



Efficacy of Burdock Tea in Healthy Japanese with a Tendency for Constipation: A Randomized, Placebo-controlled, Double-blind Crossover Study

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● Abstract

Objective: 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 improves bowel movement.

Methods: A randomized, placebo-controlled, double-blind crossover study was conducted to verify the improvement of bowel movement. In this study we carried out subjective reporting consisting of the questions “Frequency of bowel movement”, “Days of defecation” and “Volume of stool” as the primary outcome. As for the secondary outcome, the state of stool (“Scent of stool”, “Color of stool”, and “Texture of stool”) was evaluated. “Frequency of bowel movement” is the amount of times one defecated during 2 weeks, “Days of defecation” is the number of days in which defecation occurred during 2 weeks.

Results: 24 subjects were randomly assigned to intervention groups and made a start with testing. None were withdrawn, and a total of 24 (male: 11, female: 13) subjects completed the study. According to the result of Bowel movement, after the ingestion of the test product the intergroup analysis showed a significant difference in “Volume of stool” in BG group compared to Placebo group. As for the intragroup analysis, there was a significant difference in “Frequency of bowel movement”, “Days of defecation”, “Volume of stool”, and “Texture of stool” in BG group, whereas “Frequency of bowel movement” and “Days of defecation” in Placebo group. No adverse effect associated with the test product was observed in the course of the reporting.

Conclusion: We found out that the ingestion of Burdock tea containing inulin and chlorogenic acid for 2 weeks contributed to the improvement of bowel movement such as volume of stool. In addition, no safety-related matter occurred during the test period.

Key Words: Burdock tea, inulin, chlorogenic acid, Polyphenols, Constipation, bowel movement

1. INTRODUCTION

Many Japanese are said to be distressed by constipation. According to the Comprehensive Survey of Living Conditions conducted by Ministry of Health, Labor and Welfare in 2013, about 4.7 million Japanese have a symptom of constipation¹⁾. This number corresponds to one in 26 Japanese people, and it shows quite a lot of Japanese have a problem of bowel movement in some form. It is said that one of the reasons for this problem is the softened water in Japan; although it is well-known that minerals have functions of stimulating the intestinal peristalsis and improving bowel movement²⁾, the water in Japanese rivers is low on the quantity of minerals since rapid streams deprive the water a chance to gain enough minerals from the soil at the bottom of rivers. In addition, it is also reasonable to believe that the recent switch of

Japanese dietary habit from grain and plant-based style to meat-based style (i.e. Western style) is possibly a reason as to why constipation has become an issue. Although research has shown that the fibers included in grains or vegetables increase the frequency of bowel movement³⁾, it is considered that the recent Japanese diet lacks the amount of fibers and this fact is casting a negative influence on bowel movement. Furthermore, several other factors inherent in the environment of recent Japan such as stress or lack of exercise are believed to improve the troubles related to bowel movement⁴⁾.

Constipation generally refers to the condition of having a difficulty in defecating, and it is often difficult to judge whether he/she suffers from constipation since the stool frequency or the defecation state vary considerably by individual. Typically, the problem of bowel movement is often derived from the decrease of intestinal functions

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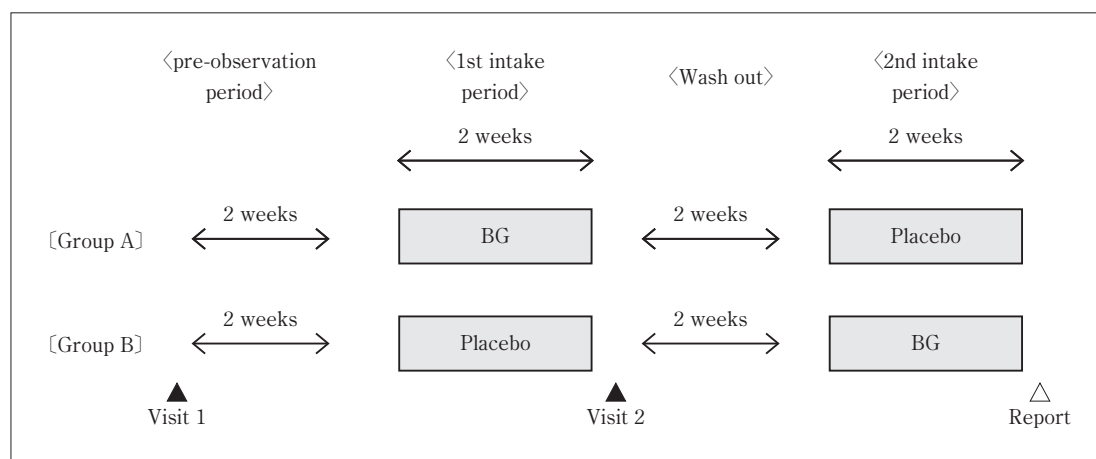


Figure 1 Trial design

due to the breakdown in lifestyle habits or stress, rather than the malfunction of defecation caused by illness. This problem also triggers the subjective symptoms such as “feeling frustrated”, “difficulty to sleep” and/or “being lazy about work or housekeeping”, all of which significantly affect one’s QOL (Quality of Life)⁵⁶⁾. Needless to say, it is important to change lifestyle habits (such as increasing the amount of exercise) or reducing stress in order to improve bowel movement. In addition, it is also effective to actively ingest nutrition such as dietary fiber (that recent Japanese are said to lack), or nutrition which stimulates the intestinal functions. In fact, a variety of food products are available on the market that promote the improvement of bowel movement. Among them, there are products of Burdock (*Arctium lappa* L.): it is rich in dietary fiber and has been known as the food warming our body and improving the condition of stomach since old times. Therefore, it is one of the foods which should actively be consumed by the person who wants to improve their bowel movement.

Since Burdock is plentiful in ingredients such as a water soluble dietary fiber called “inulin” and polyphenols which provide an anti-oxidant action⁷⁸⁾, it is easily speculated from these ingredients that its ingestion improves bowel movement. However, comparatively burdensome preparations such as removing soil on the surface or skimming off the scum when cooking are needed in order to eat Burdock, and these preparations make “busy” contemporary people avoid ingestion of this food. Also, some people do not like its unique taste or texture. Burdock tea is one of the solutions for the above-explained hurdles to ingest it. It is tea consisting of the extracted ingredients from Burdock, and therefore enables us to easily ingest Burdock in everyday life. In this study, we conducted a randomized, placebo-controlled, double-blind crossover study to verify the efficacy of Burdock tea for the improvement of bowel movement, by using healthy Japanese as 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 crossover study was conducted with the aid of a fund from AHJIKAN CO., LTD. (Hiroshima) at Japan Clinical Trial Association (JACTA, Tokyo). The study implementation period was 8 weeks, from October 23rd, to December 18th, 2016. The study consisted of pre-observation period (2 weeks), intake period I (2 weeks), wash out period (2 weeks), and intake period II (2 weeks) (Figure 1).

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. The allocation of the test product to the subjects was carried out by the person in charge of allocation. The allocation list was sealed by the person in charge of allocation and strictly controlled in a safe deposit box of JACTA until the end of the study. This trial was registered at UMIN Clinical Trial Registry (Trial ID: UMIN000024765).

2.2. Subjects

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 September through October, 2016.

2.2.1. Inclusion criteria

- (1) Healthy males and females aged between 30 and 59 years;
 - (2) Individuals with a tendency for constipation;
- The doctor conducting the present study confirmed subjects were not of ill health.

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 of 138 applicants, 114 were eliminated according to the exclusion criteria. The inclusion criteria was judged by the principle investigator. All subjects were sequentially allocated first to group A (n=13) and group B (n=11). In the process of subject assignment, age was taken into consideration to avoid biased distribution. Subjects randomly received either the test sample or the placebo for 2 weeks in a double-blind, crossover fashion.

2.4. Description of test product and blinding

The test product of burdock (*Arctium lappa* L.) roots 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 of 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 (1, 2)** shows the nutritional content of the sample. BG and Placebo were indistinguishable in viscosity, color, flavor or taste. Teas were managed by an identification symbol. All involved were blinded.

2.5. Experimental procedures

2.5.1. Experimental protocol

Subjects consumed almost 1L of boiled tea every day for 2 weeks. Subjects were instructed as follows: to avoid excessive amounts of food, drink or alcohol; to maintain a daily record of intake, frequency of bowel movement, volume of stool, and state of stool during the test period.

2.5.2. Outcome

The objective of this study was to verify the improvement of bowel movement by drinking the tea containing inulin and chlorogenic acid.

To evaluate this objective, reporting of “Frequency of bowel movement”, “Days of defecation”, and “Volume of stool” were observed as the primary outcome. As for the secondary outcome, state of stool (“Scent of stool”, “Color of stool”, and “Texture of stool”) was evaluated.

“Frequency of bowel movement” is the amount of times one defecated during 2 weeks, “Days of defecation” is the number of days in which defecation occurred during 2 weeks.

Regarding “Volume of stool” and “Scent of stool”, subjects rated every defecation on an ordinal scale of 1 to 5 with higher scores indicating a better result. Then the average score was calculated during two weeks of pre-observation and again during the intake period. Whilst “Color of stool” and “Texture of stool” of every defecation were classified into 5 categories so that #1 and #5 were graded as +1, #2 and #4 were graded as

Table 1-1 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

Table 1-2 The lower limit values for management standard

Item	BG (per 1000 ml of tea)
Inulin	100 mg
Chlorogenic acid	1 mg

+2, and #3 was graded as +3 (the best possible result). Then the average score was calculated during two weeks of pre-observation and again for two weeks during the intake period. Values were compared between pre-observation period and intake period in every outcome. The details are illustrated in **Appendix 1**.

To evaluate the safety of the test foods, adverse events were collected by means of a written questionnaire during the study.

2.6. Data analysis

Intention-to-treat (ITT) set was adopted in the present study. The sample size was calculated as 15 participants with the following settings: statistical power of 0.8, effect size of 0.8, and significance level of $p < 0.05$. All statistics were expressed as mean \pm standard deviation (SD). Numbers or scores of bowel movement were compared in the same group (intragroup) and between BG and Placebo (intergroup) by performing a paired t-test. A chi-square test and Student's t-test were used to compare subject backgrounds between groups. 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 the $< 5\%$ level in the two-sided test.

3. RESULTS

3.1. Participant demographics

24 subjects were randomly assigned to intervention groups and made a start with testing. None were withdrawn, a total of 24 (male: 11, female: 13) subjects completed the study (**Fig 2**). The ages were 32-55 year olds (mean age 44.1 ± 6.3 years old). Data sets were analyzed for evaluations on Group A and B (**Table 2**).

3.2. Validity of the crossover method

The effects of either intake period for “Frequency of

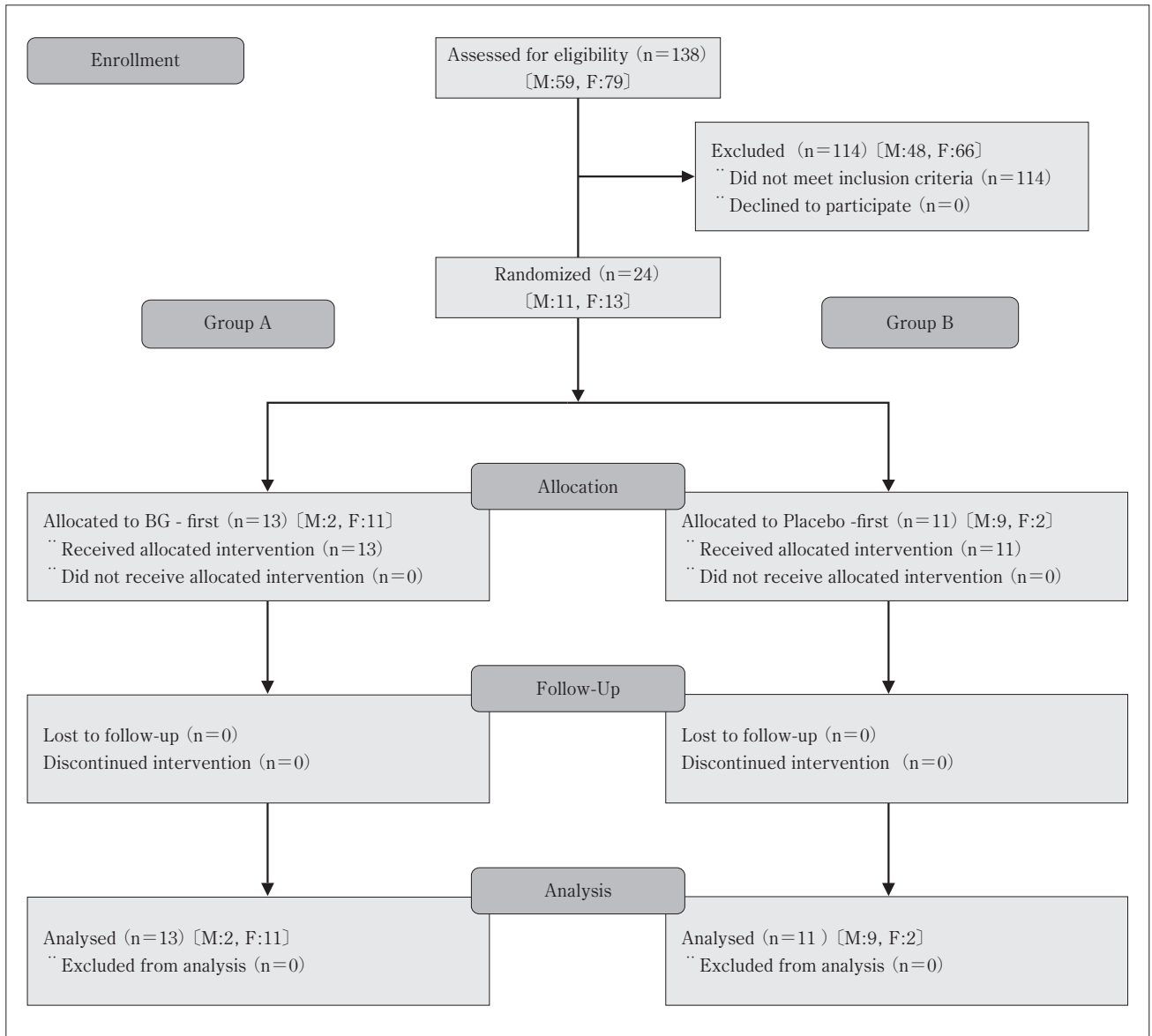


Figure 2 Flow diagram of subject disposition

Table 2 Subject demographics

Item	Unit	Group A	Group B
Subjects	numbers	13	11
Male : Female	numbers	2 : 11	9 : 2
Age *	years	45.1 ± 6.1	43.0 ± 6.7

mean ± SD

* No significant difference

bowel movement”, “Days of defecation”, and “Volume of stool” were not statistically significant ($p=0.403$, $p=0.342$, and $p=0.601$, respectively) (Table 3). Thus, we conclude that the carry-over effect can be ignored and the result obtained from the crossover design in the present study can be evaluated appropriately.

3.3. Bowel movement

Table 4 depicts the results of bowel movement. As for

“Frequency of bowel movement” and “Days of defecation”, no significant differences were yielded in the intergroup analysis, whereas a significant difference was observed between the two groups in “Volume of stool”. With regard to intragroup analysis, BG showed significant differences in “Frequency of bowel movement”, “Days of defecation”, and “Volume of stool”, whilst significant differences were found in “Frequency of bowel

Table 3 Bowel movement of baseline

Bowel movement	Unit	1st period (n = 24)	2nd period (n = 24)	p-value ¹⁾
Frequency of bowel movement	number	9.65 ± 3.66	10.04 ± 4.19	0.403
Days of defecation	day	8.46 ± 2.96	8.79 ± 3.07	0.342
Volume of stool	score	3.60 ± 0.84	3.55 ± 0.82	0.601

Values are expressed mean ± SD

1) between the values of baseline of 1st period and 2nd period

Table 4 Results of bowel movement

Item	Unit	Time point	BG (n=24) ¹⁾	Placebo (n=24) ¹⁾	P-value ²⁾
Frequency of bowel movement	number	Pre-intake	8.9 ± 3.6	8.9 ± 3.6	0.551
		Post-intake	11.1 ± 4.0**	10.5 ± 4.2*	
		Δ	2.3 ± 3.4	1.6 ± 3.1	
Days of defecation	day	Pre-intake	7.9 ± 2.9	7.9 ± 2.9	0.451
		Post-intake	9.7 ± 2.9**	9.1 ± 3.1*	
		Δ	1.8 ± 2.6	1.2 ± 2.2	
Volume of stool	score	Pre-intake	3.5 ± 0.8	3.5 ± 0.8	0.014 [#]
		Post-intake	3.9 ± 0.6*	3.4 ± 0.9	
		Δ	0.3 ± 0.7	- 0.2 ± 0.6	

Numbers and Scores are expressed as the mean ± SD.

Frequency of bowel movement: the amount of times one defecated during 2 weeks

Days of defecation: the number of days in which defecation occurred during 2 weeks

Volume of stool: the score of each stool during 2 weeks period calculated as an average

1) * p < 0.05, ** p < 0.01 against pre-intake.

2) # p < 0.05 between-group difference in change from baseline.

Table 5 Results of the state of stool

Item	Unit	Time point	BG (n=24)	Placebo (n=24)	P-value
Scent of stool	score	Pre-intake	3.3 ± 0.7	3.3 ± 0.7	0.109
		Post-intake	3.5 ± 0.7	3.2 ± 0.7	
		Δ	0.2 ± 0.6	0.0 ± 0.5	
Color of stool	score	Pre-intake	2.5 ± 0.4	2.5 ± 0.4	0.719
		Post-intake	2.5 ± 0.4	2.5 ± 0.4	
		Δ	0.0 ± 0.3	0.0 ± 0.3	
Texture of stool	score	Pre-intake	2.4 ± 0.3	2.4 ± 0.3	0.662
		Post-intake	2.6 ± 0.4*	2.5 ± 0.3	
		Δ	0.2 ± 0.3	0.1 ± 0.4	

Scores are per each stool calculated as an average, and expressed as the mean ± SD.

* p < 0.05, against pre-intake.

movement” and “Days of defecation” of Placebo.

3.4. State of stool

Table 5 depicts the results of the state of stool. As for “Scent of stool”, “Color of stool”, and “Texture of stool”, no significant differences were yielded in the intergroup analysis. With regard to intragroup analysis, BG represented a significant improvement in “Texture of

stool”.

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 crossover study to verify the effects of the Burdock tea (Baisen-GOBOUCHA) containing inulin and chlorogenic acid. The objective of this study was to verify whether the ingestion of the tea affects the conditions of bowel movement. As the primary outcome, after the ingestion of the test product the intergroup analysis showed a significant difference in “Volume of stool” in the test group (BG), compared to Placebo. In addition, as for the intragroup analysis, there was a significant difference in “Frequency of bowel movement”, “Days of defecation”, “Volume of stool”, and “Texture of stool” in BG, as opposed to only “Frequency of bowel movement” and “Days of defecation” in Placebo. In addition, no adverse effect associated with the test product was observed in the course of the reporting.

Main Findings

This study examined the effects of Burdock tea, which contains inulin, a type of water soluble dietary fiber, and chlorogenic acid, a type of polyphenols. As a result of ingesting the Burdock tea, “Volume of stool” of BG significantly improved compared to Placebo. On the other hand, “Frequency of bowel movement” and “Days of defecation” of BG showed a better result than that of Placebo, meanwhile both groups showed some levels of significant difference in the intragroup analysis.

The Burdock tea used in this study is the extract of Burdock (*Arctium lappa* L.) which is washed, shredded finely (including its skin) and then roasted. It is well known that Burdock contains ingredients with a wide variety of health functions, such as dietary fibers, polyphenols or oligosaccharide⁹⁾. Among them, inulin¹⁰⁾ (a type of water soluble dietary fiber) and chlorogenic acid¹¹⁾ (a type of polyphenols) are easily eluted in hot water, therefore it is highly possible that Burdock tea extracted with hot water has an abundance of these two ingredients. On the other hand, the mechanism of defecation is explained as follows. Firstly, digested foods are brought to the large bowel and their moisture is absorbed. Then solid foods are forwarded to the anus by intestinal peristalsis, and they are excreted by the defecation reflex. The digestion of food is closely associated with intestinal bacteria, the carcass of which forms almost all parts of stool. Healthy and effectual intestinal bacterial flora stimulates the intestinal peristalsis and positively supports bowel movement. Functional constipation, which is not caused by intestine diseases, is said to occur as a result of malfunction of autonomic nervous system which inhibits the defecation reflex and intestinal peristalsis. These troubles force the stool to stay in the large bowel for too long and too much moisture is absorbed from the stool, which then becomes too firm to pass through the anus comfortably¹²⁾. Therefore, it is speculated that for the improvement of bowel movement, it is necessary to have a healthy function of the intestinal peristalsis and make the defecation reflex regularly.

In this study, after the ingestion of the Burdock tea by healthy Japanese test subjects, their “Volume of stool” significantly increased compared to the Placebo. Also, the result of the intragroup analysis revealed that “Frequency of bowel movement”, “Days of defecation”, “Volume of stool”, and “Texture of stool” significantly improved. These results are thought of as the result of the ingredients contained in the test product. Inulin included in the Burdock tea is a batch of Fructan of the polysaccharide, which is a polymer of fructose. It cannot be decomposed in human digestive organs, and is treated as a dietary fiber since it is metabolized in the microflora of a human’s large bowel¹³⁾. It is reported that inulin has a possibility of increasing the amount of bifidobacteria in the human colon and changing the composition of the mucosa associated flora significantly¹⁴⁾¹⁵⁾. There is also a report that it influences the amount and nature of the end products of fermentation (i.e. stools) by affecting the metabolic activity of microorganisms in the microflora¹⁶⁾. In addition, there is a report that the ingestion of bread with inulin by Japanese women improved their frequency, number of times and volume of stool¹⁷⁾. These test findings support the hypothesis that inulin improved the condition of microflora of the human large bowel, stimulated the intestinal peristalsis and improved bowel movement. Furthermore, it is considered that since inulin itself is a dietary fiber, it increased the stool volume, encouraged defecation and shortened the detention period of food in the bowel¹⁸⁾. At the same time, the fresh roots of burdock contains 0.78% of the polyphenols with antioxidant activity, and they mainly consist of chlorogenic acid and caffeic acid¹⁹⁾. They are also included in coffee, and there is a report that drinking coffee significantly increases the amount of bifidobacteria in the human colon and chlorogenic acid itself also induces a significant increase in the growth of the *Clostridium coccoides-Eubacterium rectale* group that may act beneficially in the environment of large intestine²⁰⁾. Therefore, it is thought that the chlorogenic acid contained in Burdock tea also improves the microflora (at least the *C. coccoides-E. rectale* group) of the human large bowel, stimulated the intestinal peristalsis and improves bowel movement. In addition, increasing the amounts of bacteria in the intestines contributes to the increase of the stool itself, since a large part of stool consists of the remains of the bacteria. Furthermore, the microflora of the human large bowel significantly affects the state of stool. It is considered that since the good condition of microflora of the human large bowel contributes to the scent, color and texture of stool²¹⁾, the ingestion of Burdock tea improved the texture of stool.

In this study, Placebo also showed an improvement in “Frequency of bowel movement” and “Days of defecation”. This can be explained by the fact that since the condition of functional constipation is significantly

affected by the stress or autonomic nerves, the exaltation of “the test is about to be carried out” triggered the defecation reflex and increased the frequency of bowel movement; in other words, it was caused by the placebo effect²²⁾. However, it seems that only the exaltation was not enough to stimulate the intestinal peristalsis or to increase the amount of stool. This leads the possibility that the quality of bowel movement of Placebo such as the clear feeling after the defecation or the state of stool, is different from that of BG, who improved the condition of the microflora of the human large bowel, increased the amount of stool and stimulated the intestinal peristalsis by obtaining the ingredients contained in the Burdock tea.

Based upon the discussion above, we can speculate that the ingestion of Burdock tea contributed to the increase of amount of stool and the improvement of bowel movement.

Secondary Findings

To evaluate the safety of the test product, adverse events were collected by means of a written questionnaire during the study, and no abnormal change caused by the test product was observed during the ingesting period. This result indicated the safety of the ingestion of the test product for the whole test period.

General Information

The condition of bowel movement is one of the key parameters of health. It is often said that the frequency, amount or scent of stool represent the patterns of diet, lifestyle or stress situation. According to the study finding, females tend to have the problem of constipation since their muscular strength is weaker and their pelvis is wider²³⁾, but the Comprehensive Survey of Living Conditions¹⁾ revealed this problem is also seen among elderly people and men who have problems of irregular dietary habits or stressful situations. Recently there are a number of books or articles that give guidance on the improvement of dietary habits or lifestyle habits to tackle the constipation problem, and a wide variety of laxatives are sold in the drugstore. Although there are several types of laxatives, the basic function of the laxatives is simply stimulating the bowel peristalsis. Therefore, it is not a fundamental solution for the constipation, and the intestinal environment does not regain its normal function. Constipation also brings about many physical troubles such as abdominal discomfort, bad breath, strong body odor, headache, shoulder discomfort, chalk mark, swelling and/or fatigue, all of which seriously affect the QOL²⁴⁾.

From ancient times, tea has been used for relaxation or stress reduction²⁵⁾. The fragrance of tea positively affects brain waves and provides a relaxing effect on the brain²⁶⁾. Also hot tea warms the body and promotes blood circulation. Therefore, regardless of the type, tea can provide us a variety of positive effects. The test product is a tea-bag type and is therefore easily ingested. It is

considered that if we can obtain not only the relaxing effect but also the effect of improving the condition of constipation just by adding the Burdock tea to our everyday tea-drinking habit, we can improve the level of QOL and live our life more easily and comfortably.

Limitations

Bowel movement tends to be significantly affected by the mental stress, as the placebo effect occurs. Also, the definition of constipation is ambiguous, and it is often judged by the subjective decision such as a feeling of incomplete defecation. In addition, it is reasonable that even though the frequency of bowel movement increases, if there are still a sense of discomfort or a tight feeling of stomach, they cannot feel the bowel movement has fundamentally improved. Furthermore, Japanese have a tendency to avoiding talking about excretion (such as stool) since ancient times. In this study we used a written questionnaire for collecting the objective data such as the volume or texture of stool, and the frequency of bowel movement. However, it is undeniable that the test subjects could not gather the precise information about the volume or texture, and eventually the data varied between individuals. Also, since we did not carry out the questionnaire for collecting the subjective assessment of the test subjects, we could not check for conditions such as a sense of incomplete defecation or a tight feeling in the stomach after bowel movement. Therefore, it is desirable for the further study to introduce both the objective measuring method for checking the conditions of bowel movement, and the subjective assessment (such as questionnaire) for evaluating the subjective view among the test subjects after defecation. We believe they enable us to carry out more objective and comprehensive analysis of bowel movement.

5. CONCLUSION

In conclusion, we found out that the ingestion of Burdock tea containing inulin and chlorogenic acid for 2 weeks contributed to the improvement of bowel movement such as volume of stool. 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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Appendix 1 Bowel movement

#	Item	Choices	Unit	Valuation method
1	Frequency of bowel movement	To be fulfilled	Numbers/ 2w	More frequencies indicating good result
2	Days of defecation	To be fulfilled	Days/ 2w	More days indicating good result
3	Volume of stool *	1; Below 0.5, 2; 1.0, 3; 1.5, 4; 2.0, 5; Over 2.5	Score/ 1 defecation	5 grades with higher number indicating good result
4	Scent of stool	1; Very bad odor, 2; Bad odor, 3; A little bad odor, 4; Not bad odor, 5; No bad odor	Score/1 defecation	5 grades with higher number indicating good result
5	Color of stool	1; Chestnut color (+1), 2; Light brown color (+2), 3; Mid brown color (+3), 4; Dark brown color (+2), 5; Black (+1)	Score/1 defecation	3 grades with higher number indicating good result
6	Texture of stool	1; Hard (+1), 2; Slightly Hard (+2), 3; Normal (+3), 4; Soft (+2), 5; Liquid (+1)	Score/1 defecation	3 grades with higher number indicating good result

*: Subjects compared volume to a 5 x 2.5cm cylindrical object and recorded equal to 1 or 2 cylinders etc.