



A Study on Taheebo Tea of a Randomized Placebo-controlled Trial Part 2: Analysis of Improvement in Bodily Vigor and Alleviation of Temporal Feeling of Fatigue

Taro SHIRAKAWA¹⁾ / Masatomo NAJIMA²⁾

● Abstract

Background: Taheebo, the purple inner bark of *Tabebuia avellanedae* which is found in tropical rain forests, has been drunk as tea for the purpose of health. It seems to have some effects for bodily vigor and alleviation of temporal feeling of fatigue. On this study, we re-analyzed the data of the previous study about effect on immunological function of Taheebo tea, focusing on the bodily vigor and alleviation of temporal feeling of fatigue.

Methods: A 12-week, double-blind, randomized, placebo-controlled study was conducted. The criteria of subjects took SEIV (total of 40 items), subjective examination, ≥ 90 . 34 subjects were randomized. The SEIV score was measured as the primary outcome. Another outcome included measuring blood pressure.

Results: 24 subjects were in efficacy analysis. In the intergroup comparison of SEIV, 7 items out of 23 illustrated a significant difference after 12-week ingestion. In addition, blood pressures (both SBP and DBP) in the test group were significantly lower versus placebo group after 12 weeks.

Conclusion: These results suggest that improvement in human bodily vigor and alleviation of temporal feeling of fatigue can be seen from the ingestion of Taheebo tea after 12 weeks.

Key words: Taheebo tea, Taheebo polyphenol, bodily vigor, fatigue, SEIV

1. INTRODUCTION

Taheebo, a tree which has a botanical name of *Tabebuia avellanedae*, belongs to the *Tabebuia* species of the bignonia family, and its place of origin is the Amazon river basin of Brazil. It has been worshiped as “a gift tree from God” in the local Indian tongue since the ancient times, and they have drunk the “Taheebo tea” by brewing the inner bark. Since it uniquely contains lots of ingredients such as vitamins, minerals, proteins, fibers and carbohydrates, it is being used for the cure of diseases and health the maintenance even now. A full-fledged study of Taheebo started mainly in Europe from 1960s, and so far it is reported that Taheebo has various health benefits such as anti-inflammatory effects¹⁾⁻³⁾, anti-obesity-effect⁴⁾, antidepressant effect⁵⁾ and immunostimulatory activity⁶⁾.

On the other hand, in present Japan more and more people suffer from various disorders derived from the weakening of their immune system and fatigue which are both caused by stress. Fatigue has a close relationship

with immune system⁷⁾, and it is also reported that the prevention or fatigue can contribute to the maintenance of the immune system⁸⁾. The feeling of fatigue is considered to be induced by oxidant stress which is triggered as a result of muscle and/or mental over loading⁹⁾. Since Taheebo contains a lot of polyphenols with an anti-oxidative effect¹⁰⁾, it is speculated that Taheebo contributes to the prevention of oxidant stress and the alleviation of fatigue. However, there is no report so far which explains its effect of alleviating fatigue among Japanese.

We previously reported the effectiveness of ingesting a Taheebo tea on immunological function of healthy Japanese, by using the immune score measurement method¹¹⁾. In the previous article, we set “the improvement of immune system” as a main outcome, and investigated the index of immune system called “SIV (Scoring of Immunological Vigor, which quantifies the immune strength using seven immune indexes)” and “SEIV (Self-Examination of Immunological Vigor, the subjective assessment of immunological vigor by Likert scale)”. We concluded that the ingestion of the test product contributed to improving the immune strength. This study especially focuses on “the improvement of bodily vigor and alleviation of temporal feeling of

1) Integrated Gene and Immunological Therapies (IGIT) Clinic

2) JACTA (Japan Clinical Trial Association)

fatigue”, therefore extracted and studied the items directly related to the bodily vigor and feeling of fatigue, from the SEIV question items of the previous article. Since the items extracted from SEIV have similarities to those of POMS (Profile of mood states) which evaluates transient, yet definitive mood states from six criteria, we especially scrutinized the items related to “vigor” and “fatigue” among six criteria. Therefore, in this study, we reanalyzed the immunological test data, and illustrated the function of the test product for the improvement of bodily vigor and alleviation of temporal feeling of fatigue using the immunological subjective assessment scales.

2. MATERIALS AND METHODS

2.1. Subjects

This study received the approval of the Institutional Review Board of Pharmaceutical Law Wisdoms (Tokyo) in accordance with the ethical standards established in the Helsinki declaration, and informed consent was obtained from all subjects. All of the business matters were entrusted to Japan Clinical Trial Association (Tokyo). Candidate subjects were male and female volunteers aged 30 to 59 years, who were recruited by advertisement.

2.2.1. Inclusion criteria

- (1) Healthy Japanese men and women aged 30 to 59 years with daily tiredness and fatigue;
- (2) With a relatively low Self-examination of immunological vigor (SEIV, total of 40 items, not shown)^{8) 11)}, 90 and over.

2.2.2. Exclusion criteria

- (1) Previously suffered malignant tumors, heart failure, or cardiac infarction;
- (2) Under the care of a doctor for the treatment of chronic diseases such as atrial fibrillation, uneven heartbeat, rheumatism, diabetes, high blood pressure, and diseases of the liver, kidney, cerebral system, circulatory system, and lipid metabolism;
- (3) Taking medicines, including herbal medicines;
- (4) With pollen allergy;
- (5) Pregnant, nursing, or were likely to become pregnant during the trial;

(6) Judged to be unsuitable to participate in the test by the doctor responsible for the present study.

2.3. Experimental protocol

The subjects were instructed as follows: to take the assigned items as indicated; to maintain their usual lifestyles and habits, avoiding too much food, drink, or alcohol; to avoid excessive exercise; to keep a daily record that included the intake of the assigned item (or not) and lifestyle factors during the test period, and to send the diary by mail to the study coordinator every 7 days; and to contact Japan Clinical Trial Association if they felt unwell.

2.4. Test foods

“Taheebo NFD Marugoto” was prepared by TAHEEBO JAPAN CO., LTD. Calcium powder was used as the placebo. The nutritional constituents of the test samples are shown in **Table 1**.

Table 1-1 Components and nutritional constituents of the test samples

Taheebo		Placebo	
Tabebuia avellanedae	100%	Calcium powder	100%

Table 1-2 nutritional constituents (per 100 g)

Item	Taheebo	Placebo
energy	358 kcal	20 kcal
water	4.1 g	1.0 g
protein	2.9 g	0.6 g
fat	2.0 g	0.3 g
ash	8.8 g	94.5 g
carbo	82.2 g	3.6 g
Na	0.0032 g	1.32 g
Cal	3.29 g	36.9 g
K	0.188 g	0.059 g
Mag	0.0535 g	0.0843 g
Cu	0.28 mg	0.02 mg
Zn	0.77 mg	0.12 mg

Table 2 Schedule for the study

Item	Term	Screening	Pretrial test	Test period (12 w)
SEIV		●		●
Informed consent		●		
Selection and/or allocation		●		
Blood pressure			●	●
Biochemical analysis of blood and urine			●	●
Ingestion of test foods				↔
Log				↔

● : Implementation

↔ : Daily practice during the test period

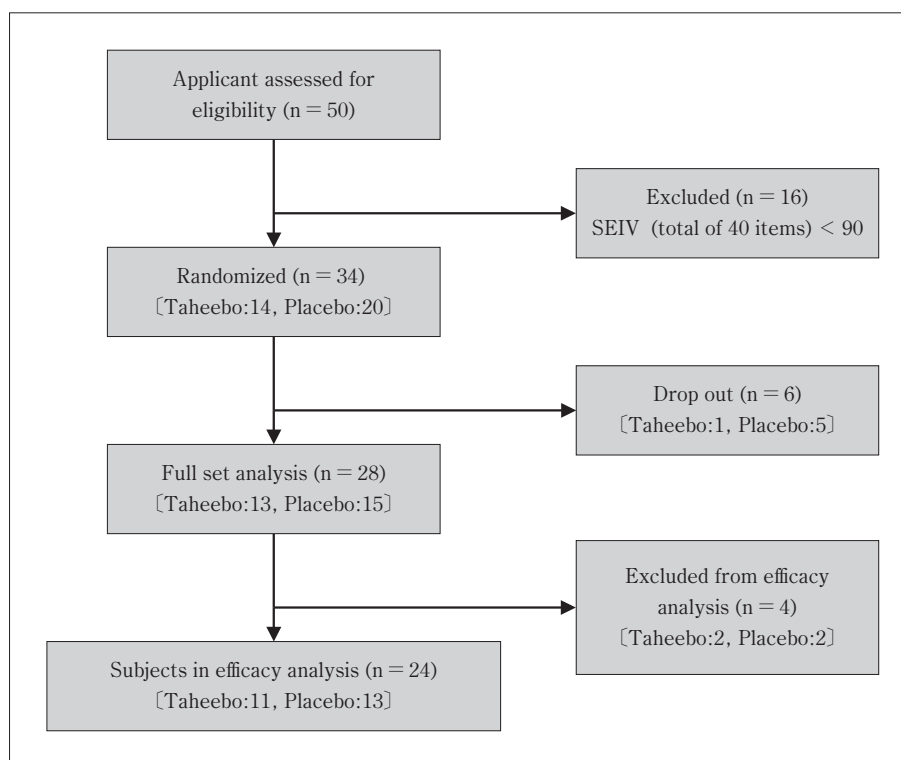


Figure 1 Flow diagram of subject disposition

Table 3 Characteristics of the subjects

Item	Unit	Taheebo	Placebo
Subjects (male : female) *	—	11 (1 : 10)	13 (4 : 9)
Age *	y	46.2 ± 7.4	45.3 ± 6.1

mean ± SD

*No significant difference

2.5. Study design and outcome

According to the schedule shown in **Table 2**, this study was a randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy, along with the safety, of Taheebo ingestion on bodily vigor and alleviation of temporal feeling of fatigue. The study was performed from November 2014 to February 2015. SEIV¹²⁾, blood pressure, biochemical analysis of blood and urine was tested. Subjective symptoms were measured by SEIV with Likert scales in the range of 1-5.

Regarding the analysis of efficacy, the criteria of exclusion was set as follows:

- (i) Those who consumed less than 80% of the expected dose;
- (ii) Those who did not adequately record a diary;
- (iii) Those who fell under the exclusion criteria after the enrollment;
- (iv) Those who did not follow restrictions of the subject.

2.6. Data analysis

Per protocol set principal was adopted in the present study and no sample size was used. Data was expressed

as mean ± standard deviation (SD). For SEIV, blood pressure, biochemical blood and urine, the change from baseline in the same group was assessed using paired-t test, and intergroup comparison was performed using Student's-t test. Student's t-test was 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. The statistical analyses were performed with Statcel 4 (Yanai, 2015). The results were considered significant at the < 5% level in the two-sided test.

3. RESULTS

3.1. Participant demographics

Of 50 applicants for this study, 16 were eliminated due to not meeting inclusion criteria. Overall, 34 applicants were randomly assigned to the interventions, and 6 dropped out of this study mainly due to personal reasons (work commitment or bodily discomfort). Consequently, 28 subjects, of whom 13 received Taheebo and 15 received the placebo, completed the trial. Out of 28

Table 4 SEIV

	Item	Time points	Scores ¹⁾		P-value ²⁾
			Tahebo (n = 11)	Placebo (n = 13)	
1	Enjoyment of meal	Baseline Week 12 Change	1.6 ± 0.7 1.0 ± 0.0 * - 0.6 ± 0.7	1.8 ± 0.7 1.4 ± 0.5 † - 0.4 ± 0.7	0.363
2	Meal is often 3 times per day.	Baseline Week 12 Change	2.2 ± 1.5 1.7 ± 1.2 - 0.5 ± 1.4	2.0 ± 1.1 1.5 ± 1.0 * - 0.5 ± 0.7	0.935
3	Nutritional balance of the meal is a considerable point.	Baseline Week 12 Change	2.3 ± 0.9 2.0 ± 1.0 - 0.3 ± 0.8	2.5 ± 1.0 2.2 ± 0.7 - 0.2 ± 0.6	0.883
4	Wake up energetically without fatigue from the previous night.	Baseline Week 12 Change	3.9 ± 0.8 2.7 ± 0.8 * - 1.2 ± 1.3	4.2 ± 1.1 3.8 ± 1.1 - 0.3 ± 1.5	0.139
5	Feeling of fatigue is reduced resting on weekends.	Baseline Week 12 Change	3.8 ± 1.2 2.2 ± 0.8 ** - 1.6 ± 1.6	3.8 ± 0.9 3.5 ± 1.0 - 0.2 ± 0.6	0.007 **
6	Going to bed before 12 pm	Baseline Week 12 Change	3.7 ± 1.3 2.9 ± 1.3 † - 0.8 ± 1.3	2.9 ± 1.5 3.4 ± 1.4 0.5 ± 1.3	0.025 #
7	Getting sufficient quantity of sleep.	Baseline Week 12 Change	3.3 ± 1.3 2.5 ± 0.7 - 0.7 ± 1.4	3.5 ± 1.1 3.1 ± 1.1 - 0.5 ± 1.0	0.593
8	Less frequency of stiff shoulder and lower back pain	Baseline Week 12 Change	4.0 ± 1.0 3.0 ± 1.2 * - 1.0 ± 1.2	4.0 ± 1.2 3.7 ± 1.0 - 0.3 ± 0.9	0.111
9	Catching a cold.	Baseline Week 12 Change	3.2 ± 1.0 1.8 ± 0.9 * - 1.4 ± 1.4	2.8 ± 1.2 2.6 ± 1.0 - 0.2 ± 0.8	0.025 #
10	Less symptoms of gastro-intestinal problem	Baseline Week 12 Change	2.7 ± 1.2 1.6 ± 1.0 * - 1.1 ± 1.4	3.0 ± 1.0 2.6 ± 1.0 * - 0.4 ± 0.5	0.099 †
11	Less symptoms of stomatitis	Baseline Week 12 Change	2.7 ± 1.4 1.6 ± 0.8 * - 1.1 ± 1.4	2.7 ± 1.2 2.6 ± 1.3 - 0.1 ± 0.8	0.032 #
12	Normal bowel movement	Baseline Week 12 Change	2.5 ± 1.0 2.6 ± 1.3 0.1 ± 0.8	2.4 ± 1.1 2.0 ± 1.0 - 0.4 ± 1.0	0.236
13	Try to take the stairs.	Baseline Week 12 Change	3.3 ± 1.2 2.5 ± 1.0 * - 0.8 ± 1.1	2.5 ± 1.3 2.7 ± 1.1 0.2 ± 0.6	0.009 **
14	Try to walk instead of vehicles.	Baseline Week 12 Change	2.4 ± 1.1 2.0 ± 0.9 - 0.4 ± 1.4	2.1 ± 1.1 2.2 ± 1.1 0.2 ± 0.6	0.242
15	Fast pace walk	Baseline Week 12 Change	2.5 ± 1.1 2.1 ± 1.1 * - 0.5 ± 0.5	2.6 ± 1.0 2.2 ± 0.7 † - 0.5 ± 0.8	0.980
16	Indifference to walking	Baseline Week 12 Change	2.6 ± 1.1 1.6 ± 0.7 * - 1.0 ± 1.2	2.7 ± 1.0 2.2 ± 0.8 ** - 0.5 ± 0.5	0.216
17	Indifference to standing in the train	Baseline Week 12 Change	3.4 ± 1.0 2.3 ± 1.3 * - 1.1 ± 1.3	3.2 ± 0.8 3.0 ± 0.9 - 0.2 ± 0.7	0.034 #
18	Indifference to running when needed	Baseline Week 12 Change	2.9 ± 1.0 2.2 ± 1.2 † - 0.7 ± 1.1	3.1 ± 1.2 2.8 ± 1.2 0.2 ± 1.1	0.281
19	Have a hobby containing physical exercise.	Baseline Week 12 Change	3.3 ± 1.6 3.0 ± 1.5 - 0.3 ± 1.3	2.8 ± 1.5 2.9 ± 1.5 0.1 ± 0.6	0.414
20	Satisfied with your daily job.	Baseline Week 12 Change	3.2 ± 0.8 2.5 ± 1.2 * - 0.7 ± 0.8	3.2 ± 1.0 2.8 ± 0.9 - 0.3 ± 0.6	0.161
21	Want to be helpful to people and society.	Baseline Week 12 Change	2.9 ± 0.7 2.5 ± 0.7 * - 0.5 ± 0.5	3.0 ± 0.7 2.8 ± 0.7 - 0.2 ± 0.6	0.188
22	Total score	Baseline Week 12 Change	62.5 ± 11.9 46.4 ± 10.0 ** - 16.1 ± 16.8	60.7 ± 8.0 56.2 ± 7.8 ** - 4.5 ± 5.0	0.026 #

Scores are expressed as the mean ± SD.

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

2) † p < 0.1, # p < 0.05, ## p < 0.01 between-group difference in change from baseline.

Table 5 Blood Pressure

Item	Unit	Time points	Values ¹⁾		P-value ²⁾
			Taheebo (n = 11)	Placebo (n = 13)	
SBP	MmHg	Baseline	122.2 ± 18.2	113.5 ± 10.5	0.027 #
		Week 12	113.5 ± 17.2 *	116.5 ± 13.7	
		Change	- 8.7 ± 12.6	3.1 ± 11.7	
DBP	MmHg	Baseline	80.0 ± 11.6	70.6 ± 10.0	0.041 #
		Week 12	76.0 ± 12.7	74.0 ± 12.3	
		Change	- 4.0 ± 9.0	3.4 ± 7.7	

Values are expressed as the mean ± SD.

1) * p < 0.05 against baseline.

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

subjects, 4 revealed to fall under the exclusion criteria for evaluation of efficacy as described in “study design.” Thus, data obtained with 24 subjects were used for the analysis of efficacy (**Figure 1**). There was no significant difference in gender or age between groups (**Table 3**).

3.2. SEIV

Table 4 shows the results of SEIV. After 12-weeks of ingestion, 7 items out of 23 illustrated a significant difference in intergroup comparison: 5, “Feeling of fatigue is reduced resting on weekends.”; 6, “Going to bed before 12 pm”; 9, “Catching a cold.”; 11, “Less symptoms of stomatitis”; 13, “Try to take the stairs.”; 17, “Indifference to standing in the train”; and 22, “Total score”.

3.3. Blood pressure

For blood pressure, amount of changes of the SBP in Taheebo was significantly lower versus Placebo after 12 weeks. The DBP in Taheebo was significantly lower versus Placebo after 12 weeks (**Table 5**).

3.4. Adverse event

No severe changes were detected on the biochemical analysis of the blood (data not shown). In the urine analysis, no severe changes attributable to Taheebo ingestion were detected. No adverse effects attributable to Taheebo ingestion were observed.

4. Discussion

We conducted a randomized, placebo-controlled, double-blind study to verify the effects of Taheebo tea among healthy Japanese. For this examination we used SEIV (Self-Examination of Immunological Vigor), which is an index for evaluating the bodily vigor, in order to evaluate the bodily vigor and alleviation of temporal feeling of fatigue. Since the items extracted from SEIV have similarities to those of POMS (Profile of Mood States), they should be suitable for the reasonably assessing the alleviation of fatigue. As the primary outcome, after 12-weeks of ingestion the Taheebo group showed a significant difference in 8 items and an improvement tendency in 1 item out of 23 items of SEIV, compared to Placebo. At the same time, as the secondary outcome the observation of clinical findings such as the medical

interview, blood test and urine test revealed no abnormal change had been triggered by the ingestion of test product. For blood pressure, the SBP and DBP in Taheebo were significantly lower versus Placebo, after 12 weeks.

Main findings

In this study, we evaluated the effect of Taheebo tea for the bodily vigor and alleviation of temporal feeling of fatigue, by comparing scores of SEIV which enables us to assess the scores from a standpoint of immunology. SEIV is an indicator for evaluating the symptoms subjectively. In this study, a significant difference was observed in several items such as “Feeling of fatigue is reduced resting on weekends.” (#5), “Try to take the stairs.” (#13), “Indifference to standing in the train” (#17), “Catching a cold.” (#9), or “Less symptoms of stomatitis” (#11). In addition, “Total score” (#22) of the Taheebo showed a significant difference compared to Placebo.

In this study we used the modified version of SEIV in which the investigator customized the test items of SEIV to meet the test objectives of evaluating the bodily vigor and alleviation of temporal feeling of fatigue. In addition, many test items of SEIV resemble those of POMS (The Profile of Mood States) which is a relatively new psychological rating scale used to assess transient, distinct mood states; for example, the items such as #4, 5, 8, 9, 16, 18, 20 and 21, which are about “wanting to be helpful to people and society” or “without any fatigue”. POMS measures six mood swings of “Tension or Anxiety”, “Depression or Dejection”, “Anger or Hostility”, “Vigor or Activity”, “Fatigue or Inertia”, and “Confusion or Bewilderment”¹³⁾. Among them, Vigor is especially defined as a physiological and psychological energy, and it is said it is able to be examined in this psychological test. In addition, Fatigue is defined as a period of extreme tiredness be caused by emotional strain, physical exertion, boredom, or a general lack of rest and/or sleep, and it can be accurately evaluated in this test. Therefore, it should be considered appropriate to evaluate the subjective symptoms of bodily vigor or

fatigue by using SEIV, since it not only resembles to POMS but also enables to measure the bodily vigor from a standpoint of immunology. SEIV is usually used for a self-assessment of autoimmunization¹⁴⁾. The function of autoimmunization declines due to various stresses. While the external stimulation can be accepted in human body as long as the amount of the stimulation is within an acceptable level. Once it exceeds the acceptability limit it disturbs the homeostasis of the internal environment of a human. This disturbance creates the stresses, and they activate the immune system, accelerate the secretion of substances such as adrenalin or glucocorticoid, and decrease an immune reaction by inhibiting the function of lymphocytes¹⁵⁾.

There are different types of fatigue such as physical fatigue, mental fatigue or brain fatigue. It is believed that they are caused by the active oxygen generated from a variety of stress such as mental stress derived from human relationship, body stress due to hard labor, physical stress like ultraviolet, chemical stress from chemical substances, and/or biological stress caused by viruses or bacteria¹⁶⁾¹⁷⁾. These stresses stimulate the secretion of the stress hormone such as adrenalin or glucocorticoid. Glucocorticoid tries to cope with the stresses by the increase in glucose metabolism or the exhibition of an anti-inflammatory effect¹⁸⁾¹⁹⁾, whereas adrenalin tries by working on the sympathetic nervous tone²⁰⁾. Also, the super secretion of other hormones or substances occurs, and it results in the reduction in activity of the immune system such as T-cells, B-cells, NK-cells, lymphocyte cells or cytokine, the deterioration of cellular function, the increase in oxygen consumption, the decline in brain function due to inhibition of secretion of neurotransmitter serotonin, or the abnormality of incretion or metabolism¹⁶⁾²¹⁾⁻²⁴⁾. The process described so far is regarded as the mechanism of fatigue. The fact that the scores of SEIV (as a self-assessment of autoimmunization) are high can be explained that the body increased the level of bodily vigor, since the alleviation of temporal fatigue indicates the condition of the vigor. Taheebo (the test product) contains plenty of polyphenols of Phenylethanoid Glycosides which contains hydroxyl group or methoxy group¹⁰⁾, for example, Acteoside. Phenylethanoid Glycosides has a very strong antioxidant activity, and possesses properties such as immunomodulatory effects²⁵⁾, neuroprotective property, anti-inflammatory and/or anticancer effect²⁶⁾. Since the Taheebo tea (the test product) is just the powder of Taheebo bark, it is highly possible that the tea contained lots of Taheebo polyphenols centering on acteoside. As described above, the main cause of fatigue or loss of bodily vigor is the active oxygen derived from stresses, and the Taheebo polyphenols (such as acteoside) contributes to removing or detoxifying it²⁷⁾²⁸⁾.

It is considered that the results such as “Feeling of fatigue is reduced resting on weekends.” (#5), which

showed a significant difference, were produced thanks to the mechanism described above. Also, the moods such as “Try to take the stairs.” or “Indifference to standing in the train” (#13, 17) may represent the expression of bodily vigor as a result of an anti-oxidative effect of Taheebo polyphenol. “Catching a cold” (#9) is considered to be produced as the immune system was not inhibited and worked normally. In addition, as for the items such as “Less symptoms of stomatitis” (#11), it is speculated that the cells have inflammation due to the active oxygen. Since it is reported that the Taheebo polyphenol has an anti-inflammatory effect⁴⁾ as it downregulates the production of various chemical mediators of inflammation, the oral administration of Taheebo polyphenol performed the anti-inflammatory effect. Therefore in this study, the Taheebo could stop the generation of active oxygen, inhibit the decrease of immunity and recover from the disorder of the body after drinking Taheebo tea; in other words, it can be said that it could recover the bodily vigor and alleviation of temporal feeling of fatigue.

In addition, as for the blood pressure, the SBP (systolic blood pressure) and DBP (diastolic blood pressure) in the Taheebo, the results admitted were significantly low compared to the Placebo after 12 weeks. Oxidative stress is implicated in the pathogenesis such as hypertension²⁹⁾, and it is reported that the antihypertensive activity can be achieved by ingesting the ingredients with an antioxidative activity³⁰⁾. This mechanism is that the peroxide is produced by NAD(P)H oxidase in the vasculature, and reduces nitric oxide bioavailability, which leads to increased blood pressure²⁹⁾. On the other hand, in this study it is speculated that the antioxidant activity of Taheebo polyphenol acted against the peroxide and significantly lowered blood pressure in the Taheebo. In addition, since high blood pressure is a cause of the tiredness of the body³¹⁾, it is thought that the vitality of the body improved thanks to the decrease of blood pressure.

Secondary Findings

In this study, no severe changes were detected on the biochemical analysis of blood and urine. Also, during the study, six (6) subjects stopped the test due to personal reasons such as work or bodily discomfort, whereas four (4) subjects were excluded from the analysis since they met an exclusion criteria (such as “consumed less than 80% of the expected dose”, “did not adequately record”, etc.) stipulated in the study design. However, they were not related to the adverse event caused by the test product. In addition, no abnormal change caused by the test product was reported from the test subject. These results indicated the safety of the ingestion of the test product for the 12-week test period.

General information

Originally, tea is believed to own unique functions such as an effect of relaxation or recovery from exhaustion, and having time for drinking tea can give us some kind of

comfort, healing and “time to breathe” in our “hectic” days³²⁾. One of the studies about tea revealed that the flavor of tea affects the condition of the brain waves and provides a relaxing effect³³⁾. By drinking hot-tea we can warm up our whole body and promote the blood circulation. Therefore, if tea is equipped with the functions of improving bodily vigor and recovering from fatigue, they additionally reinforce the merits of drinking tea. According to an epidemiological survey conducted by Ministry of Education, Culture, Sports, Science and Technology in 2004, more than sixty (60) percent of people have the feeling of fatigue, and among them more than half feel a certain level of chronic tiredness and have difficulty in working in full play due to the decreased work capacity³⁴⁾. Therefore, if they can recover from fatigue and strengthen their bodily vigor just by the daily drinking of Taheebo tea, it may contribute to increasing the volume of activity of many people, improving their QOL and eventually improving their social vitality.

Limitations

In this study we used SEIV, a type of immunological indicator, for evaluating the level of bodily vigor and alleviation of a temporal feeling of fatigue. Since the subjective impression plays an important role in the feeling of bodily vigor or fatigue, the examination of subjective symptoms is usually applied for evaluating these feelings³⁵⁾³⁶⁾. Also, POMS (Profile of Mood States) is often used as an indicator of mental fatigue since it is aimed at evaluating the effect on humans from subjective aspects such as mood or emotion³⁷⁾³⁸⁾. Now the relationship between POMS and biomarker is being researched³⁹⁾, and therefore it is highly creditworthy. SEIV, on the other hand, is a test developed by Hirokawa and colleagues for assessing the bodily vigor from immunological index, and its question items have a high similarity to those of POMS. Therefore, it is considered as a relevant measure for evaluating a feeling of fatigue, there is no test evaluating the definite resemblance between them, though. In addition, the feeling of fatigue is often quantified by various biomarkers such as Heart Rate Variability⁴⁰⁾, Biogenic Amines⁴¹⁾ or blood lactate level⁴²⁾. Theoretically, SEIV used in this study is considered relevant for evaluating the alleviation of a temporal feeling of fatigue, but if we also utilize the other measures such as the quantification of fatigue level by the biomarkers explained above or the investigation of other subjective symptom at the same time and compare all the test results, it is highly possible to obtain more objective and versatile outcomes. Conducting derivative studies as described above and confirming the effectiveness of this test product are challenges for the future.

Furthermore, it is highly possible for tea to be ingested with the other foods in our everyday life. Since the effectiveness discovered in this study is limited to the situation that only the tea is ingested, it is desirable for the further study to examine the mutual influence among

the foods ingested together with the tea, using the test settings such as in vitro testing, while securing its safety.

5. CONCLUSION

In conclusion, we found out that the ingestion of Taheebo tea for 12 weeks resulted in the improvement of human bodily vigor and alleviation of a temporal feeling of fatigue. In addition, no safety-related matter occurred during 12-weeks test period. Both conclusions indicate that Taheebo tea is a product that is both safe and effective.

CONFLICT OF INTEREST

The authors state no conflicts of interest.

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