

Acute Clinical Effects of A Liquid Dietary Supplement Containing A Combination of Indigestible Soluble Fiber, Phenylalanine, N-Acetyl-Tyrosine, Caffeine, Tea Polyphenols and *Lycium barbarum* on Anthropometric Parameters and Resting Metabolic Rate

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ABSTRACT

The impact of an orally consumed liquid dietary supplement proprietary blend (TAIslim™= the Product) containing soluble indigestible fiber, L-phenylalanine, N-acetyl-L-tyrosine, caffeine, standardized tea polyphenols and *Lycium barbarum*, some of which improve energy balance, have been examined in 2 separate human clinical studies. The product was provided to a total 48 healthy adults (18-60 years) for 14 or 90 days of consuming 120-180 ml/day. The objective of these clinical studies was to determine whether consumption of the product would have an impact on anthropometric parameters and resting metabolic rate (RMR) as measured by a hand-held indirect calorimeter. Measurements were taken at baseline and on Day 15 or 90.

Study 1: In a randomized, placebo-controlled, double-blind manner, a total of 23 healthy adults (age=33.2 y, BMI=27.8 kg/m²) consumed either the Product or placebo samples (120 ml/day) for 14 days under free-living conditions. A nutritional beverage (360 kcal) was provided at the completion of the 1st RMR background measurement after 12h fasting. Second RMR measurement 2 hours after sample intake in a group consuming the product (n=11) and placebo (n=12) was increased by 255 and 150 kcal, about 14% and 8% of baseline (1,823 kcal), respectively. The Product increased RMR to a greater extent than placebo (P < 0.05).

Study 2: All 25 subjects (age=40.7 y, BMI=29.9 kg/m²) were required to engage in a daily 30-minute walk monitored by pedometer and to curtail caloric intake after 7 PM during the 90-day test period. A protein-based diet with multi-vitamin and *Lycium barbarum* supplement resume program (about 1,200 kcal/d) was required and monitored by diary. The product (60 ml) was consumed 3 times a day immediately before every meal (total 180 ml/d). Average parameters were significantly reduced by 6.3% (body weight), 6.1% (BMI), 7.4% (waist circumference), 5.4% (waist/hip ratio), 5.4% (total body fat), 14.5% (fasting blood glucose level), blood pressure (SBP by 8.4%, DBP by 14.3%), and heart rate by 7.2% (P < 0.05) from the starting point. On Day 90, RMR was significantly increased by 220 kcal, about 14% over baseline (1,679 kcal) 2h after the Product consumption. Baseline RMR on Day 90 was unchanged from the starting point. No severe adverse reactions or abnormal symptoms were observed.

These results suggest that the product may affect anthropometric parameters by enhancing energy expenditure without any adverse effects. A longer term study may further clarify potential for body weight control.

INTRODUCTION

TAIslim is designed to provide increased metabolism/thermogenesis, increased fat burning, decreased absorption of dietary fats and starches by inhibiting lipase and amylase enzymes, improved insulin sensitivity, appetite suppression, blood lipid reduction, blood glucose control, and remodeling of intestinal flora to eliminate those implicated in obesity. The formula features dietary ingredients such as L-phenylalanine, N-acetyl-L-tyrosine, a special blend of green, black, oolong, and white tea extracts providing 200 mg of tea polyphenols (90 mg as EGCG) and 100 mg of caffeine, soluble indigestible dietary fiber and *Lycium barbarum* provided in the form of a fruit juice, GoChi® (FreeLife International, Phoenix, Arizona), standardized for its polysaccharides (LBP) content. This is the first clinical study of TAIslim on body weight and related morphometric parameters, appetite and energy metabolism, all of which are related to body weight control, evaluated in healthy overweight human adults (BMI 25 to 35) under calorie restriction and exercise program for 3 months. The purpose of this study was the following:

- To evaluate TAIslim on various physical parameters, such as body weight, waist circumference, hip circumference, body mass index (BMI), total body fat content (%), energy metabolism activity evaluated by resting metabolic rate (RMR) measured with VO₂ in breath, blood pressure, pulse, fasting blood glucose level, appetite suppression, energy metabolism and any additional acute synergistic indication(s) which may have potential effects on body weight.
- RMR was further investigated in kinetic manner and evaluated with the area under the curve (AUC) over the course of 4 hours after consumption.
- To investigate any inadvertent side effects of TAIslim on gastrointestinal (GI) conditions evaluated by the ranked scale questionnaire for flatulence, diarrhea, constipation, or other GI side effects.

MATERIALS AND METHODS

Test Product preparation. FreeLife International LLC, in Phoenix, Arizona supplied commercially available TAIslim product (Lot No. ASA09048US, APP318T2, APP329T2, APP338T2, APP341T2) containing LBP-standardized *Lycium barbarum* fruit juice, soluble indigestible fiber, phenylalanine, N-acetyl-L-tyrosine, and tea extract blend containing 200 mg polyphenols and 100 mg of caffeine.

Study population. Subjects, 18 years old and older with body mass index (BMI) 25-35 kg/m² were recruited for the study and participants selected for the trial were judged to be healthy. Subjects were excluded from the study if they had known allergies to ingredients in TAIslim, use of any fiber materials, medication or supplements for weight loss, weight control, and/or appetite suppression; had gastrointestinal disease or problems including chronic symptoms such as irritable bowel syndrome, diabetes, cardiac problems (previous myocardial infarction or cardiovascular diseases); had engaged in a weight control diet program with unstable body weight (more than 2% loss/gain over the previous 3 months); were pregnant or breast feeding; or were under anticoagulant therapy with Coumadin® (warfarin). A total of 25 subjects completed the study, of which 43% were women. All subjects were fully informed of the purpose of the study, and signed the Human Subjects Informed Consent forms approved by the Internal Review Board under the Helsinki Declaration.

Study design.
Study-1. In a randomized, placebo-controlled, double-blind manner, a total of 23 healthy adults (age=33.2 y, BMI=27.8 kg/m²) consumed either the Product or placebo samples (120 ml/day) for 14 days under free-living conditions. TAIslim was taken on an empty stomach 2 times a day between 10 to 30 minutes before the meal at breakfast and lunch, with dosing at least 3 hours after last food consumption. All subjects took 60 ml sample fluid bottles with 240 ml of water 2 times a day during the 2-week test period.

Study-2. All 25 subjects (age=40.7 y, BMI=29.9 kg/m²) were required to engage in a daily 30-minute walk monitored by pedometer and to curtail caloric intake after 7 PM during the 90-day test period. A protein-based diet with multi-vitamin and *Lycium barbarum* supplement resume program (about 1,200 kcal/d) was required and monitored by diary. The product (60 ml) was consumed 3 times a day immediately before every meal (total 180 ml/d). Subjects followed low calorie diet (1,200 kcal) throughout entire study and to report all foods, snacks, drinks, and any other consumed food materials for precise calculation of daily caloric intake for the selected days. All subjects were then administered a written questionnaire for gastrointestinal conditions, and appetite, for which the subjects provided a rating (scale of 0 – 10) on visual analogue scale (VAS) at 0, 30, 60, and 90 days. TAIslim was taken on an empty stomach 3 times a day between 10 to 30 minutes before the meal at breakfast, lunch and dinner, with dosing at least 3 hours after last food consumption. All subjects took 60 ml sample fluid bottles with 240 ml of water three times a day during the 3-month test period.

All subjects were given a medical exam and physical morphometric measurements [waist and hip circumferences, body weight, body-mass-index (BMI), total body fat, energy metabolism activity by breath oxygen volume (VO₂) using indirect calorimeter (MedGem test kit), blood pressure and pulse, fasting blood glucose level] were assessed. All subjects were to discontinue use of any *L.barbarum*-containing foods, any weight-loss or weight-control products, or energy drinks, and this was continued throughout the study. Also, background information regarding dietary habits, smoking, and disease history was recorded for each participant. Caffeinated drinks were allowed without sugar and cream but with artificial non-caloric sweetener, with request to record in the diary. All subjects visited the researcher at the office every weekdays to receive 2 or 3 bottles of sample fluid during the intervention period. Before the weekend, all subjects brought appropriate samples home, and drank them on same schedule as weekdays. Empty bottles were returned to the researcher on the following Monday for compliance check. Subjects were instructed not to consume any *L.barbarum*-related product, energy drink, weight-loss or weight-control products or follow any weight loss program throughout the study period. **Statistical Analysis.** All morphometric parametric data were analyzed by t-test for dependent groups. Descriptive statistics were calculated for pre-intervention and each measurement period for all dependent measures and summarized as means and standard errors. All clinical symptom questions were graded and the scores analyzed for changes between pre-intervention and each measurement with the nonparametric Wilcoxon matched pairs tests. Differences were considered significant at P<0.05.

RESULTS (1)

RMR in the subjects after consumption of TAIslim in conjunction with a nutritional beverage (360 kcal) after at least 12 hours overnight fasting was increased by 290 ± 36 kcal, which is about 17% above average basal level (1,745 kcal) at 1 hour after consumption, statistically higher than baseline level (P<0.05). This increase was kept at a similar level – over 220 kcal – throughout the 3-month intervention period, and baseline RMR was not statistically changed in 3 months by TAIslim intake. The control group, who did not take TAIslim but took 360 kcal nutritional beverage only, increased RMR by 150 kcal, about 8% of basal level. Kinetic behavior of TAIslim on VO₂, resting metabolic rate (RMR), and area under the curve (AUC) 0 through 4 hours after consumption in a separate study were significantly increased by a bolus intake of TAIslim (Figure 1). AUC throughout 0-4 hours after consumption was 752 ± 176 kcal-hr in TAIslim group, which is about double of the control group (382 ± 168 kcal-hr) (Figure 2).

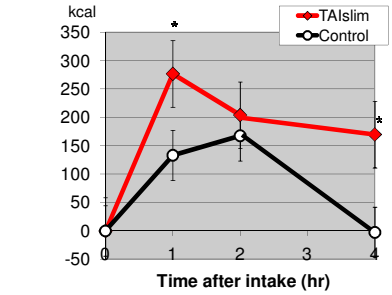


Figure 1. Impact of TAIslim on resting metabolic rate (RMR) in human subjects. Each value indicates mean ± SEM.

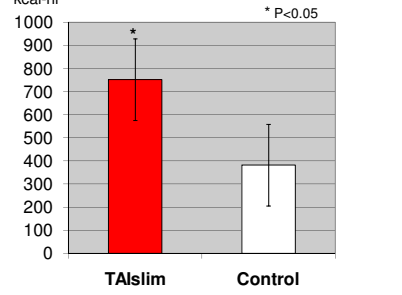


Figure 2. Impact of TAIslim on area under the curve (AUC) throughout 0-4 hours after consumption on resting metabolic rate (RMR) in human subjects. Each value indicates mean AUC ± SEM (0-4 hr after intake).

RESULTS (2)

Body weight was significantly lowered by taking TAIslim compared to the baseline by 5.4 kg (P<0.05) in average, which is about 6.3% of the starting point after 3-month intervention (P<0.05) (Figure 3). Other morphometric parameters were also significantly reduced from the baseline, such as BMI by 6.1%, waist circumference by 6.7%, hip circumference by 7.4%, total body fat by 5.4%, fasting glucose level by 14.5%, blood pressure (SBP by 8.4%, DBP by 14.3%), and heart rate by 7.2% after 3-month intervention (Figure 3 and 4).

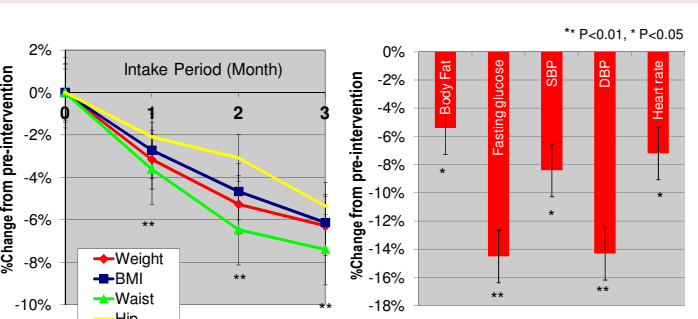


Figure 3. Impact of TAIslim (3 month intake) on various morphometric parameters (body weight, BMI, waist and hip circumferences). Each value indicates mean ± SEM. **Figure 4.** Impact of TAIslim (3 month intake) on various parameters (total body fat, fasting blood glucose level, blood pressure, and pulse/heart rate). Each value indicates mean ± SEM at the time of 3 month post-intake.

Feeling of appetite in TAIslim group tended to be lowered compared to the starting point (Figure 5). Gastrointestinal conditions were normal except for noticeable abdominal rumbling noises in some of the subjects, but these were minor effects with no need to discontinue use of TAIslim. No severe conditions were found (Figure 6).

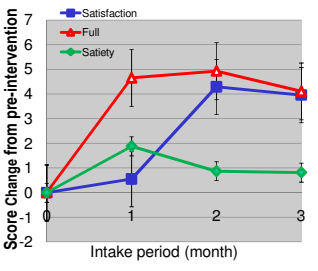


Figure 5. Impact of TAIslim (3 month intake) on various subjective parameters (full, satisfactory and satiety feelings). Each value indicates mean ± SEM.

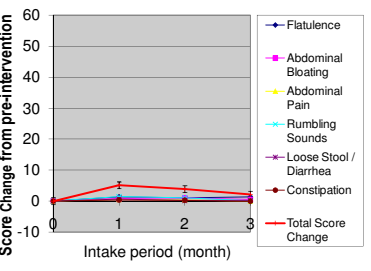


Figure 6. Impact of TAIslim (3 month intake) on various subjective gastrointestinal parameters. Each value indicates mean ± SEM.

CONCLUSION

These results suggest that TAIslim consumption raises RMR, which may explain body weight loss, waist circumference and other morphometric parameters observed in the study. It might also control appetite. Detailed analysis of biochemical markers in the blood may clarify mechanism of actions of TAIslim.