

The Effects of Food Containing *Pueraria* Flower Extract on Resting Energy Metabolism: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study

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Abstract

Background: Obesity is associated with an increased risk of various lifestyle-related diseases. Enhancing fat oxidation may improve energy metabolism and help prevent obesity. Basal metabolic rate (BMR) accounts for approximately 50% - 70% of total daily energy expenditure, and resting energy expenditure (REE) closely reflects BMR. Therefore, this study examined the effects of *Pueraria* flower extract (PFE) on resting fat oxidation and REE in healthy adult men. **Methods:** This randomized, double-blind, placebo-controlled, parallel-group study included healthy adult men. Participants were randomly assigned to the active or placebo group and consumed either active food containing PFE (35 mg/day of isoflavones as tectorigenins) or placebo food for 8 weeks. The primary outcome was resting fat oxidation, measured before and after the intervention by indirect calorimetry under resting conditions. Secondary outcomes were REE, carbohydrate oxidation, and respiratory exchange ratio (RER), each measured under resting conditions. **Results:** Resting fat oxidation increased significantly more in the active group than in the placebo group ($P < 0.05$). In addition, REE at week 8 and the change in REE from baseline were significantly higher in the active group than in the placebo group ($P < 0.05$). No adverse events related to the active food were observed during the study. **Conclusions:** The increases in resting fat oxidation and REE suggest that PFE may enhance energy metabolism under resting conditions in healthy adult men.

Keywords

Pueraria Flower Extract, Resting Fat Oxidation, Resting Energy Expenditure, Resting Energy Metabolism, Kudzu

1. Introduction

Obesity is defined as excessive fat accumulation in adipose tissue and is associated with several diseases, including hypertension, coronary artery disease, and cerebral infarction [1]. Metabolic syndrome is characterized by visceral fat accumulation and the clustering of cardiovascular risk factors, including hyperglycemia, dyslipidemia, and high blood pressure [1]. Recent surveys in Japan showed that the prevalence of obesity, defined as a body mass index (BMI) of 25 or higher, was 32.4% among men and 19.3% among women aged 20 years or older [2]. Because obesity increases multiple health risks, preventing and improving obesity are important for maintaining and promoting health. One major cause of obesity is an imbalance between energy intake and energy expenditure [3]. When energy intake exceeds energy expenditure, excess energy accumulates as fat and results in obesity. Therefore, enhancing fat oxidation and increasing energy expenditure are important strategies for preventing obesity. Human energy expenditure is broadly classified into basal metabolic rate (BMR), diet-induced thermogenesis, and physical activity-related energy expenditure [4]. Among these components, BMR accounts for the largest proportion, representing 50% - 70% of daily energy expenditure [5]. BMR is the minimum energy expenditure required to sustain life and is measured as energy expenditure under resting conditions [4]. Increasing BMR is considered effective for improving energy expenditure and preventing and improving obesity.

Kudzu (*Pueraria thomsonii*) is a perennial vine in the legume family and has been used as both food and herbal medicine in China and Japan since ancient times [6]. In China, kudzu has been used to treat alcohol dependence for approximately 1000 years [7]. Today, kudzu flowers are used in beverages such as five-flower tea in Chinese mainland and Taiwan region [6]. Kudzu is characterized by its high isoflavone content [8]. The *Pueraria* flower extract (PFE) used in this study is a hot-water extract prepared from kudzu flowers. Clinical trials have shown its anti-obesity effects, including reductions in abdominal fat, and promotion of fat oxidation and energy expenditure when combined with light exercise [9]-[14]. The active components of PFE are isoflavones, specifically tectorigenin, and tectorigenin derivatives, including tectoridin and tectorigenin-7-*O*-xylosylglucoside. Its mechanism of action includes complex effects on energy metabolism, such as inhibiting lipogenesis in the liver, enhancing lipolysis in white adipose tissue, and increasing thermogenesis in brown adipose tissue [7] [15]-[17].

Although the effects of PFE on promoting fat oxidation [13] and energy expenditure [14] during exercise have been reported, its effects on fat oxidation un-

der strict resting conditions and BMR have not been verified. Therefore, this randomized, double-blind, placebo-controlled, parallel-group study examined the effects of PFE intake on resting fat oxidation and BMR in healthy adult men. To evaluate these effects, resting fat oxidation and resting energy expenditure (REE) were measured by indirect calorimetry in participants who were fasting and in the supine position [5] [18] [19].

2. Materials and Methods

2.1. Study Participants and Setting

The target sample size was determined on the basis of a previous report of the anti-obesity effects of continued intake of PFE [12]. Using a significance level of 0.05 and statistical power of 0.80, the calculated sample size was 37 per group. Allowing for dropouts and withdrawals, the sample size was set at 40 participants per group (80 in total).

Volunteers were recruited with compensation, and participants were enrolled by the principal investigator in accordance with the inclusion and exclusion criteria. Before study initiation, all participants received a thorough explanation of the study and provided written informed consent.

Inclusion criteria were as follows: 1) healthy Japanese men aged 30 to 60 years at the time of consent; 2) BMI < 30; and 3) participants who received sufficient explanation of the study purpose and procedures, had decision-making capacity, voluntarily agreed to participate with full understanding, and provided written informed consent.

Participants were excluded if they: 1) had sleep disorders or chronic insomnia; 2) used medications that may affect obesity, hyperlipidemia, or lipid metabolism; 3) had a current or past history of thyroid dysfunction; 4) had a current or past history of serious hepatic, renal, gastrointestinal, cardiac, respiratory, endocrine, or other metabolic diseases; 5) had current otolaryngologic conditions or other diseases that preclude nasal breathing; 6) had a current or past history of drug or alcohol dependence; 7) had substantial body-weight fluctuations within the previous year (± 5 kg or more); 8) had a habit of vigorous exercise; 9) had gastrointestinal diseases or a surgical history that affects digestion or absorption; 10) were unable to abstain from supplements or health foods, including Foods for Specified Health Uses and Foods with Function Claims, during the study period; 11) had self-reported food allergies; 12) had highly variable lifestyle habits or daily routines; 13) were following specific dietary restrictions or regimens, such as fasting, extreme carbohydrate restriction, or vegan diets; 14) were unable to abstain from alcohol from 2 days before screening and each assessment; 15) habitually consumed alcohol on 4 or more days per week in amounts exceeding 20 g/day of pure alcohol; 16) were smokers; 17) were shift workers or night-shift workers; 18) were judged by the principal investigator to be unsuitable on the basis of clinical examinations conducted at screening; 19) had donated more than 200 mL of blood within 1 month or more than 400 mL of blood, including component donation,

within 3 months before consent; 20) were currently participating in, or intending to participate in, other studies involving consumption of foods, use of pharmaceuticals, or application of cosmetics; and 21) were judged as unsuitable for the current study by the principal investigator for other reasons.

This study was conducted under the oversight of a physician at the Nihonbashi Cardiology Clinic, Medical Corporation Foundation Kenko Suiminkai, in accordance with the Declaration of Helsinki (amended at the World Medical Association (WMA) Fortaleza General Assembly, Brazil, October 2013) and the Ethical Guidelines for Life Sciences and Medical Research Involving Human Subjects (partially revised March 27, 2023), following review and approval by the Ethical Committee of Kobuna Orthopedics Clinic (Chair: Toshio Kawada; approval date: December 18, 2025).

The study protocol was registered in the clinical trial registry system operated by the University Hospital Medical Information Network (UMIN) Center (Trial ID: UMIN000060312; title: Effects of Consumption of a Food Containing Plant Extracts on Resting Energy Metabolism - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study).

2.2. Study Design

This study was conducted from January to April 2026 as a randomized, double-blind, placebo-controlled, parallel-group comparative trial (allocation ratio 1:1) over a total of nine weeks, consisting of a one-week pre-observation period and an eight-week intake period. No methodological changes were made after study initiation.

Using computer-generated random numbers, the biostatistician performed block randomization (block size of four), adjusting for age, BMI, and estimated muscle mass. An allocation manager, who was not otherwise involved in the study, assigned the two randomized groups to the active group and the placebo group. The allocation manager prepared a table (key code) documenting the allocation results, sealed it, and kept it secured until after the analysis population had been determined, at which time the key code was unsealed. This procedure ensured blinding for all individuals other than the allocation manager.

To maintain blinding of both participants and intervention implementers, the study food was packaged in plain aluminum packets, with two tablets per packet, and distributed to participants. Throughout the study period, participants were instructed to refrain from using supplements and health foods, maintain their usual lifestyle as before study initiation, avoid excessive alcohol consumption, and refrain from participating in other trials. Participants were also instructed to consume the distributed standardized meal in the prescribed amount by 21:00 on the day before each comprehensive assessment; remain fasted from 12 hours before the measurements until all measurements were completed; limit fluid intake from waking until 1 hour before the assessment to no more than 200 mL of room-temperature water, with no further fluids consumed until completion of the measure-

ments; avoid brisk walking and exercise on the assessment day; and avoid using stairs as much as possible. In addition, from 2 days before each comprehensive assessment, participants were instructed to abstain from alcohol and avoid strenuous exercise. From the day before each comprehensive assessment, they were instructed to refrain from physical labor and caffeine-containing beverages and to go to bed by around midnight to ensure sufficient sleep. Participants were required to use medications only with the approval of the principal investigator or a sub-investigator, except in emergencies.

2.3. Intervention

During the intake period, participants consumed the study food as the intervention. The active food consisted of tablets manufactured by combining PFE (Toyo Shinyaku Co., Ltd.) with reduced maltose, cellulose, sucrose fatty acid ester, and silicon dioxide. For the placebo food, the PFE in the active food was replaced with caramel coloring, and the amount of reduced maltose was adjusted to render it indistinguishable in appearance from the active food. Both the active and placebo foods were designed to be taken at a daily dose of two tablets, each containing 250 mg. During the intake period, participants were instructed to consume one packet (two tablets) once daily with water or lukewarm water (the active group received the active food, and the placebo group received the placebo food). **Table 1** shows the caloric content and nutritional composition per daily intake of the active food. The active food contained 35 mg of *Pueraria* flower-derived isoflavones (as tectorigenins) per daily intake, expressed as the sum of tectorigenin-7-*O*-xylosylglucoside, tectoridin, and tectorigenin.

Table 1. Analysis of nutrient composition values of study foods.

	Placebo food (2 tablets)	Active food (2 tablets)
Energy (kcal) ^a	2	2
Protein (mg) ^b	0	44
Fat (mg)	18	20
Carbohydrate (mg)	465	392
Salt Equivalent (mg)	5.0	0.3

^aEnergy conversion factors: protein, 4; fat, 9; carbohydrate, 4; ^bNitrogen-to-protein conversion factor: 6.25.

2.4. Outcome Measures

The primary outcome was the resting fat oxidation, and the secondary outcomes were the resting carbohydrate oxidation, resting energy expenditure (REE), and respiratory exchange ratio (RER). Assessments were conducted twice: at baseline (pre-intake) and after 8 weeks of intake. No changes to outcomes were made after study initiation.

Both the primary and secondary outcomes were measured using the Aeromonitor AE-310S pulmonary exercise load monitoring system (Minato Medical Science Co., Ltd.). The resting fat oxidation, carbohydrate oxidation and REE were automatically calculated by the device using Elwyn's equation for fat oxidation and carbohydrate oxidation and Weir's equation for REE, respectively [20] [21]. Assuming that protein oxidation was negligible, urinary nitrogen excretion (Nu) was set to zero in both equations.

On each assessment day, participants underwent a health status check after arrival, followed by measurements of blood pressure and body weight. Measurements were conducted in a room maintained at 23°C - 25°C. Participants remained seated at rest for 30 minutes while wearing a mask for expired-gas collection, then rested in the supine position for 30 minutes with data collected during the final 10 minutes after the first 20 minutes had elapsed. The gas analyzer and flow meter were calibrated before each measurement according to the device procedure, and proper values displayed on the device were confirmed after calibration. The first and last 1 minute of each measurement were excluded, and the mean values over the remaining stable 8 minutes were used to calculate each parameter following a previous study that used the same device [22].

Participants received a dietary diary and a participant diary and were instructed to record the following items daily from 1 week before the start of intake through the intake period: 1) meal start time, location, and meal contents; 2) study product intake status, during the intake period only; 3) presence or absence of any changes in physical condition; 4) sleep duration; 5) number of steps; 6) performance of any irregular exercise; 7) presence or absence of changes in lifestyle circumstances; and 8) use of medicinal products, excluding nutritional tonics and including newly designated quasi-drugs and newly classified quasi-drugs. In addition, from 1 week before the start of intake through the day before the 8-week post-intake assessment, daily physical activity was assessed using a pedometer. Dietary surveys were performed at baseline and on the day before the 8-week post-intake assessment using the Food Frequency Questionnaire (FFQ) Next, short form.

2.5. Statistical Analysis

The analysis population was defined as the per-protocol set (PPS). Between-group comparisons of baseline values, week 8 post-intake values, and changes from baseline were conducted using unpaired *t*-tests. All tests were two-sided, with a significance level of 5%. Statistical analyses were performed using IBM SPSS Statistics 28 (IBM Corp., Armonk, NY, USA). Participant baseline characteristics are presented as mean $\pm$ standard deviation, and other data are presented as mean $\pm$ standard error. No additional analyses were performed.

3. Results

3.1. Participants Included in the Analysis

Eighty participants were enrolled in this study. After randomization, no partici-

pants dropped out before the start of the study, and all 80 participants started the study, with 40 in each group receiving the allocated intervention. During the study period, one participant in the active group met a discontinuation criterion because he was unable to attend scheduled visits for reasons unrelated to the study. Consequently, 79 participants completed the study.

After study completion, 11 participants met exclusion criteria, leaving 68 participants for analysis. Reasons for exclusion were violation of study precautions during the intervention period (three participants in the active group and five in the placebo group) and substantial disruptions to lifestyle or dietary habits during the study period (two participants in the active group and one in the placebo group). Analyses were conducted for each group according to the original allocation.

Participant recruitment through completion of follow-up occurred from January 2026 to April 2026. Because follow-up was completed for all participants, the study was concluded. Baseline characteristics of participants included in the analysis set are presented in **Table 2**, and participant flow from enrollment to analysis is shown in **Figure 1**.

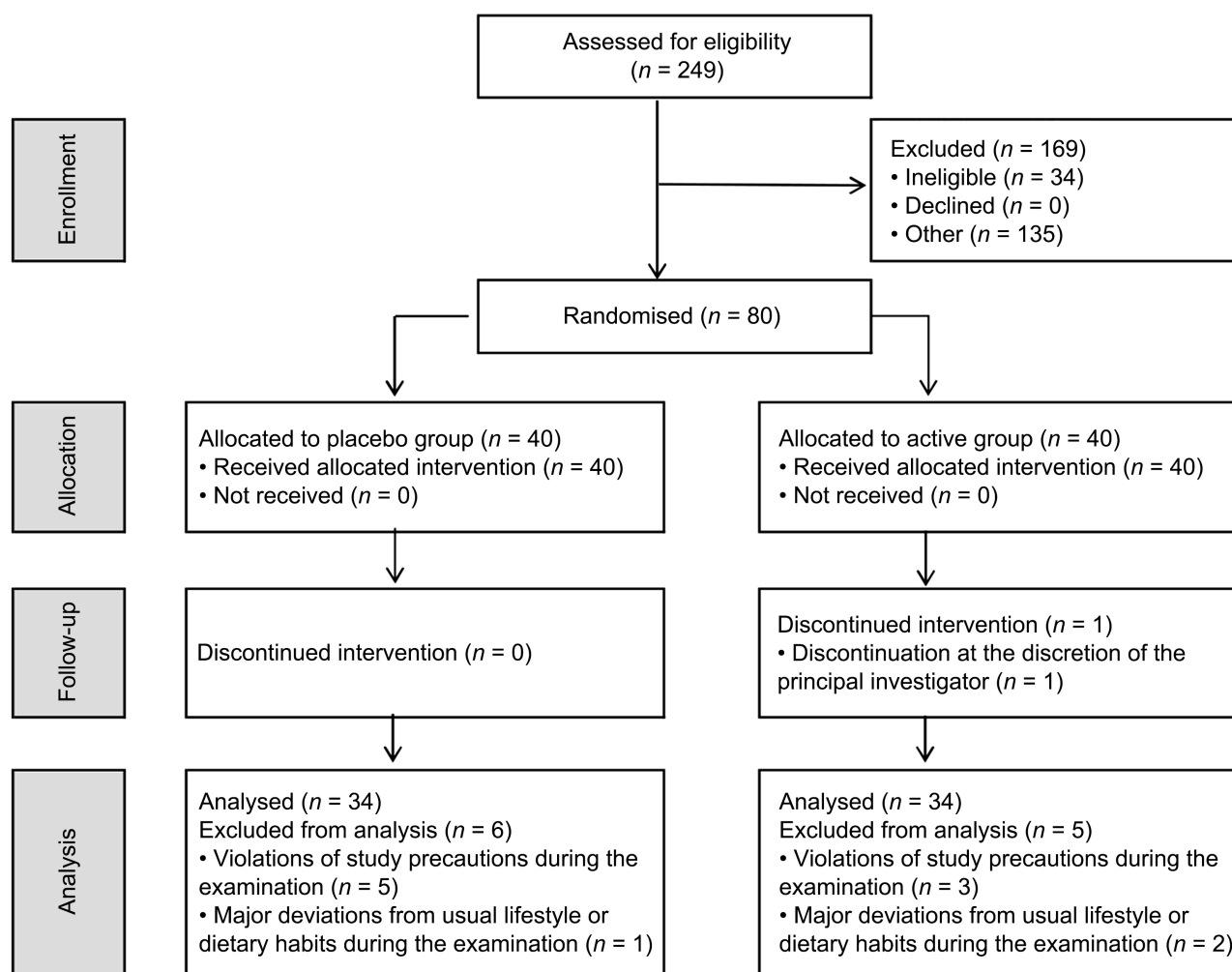


Figure 1. Flow diagram of progress through phases of randomized, double-blind, placebo-controlled, parallel-group study.

Table 2. Baseline characteristics of the participants.

Parameter	Placebo group (<i>n</i> = 34)	Active group (<i>n</i> = 34)
Age (years old)	47.2 ± 8.2	46.9 ± 7.0
Height (cm)	171.4 ± 5.8	170.6 ± 3.9
Body weight (kg)	65.5 ± 4.8	65.6 ± 6.2
Body mass index (kg/m ²)	22.3 ± 1.6	22.5 ± 1.8
Estimated muscle mass (kg)	48.5 ± 4.0	48.2 ± 4.1

Values are expressed as means ± SDs. No significant difference was observed.

3.2. Analysis Results

Table 3. Resting energy metabolic parameters measured by indirect calorimetry.

Group			Baseline	8 weeks
Fat oxidation (mg/min)	Placebo	Measured	78.5 ± 4.5	63.5 ± 3.8
		Changes from baseline		−15.0 ± 5.5
	Active	Measured	71.5 ± 3.9	72.1 ± 4.1
		Changes from baseline		0.5 ± 4.8*
Carbohydrate oxidation (mg/min)	Placebo	Measured	104.2 ± 9.8	79.5 ± 6.0
		Changes from baseline		−24.8 ± 9.0
	Active	Measured	124.0 ± 9.4	93.1 ± 7.4
		Changes from baseline		−30.9 ± 9.6
REE (kcal/day)	Placebo	Measured	1663.0 ± 51.8	1337.3 ± 63.1
		Changes from baseline		−325.7 ± 55.1
	Active	Measured	1699.2 ± 60.1	1532.2 ± 48.0*
		Changes from baseline		−167.0 ± 54.9*
RER (−)	Placebo	Measured	0.811 ± 0.011	0.806 ± 0.006
		Changes from baseline		−0.005 ± 0.012
	Active	Measured	0.826 ± 0.009	0.809 ± 0.008
		Changes from baseline		−0.018 ± 0.011

Values are expressed as means ± SEs. (Placebo: *n* = 34, Active: *n* = 34); *Significantly different from the placebo group (*P* < 0.05).

The expired-gas measurement results are shown in **Table 3**. Resting fat oxidation increased from baseline to week 8 in the active group but decreased in the placebo group. No significant between-group difference was observed in post-intake measured values ($P = 0.13$). However, the change from baseline differed significantly between groups ($P < 0.05$). REE decreased from baseline to week 8 in both groups, but the measured REE value at week 8 was significantly higher in the active group than in the placebo group ($P < 0.05$). The change in REE from baseline also differed significantly between groups ($P < 0.05$). Carbohydrate oxidation decreased from baseline to week 8 in both groups; however, neither the measured values nor the changes from baseline differed significantly between groups (measured values, $P = 0.16$; changes from baseline, $P = 0.64$). Similarly, neither the measured RER values nor the changes in RER from baseline differed significantly between the placebo and active groups (measured values, $P = 0.79$; changes from baseline, $P = 0.43$).

3.3. Adverse Events

During the study period, adverse events included common cold, nasal congestion, and eye fatigue in the placebo group and influenza in the active group. In all cases, the principal investigator determined that the adverse events were not causally related to the study foods. No serious adverse events were observed.

4. Discussion

In this randomized, double-blind, placebo-controlled, parallel-group study, we examined the effects of food containing PFE on resting energy metabolism in healthy adult men. Participants consumed either the active food containing PFE or placebo food once daily for 8 consecutive weeks.

The active group showed significantly higher changes from baseline in resting fat oxidation and REE than the placebo group. Although the week 8 REE value differed significantly between groups, the week 8 fat oxidation value did not. Carbohydrate oxidation showed no significant between-group differences in either measured values or changes from baseline; however, the decrease was higher in the active group than in the placebo group. Energy metabolism is affected by factors such as body composition and lifestyle habits [4] [5], and substantial interindividual variation is expected. Therefore, the effects of PFE may have been detected more clearly by evaluating within-participant changes from baseline than by comparing measured values alone. These findings suggest that PFE intake increases resting fat oxidation and REE.

The RER reflects the whole-body substrate utilization ratio of lipids to carbohydrates. In this study, RER did not differ significantly between the active and placebo groups. Thus, PFE may increase fat oxidation and REE without substantially changing the overall ratio of energy substrates used under resting conditions.

Although REE decreased from baseline in both groups, the active group had significantly higher week 8 REE values and significantly higher changes from

baseline than the placebo group. REE varies by season: it is highest in winter, when outdoor temperatures are low, and gradually decreases from spring to summer as outdoor temperatures rise [23]. Because this study was conducted from winter to spring, seasonal variation may explain the decrease in REE observed in both groups. Even with this seasonal decrease, the active group showed a smaller reduction in REE and an increase in fat oxidation from baseline. These findings suggest that PFE intake helps maintain REE at a high level and increases fat oxidation, even in the presence of seasonal decreases in REE.

A previous study reported that PFE intake increased blood free fatty acids, glycerol, and total ketone bodies during or after exercise at 50% VO_2max , indicating enhanced lipolysis and fat oxidation [13]. PFE intake has also been reported to increase energy expenditure during exercise at approximately 3.5 metabolic equivalents (METs) [14]. In the present study, fat oxidation calculated from expired-gas measurements reflected the amount of fat actually used as an energy substrate. The observed increases in resting fat oxidation and REE are therefore consistent with the improvements in lipid metabolism and energy expenditure reported previously. These findings suggest that PFE promotes lipid metabolism and energy expenditure during both exercise and rest.

The mechanism by which PFE promotes resting fat oxidation and energy expenditure can be interpreted in light of previous findings. An animal study reported that PFE intake increased the expression of hormone-sensitive lipase (HSL), a gene related to lipolysis, in white adipose tissue and increased the expression of uncoupling protein 1 (UCP-1), a gene related to thermogenesis, in brown adipose tissue [17]. A further animal study reported that tectoridin, one of the active components of PFE, increased the expression of hepatic genes involved in fat oxidation, including carnitine palmitoyltransferase 1 (CPT1), medium-chain acyl-CoA dehydrogenase (MCAD), and acyl-CoA oxidase (ACO) in the liver [15]. These findings suggest that PFE promotes resting fat oxidation and energy expenditure by enhancing lipolysis in white adipose tissue, promoting fat oxidation in the liver, and increasing thermogenesis in brown adipose tissue.

REE reflects the energy expenditure required to sustain vital functions and, although measurement conditions differ, generally yields values close to BMR [18]. BMR represents the minimum energy expenditure required to sustain life and is usually measured under conditions that minimize the effects of food intake, physical activity, and external stimuli, such as after waking in the early morning, in the supine resting position, and after fasting [18]. However, these conditions are difficult to standardize in human trials because of constraints related to participant lifestyle and the measurement environment. Therefore, REE is often measured as a practical indicator for evaluating BMR [24]. In this study, REE likely reflected BMR for three reasons. First, the effect of food intake on metabolism was eliminated. The influence of food intake on resting metabolic rate reportedly becomes negligible approximately 7 hours after a meal [25], and approximately 12 hours of fasting is standard for BMR measurement [19]. Because participants fasted for 12

hours before measurement, the effect of food intake on metabolic rate was effectively eliminated. Second, the effect of physical activity on metabolism was eliminated. The influence of light exercise reportedly returns to baseline after 30 minutes of rest [25], and standard BMR measurements are conducted after approximately 30 minutes of rest [26]. Because participants were instructed to minimize physical activity before visiting the clinic and, furthermore, to allow participants to become accustomed to the expired-gas mask, they rested in a seated position for 30 minutes while wearing the expired-gas mask before measurement, the effect of physical activity on metabolic rate was effectively eliminated. Third, the supine position used for standard BMR measurement was selected [26]. Participants then rested in the supine position for 30 minutes, and data were collected during the final 10 minutes after the first 20 minutes had elapsed. These procedures suggest that the REE measured in this study closely represented BMR. The higher REE observed with PFE intake indicates an increase in BMR.

At week 8, the change in REE differed by approximately 160 kcal/day between the active and placebo groups (−167.0 kcal/day vs. −325.7 kcal/day). Improving the balance between energy expenditure and intake by 100 kcal/day has been suggested to help prevent weight gain [27]. In a previous study, PFE intake for 8 weeks increased exercise-related energy expenditure by approximately 140 kcal/day in adult men aged 30 to 39 years [14]. The present findings are consistent with that increase in energy expenditure. In a previous study, PFE-related improvements in energy expenditure, lipolysis, and fat oxidation have been observed at moderate exercise intensities, including 3.5 METs and 50% VO_2max , which correspond to physical activity levels encountered in daily life [28]. Because the resting condition in this study corresponds to 1 MET [29], these findings suggest that PFE enhances energy metabolism across a broad activity range, from rest to daily life-level physical activity. Therefore, PFE intake may contribute to obesity prevention by enhancing energy metabolism under both resting and daily activity conditions.

This study also confirmed the safety of PFE. No adverse events attributable to the food containing PFE were observed.

This study has several limitations. The study included participants aged 30 to 60 years with BMI < 30; therefore, the effects of PFE in individuals with BMI ≥ 30 or those younger than 30 years remain unknown. Women were excluded to reduce measurement variability related to menstrual-cycle-associated fluctuations in energy metabolism. Although previous reports suggest no sex difference in the anti-obesity effects of isoflavones (as tectorigenins) derived from *Pueraria* flowers [11], it would be beneficial to directly verify whether the effects observed in this study are also applicable to women. Future studies should evaluate the effects of PFE on resting energy metabolism in a broader range of participants.

5. Conclusion

In healthy adult men with BMI < 30, food containing PFE may increase resting fat oxidation and resting energy expenditure, which closely reflects basal metabolic

rate.

Funding

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Institutional Review Board Statement

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethical Committee of Kobuna Orthopedics Clinic (approval date: 18 December 2025; approval number: MK-2512-01).

Informed Consent Statement

All participants provided informed consent before participating in the study.

Data Availability Statement

The data used in this manuscript are not publicly available because of commercial restrictions but are available from the corresponding author on reasonable request.

Author Contributions

Conceptualization, T.K. and K.T.; methodology, D.A. and T.I.; validation, T.I.; formal analysis, D.A. and T.I.; investigation, D.A. and R.K.; original draft preparation, D.A. and T.E.; supervision, K.T. and Y.I.; review and editing, T.M., S.T., and R.K.; visualization, D.A. and T.I.; project administration, S.T. and T.K. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

This study was conducted by KSO Corporation under commission from Toyo Shinyaku Co., Ltd., which also provided the study foods. D.A. is an employee of Toyo Shinyaku Co., Ltd. and receives a salary from the company. Coauthor Y.I. is a physician affiliated with Nihonbashi Cardiology Clinic, Medical Corporation Foundation Kenko Suiminkai, and conducted this study as the principal investigator under contract with KSO Corporation. Coauthor R.K. served as the trial implementation manager and advised on the study design.

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