports that inulin has a function of controlling lipid metabolism[23]. Based on the above discussion, it is reasonable to speculate that the inulin contained in the test product also contributed to the promotion of the decomposition of fatty acids and inhibiting the accumulation of fat.

In this study, we could observe the decrease of body weight and the improvement of BMI by the ingestion of the Burdock tea. These results ware possibly produced by the fact that the ingestion of the test product promoted the digestion of fat (which was supposed to be accumulated under the normal diet) caused by the fat accumulation-inhibiting effect[13], and it lead to the decrease in body weight and the improvement of BMI. In addition, it is speculated that the continuous energy consumption such as the activation of intestinal environment or stimulation of lipid metabolism contributed to the decrease of body weight. The circumference of body parts might have changed as a result of stimulating digestion of the fat accumulated in the body parts. However, since the test period was not sufficient for promoting the significant lipid decomposition, the test results of subcutaneous fat or visceral fat did not show a significant improvement, there were still some decreasing tendencies, though. This tendency is actually speculated from the fact that the stratified analysis excluding the criteria for obesity in Japan[8](BMI ≧ 25 kg/m^2 as well as visceral fat area ≧ 100 cm^2) showed the same results as those of all the subjects. Based upon the discussion above, we can consider that the ingestion of Burdock tea contributed to the anti-obesity effect achieved by inhibiting the accumulation of fat and by promoting the decomposing of fat.

Secondary Findings

During the test period, five subjects discontinued the test. Four of them discontinued due to an unexpected business matter, the other one stopped the test due to illness (fever) that has both have nothing to do with the ingestion of the test product. In addition, the diaries of the subjects did not show any adverse events. These results indicated the safety of the ingestion of the test product for the 12-weeks test period.

General Information

Obesity can be defined as a state of excessive body fat accumulation than a prescribed level. Especially "Visceral fat obesity", a type of obesity that accumulates excessive fat around the organs, tends to increase the level of cholesterol and/or blood glucose level, and also increase the risk of arterial sclerosis[1]. Therefore, obesity is described as the state with high possibility of physical failure which can be a serious obstruction for living a healthy life, and the state to avoid regardless of how fat you are[24]. At the same time, however, for contemporary people it is difficult to abandon their "comfortable" life of having delicious but high-calorie dishes or irregular habits, and shift their life to a regular and healthier style, just for reaching fat. On the other hand, habits such as taking supplements or drinking tea with the effect of anti-obesity do not require them to change their lifestyle substantially, and therefore they are a much easier way for them to continue for a long period. Fortunately, Japanese have been drinking tea since ancient times. After introducing tea from China, Japanese have contrived ways to infiltrate Japanese society with the tea-drinking habits.

The flavor of tea has an effect on the brain waves and gives the feeling of relaxation, and the drinking of hot tea can also heat up the whole body and promote blood circulation[25][26]. To sum up, the action of drinking tea contributes to stress reduction or improvement of one's physical condition. Since the test product is a tea-bag type and easily prepared, it can be introduced to our daily lifecycle without any circumstance. If the introduction of such tea to one's daily life improves the conditions of bowel movement and/or metabolism, and eventually preventing obesity, it can contribute to the improvement of the eating habits of overweight individuals for reducing body weight. In addition, even people with regular body weight can make good use of the tea for the maintenance and enhancement of their health.

Limitations

In this study we examined the anti-obesity effect of the

Burdock tea by using BMI or body weight as the outcome. Generally, body fat gradually accumulates in our excessive caloric intake. The test results showed the decrease of body weight, whereas there is no significant difference observed in items such as subcutaneous fat or visceral fat. Therefore, a longer test period might have been needed for obtaining more sufficient data to support the efficacy of this product. On the other hand, in this test, we advised the subjects to have the dietary life same as their regular one and let them submit the diary. However, there is possibly of variation of test results among the test subjects due to a feeling of tension stemming from the awareness that they are under examination. Furthermore, the focus on the other ingredients contained in the Burdock tea in addition to inulin and chlorogenic acid and the examination of their functional mechanisms can contribute to further exploring the capability of Burdock tea.

5. CONCLUSION

In conclusion, we found out that the ingestion of Burdock tea containing inulin and chlorogenic acid for 12 weeks contributed to the prevention of obesity, which was proved by the decrease of BMI, body weight and the circumference of several body parts (waist, hip, upper arm, and upper leg). In addition, no safety-related matter occurred during the test period.

CONFLICT OF INTEREST

All parts of this study were funded by AHJIKAN CO., LTD. Junji Inoue, Takahiko Hada, and Shu Takayanagi are employees. All authors state that the study was conducted in the absence of any other relationships that could be interpreted as a conflict of interest.

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