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# Short-term Effects of Supplementation with a Multi-ingredient Weight-loss Product on Weight Maintenance and Fat Oxidation in Obese Female with Weight Reduction: Preliminary Results

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## Abstract

**Background:** Numerous multi-ingredient weight-loss supplementation products are marketed, whereas the effects of these supplements on weight maintenance have rarely been studied. This study aimed to investigate preliminarily whether a 4-week supplementation of a multi-ingredient weight-loss product (named 'diet's BB'), containing L-carnitine, banaba, caffeine, capsaicin, *Nelumbo nucifera* leaf extract and sesamin, could contribute to weight maintenance and its related parameters among obese women with weight reduction following a Low-calorie Diet (LCD).

**Methods:** In a prospective, randomized, double-blind intervention design, subjects with ≥5% of weight reduction following LCD were randomized to the group who used the diet's BB (Group A) or tablet containing six types of vitamins (Group B) for four weeks. Their body weight and related parameters, including Respiratory Quotient (RQ) and fat oxidation, were measured pre- and post-intervention.

**Results:** The changes in body weight and related parameters were not significantly different between the groups. Group A showed significantly reduced RQ and increased fat oxidation more than the Group B.

**Conclusion:** The short-term multi-ingredient weight-loss supplementation product did not yield further weight-loss for obese women with weight reduction, while it could potentially lead to favorable changes of fat oxidation levels. The effects of the supplementation on weight traits merit large-scale and long-term investigations.

**Keywords:** Fat oxidation; Multi-ingredient weight-loss supplementation; Low-calorie diet; Respiratory quotient

## Introduction

The increasing trend of obesity is a recognized health problem all over the world [1]. Obesity is a major factor in a number of diseases, such as hypertension, type 2 diabetes mellitus, cardiovascular diseases, pulmonary dysfunction, osteoarthritis and certain types of cancer [1]. Treatment of obesity is anticipated, because weight management can reduce the risk for mortality and morbidity of the diseases [1-3]. Weight-loss methods lead to short-term success; however, weight maintenance following the weight-loss is hard to achieve [2,3]. Although strategies for weight maintenance generally are based on diet components and physical activities [4-6], the typical programs produce unsatisfactory results [7]; therefore, alternative modalities for weight maintenance, including dietary supplementations, are widely required.

Very many dietary supplementation products are currently available for weight-loss [8]. Despite this situation, evidence using the supplementation for weight-loss has not yet been established, and moreover, trials on the effects of the supplementation on weight maintenance following successful weight-loss are limited.

There have been several dietary components that are used as the supplementation products for weight-loss and its maintenance. For instance, Carnitine plays an essential role in the integration of fat and carbohydrate oxidation in skeletal muscle, which is impaired in obesity [9]. L-carnitine (L-C) transports fatty acids into mitochondria for oxidation; therefore, L-C itself is applicable to control body weight

[10,11]. However, there has been a report that the supplementation of L-C failed to reduce body weight in obese women [12]. The effects of such supplementations of single dietary component are lately thought to be restricted for weight management [13]. Various supplementation products can, thus, be mixed by several dietary components for weight management.

A multi-ingredient supplementation product (called 'diet's BB'), containing anti-obesity and thermogenic dietary components (L-C, banaba, *Nelumbo nucifera* extract, caffeine, capsaicin and sesamin), was recently developed to manage body weight (Tables 1 and 2). The aim of this study was to investigate preliminarily whether a 4-week supplementation of the multi-ingredient product (diet's BB) could contribute to weight maintenance and its related parameters among obese women with weight reduction following a Low-calorie Diet (LCD), based on a prospective, randomized, double-blind intervention study design.

| | Group A | Group B |
|---|---|---|
| Vitamin B1, mg | 1.1 | 1.1 |
| Vitamin B2, mg | 1.2 | 1.2 |
| Vitamin B6, mg | 1.2 | 1.2 |
| Niacin, mg | 1.2 | 1.2 |
| Pantothenic acid, mg | 5.0 | 5.0 |
| L-carnitine, mg | 300 | 0 |
| Banaba, mg | 100 | 0 |
| *Nelumbo nucifera* | 100 | 0 |
| Caffeine, mg | 100 | 0 |
| Capsaicin, mg | 25 | 0 |
| Sesamin, mg | 10 | 0 |
| Total energy, kcal | 6.76 | 7.36 |
| Protein, g | 0.21 | 0.03 |
| Fat, g | 0.08 | 0.14 |
| Carbohydrate, g | 1.29 | 1.50 |
| Sodium, mg | 0-2 | 1.10 |

**Table 1:** Components of dietary supplements in group A and B.

| Dietary supplements | Origin | Potential activity | Safety of usage |
|---|---|---|---|
| Vitamin B1 (Thiamine) | Synthesis | Support TCA Cycle, properly use carbohydrates | Rare, allergic reactions and skin irritation |
| Vitamin B2 (Riboflabin) | Synthesis | Support TCA Cycle | High doses, a yellow-orange color in urine, diarrhea, an increase in urine |
| Vitamin B6 (Pyridoxine) | Synthesis | Support TCA Cycle | Rare, nausea, vomiting, stomach pain, loss of appetite, headache, tingling, sleepiness |
| Niacin | Synthesis | Support TCA Cycle | A flushing reaction |
| Pantothenic acid | Synthesis | Support TCA Cycle | High doses, diarrhea |
| L-carnitine | Synthesis | Increase fatty acid uptake to mitochondria | Nausea, vomiting, stomach upset, heartburn, diarrhea, and seizures |
| Banaba | *Lagerstroemia speciosa* | Hypoglycemic activity | None well documented |
| Nelumbo nucifera extract | *Nelumbo nucifera* | Thermogenesis (Act ADRB3 in fat cells, increase UCP3 in muscle) | None well documented |
| Caffeine | Coffee bean | Inhibit cAMP | Toxicosis |
| Capsaicin | Capsicum | Thermogenesis | Burning, itching, dryness, pain, redness, swelling, or soreness |
| Sesamin | Sesame | Activate beta-oxidation | An allergic reaction |

**Table 2:** Characterization of dietary supplements.

## Materials and Methods

### Study design

The study was performed according to the CONSORT statement for randomized trials [14]. As a LCD for weight reduction (the pre-treatment of the multi-ingredient supplementation product), subjects replaced one daily meal with a soy-based drink (180 kcal of calories, total fat 1.5 g, carbohydrate 16 g, protein 25 g) for 8 weeks. Those who met the following criteria were recruited in the study: 1) Japanese adults aged 20-70 years, 2) female gender and 3) obesity (defined based on ≥25 kg/m$^2$ of the Body Mass Index (BMI) using the WHO Western Pacific Regional Office criteria [15,16]). Those with the following criteria were excluded: 1) past history of allergic reaction to soy products and dietary supplementation products, 2) forbidden a LCD because of disease, 3) alcoholism, 4) smokers, 5) pregnancy, 6) lactating state and 7) inadequate states because of obviously severe diseases (i.e., heart diseases). Participants were recruited by flyers, word-of-mouth and e-mail.

As shown in Figure 1, subjects who showed ≥5% of their weight reduction following the LCD were randomized into groups by an independent statistician using sequentially numbered sealed envelopes to the group who received the diet's BB (Group A) or received tablets containing six types of vitamins (Group B).

### Ethics

The study was approved by the Ethics Committee of Kyoto Medical Center in accordance with the Helsinki Declaration. All subjects gave written informed consent to participate in the study.

### Intervention

This study was conducted during a 4-week intervention period. Group B used one tablet containing five types of vitamins: vitamin B1 (1.1 mg), B2 (1.2 mg), B6 (1.2 mg), niacin (12 mg) and pantenoic acid

(5.0 mg). On the other hand, Group A used the diet's BB (Suntory Ltd, Osaka, Japan) containing of six types of dietary components: L-C (300 mg), banaba (100 mg), caffeine (100 mg), capsaicin (25 mg), *Nelumbo nucifera* leaf extract (100 mg), sesamin (10 mg), and five types of vitamins (Table 1). All subjects recorded to confirm the intake of the tablet every day. There was the same appearance of the tablets.

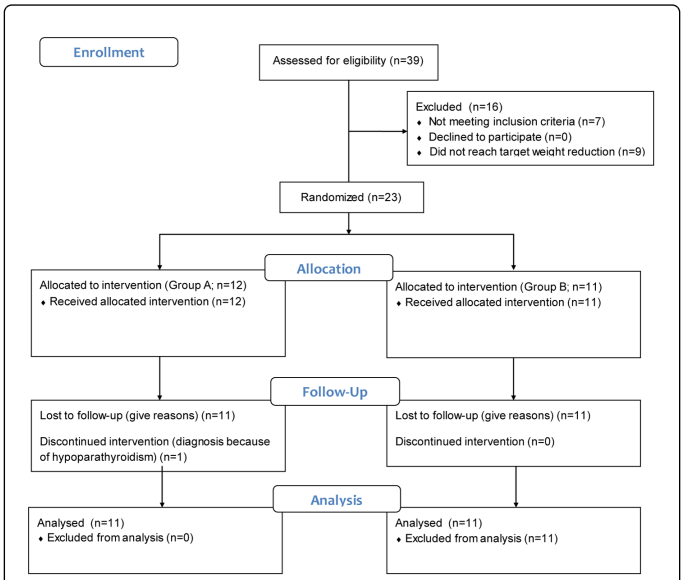


**Figure 1:** Randomization by intervention of the study.

## Measurements

After an overnight fast, body weight, fat composition and blood pressure were measured, and blood samples were collected. Besides waist circumference at the umbilical level, height, body mass and fat composition levels were determined using a bioelectrical impedance analyzer (Omron Corp., Kyoto, Japan). Blood pressure was measured while the subject was seated using a digital monometer machine (Omron Corp., Kyoto, Japan). Total cholesterol, triglyceride, High-density Lipoprotein (HDL) cholesterol, glucose and carnitine levels in blood were measured enzymatically. A food diary on the self-selected foods and beverages was recorded by each subject for three consecutive days (one weekend day and two weekdays) prior to the assessment day. The nutritional analysis of the three-day food records was performed using a licensed Mushroom Soft (Okayama, Japan). A questionnaire on exercise habits was recorded by each subject, and the frequency of moderate exercise (≥3METs) sessions lasting at least 30-minutes per week was calculated by the record.

In the metabolic measurements, the coffee, tea and alcohol consumption was not allowed, and vigorous sports activities were not permitted. The subject was equipped with electrocardiogram electrodes, and then rested for at least 30-minutes in a temperature- and humidity-controlled environment [17,18]. After the subject had received an explanation of the procedure and adjusted the mask, gas exchange parameters were recorded using an open-circuit computerized indirect calorimeter (Aero monitor AE 280; Minato Medical Science Ltd., Tokyo, Japan) while the subject is seated in a comfortable chair. The calorimeter was calibrated before each test with a reference gas mixture (15% $O_2$ and 5% $CO_2$). Continuous ventilator volumes, $VO_2$ (oxygen consumption) and $VCO_2$ (carbon dioxide production) were monitored on a computer at 15-second intervals, and the mean value for each minute was recorded. The Respiratory Quotient (RQ) is defined by the ratio of c $VCO_2/VO_2$, and a high RQ indicates a relatively low level of fat (lipid) oxidation, which is known to be a risk for weight gain [19-22].

## Sample-size estimation

The intervention of this study was performed for the subjects who had had already reduced body weight (i.e., >5% of initial weight). Additionally, the effects of supplementation products on weight management are generally thought to be weaker than those of anti-obesity drugs used in medical practice. Thus, more weight-loss was not assumed via this intervention in these subjects. With the power (1-beta level) of 80% at the alpha (significance) level of 5% to detect a difference of 0.3 kg/m$^2$ of BMI changes (versus the control group) and a standard deviation of 0.2 kg, a sample size of 16 was estimated.

## Statistics

Differences between the groups were compared using unpaired t-test for continuous variables and Chi-square test for categorical variables where appropriate. Differences between pre- and post-intervention were compared using paired t-test. A P-value of <0.05 was considered significant.

## Results

The LCD treatment was conducted in 32 women, 49.9 (8.4) years, mean BMI 28.4 (3.3) kg/m$^2$. Following the LCD, 24 subjects showed ≥5% of their weight reduction. One subject was withdrawn only after one-week from starting the intervention in Group A, because of a diagnosis of idiopathic hypoparathyroidsm (Figure 1). On the other hand, one subject lost follow-up during the intervention period in Group B. Finally, twenty-two subjects completed the study. No serious adverse events were observed during the intervention period.

As shown in Table 3, in the pre-intervention, characteristics of all variables measured did not significantly differ between the groups. Between pre- and post-intervention, non-significant differences in changes of most variables measured were observed between the groups. However, in the metabolic measurements, RQ was significantly reduced and fat oxidation was significantly increased in Group A than in Group B.

In the nutritional analysis, total intake energy from the pre- to post-post-intervention, was from 1266 (259) to 1546 (271) kcal in Group A and from 1423 (274) to 1611 (680) kcal in Group B (P>0.05 in the pre-intervention, P>0.05 in the post-intervention).Overall, the nutritional analysis did not find significant differences in any variables between the groups (Table 4). The analysis of exercise habits did not find significant differences between the groups (data not shown).

## Discussion

This study showed that the supplementation of the multi-ingredient weight-loss product, the diet's BB, did not obviously produce further weight-loss for obese women with weight reduction. However, compared to the control subjects, RQ was significantly reduced and fat oxidation was significantly increased in subjects with the supplementation of the diet's BB. The results imply that the diet's BB can potentially affect favorable weight management, given the previous knowledge [19-22].

| Measured variables | Group A (n=11) | | | Group B (n=11) | | |
|---|---|---|---|---|---|---|
| | Baseline | Post-supplementation | Difference | Baseline | Post-supplementation | Difference |
| Age, years | 48.3 (7.1) | - | - | 49.3 (10.8) | - | - |
| Body weight, kg | 63.1 (7.8) | 62.8 (7.0) | -0.26 (0.95) | 65.6 (6.7) | 65.5 (7.4) | -0.02 (1.15) |
| Body mass index, kg/m$^2$ | 25.5 (3.6) | 25.3 (3.3) | -0.19 (0.47) | 26.3 (2.7) | 26.2 (2.9) | -0.05 (0.42) |
| Body fat, % | 33.2 (3.5) | 33.0 (3.0) | -0.2 (0.9) | 33.9 (3.4) | 33.5 (4.1) | -0.5 (0.9) |
| Waist circumference, cm | 85.9 (8.5) | 84.3 (9.3) | -1.6 (3.2) | 89.8 (8.8) | 88.3 (8.5) | -1.5 (2.3) |
| Systolic blood pressure, mmHg | 124 (17) | 122 (14) | -2 (12) | 123 (13) | 125 (16) | 2 (8) |
| Diastolic blood pressure, mmHg | 75 (10) | 76 (9) | 1 (5) | 73 (8) | 77 (9) | 4 (7) |
| Fasting plasma glucose, mg/dL | 87 (13) | 84 (10) | -2 (8) | 85 (8) | 87 (6) | 2 (7) |
| Total cholesterol, mg/dL | 199 (33) | 204 (37) | 5 (11) | 201 (44) | 218 (56) | 17 (20) |
| HDL-cholesterol, mg/dL | 62 (10) | 64 (11) | 2 (4) | 57 (10) | 62 (13) | 5 (6) |
| Triglyceride, mg/dL | 68 (26) | 77 (33) | 8 (26) | 99 (91) | 131 (129) | 31 (50) |
| Total carnitine, μmol/L | 65.5 (14.3) | 61.6 (13.7) | -3.9 (6.4) | 60.5 (11.8) | 50.5 (10.4) | -10 (8.9) |
| $VO_2$, mL/min/kg | 2.94 (0.35) | 3.11 (0.50) | 0.17 (0.33) | 2.67 (0.29) | 3.00 (0.42) | 0.33 (0.41) |
| Respiratory quotient | 0.776 (0.018) | 0.757 (0.020) | -0.019 (0.026)* | 0.781 (0.027) | 0.796 (0.028) | 0.015 (0.030) |
| Fat oxidation, % | 59.4 (8.9) | 68.8 (9.6) | 9.4 (12.6)* | 57.6 (12.8) | 52.8 (11.6) | -4.8 (15.0) |

**Table 3:** Baseline, post-supplementation, and differences of subject's data between group A and B. Data are presented as the means (standard deviations); *p<0.05 (vs. Group B).

One of the major components of the diet's BB is L-C (300 mg). There have been several studies that examined the associations between RQ, fat oxidation and the supplementation of L-C. For instance, Iwami et al. have previously reported that the RQ was reduced after a continuous supplementation of L-C alone in rats fed a high-fat diet [23]. Wutzke et al. have also reported that the supplementation of L-C (3g/day for 10-days) increased in fat oxidation in overweight human subjects [22]. Vecchiet et al. have reported that the supplementation of L-C (2 g) significantly increased maximal oxygen uptake before exercise in trained men [24]. Gorostiaga et al. have reported that, RQ was reduced during submaximal exercise with a high-dose supplementation of L-C (2 g for 28 days) than with a placebo in endurance-trained people [25]. The dosage of L-C used in our current study was considerably lower than in these previous studies, while the results observed in our study seems to be in line with the previous studies.

Besides L-C, caffeine [26,27] and capsaicin [28-30] have been known as potent themogenic and obesity-alleviating components. Banaba has also been used as a log-term folk medicine especially among patients with diabetes mellitus in the Philippines, and it can be effective for phenotypic improvements in diabetic mice [31]. Ashakumary et al. have reported that sesamin induces hepatic fatty acid oxidation in rats [32]. Ono et al. have reported that *Nelumbo nucifera* leaf extract suppresses an increase in body weight, parametrial adipose tissue weight and liver triacylglycerol levels in mice with obesity caused by a high-fat diet [33]. These data are suggestive of the positive effects on not only fat oxidation levels but weight traits. Future interest is the remaining possibility that the changes of on RQ and fat oxidation by the supplementation of the diet's BB may affect body weight in a long-term period.

## Strengths and Limitations

Strength of this study is conduction in a dedicated-randomized controlled design with measurements of various metabolic variables underlying weight pathophysiology, e.g., substrate oxidation. There are limitations to this study. The study was preliminary, but performed with a small sample-size and a short-term intervention. Some side effects, which cannot be occurred 4-weeks intervention, can be occurred later. Studies with a larger sample-size and longer intervention should be performed. Moreover, not drugs used in medical practice but supplementation products like the diet's BB have generally a preference for obese individuals who are in fear of adverse reactions caused by drugs, and this would possibly lead to fewer dropout rates in this study. However, because the diet's BB consist of the multi-ingredient components; we did not identify which components were most effective on weight metabolism.

| Measured variables | Group A (n=11) | | | Group B (n=11) | | |
|---|---|---|---|---|---|---|
| | Baseline | Post-supplementation | Difference | Baseline | Post-supplementation | Difference |
| Total energy, kcal | 1266 (259) | 1546 (271) | 273.1 (533.1) | 1423 (274) | 1611 (680) | 181.8 (281.1) |
| Protein, g | 65.0 (10.3) | 67.1 (14.9) | 1.9 (20.7) | 67.8 (11.4) | 66.2 (25.2) | -1.5 (14) |
| Fat, g | 36.0 (9.5) | 42.9 (11.6) | 6.8 (26.3) | 43.8 (9.1) | 55.3 (22.7) | 11.4 (18.1) |
| Carbohydrate, g | 168 (41.4) | 222 (43.3) | 52.3 (65.1) | 185 (58.1) | 210 (105.7) | 23.1 (25.2) |
| Vitamin B1, mg | 1.01 (0.15) | 2.01 (0.21) | -0.1 (0.3) | 0.99 (0.23) | 1.97 (0.43) | -0.1 (0.2) |
| Vitamin B2, mg | 1.49 (0.65) | 2.37 (0.36) | -0.3 (0.4) | 1.41 (0.35) | 2.32 (0.53) | -0.3 (0.6) |
| Vitamin B6, mg | 1.62 (1.43) | 2.46 (0.38) | -0.4 (0.3) | 1.48 (0.79) | 2.43 (0.86) | -0.3 (1.3) |
| Vitamin B12, μg | 5.51 (2.28 | 9.64 (6.65) | 4.1 (8.4) | 7.23 (6.12) | 5.93 (4.40) | -1.3 (5.7) |
| Vitamin C, mg | 150 (79) | 109 (50) | -41.5 (53.8) | 163 (81) | 108 (67) | -54.8 (71) |
| Vitamin A, μgRE | 700 (213) | 612 (250) | -88.5 (233) | 607 (157) | 379 (196) | -228 (374.4) |
| Vitamin D, μg | 6.3 (2.8) | 9.8 (6.4) | 3.5 (4.8) | 4.6 (3.0) | 5.8 (4.8) | 1.2 (5.6) |
| Vitamin E, mg | 8.0 (1.7) | 6.6 (1.5) | -1.4 (2.2) | 8.4 (3.3) | 7.1 (3.9) | -1.2 (2.4) |
| Magnesium, mg | 311 (42) | 276 (66) | -34.7 (118.8) | 323 (82) | 269 (159) | -54.1 (52.8) |
| Calcium, mg | 646 (157) | 551 (212) | -95.3 (648.7) | 628 (211) | 787 (796) | 159 (128.7) |
| Iron, mg | 9.3 (1.5) | 8.1 (1.5) | -1.2 (3.9) | 9.2 (1.9) | 8.4 (5.1) | -0.8 (1.6) |
| Potassium, mg | 2319 (492) | 2687 (615) | 367.9 (1053.2) | 2451 (909) | 2660 (1654) | 208.9 (436.4) |
| Fiber, g | 16.7 (3.1) | 15.5 (5.6) | -1.3 (5.8) | 17.7 (6.0) | 16.4 (10.6) | -1.3 (4.2) |
| Salt, g | 6.6 (1.7) | 9.5 (2.4) | 2.9 (2.9) | 7.0 (3.3) | 8.5 (2.7) | 1.5 (2.5) |

**Table 4:** Baseline, post-supplementation, and differences of dietary intake analyses between group A and B. Data are presented as the means (standard deviations); recommended daily intake in Japan: Vitamin B1 (Thiamine): 1.4 mg/day in men and 1.1 mg/day in women, Vitamin B2 (Riboflabin): 1.6 mg/day in men and 1.2 in women, Vitamin B6 (Pyridoxine): 1.4 mg/day in men and 1.1 mg/day in women, Niacin: 15 mg/day in men and 12 mg/day in women, 5 mg/day in men and women; acceptable daily intake in Japan: L-carnitine: less than 1000 mg/day.

## Conclusion

In summary, the short-term supplementation of the multi-ingredient weight-loss product, the diet's BB, did not clearly yield further weight-loss for obese women with weight reduction, while the supplementation potentially lead to favorable changes of fat oxidation levels. The effects of the supplementation on weight traits merit large-scale and long-term investigations.

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NS, the project leader, was involved in all aspects of the study. TH, KE, MY, YK and SH designed the study and prepared the intervention. Kokoro Tsuzaki, NN and TM designed the study and coordination of the intervention. KK prepared the draft and coordination of the intervention. Kaoru Takahashi performed the statistical analyses. All authors have read and approved the final version of the manuscript.

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