

Sub-Chronic Effects of Orally Ingested Liquid Dietary Supplement, TAlslim®, Containing A Combination of Soluble Dietary Fiber, L-Phenylalanine, N-Acetyl-Tyrosine, Tea Polyphenols with Caffeine and *Lycium barbarum* on Body Weight and Other Anthropometric Parameters in a Controlled Cross-over Human Clinical Study

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ABSTRACT

Three month intake of TAlslim® containing soluble dietary fiber, L-phenylalanine, N-acetyl-L-tyrosine, standardized tea polyphenols with caffeine and *Lycium barbarum* was examined in a controlled human clinical study in a cross-over design. Total 25 healthy overweight adults (age=40.7 y, BMI=29.9 kg/m²) consumed 60 ml of TAlslim 3 times/d immediately before meals. Anthropometric parameters and resting metabolic rate (RMR) measured by an indirect calorimeter were examined at baseline, on 30, 60 and 90 days in both phases. The phase interval was 60 days. Subjects were required to walk 30 min daily monitored by pedometer and to curtail caloric intake after 7 PM. A protein-based diet with multi-vitamin and *Lycium barbarum* supplement resume program (about 1,200 kcal/d) was required and monitored by diary. 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 pre-intervention. RMR was significantly increased by 220 kcal, about 14% over baseline (1,679 kcal) 2h after TAlslim intake. To the contrary, during the control phase, all parameters were not significantly changed compared to the baseline. These results suggest that TAlslim may affect anthropometric parameters by enhancing energy expenditure.

INTRODUCTION

TAlslim 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. In our previous study, TAlslim has been shown to reduce 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 to evaluate TAlslim in a controlled cross-over design, various physical parameters, such as body weight, waist circumference, hip circumference, body mass index (BMI), total body fat content (%), blood pressure, and fasting blood glucose level.

MATERIALS

Test Product preparation. FreeLife International LLC, Phoenix, Arizona supplied commercially available TAlslim 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. LBP-standardized *Lycium barbarum* fruit juice was produced from fresh ripe *Lycium barbarum* fruit. Sample was kept refrigerated before use at 2-8 °C.

METHODS

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 TAlslim, 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 healthy adults (20-56 years, average age= 40.7 ± 2.2 years old, BMI= 29.9 ± 0.97 kg/m²) 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. No participants were pregnant during the study based upon standard urine pregnancy test.

Study design. The present study is a randomized, cross-over controlled clinical trial. An interval of each phase was about 60 days. All subjects 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) with 240 ml of water. Subjects followed to report all foods, snacks, fluids and any other consumed food materials for precise calculation of daily caloric intake for the selected days. 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.

Dependent measures. All subjects were given a physical morphometric measurements [waist and hip circumferences, body weight, body-mass-index (BMI), total body fat, blood pressure and pulse, fasting blood glucose level] were assessed. All following measurements was taken at day 1 (pre-intervention) and 15 (post-intervention) of the study under the fasted state. Morphometric parameters, such as body weight, body-mass index (BMI), waist circumference, hip circumference, body fat, total body water content, blood pressure, pulse, and fasted blood glucose level were measured. Dietary background was collected from food diary for energy intake (kcal/day), fat intake (g/day), carbohydrate intake (g/day) and protein intake (g/day). Quantitative data included body weight, height, BMI, total body fat, total water content (Tanita BF-679W, Japan), blood pressure and pulse (Digital wrist blood pressure monitor, Model# HEM-637, Omron Healthcare, Inc., Vernon Hills, IL), fasting blood sugar (mg/dl) in the fasted state using conventional test kit (True track™, Code# 2612, Home Diagnostics, Ft. Lauderdale, FL) were collected on day 1 (baseline), 30, 60 and 90.

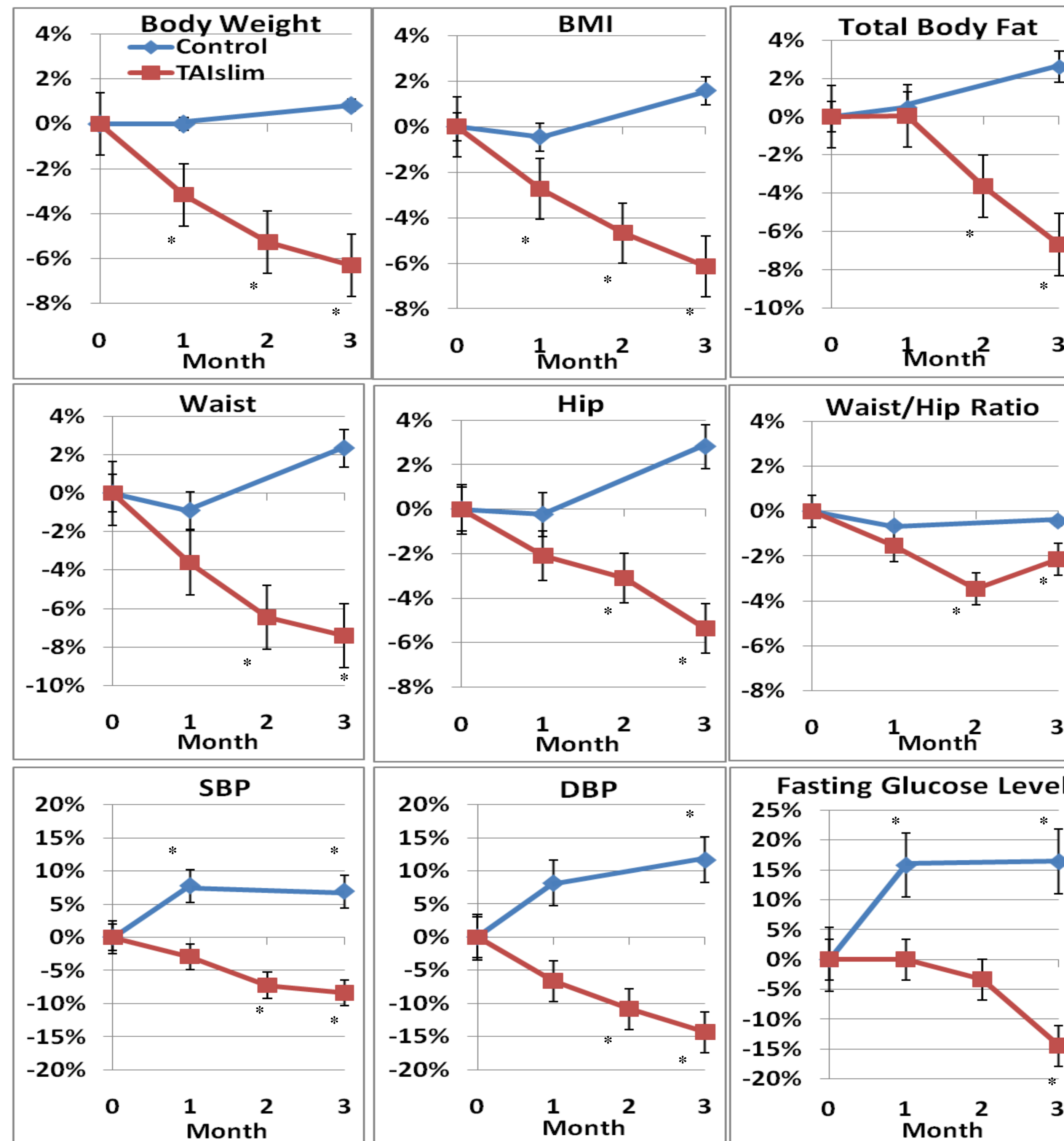
Statistical Analysis. All morphometric parametric data were analyzed by t-test for dependent groups. Descriptive statistics were calculated for pre-intervention and each measurement period for all dependent measures and summarized as means and standard errors. Differences were considered significant at P<0.05.

RESULTS

Body weight was significantly lowered by taking TAlslim 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) (Fig. 1). 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 (Fig. 1).

Conversely, in the control phase, there were no statistically significant changes in body weight, BMI, total body fat, and waist and hip circumference. Fasting blood glucose level, SBP and DBP were rather increased in the control phase (Fig.1).

Fig. 1 Impacts of TAlslim on various antropometric parameters compared to pre-intervention (baseline) and control phase.



* P<0.05 compared to baseline

CONCLUSION

As TAlslim significantly reduced various antropometric parameters in the present controlled cross-over human clinical study under exercise and dietary restriction, TAlslim may be useful material in a weight loss program.