

Body Weight Reduction, Appetite Suppression and Caloric Expenditure Stimulation by TAlslim® Total Body System*: Randomized, Placebo-controlled, Double-blind Human Clinical Studies

*A Combination of Liquid Dietary Supplement Containing Indigestible Soluble Dietary Fiber, L-Phenylalanine, N-Acetyl-L-Tyrosine, Tea Extract with Polyphenols plus Caffeine and *Lycium barbarum* (TAlslim®) with Glucomannan Fiber-containing Meal Replacement Shake (TAlslim® SHAKE) and Chew (TAlslim® SKINNY) under Exercise and Diet Control

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ABSTRACT

We hypothesized that negative energy balance by the systematic procedure (TAlslim® System) with increasing metabolic rate through physical activity and use of dietary supplement, TAlslim (containing indigestible dietary fiber, L-phenylalanine, N-acetyl-L-tyrosine, tea extract with polyphenols plus caffeine and *Lycium barbarum*), and decreasing caloric intake by consuming fiber-containing meal replacement (TAlslim SHAKE) and chew (TAlslim SKINNY) would be successful to lose weight in obese humans. Randomized, double-blind, placebo-controlled human clinical studies have shown that TAlslim System significantly reduced body weight by 5.8 ± 0.8 (SEM)% compared to pre-intervention or placebo group ($1.6 \pm 0.6\%$) in 1 to 3 months. Other metabolic syndrome, such as waist circumference, total body fat, blood pressure, and fasting blood glucose level were also significantly reduced by TAlslim System in a range of 4.2-7.0% compared to pre-intervention or placebo (0.2-1.9%). Resting metabolic rate was significantly increased by TAlslim System compared to placebo and baseline levels for more than 4 h post-intake. TAlslim System also significantly suppressed appetite, measured by subjective visual analogue scale by 39% compared to the baseline (11% reduction in the placebo). These results suggest that TAlslim System may be useful and effective body weight management procedure.

INTRODUCTION

Our recent clinical trials have shown that consumption of *Lycium barbarum* (*L. barbarum*) fruit (goji) juice stimulated postprandial energy expenditure (PPEE) through adrenocortical hormone control. This rise in PPEE may in part explain the improvements in waist circumference observed in our previous clinical trials. To strengthen the effects of *L. barbarum* on central adiposity and further expand its effects for better body weight control, we have developed a liquid dietary supplement, TAlslim®, by combining *L. barbarum* with soluble indigestible dietary fiber, appetite-suppressing amino acids, a blend of tea extracts standardized with polyphenols, including epigallocatechin gallate (EGCG), and caffeine. It is designed to provide appetite suppression, increased metabolism/thermogenesis, increased fat burning, decreased absorption of dietary fats and starches, improved insulin sensitivity, blood lipid reduction, blood glucose control, and remodeling of intestinal flora to reduce counts of those implicated in obesity.

We hypothesized that negative energy balance by the systematic procedure (TAlslim System) with increasing metabolic rate through physical activity and use of TAlslim, and decreasing caloric intake by consuming chewable confection (TAlslim SKINNY) and meal replacement shake (TAlslim SHAKE) would be successful to lose weight in obese humans. We examined these products combined as TAlslim System on PPEE, appetite and anthropometrics during a weight loss program. A randomized, placebo-controlled, double-blind human clinical study was performed to investigate if TAlslim has a combination effect with glucomannan fiber-containing products on appetite and anthropometric parameters evaluated in healthy overweight human adults under calorie restriction and exercise program for 3-month weight loss study.

MATERIALS AND METHODS

Test Products. FreeLife International Inc, in Phoenix, Arizona supplied commercially available TAlslim products. All product information is shown in Figure 1. Fiber content in TAlslim, chewable confection (TAlslim SKINNY), or meal replacement shake (TAlslim SHAKE) was 5, 1, or 5 g, respectively. **Study population.** Healthy subjects, 18 y and older with body mass index (BMI) 25-35 kg/m² were recruited for the study. 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 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; were pregnant or breast feeding; or were under anticoagulant therapy with warfarin (Coumadin®). All subjects were fully informed and signed the Human Subjects Informed Consent forms approved by the Internal Review Board under the Helsinki Declaration. 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 weekday to receive 2 or 3 bottles of sample fluid during the intervention period. During the weekend, all subjects brought appropriate samples home, and

drank them on same schedule as weekdays. Empty bottles were returned for compliance check. **Study design.** Combination of Product A with Product B and/or Product C was studied in a randomized, placebo-controlled, double-blind manner. A total of 79 healthy adults (age=37.5 y; BMI=30.8 kg/m²) consumed either the Product(s) or placebo samples for 3 months. Intake procedures were; Product A, 60 ml (20 kcal) t.i.d. immediately before meal on an empty stomach with 240 ml of water; Product B, 1 chew (20 kcal) t.i.d. between meals and after dinner with 240 ml of water; Product C, 40.5 g (158 kcal) mixed with water as breakfast. A calorie-restricted diet (1,200-1,800 kcal/d) with multi-vitamin supplement and daily exercise was required. Visual analogue scales for appetite and ranked scale questionnaire (0-10) for gastrointestinal conditions were assessed after 12 h fast at baseline and during the first 3 days. All subjects were 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 diet was monitored by diary. 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 0-3, 7-10, 14-17, 30, 60, and 90 days. **Statistical Analysis.** 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.

Figure 1. Supplement and Nutrition Facts of the Products.

TAlslim		TAlslim SKINNY	
Supplement Facts Serving Size: 2 fl. oz. (60 mL) Servings Per Container: Approx. 67		Supplement Facts Serving Size: 1 SKINNY Servings Per Container: 60	
Amount Per Serving	% Daily Value	Amount Per Serving	% Daily Value
Calories	20	Calories	20
Total Carbohydrates	7 g 21%	Calories from Fat	5
Dietary Fiber	5g 20%	Total Fat	1g 2%
Sugar	2g	Saturated Fat	1g 5%
Sodium	20mg 1%	Trans Fat	0g
Potassium	15mg <1%	Cholesterol	0mg
Appitol Plus™ (appetite controlling complex)	700 mg	Sodium	10mg <1%
L-Phenylalanine		Potassium	15mg <1%
N-Acetyl-L-tyrosine		Total Carbohydrate	5g 2%
Lipitol Ultra™ (fat burning complex)	330 mg	Dietary Fiber	1g 4%
Standardized extracts of green, black, oolong and white tea leaf providing 200 mg polyphenols (90 mg as EGCG) and 100 mg caffeine		Sugars	0g
NuFlora™ (advanced soluble fiber complex)	5.7 g	Protein	0g
Modified dextrin with whole fruit goji fiber		GojiMannan	1g
GoChi® 0.5 fl. oz. (15 mL)		Proprietary blend of patented, clinically tested Glucomannan fiber with standardized goji berry (<i>Lycium barbarum</i>) polysaccharide extract.	
HIMALAYAN GOJI® Juice (reconstituted goji juice from fresh whole <i>Lycium barbarum</i> fruit utilizing our exclusive Spectral Signature LBP Process™), white grape juice concentrate, red grape juice concentrate, pomegranate juice concentrate, and natural flavor)		Other ingredients: Palm fruit oil, cocoa powder, natural flavor, cacao mass (pure liquid chocolate), vegetable-source emulsifiers (soybean oil mono- and diglycerides, soybean lecithin) and salt, in a natural-source sugar-free base of polyglycolol syrup, isomalt, and rebaudioside-A (purified stevia extract). CONTAINS SOY	
†Daily Values based on a 2,000 calorie diet.		INGREDIENTS: MANUFACTURED ON EQUIPMENT USED TO PROCESS DAIRY, PEANUT, ALMOND, WALNUT, PECAN, NUTMEG, AND SOY PROTEIN.	
*Daily Value not established.			
Other ingredients: Ultra-purified reverse osmosis water, natural flavors, potassium sorbate and sodium benzoate (to maintain freshness), malic acid (for tartness) and sucralose.			

Nutrition Facts TAlslim SHAKE

Nutrition Facts TAlslim SHAKE		
Serving Size: 1 scoop (40.5 g) Servings Per Container: 15		
Amount Per Serving	% Daily Value*	
Calories	158	
Calories from Fat	40	
Total Fat 4g	8%	
Saturated Fat (from MCT/EFA complex) 1g	2%	
Trans Fat 0g		
Cholesterol 29mg	6%	
Sodium 173mg	7%	
Potassium 1000mg	29%	
Total Carbohydrate 19g	4%	
Dietary Fiber 5g	20%	
Sugars 14g		
Protein 10g	20%	
Vitamin A	35%	
Vitamin C	35%	
Calcium	30%	
Iron	17%	
Vitamin D	35%	
Vitamin E	35%	
Thiamin	35%	
Riboflavin	35%	
Niacin	35%	
Vitamin B6	35%	
Folate	35%	
Vitamin B12	33%	
Biotin	35%	
Pantothenic acid	35%	
Phosphorus	20%	
Iodine	35%	
Magnesium	35%	
Zinc	33%	
Selenium	25%	
Copper	25%	
Manganese	50%	
Chromium	28%	
Molybdenum	35%	
*Amount in Mix. Skim milk provides additional nutrients.		
**Percent Daily Values are based on a 2,000 calorie diet.		
Your daily values may be higher or lower depending on your calorie needs:		
	Calories	2,000
Total Fat	Less than	65 g
Saturated Fat	Less than	20 g
Cholesterol	Less than	300 mg
Sodium	Less than	2400 mg
Potassium		3500 mg
Total Carbohydrate		300 g
Dietary Fiber		25 g
Protein		50 g
Calories Per Gram: Fat 9, Carbohydrate 4, Protein 4		



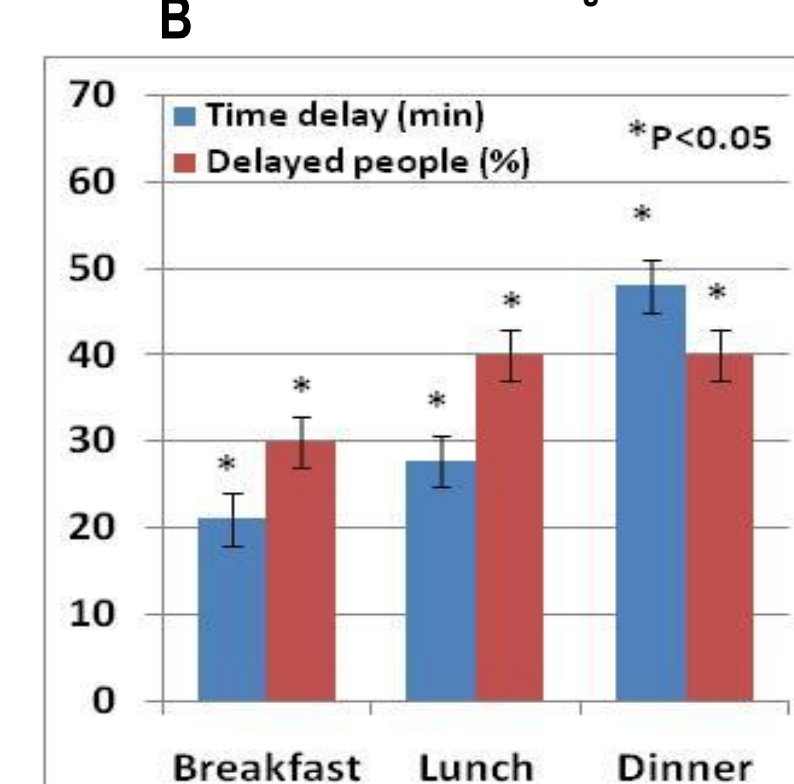
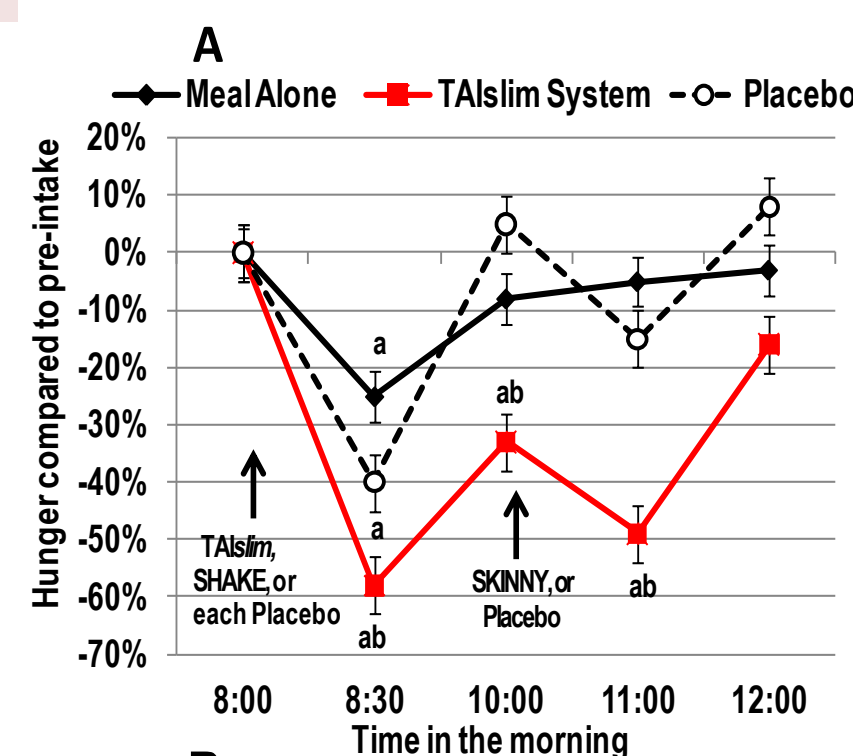
RESULTS

Feeling of appetite in all groups was lowered about a half hour after the breakfast nutritional beverage and/or products compared to the starting point/pre-intervention (Figure 2A). However, degree of the effects by the products was different. TAlslim+SKINNY+SHAKE was the most effective to suppress appetite among the treatments (Figure 2A). An average of appetite was significantly reduced by 21.2 ± 5.3 and $38.6 \pm 6.5\%$ (mean \pm SEM) compared to the baseline level by TAlslim+SKINNY and TAlslim+SKINNY+SHAKE, respectively, and better than placebo (P<0.05). No significant changes were found in placebo group.

A combination of TAlslim, TAlslim SKINNY, and TAlslim SHAKE significantly delayed time of the meal intake and population of delayed subjects (Figure 2B).

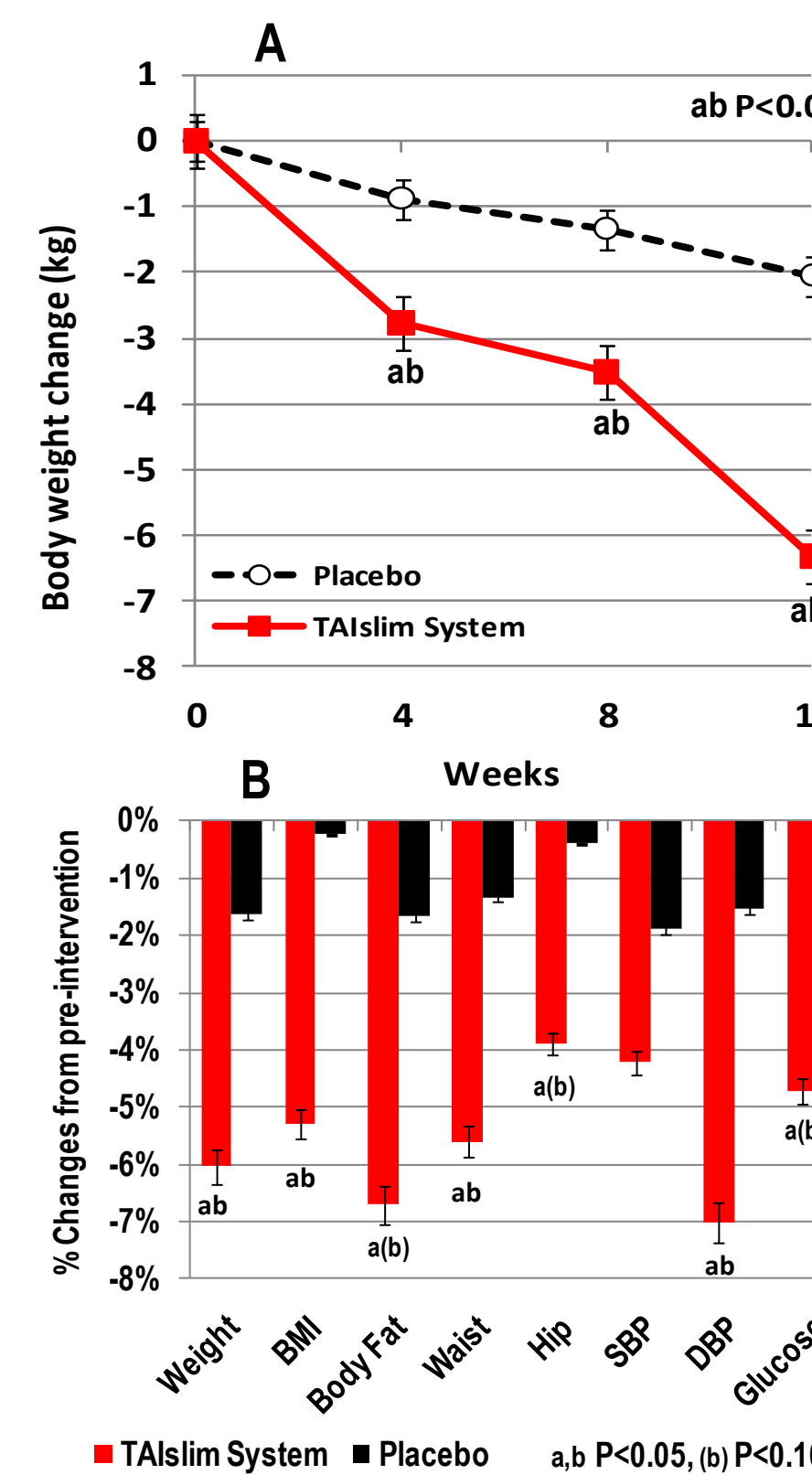
Gastrointestinal side effects were not detected except for noticeable abdominal rumbling noises in some of the subjects, but these were minor effects with no need to discontinue use of samples.

Figure 2. Kinetic analysis of appetite suppressing effect of TAlslim, TAlslim SKINNY and TAlslim SHAKE (A) and on the delayed time of the meal intake and population of delayed subjects (B).



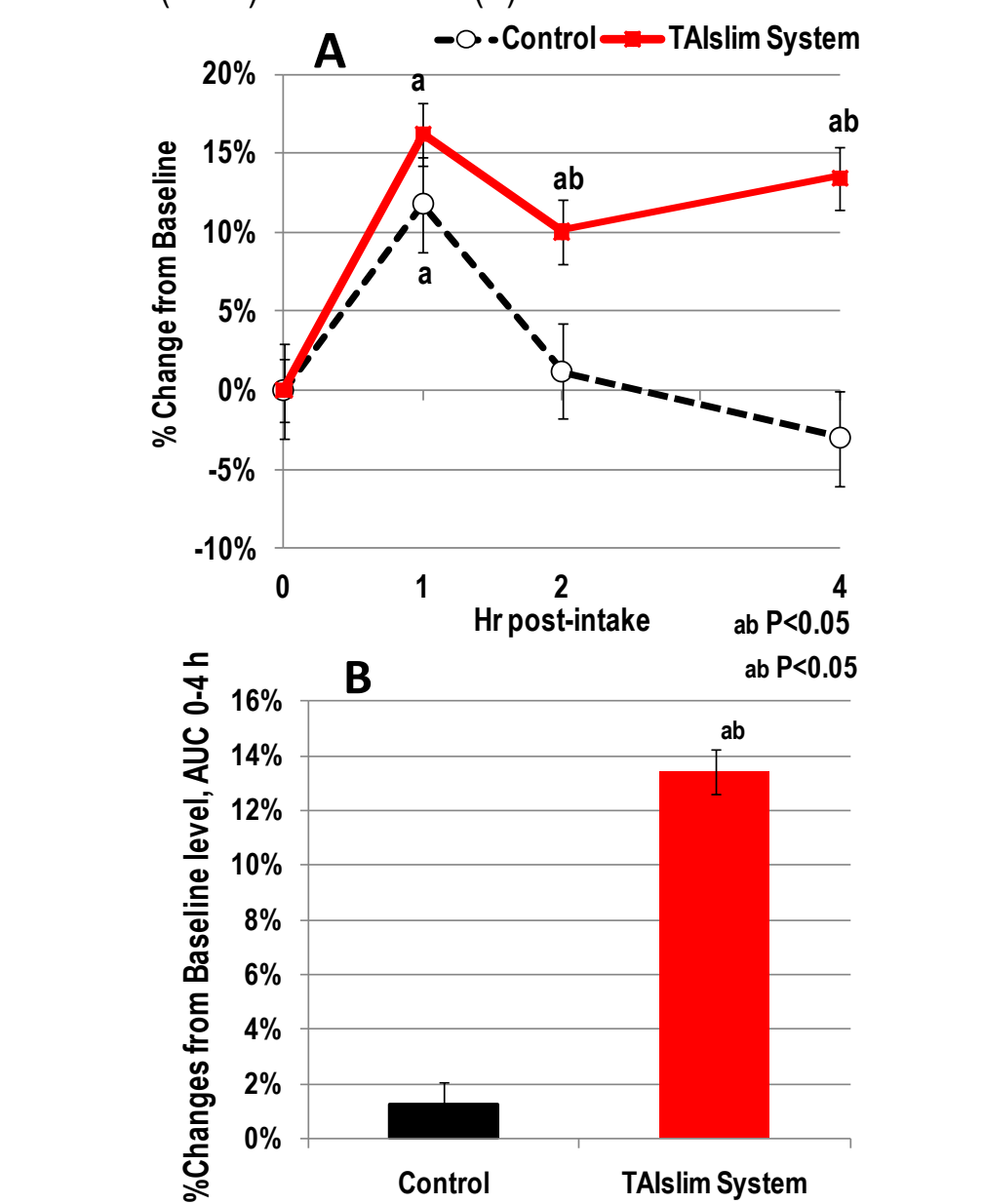
As shown in Figure 3A, at the 12 w post-intervention, body weight was significantly lowered by taking TAlslim System by 6.3 ± 1.3 kg (mean \pm SEM) (P<0.01), which is about $6.3 \pm 1.1\%$ compared to the pre-intervention baseline level. Both groups have shown significantly better reduction than placebo group. Placebo group showed no significant difference. Body weight change was slightly lowered by $2.0 \pm 0.6\%$ compared to the pre-intervention at 12 w post-intervention, but no significant difference was detected compared to the pre-intervention. As shown in Figure 3B, other morphometric parameters related to the metabolic syndrome, such as body-mass-index (BMI), waist and hip circumference, total body fat, fasting glucose level, blood pressure (SBP, DBP) and fasting glucose level in the group of TAlslim System were also significantly reduced from the starting point/pre-intervention by 5.3%, 5.6%, 3.9%, 6.7%, 4.2%, 7.0%, and 4.7%, respectively compared to the pre-intervention at 12 w post-intervention. In the placebo group, they were by 0.2%, 1.4%, 0.4%, 1.7%, 0.2%, 0.4% and 0.2%, respectively compared to the pre-intervention.

Figure 3. Changes of body weight and other anthropometric parameters from pre-intervention during (A) and post-intervention (B).



Kinetic behavior of TAlslim System on breath oxygen volume (VO₂) or postprandial energy expenditure (PPEE), and area under the curve (AUC) 0 through 4 h after the consumption measured by the indirect calorimeter were all significantly increased by single bolus intake of TAlslim System. The baseline RMR level in average of all subjects before intake of samples was 1,633 kcal/d. TAlslim System was compared to this placebo baseline level. Placebo RMR at 1 h post-intake after over 12 h overnight fasting was significantly increased by $6.7 \pm 1.9\%$ due to the nutritional beverage intake of 158 kcal, which is the placebo of the SHAKE (Figure 4A). PPEE was significantly increased by TAlslim System compared to the placebo baseline levels for more than 4 h post-intake. PPEE at 1 h post-intake was significantly increased by $16.2 \pm 2.6\%$ with TAlslim System, which was statistically significantly higher than placebo group (Figure 4A). RPPEE in the control returned to baseline within 2 h. Conversely, PPEE at 4 h post-intake with TAlslim System remained elevated by $13.4 \pm 2.4\%$ over baseline, representing statistically higher levels than the control all times (P<0.05) (Figure 4A). Area under the curve (AUC) during the 4 h study was shown in Figure 4B. AUC throughout 0-4 h post-consumption was increased by 13.8% in TAlslim System group, which is significantly higher than the control group (Figure 4B). Placebo control did not show any significant increases over the baseline. This acute RMR increase was kept at the similar level throughout the 12 w intervention period, and baseline RMR has not been statistically changed in 12 w by TAlslim System intake (data not shown).

Figure 4. Kinetic analysis of postprandial energy expenditure (PPEE) of TAlslim, TAlslim SKINNY and TAlslim SHAKE, or placebo (A), and comparison of area under the curve (0-4 h) on the PPEE (B).



CONCLUSION

The present studies suggest that TAlslim System controls appetite and PPEE which may be caused by improving caloric metabolism and as a result, body weight, waist circumference and other morphometric parameters seem to be reduced significantly from the pre-intervention. It is suggested that combining these products may be useful as part of a weight loss program.