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Research Article

Effects of *Camellia sinensis* Flower Bud Powder on Bowel Function in Healthy Adults -A Randomized, Placebo-controlled, Double-blind, Clinical Study

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Abstract

There has been growing interest in functional foods that improve gut health and bowel movements. *Camellia* flower extract, which is derived from the flower buds of the "tea plant" (*Camellia sinensis*), contains various bioactive components, such as polyphenols and saponins, that interact with the gut microbiota. While these components are expected to effectively treat constipation, the clinical efficacy of *Camellia* flower extract has not yet been sufficiently verified. This randomized, double-blind, placebo-controlled, parallel-group comparative study examined the effect of consuming 300 mg of *Camellia* flower extract powder daily for 4 weeks on improving bowel movements in 29 subjects with constipation. Bowel movement status was evaluated using two questionnaires: the Japanese version of the Constipation Assessment Scale (CAS) and the Visual Analogue Scale for evaluating bowel movements (VAS-BM). Statistically significant changes ($P < 0.05$) in total CAS and VAS scores were only observed in the test group, indicating that *Camellia* flower extract powder effectively treats constipation. Results for the individual VAS-BM items suggest that intake of the test product changed stool quality, including color and odor, and enabled smoother bowel movements without pain or straining. Many people in Japan suffer from constipation, and the *Camellia* flower extract powder is expected to improve their quality of life (QoL) and reduce healthcare costs.

Keywords: Tea Flowers; *Camellia Sinensis*; Flower Buds; Constipation; Clinical Trial

Introduction

Constipation is a functional bowel disorder characterized by decreased frequency and volume of bowel movements, difficulty defecating, and a sensation of incomplete evacuation [1,2]. Constipation carries the risk of serious complications, including hemorrhoids, rectal prolapse, fecal impaction, colonic ulcers, and peritonitis [3]. Therefore, constipation is not merely an uncomfortable symptom; it necessitates appropriate treatment. According to the 2022 Basic Survey on National Living Conditions by the Japan's Ministry of Health, Labor and Welfare, the prevalence of constipation was reported to be 27.5% among Japanese men and 43.7% among Japanese women [4]. Consequently, constipation is a significant health issue for many people and has a major impact on healthcare finances.

Although lifestyle modifications, such as improving dietary habits and establishing a regular exercise routine, are considered the foundation of constipation treatment, there has been a growing

interest in foods that promote gut health and regular bowel movements with functional claims. One such food is *Camellia* flower extract, which is derived from the flower buds of the "tea plant" (*Camellia sinensis*), an evergreen tree of the genus *Camellia* and the family Theaceae. The leaves of this plant are popularly used to make green tea, black tea, and other varieties that are widely consumed around the world. Many studies have examined the health benefits of these teas from the leaves [5]. In contrast, research into the health benefits of *Camellia* flowers, particularly in human clinical trials, has yet to advance significantly.

Tea flowers and tea tree seeds have traditionally been used for medicinal purposes. In Traditional Chinese Medicine (TCM), tea flowers are believed to have effects that clear heat, eliminate toxins, and improve digestive health [6,7]. In addition to having the same chemical components as tea leaves -such as catechins, flavonols and amino acids -which are expected to provide similar health benefits [8], tea flowers also contain several unique components. One such component is florateasaponin, which has been reported to protect the gastric mucosa [9]. Tea Flower Polysaccharides (TFPS), which are present in high concentrations in tea flowers, have anti-aging properties [10] and could enhance intestinal barrier function by influencing the gut microbiota [11]. The health benefits of tea flowers have also been demonstrated, including hypoglycemic, anticancer, antioxidant, lipid-lowering, antibacterial, and anti-inflammatory effects, among others [6]. While it is anticipated that these bioactive components of tea flowers could interact with the gut microbiota to treat constipation effectively, their clinical efficacy in treating constipation has not been sufficiently verified. This study used a randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the effect of a 4-week daily intake of tea flower extract powder on improving bowel movements in subjects with constipation.

Materials and Methods

Subject Selection and Ethical Considerations

This study strictly adhered to the Declaration of Helsinki (revised in Fortaleza in 2013) and the Ethical Guidelines for Medical and Health Research Involving Human Subjects, which were published by the Japanese government in 2021. All examinations were conducted via mail correspondence. Before the trial began, participants were given a detailed explanation of its purpose, methods, expected outcomes, and privacy protection measures. After confirming their full understanding and agreement, written informed consent was obtained for their participation. This clinical trial was reviewed by the internal ethics committee of User Life Science Co., Ltd. (Iizuka, Fukuoka, Japan), the trial organizer, and was approved on March 6, 2024, under approval number ULS202403. The trial is also registered with UMIN-CTR under number UMIN000056893.

The trial aimed to evaluate the effect of a daily intake of *Camellia* flower extract powder on improving bowel movements over a period of 4 weeks. A randomized, double-blind, placebo-controlled, parallel-group trial was conducted on selected subjects, who were generally considered to be healthy aside from self-reported constipation. A sample size of $n = 14 \pm 1$ was deemed sufficient to achieve 80% statistical power and a 5% significance level; therefore, 40 subjects were recruited for the analysis. Members of the public aged 18–70 who had pre-registered on the trial's introductory website and had self-reported symptoms of constipation were invited to participate in the trial. Subjects were selected from among the volunteers who met all following 4 inclusion criteria and none of the 10 exclusion criteria.

Inclusion criteria: (1) Individuals aged 18 to 70 years old at the time of consent; (2) Individuals generally considered to be in good health; (3) Individuals capable of providing written, voluntary consent to participate in the study; and (4) Individuals who self-report experiencing constipation.

Exclusion criteria: (1) Individuals who continuously consume health foods, quasi-drugs, or pharmaceuticals that claim or emphasize efficacy similar to or related to that being evaluated in this trial; (2) Individuals who have changed or started a new health food regimen within the past 4 weeks; (3) Individuals who work night shifts or rotating day-night shifts; (4) Individuals who, at the time informed consent is obtained, receive treatment at a medical institution or similar facility for the treatment or prevention of a disease (e.g., hormone replacement therapy, drug therapy, exercise therapy, dietary therapy, or other interventions) or are deemed to require treatment; (5) Individuals with a history of serious diseases affecting glucose metabolism, lipid metabolism, liver function, kidney function, the heart, circulatory system, respiratory system, endocrine system, immune system, or nervous system. (1) Individuals with a history of mental illness; (6) Individuals with a history of alcohol or drug dependence; (7) Individuals at risk of developing food allergies; (8) Individuals who are pregnant or breastfeeding at the time of consent, or who wish to become pregnant during the study period; (9) Individuals who have participated in another human study involving food, pharmaceuticals, quasi-drugs, medical devices, etc., within the past 4 weeks, or who plan to participate in another such study during the scheduled duration of this study; (10) Individuals deemed unsuitable for participation in the study by the principal investigator.

Trial Method

This trial protocol was based on our previous study of natto powder [12]. A randomization officer from User Life Sciences, who was not involved in preparing this trial, used the RANDBETWEEN function in Microsoft Excel to randomize the subjects by stratifying them by age and then randomly assigning them to the test group or

placebo group. This assignment was kept confidential from both the participants and the administrators of the intervention until all subjects had completed both the pre- and post-measurements. The subjects in the test group were instructed to take 3 capsules of *Camellia* flower extract powder per day with every meal for 4 weeks (300 mg/day for 28 days), while the subjects in the placebo group were instructed to take an identical-looking placebo lacking the active ingredients.

The primary outcomes of this study were bowel movement status as assessed by 2 questionnaire surveys: the Japanese version of the Constipation Assessment Scale (CAS) and the Visual Analogue Scale for evaluating bowel movements (VAS-BM). The CAS is a questionnaire designed to objectively assess the severity of constipation. It consists of 8 items, and participants self-rate each item on a 3-point scale (0–2 points); their condition is evaluated based on the total score. A lower total score indicates better bowel function [13,14]. VAS-BM is a tool that evaluates constipation symptoms and treatment effects based on the patients' subjective sensations. It consists of 6 items: "sensation of incomplete evacuation," "straining during defecation," "pain during defecation," "stool color," "stool volume," and "stool odor." Subjects mark their current condition on a 100-mm straight line, with 0 representing poor condition and 100 representing good condition. A higher numerical value indicates better stool consistency [15]. Subjects underwent these assessments twice: once 4 weeks before the intervention and once after.

Sleep, mood, and gut health are closely related [16,17]. In our previous research, we found that natto powder improves gut health, thereby alleviating constipation and improving sleep quality [12]. As secondary outcomes, we administered the Pittsburgh Sleep Quality Index (PSQI) and the adult version of the Profile of Mood States 2nd Edition (POMS 2) twice-once before and once after the 4-week intake of the test product or placebo. The PSQI is a scale that evaluates sleep quality and the severity of sleep disturbances over the past month. It consists of 7 items: "Sleep Quality," "Sleep Latency," "Sleep Duration," "Sleep Efficiency," "Sleep Disturbance," "Use of Sleep Medication," and "Daytime Dysfunction." Each item is self-rated on a 4-point scale from 0 to 3, and a higher total score indicates a more severe degree of sleep disturbance [18]. POMS 2 is a test that quantifies and evaluates psychological states. Participants rate each item on a 5-point scale ranging from 0 (not at all) to 4 (very much). Responses are categorized into 7 scales. For the 5 scales-AH (Anger-Hostility), CB (Confusion-Bewilderment), DD (Depression–Dejection), FI (Fatigue-Inertia), and TA (Tension-Anxiety)-lower scores indicate a better state. For the other 2 scales-VA (Vigor-Activity) and F (Friendliness)-higher scores indicate a better state. Furthermore, the TMD (Total Mood Disturbance) score serves as a composite indicator of negative emotions, with higher scores indicating a greater degree of these emotions [19].

Statistical Analysis

Microsoft Excel was used for analysis. For each evaluation parameter, the mean and the standard error were calculated for both the test group and the placebo group, and the values before and after intake were compared for each parameter using a paired t-test. In addition, an unpaired t-test was used for between-group comparisons. In these tests, a p-value of < 0.05 was considered statistically significant.

Results

Subjects of the Analysis

Thirty-four subjects who met the inclusion criteria and did not meet the exclusion criteria consented to participate in this trial (Figure 1). The randomization officer randomized them into the test group (n = 17) and the placebo group (n = 17). The mean age was 51.1 years in the test group and 52.4 years in the placebo group. Recruitment began on January 14, 2025, and all subjects completed the pre- and post-assessments by March 12. During the study period, none of the subjects reported any adverse events attributable to the study. However, 2 subjects from the test group and 3 from the placebo group withdrew for personal reasons unrelated to the study. Consequently, the final analysis included 15 subjects in the test group (mean age: 52.5 ± 10.6 years) and 14 subjects in the placebo group (mean age: 54.9 ± 9.6 years). As one subject in the placebo group had incomplete pre-intervention PSQI data, the PSQI analysis included 15 subjects in the test group (mean age: 52.5 ± 10.6 years) and 13 subjects in the placebo group (mean age: 55.3 ± 9.8 years).

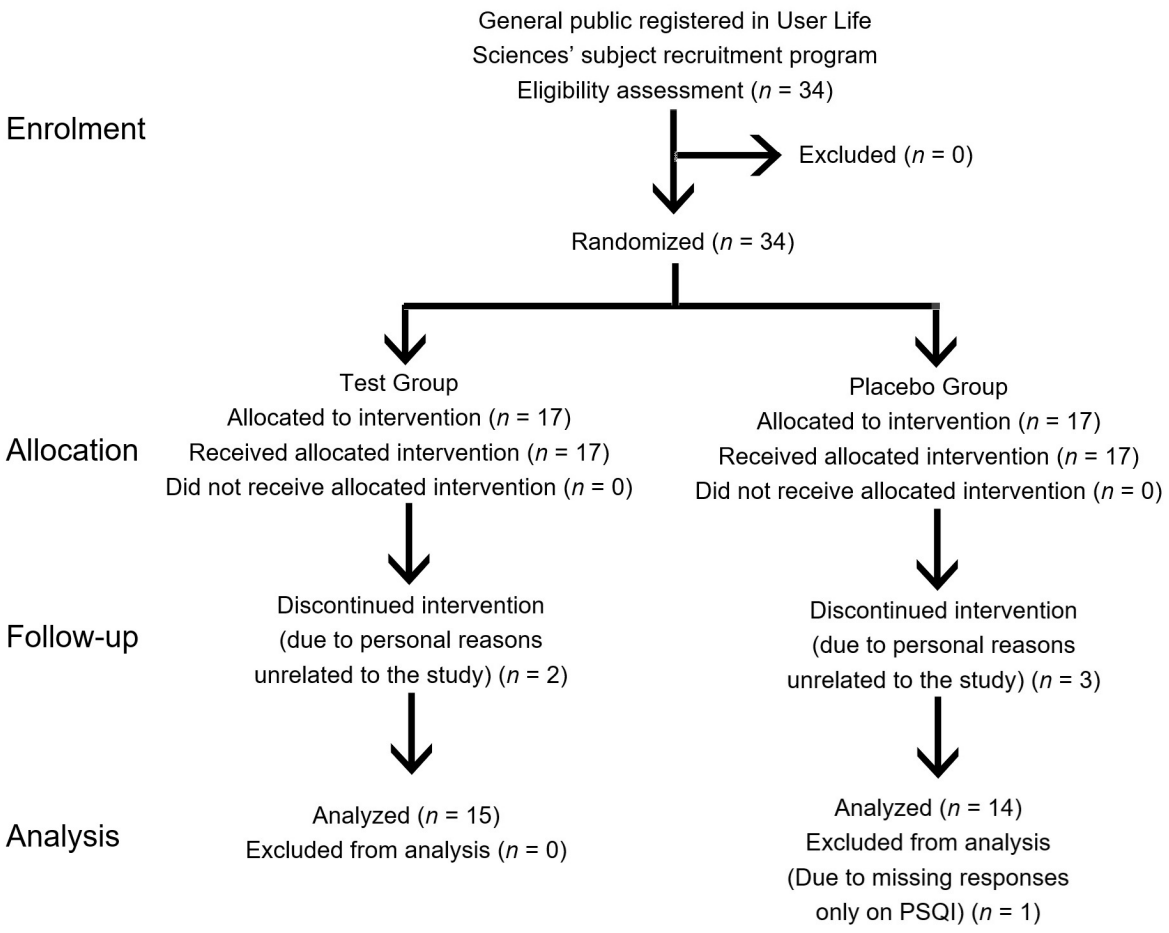

Figure 1: Flow diagram of the progress through the phases of a parallel randomized trial of two groups.

CAS

The CAS includes eight characteristics that are commonly associated with constipation [13,14]. No statistically significant differences were observed between the two groups in the pre-intervention measurements. After the 4-week test period, scores decreased for many items in both the test and placebo groups. However, a comparison of the pre- and post-intervention results revealed significant changes ($p < 0.05$) in the total score and in the following 6 items only in the test group; "Abdominal distention or bloating," "Less frequent bowel movements," "Rectal fullness or pressure," "Rectal pain with bowel movement," "Smaller stool size," and "Urge but inability to pass stool" (Table 1, Figure 2). In contrast, the total score and the individual item scores did not show any statistically significant changes in the placebo group. These results suggest that the improvements in constipation occurred only in the test group.

Items	Group	Mean score at pre-intervention	Mean score at post-intervention	*p*-value between pre- and post-intervention	*p*-value between two groups
Abdominal distention or bloating	Test group (n = 15)	1.13 (0.19)	0.47 (0.17)	0.012*	0.017*
	Placebo group (n = 14)	0.46 (0.14)	0.43 (0.14)	1.0	
Change in the amount of gas passed rectally	Test group (n = 15)	0.07 (0.07)	0.33 (0.13)	0.10	0.076
	Placebo group (n = 14)	0.50 (0.23)	0.29 (0.13)	0.34	
Less frequent bowel movements	Test group (n = 15)	0.87 (0.17)	0.20 (0.11)	< 0.001**	0.27
	Placebo group (n = 14)	1.0 (0.18)	0.64 (0.20)	0.14	
Rectal fullness or pressure	Test group (n = 15)	0.87 (0.13)	0.40 (0.13)	0.029*	0.19
	Placebo group (n = 14)	0.79 (0.16)	0.64 (0.17)	0.34	
Rectal pain with bowel movement	Test group (n = 15)	0.40 (0.13)	0.13 (0.09)	0.041*	0.17
	Placebo group (n = 14)	0.36 (0.13)	0.36 (0.13)	1.0	
Smaller stool size	Test group (n = 15)	0.67 (0.13)	0.13 (0.09)	0.0013**	0.37
	Placebo group (n = 14)	0.79 (0.19)	0.50 (0.20)	0.26	

Urge but inability to pass stool	Test group (n = 15)	0.80 (0.15)	0.27 (0.12)	0.0013**	0.25
	Placebo group (n = 14)	1.07 (0.17)	0.79 (0.21)	0.10	
Oozing liquid stool	Test group (n = 15)	0.47 (0.19)	0.40 (0.13)	0.72	0.63
	Placebo group (n = 14)	0.29 (0.13)	0.36 (0.17)	0.75	
Total	Test group (n = 15)	5.3 (0.4)	2.3 (0.5)	< 0.001**	0.060
	Placebo group (n = 14)	5.2 (0.7)	4.0 (0.9)	0.069	

() denotes standard error.

Paired t-tests were used to compare pre- and post-intervention data, while unpaired t-tests were used to compare groups.

*p < 0.05, **p < 0.01.

Table 1: Result of the Japanese version of the Constipation Assessment Scale (CAS).

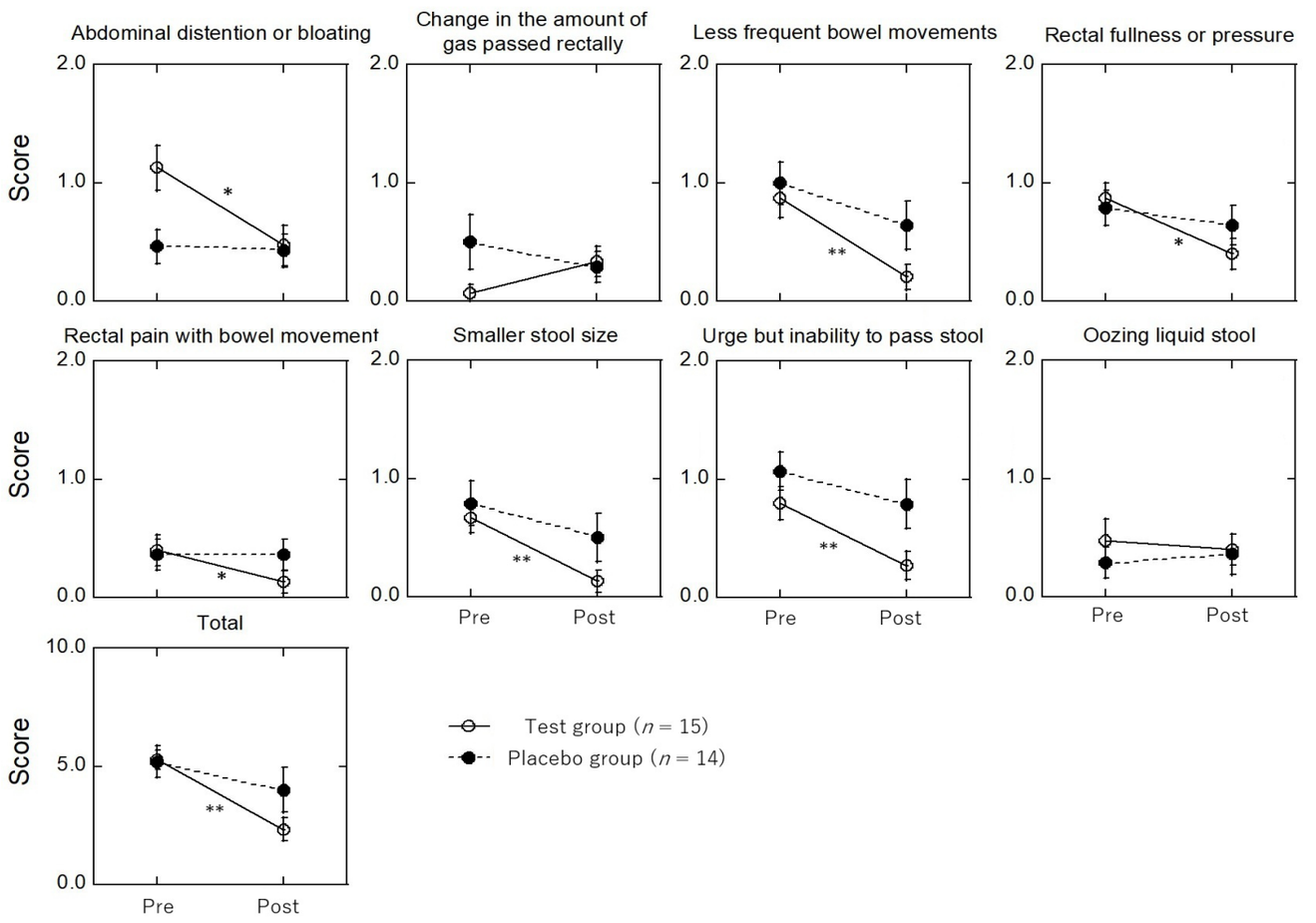

Figure 2: Changes in CAS scores before and after taking the test or placebo powder for 4 weeks. Lower scores indicate better bowel function. Error bars: standard error. $^{*}p < 0.05$, $^{**}p < 0.01$.

VAS-BM

The detailed effects of the test product were assessed using the VAS-BM (Table 2). A pre-post comparison revealed significant increases in scores ($p < 0.05$) for the test group across 5 items ("Sensation of incomplete evacuation," "Straining during defecation," "Pain during defecation," "Stool color," and "Stool odor"), as well as a statistically significant difference in the total score (Figure 3). In contrast, no items in the placebo group showed statistically significant changes in the pre- and post-test comparisons. This supports the effectiveness of *Camellia* flower extract powder in treating constipation. Furthermore, an intergroup comparison revealed statistically significant differences in "Straining during defecation," "Odor of stool," and the total score. These results indicate that intake of the test product altered stool quality, such as color and odor, and enabled smoother bowel movements without pain or straining.

Items	Group	Mean score at pre-intervention	Mean score at post-intervention	*p*-value between pre- and post-intervention	*p*-value between two groups
Sensation of incomplete evacuation	Test group (n = 15)	48.5 (6.6)	75.3 (6.1)	< 0.001**	0.068
	Placebo group (n = 14)	45.4 (7.6)	48.9 (7.8)	0.75	
Straining during defecation	Test group (n = 15)	49.9 (6.2)	77.9 (4.6)	< 0.001**	0.022*
	Placebo group (n = 14)	46.5 (7.0)	49.0 (7.9)	0.79	
Pain during defecation	Test group (n = 15)	69.1 (6.0)	86.3 (3.5)	0.0034**	0.052
	Placebo group (n = 14)	65.9 (7.1)	59.5 (9.5)	0.57	
Stool color	Test group (n = 15)	44.8 (3.9)	69.7 (5.3)	< 0.001**	0.10
	Placebo group (n = 14)	44.5 (6.2)	52.9 (6.9)	0.29	
Stool volume	Test group (n = 15)	47.0 (4.2)	59.9 (5.6)	0.094	0.82
	Placebo group (n = 14)	31.2 (5.4)	41.8 (5.4)	0.16	
Stool odor	Test group (n = 15)	35.3 (5.6)	61.3 (5.2)	< 0.001**	0.016*
	Placebo group (n = 14)	50.1 (6.6)	48.6 (7.1)	0.86	

Total	Test group (n = 15)	294.7 (18.7)	429.0 (20.4)	< 0.001**	0.018*
	Placebo group (n = 14)	283.6 (23.2)	300.6 (37.6)	0.68	

() denotes standard error.

Paired t-tests were used to compare pre- and post-intervention data, while unpaired t-tests were used to compare groups.

*p < 0.05, **p < 0.01.

Table 2: Results of the Visual Analogue Scale for evaluating Bowel Movements (VAS-BM).

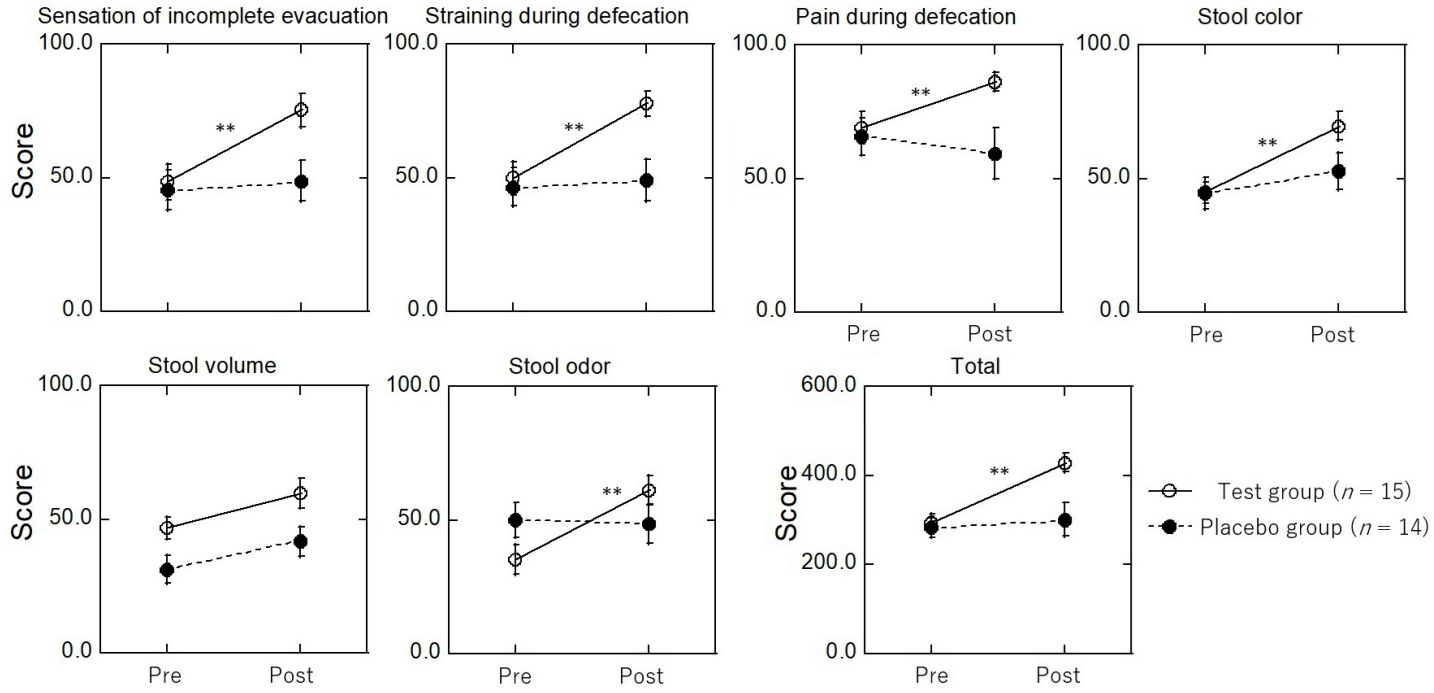

Figure 3: Changes in the VAS-BM scores before and after taking the test or placebo powder for 4 weeks. Higher scores indicate better conditions. Error bars: standard error. *p < 0.05, **p < 0.01.

PSQI

As a secondary outcome, we analyzed the effects of *Camellia* flower extract powder on sleep using the PSQI (Table 3). A pre- and post-test comparison revealed significant changes (p < 0.05) in "Sleep Quality" and "Daytime Dysfunction" scores in the test group. A significant change in score was also observed in the placebo group for "Daytime Dysfunction."

Items	Group	Mean score at pre-intervention	Mean score at post-intervention	*p*-value between pre- and post-intervention	*p*-value between two groups
Sleep Quality	Test group (n = 15)	1.40 (0.13)	0.93 (0.18)	0.004**	0.74
	Placebo group (n = 13)	1.23 (0.12)	0.85 (0.19)	0.054	
Sleep Latency	Test group (n = 15)	1.53 (0.29)	1.27 (0.27)	0.22	0.054
	Placebo group (n = 13)	1.15 (0.29)	0.62 (0.18)	0.089	
Sleep Duration	Test group (n = 15)	1.13 (0.27)	1.27 (0.27)	0.55	0.91
	Placebo group (n = 13)	1.31 (0.26)	1.23 (0.20)	0.67	
Sleep Efficiency	Test group (n = 15)	1.07 (0.37)	2.36 (0.34)	0.062	0.090
	Placebo group (n = 13)	0.69 (0.37)	1.39 (0.43)	0.34	
Sleep Disturbance	Test group (n = 15)	1.00 (0.10)	0.93 (0.12)	0.33	0.58
	Placebo group (n = 13)	1.00 (0.0)	1.00 (0.0)	1.0	
Use of Sleep Medication	Test group (n = 15)	0.07 (0.07)	0.0 (0.0)	0.33	1.0
	Placebo group (n = 13)	0.23 (0.17)	0.0 (0.0)	0.19	
Daytime Dysfunction	Test group (n = 15)	0.87 (0.19)	0.20 (0.11)	0.007**	0.76
	Placebo group (n = 13)	0.54 (0.18)	0.15 (0.10)	0.018*	

Global Score	Test group (n = 15)	7.07 (0.85)	6.80 (0.91)	0.70	0.17
	Placebo group (n = 13)	6.15 (0.62)	5.23 (0.63)	0.27	

() denotes standard error.

Paired t-tests were used to compare pre- and post-intervention data, while unpaired t-tests were used to compare groups.

*p < 0.05, **p < 0.01.

Table 3: Result of the Pittsburgh Sleep Quality Index (PSQI).

POMS 2

The effects of the test product on the mood of the subjects were also investigated using POMS 2 questionnaire (Table 4). While a significant change in AH (Anger-Hostility) was observed in the placebo group ($p < 0.05$), no significant differences were found for the other items in either group.

Items	Group	Mean score at pre-intervention	Mean score at post-intervention	*p*-value between pre- and post-intervention	*p*-value between two groups
AH (Anger–Hostility)	Test group (n = 15)	2.6 (0.6)	2.9 (0.7)	0.57	0.95
	Placebo group (n = 14)	5.0 (1.0)	3.0 (0.7)	0.038*	
CB (Confusion–Bewilderment)	Test group (n = 15)	3.2 (0.6)	3.0 (0.7)	0.72	0.51
	Placebo group (n = 14)	2.9 (0.7)	3.9 (1.1)	0.28	
DD (Depression–Dejection)	Test group (n = 15)	2.5 (0.5)	2.5 (0.6)	0.87	0.97
	Placebo group (n = 14)	3.4 (0.6)	2.6 (1.0)	0.35	
FI (Fatigue–Inertia)	Test group (n = 15)	4.7 (1.1)	5.1 (1.0)	0.69	0.42
	Placebo group (n = 14)	4.3 (0.7)	4.0 (0.9)	0.78	

TA (Tension–Anxiety)	Test group (n = 15)	5.1 (0.9)	4.7 (0.9)	0.71	0.95
	Placebo group (n = 14)	5.1 (0.8)	4.6 (1.2)	0.66	
VA (Vigor–Activity)	Test group (n = 15)	7.3 (0.8)	8.1 (0.6)	0.42	0.96
	Placebo group (n = 14)	7.8 (1.0)	8.1 (1.4)	0.66	
F (Friendliness)	Test group (n = 15)	9.0 (0.9)	10.7 (0.7)	0.11	0.86
	Placebo group (n = 14)	9.7 (0.8)	10.4 (1.1)	0.52	
TMD (Total Mood Disturbance) score	Test group (n = 15)	10.8 (2.9)	10.3 (3.1)	0.82	0.95
	Placebo group (n = 14)	12.9 (3.8)	9.9 (4.9)	0.44	

() denotes standard error.

Paired t-tests were used to compare pre- and post-intervention data, while unpaired t-tests were used to compare groups.

*p < 0.05, **p < 0.01.

Table 4: Result of the Profile of Mood States 2nd Edition (POMS 2).

Discussion

This study used two questionnaire-based surveys, CAS and VAS-BM, to evaluate changes in bowel movements in healthy adults who consumed *Camellia* flower extract for four weeks. The test product is commercially available, and the safety of *Camellia* flower extract has already been established. Four subjects withdrew from the trial due to personal circumstances, but no health problems related to consumption of the test product were reported.

Total scores on the CAS and VAS-BM changed significantly only in the test group, suggesting that the test product improved constipation. Changes in the individual VAS-BM items indicate that consumption of the test product enhanced stool quality and facilitated smoother bowel movements. *Camellia* flower extract contains bioactive compounds, including polyphenols (such as catechins) and saponins. Polyphenols have been reported to promote the growth of beneficial bacteria [20] and inhibit pathogenic bacteria [21], while saponins have been shown to improve the intestinal environment by regulating lipid metabolism and bile acids [22]. They are also known to help maintain intestinal barrier function and exert anti-inflammatory effects [23]. The combined effects of these actions on the gut microbiota and intestinal environment may have contributed to the improvement in bowel movements observed in the test group under placebo-controlled conditions. Moving forward, it would be beneficial to verify the mechanism of action and efficacy more clearly by introducing objective indicators, such as gut microbiota analysis.

The gut and the brain communicate with each other via a two-way network known as the gut-brain axis [24]. For example, around 90% of the body's serotonin is produced in the gut. Serotonin and microbial byproducts stimulate the vagus nerve, which helps regulate mood, digestion, and sleep cycles [25]. In this study, PSQI revealed improvements in sleep quality and daytime sleepiness in the test group. However, POMS 2 did not reveal any clear changes in psychological state associated with taking the test product. Clear

results for these items may take longer to achieve, and larger-scale, more detailed clinical trials are expected in the future.

Conclusion

This clinical trial was a randomized, double-blind, placebo-controlled, parallel-group study conducted on subjects who self-reported constipation. The results suggested that taking 300 mg of Camellia flower extract powder daily for 4 weeks could alleviate constipation. It is expected that *Camellia* flower extract will improve the quality of life (QoL) of many Japanese people suffering from constipation and reduce healthcare costs.

Conflict of Interest

This study was conducted by User Life Science Co., Ltd. with funding and samples provided by Japan Medicinal Foods Laboratory Co., Ltd.

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