

Effect of a Thermogenic Composition on Healthy Adult Women and Men in a 12-Week Weight Management Study

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ABSTRACT

Background: Weight loss medications can have severe side effects and thus there is a need to identify safe and effective alternative treatments. Diet-induced thermogenesis and a potential stimulation of fat metabolism might be achieved by consumption of certain foods. **Objectives:** The aim of the present study was to explore the effects of a Thermogenic Composition (TC) composed of dihydrocapsiate, red pepper (*Capsicum annuum*), citrus (*Citrus* spp.) peel extract, *Coleus forskohlii* and African mango (*Irvingia gabonensis*) to support body composition, weight management and improve satiety in healthy adults. **Methods:** Thirty-six participants were instructed to take TC daily over a 12-week interval. Body composition, energy levels, feelings of hunger and satiety were measured. **Results:** Body Fat percentage showed significant reduction at week 7 and 12 compared to week 0. Waist to Hip Ratio results showed significant reduction at week 7 compared to week 0. Feelings of Hunger and Feelings of Fullness showed significant improvement at week 3, 7 and 12 compared to week 0. Desire to Eat showed a significant reduction at week 3, 7 and 12 compared to week 0. Appetite showed significant reduction at week 7 and 12 compared to week 0. **Conclusion:** TC showed significant improvements in hunger cravings and feelings of fullness as well as significant reduction in percent body fat and waist to hip ratio. The good safety and tolerability profile of TC supported its use as a daily nutritional supplement for weight management and body composition.

Keywords: African mango (*Irvingia gabonensis*), Citrus (*Citrus* spp) peel extract, *Coleus forskohlii*, dihydrocapsiate, Red pepper (*Capsicum annuum*), Thermogenesis.

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INTRODUCTION

Arguably due to high-calorie diet and sedentary lifestyle, obesity has become highly prevalent within the United States and globally.^[1] Lockdown measures to limit the transmission of coronavirus negatively affected a range of weight management practices, including physical activity and healthy eating. In addition to being a major risk factor for Cardiovascular Disease (CVD) and all-cause mortality, high Body Mass Index (BMI) was also considered a risk factor for the Coronavirus Disease 2019 (COVID-19) mortality.^[2] Weight management is one of the primary challenges for a group of people trying to lose or slow the progression of overweight and obesity these days. The search for options to support weight control using the natural properties of foods that can help naturally limit calorie intake^[3] is given more attention as an innovative and safe solution. Prescription weight loss drugs are now considered a frontline treatment. Example

of anti-obesity medications approved by the Food and Drug Administration (FDA) in the United States:

Semaglutide a GLP-1 receptor agonist noradrenergic agonists phentermine, benzphetamine and phendimetrazine, a serotonin-norepinephrine -dopamine-releasing agent diethylpropion, an opioid receptor antagonist naltrexone with a DA and NE reuptake inhibitor bupropion, a selective 5-Hydroxytryptamine 2C (5HT-2C) receptor agonist lorcaserin, a gastrointestinal and pancreatic lipase inhibitor orlistat, GLP-1 analog liraglutide and a Melanocortin-4 Receptor (MC4R) agonist setmelanotide, as well as phentermine with a Gamma-Aminobutyric acid (GABA) agonist topiramate extended-release.^[4] Despite of the numerous weight loss drugs options, some of them are under clinical trial evaluation or have been withdrawn (e.g., diethylpropion in Europe) due to their side effects such as raised heart rate, pancreatitis, gallbladder disease and kidney problems.^[5] As a result, there is a need to identify safe and effective alternative treatments.

A physiological process of generating heat known as thermogenesis plays a crucial role in weight loss. An important site of thermogenesis is Brown Adipose Tissue (BAT). BAT generates heat in response to cold temperatures for protection against



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hypothermia, as well as in response to feeding for dissipation of excess energy from food.^[6,7] Diet-induced thermogenesis and a potential stimulation of fat metabolism, can be achieved by consumption of certain foods. Information about Capsinoids, which consist of capsaicin, capsiate and dihydrocapsiate, are the naturally occurring spicy components in *Capsicum annuum* peppers and known to activate thermogenesis via β 3adrenergic receptors^[8] and upregulation of Uncoupling Protein 1 (UCP1),^[9] a downstream signal from β 3adrenergic receptors in BAT.^[10] In clinical studies, capsinoid administration reduced body weight and fat.^[11] The seed extract of *Irvingia gabonensis*, also known as African mango, was shown to reduce body weight and fat in clinical trials^[12,13] by potentially modulating PPAR γ and leptin genes.^[14] Similarly, the root extract of the plant *Coleus forskohlii*, extensively known for its stimulation on intracellular cyclic adenosine monophosphate production, increases UCP1 mRNA and protein *in vitro*^[15] and reduces weight gain and body fat in rodents and humans.^[16,17] Finally, p-Synephrine, the natural stimulant present in *Citrus aurantium* and other citrus fruits, increases energy expenditure in humans.^[18,19]

Due to potential thermogenic effect from dihydrocapsiate, red pepper (*Capsicum annuum*), african mango (*Irvingia gabonensis*) seed extract, citrus (*Citrus* spp) peel extract and coleus (*Coleus forskohlii*) root extract, a Proprietary Thermogenic Composition (TC hereafter) containing these ingredients was tested for their effects on body composition and thermogenesis in the present study. Use of multiple ingredient types with different mechanisms of action such as increasing energy expenditure or satiety and modulating fat metabolism, are thought to potentially provide additive or synergistic advantage over single ingredient products.^[20]

The primary aim of the present study was to explore the potential of TC to attenuate body weight and fat gain without altering muscle mass, improve body composition and signals related to energy levels, feelings of hunger and satiety. Furthermore, it was hypothesized that TC would stimulate thermogenesis in BAT similarly to the preclinical study: Thermogenic Blend Alone or in Combination with Whey Protein Supplement Stimulates Fat Metabolism and Improves Body Composition in Mice.^[21] This study was also designed to assess the safety and tolerability of TC for daily use.

MATERIALS AND METHODS

Study Materials

The study product (TC) is manufactured and provided by 4Life Research LLC, Sandy, UT (Patent number US 2023/0302078A1). Participants were instructed to take the TC daily, five days a week Monday through Friday. TC contains dihydrocapsiate, red pepper (*Capsicum annuum*) fruit extract, citrus (*Citrus* spp) peel extract, coleus (*Coleus forskohlii*) root extract and African mango (*Irvingia gabonensis*) seed extract.

More information about the product can be found on the 4Life website (<https://www.4life.com/corp/product/burn/811>).

Study Procedure

The study was reviewed and approved by 4Life Research Ethics Committee before its commencement. The participants were employees of 4Life or their friends or family. The study has been registered on clinicaltrials.gov (NCT06092840).

Inclusion Criteria

Individuals who were at least 18 years old and non-smokers were able to participate. Participants were not currently taking a dietary supplement or prescription for weight loss. Exercising volunteers were asked to maintain their regimen consistently throughout the course of the 12-week study and caffeine-drinking volunteers maintained their caffeine intake consistently throughout the course of the 12-week study.

Exclusion Criteria

Participants were not allowed to participate if they were pregnant or planning to become pregnant in the following 12 weeks, or lactating. Individuals were not allowed to participate if they were taking any stimulant medications.

Participants Characteristics

A total of thirty-six (36) healthy adult subjects (19 women and 17 men) with varying BMI (between 19.66 and 48.13 kg/m²), aged 25 to 71, various ethnicities (Hispanic, Caucasian and Other) were enrolled in the study. Study participants were asked to maintain a consistent diet and exercise regimen throughout the study. At the beginning of the study a participant number was assigned and asked to fill out an Information Form and Informed Consent.

Participants were supplied with one bottle of TC for each visit, labeled with their participant number. They were required to take the product consisting of 4 capsules per day, taken on an empty stomach at least 30 min prior to eating each morning, 5 days on Monday through Friday. Product was taken at the beginning of each visit for a total of 12 weeks and empty bottles were returned at each visit. Any dosing days that were missed were skipped and noted in the questionnaire. Exercisers were encouraged to take TC immediately prior to the workout. Visits were done over a 12-week period. Those visits occurred at Week 0, Week 3, Week 7 and Week 12. Prior to each visit, participants were asked to fast and refrain from exercise for at least 4 hr. At each visit, participants were asked to take TC immediately prior to any measurements.

Measurements

Each visit consisted of the following outcome measurements except for height, which was only recorded at Week 0:

Body weight and body fat were measured by a pre-calibrated Tanita BC-418 Body Composition Analyzer following manual

instructions (Tanita Corporation. Body Composition Analyzer BC-418: Instruction manual. Arlington Heights, IL).

Waist and Hip circumference (WHR) measurements were measured according to NHANES III protocol.

Resting Metabolic Rate (RMR) was measured by MedGem Approved Indirect Calorimeter by MicroLife Medical Home Solutions according to manufacture instructions (Microlife Medical Home Solutions. MedGem Indirect Calorimeter: Instruction manual. Golden, CO).

Thermal images of brown adipose tissue in the supraclavicular region were measured by Flir T430sc or T630sc Infrared Camera (Teledyne FLIR LLC. FLIR T430sc Thermal Imaging Camera: Instruction Manual. Wilsonville, OR). Participants were measured in a thermo-neutral environment, with upper torso from the chest area to neck region exposed, with camera positioned level with the neck one meter from the subject's face, camera acquired images of the anterior neck and upper chest region.

Height was measured according to the US National Health and Nutrition Examination Survey III (NHANES III) protocol.

Blood pressure and heart rate were measured using the Omron Intellisense digital blood pressure monitor, Model HEM-739 according to equipment manual guidelines (Omron Healthcare, Inc. Automatic Digital Blood Pressure and Pulse Monitor model HEM-739: Instruction Manual. Vernon Hills, IL).

Questionnaires via SurveyMonkey positive/negative effects, energy levels, feelings of hunger and satiety parameters. The presence of positive and negative effects was measured by a participant survey. The survey also asked for the time to effect as well as description of those effects. Energy levels, hunger and satiety were measured by Visual Analog Scale (VAS)^[22] incremented from 1 to 10.

Cholesterol and glucose were measured by CardioChek Plus following manufacture manual instructions. Polymer Technology Systems, Inc (CardioChek Plus Test System: Instruction Manual. Whitestown, IN).

DATA ANALYSIS

For the statistical analyses, a series of one-way analysis of variance was used. The measures from the last week of the study (week 12) were used as the dependent variables. These variables included energy, hungry, fullness, desire to eat, appetite, RMR, systolic blood pressure, diastolic blood pressure, heart rate, total cholesterol, glucose, body weight, BMI, body fat, fat mass, fat-free mass, WHR, supraclavicular fossa temperature and average of chest and chin temperatures. The independent variables used were BMI category, age category, WHR category, body fat category and gender.

Post-hoc Tukey-adjusted pairwise comparisons were performed for each of the analyses. All analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). A p -value of ≤ 0.05 was considered statistically significant.

RESULTS

Recruitment and Dropout

A total of forty-six (46) participants were determined to be eligible for the study, screened upon consent and completed Visit 1. After visit 1, 10 participants dropped out and did not complete the study. Therefore, the results are based on data from thirty-six (36) participants (19 women and 17 men) who completed the study.

Body Composition: Body Weight, Body Fat, BMI, Fat Free Mass (FFM), Fat Mass (FM), WHR

For body weight, BMI, FFM and FM, no statistically significant results were found on any measure evaluated.

Body Fat

Results of percent body fat analysis are summarized in Figure 1. It shows that there is no significant difference between week 0 and week 3. There is a significant reduction in percent body fat between weeks 0 and 7 and weeks 0 and 12.

Waist to Hip Ratio

Results of WHR Analysis are summarized in Figure 2. It shows that there is no significant difference between 0 and 3 weeks nor 0 and 12 weeks. A significant reduction in WHR between week 0 and week 7 is shown.

Resting Metabolic Rate

Results of RMR analysis are summarized in Figure 3. It shows that there is no significant difference between weeks 0 and week 3. There is a significant reduction in RMR between weeks 0 and 7 and weeks 0 and 12.

Thermal Images of Brown Adipose Tissue in the Supraclavicular Region and Body Pictures

No statistically significant results were found on any measure evaluated. Thermal Images of Brown Adipose Tissue in the Supraclavicular Region (Figure 4).

Energy Levels, Hunger Cravings

Results obtained from a validated ten-point scale VAS^[22] for all participants at week 0, 3, 7 and 12. *Indicates values significantly different ($p < 0.05$).

Results presented in Figure 5 show that there is a significant reduction in feelings of hunger between weeks 0 and 3, week 0 and 7 and week 0 and 12. No statistically significant difference between 0 and 3 weeks nor 7 and 12 weeks for energy levels.

Satiety

Results presented in Figure 6 show there was a significant improvement in feelings of fullness from week 3 to week 12 compared to week 0. There was a significant reduction in appetite at week 7 and week 12 compared to week 0. There was a significant reduction in the desire to eat from week 3 to week 12.

Safety Parameters (Blood Pressure, Heart Rate, Total Cholesterol, Glucose)

The product was well-tolerated throughout the study and did not negatively impact physical health parameters such as heart rate, blood pressure, cholesterol and glucose.

DISCUSSION

The purpose of this study is to evaluate the potential thermogenic effects of TC to attenuate body weight, fat gain and improve body composition. One of the primary endpoints investigated

was percent body fat. Measurements indicated that TC supplementation reduced percent body fat over the 12 weeks study. Waist to hip ratio results also revealed a potential reduction in fat mass in the abdominal region. These findings are consistent with previous studies where oral administration of *Irvingia gabonensis*^[12] and *Coleus forskohlii*^[16,23] in healthy individuals resulted in both, weight reduction (body weight, body fat, waist size) and an improvement in metabolic parameters associated with insulin resistance. A previous human study has revealed that administration of 9 mg of capsinoids daily over a 3-month period, reduced waist circumference, percent body fat and visceral fat volume in middle-aged and older adults.^[24] In our previous pre-clinical study, 30 days oral administration of the TC blend to mice stimulated thermogenesis and attenuated the gain in body weight and fat.^[21] Similarly, in the present investigation, oral administration of TC showed a significant reduction in percent body fat at week 7 and week 12 compared to week 0 and a significant reduction in WHR at week 7 compared to week 0.

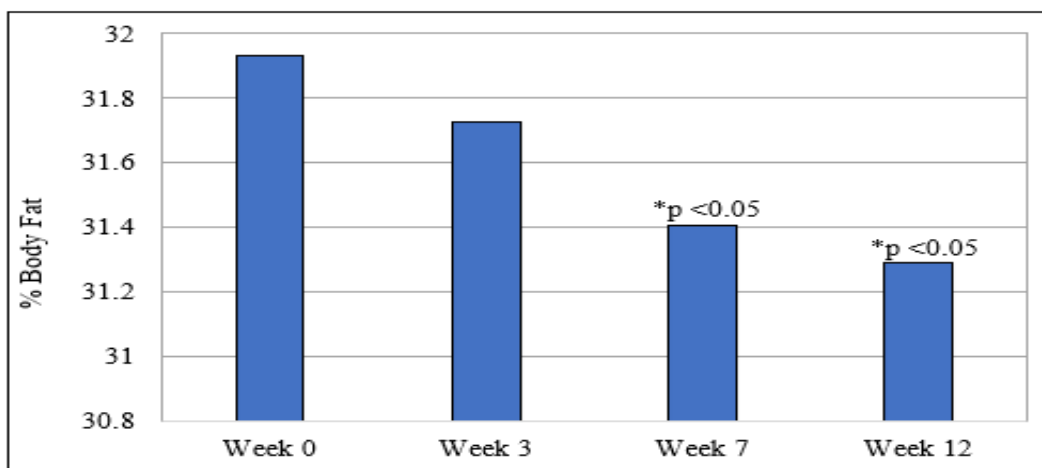


Figure 1: Percent body fat for all participants at week 0, 3, 7 and 12. *p* values indicate the significance of differences compared to week 0.

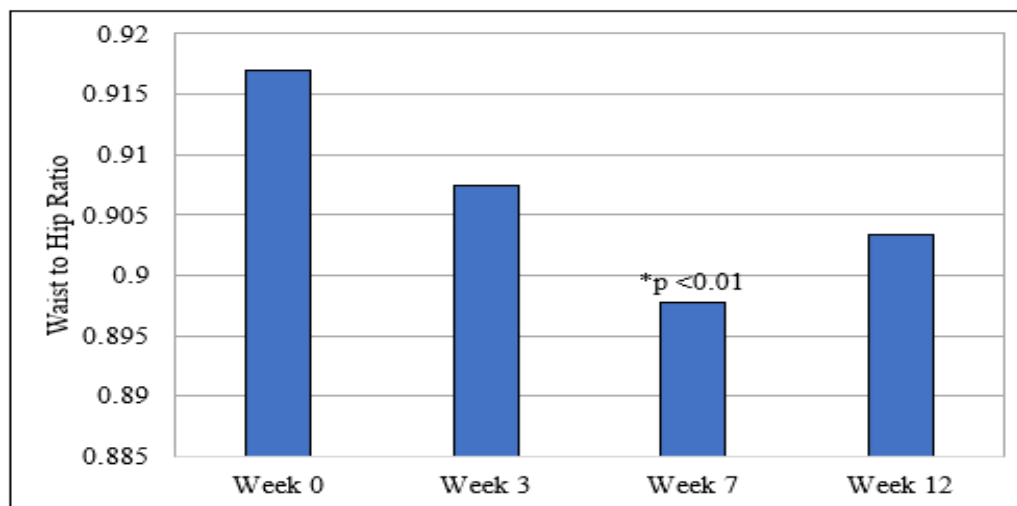


Figure 2: Waist to hip ratio for all participants at week 0, 3, 7 and 12. *p* values indicate the significance of differences compared to week 0.

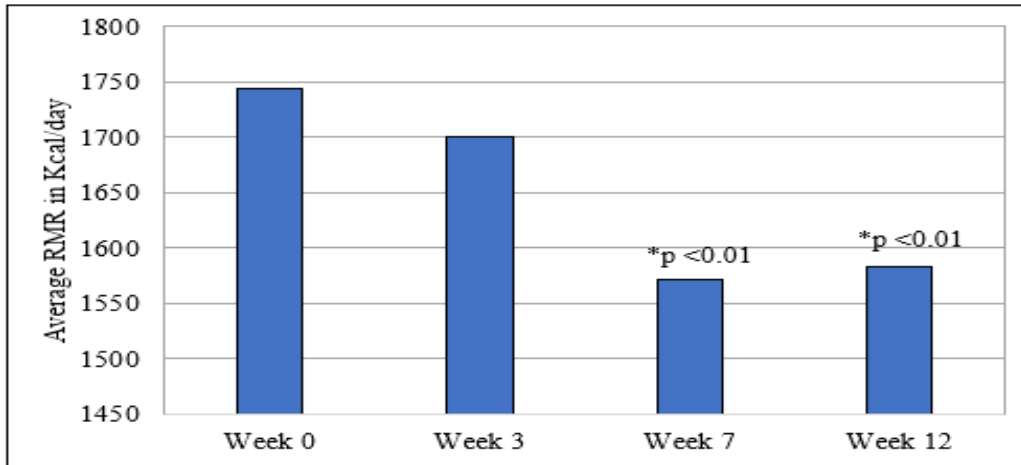


Figure 3: Kcal/day for all participants at week 0, 3, 7 and 12. *p* values indicate the significance of differences compared to week 0.

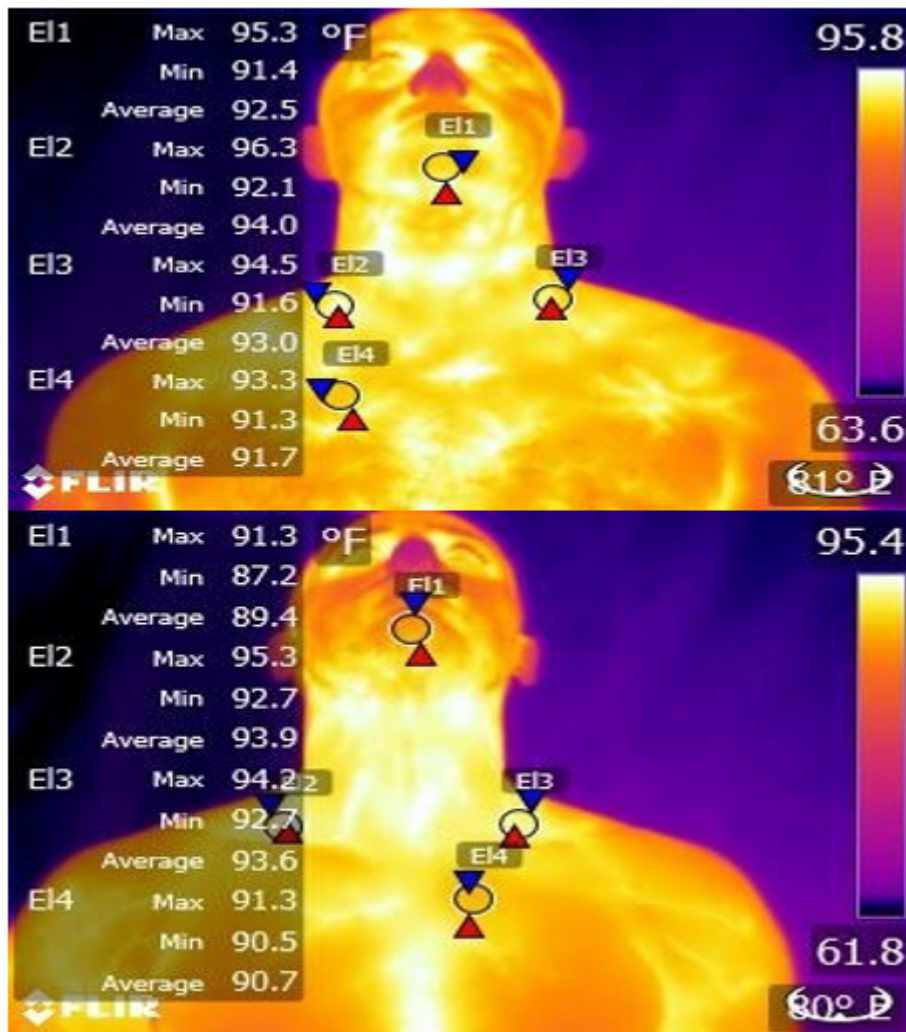


Figure 4: Thermal imaging of brown adipose tissue in the supraclavicular of a male participant.

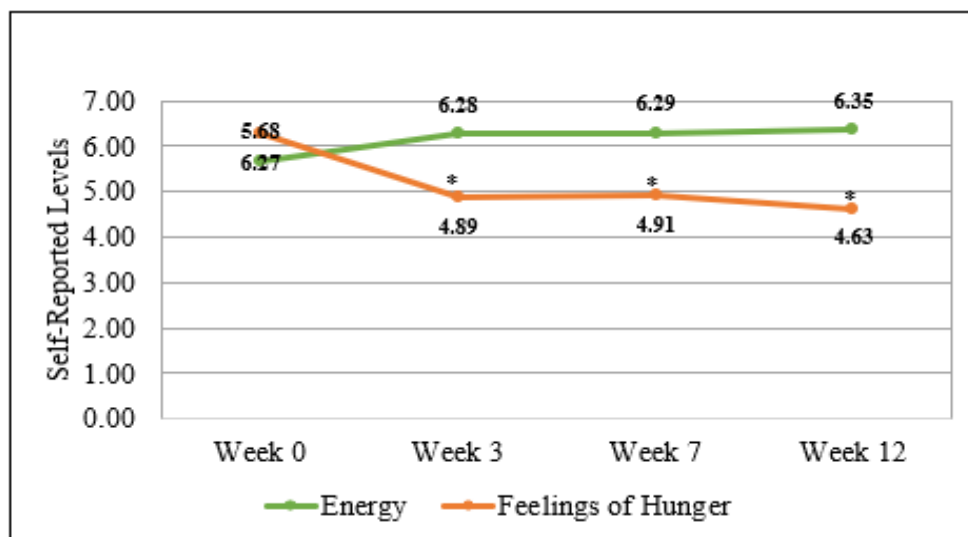


Figure 5: Energy levels-how much energy do you have right now? feelings of hunger-how hungry do you feel right now? (On a scale 1-10, with the lowest being 1 and the highest being 10).

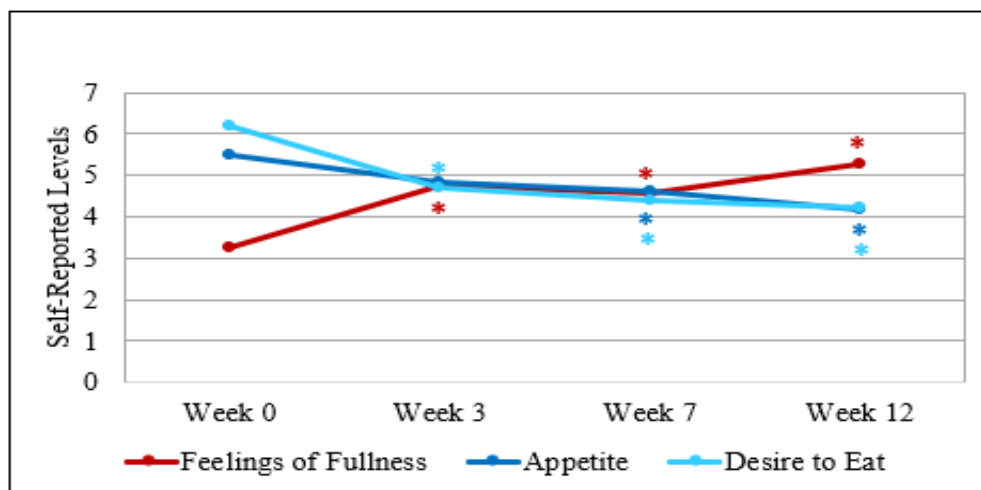


Figure 6: Satiety results from a self-reported VAS^[22] incremented from 1 to 10, with the lowest being 1 and the highest being 10 for all participants at week 0, 3, 7 and 12. * Indicates values significantly different ($p < 0.05$).

Fat-free mass represents a key determinant of the magnitude of RMR and a decrease in lean tissue could hinder the progress of weight loss. Therefore, with respect to long-term effectiveness of weight-loss, the loss of fat mass while maintaining FFM and RMR is desirable.^[25] In the present study, no statistically significant changes were observed in FFM and FM, however, there is a downward trend in both, specifically a reduction of 1.20 pounds (0.54 kg) in FM between week 0 and week 7 and a reduction of 1.27 pounds (0.58 kg) in Fat Mass between week 0 and week 12. Resting Metabolic Rate showed a significant reduction in kcal/day at week 7 and week 12 compared to week 0 which in correlation with the results presented in hunger cravings and satiety, collectively suggest that participants decreased the intake due to feelings of fullness and lower desire to eat, which might be the explanation of reduction in RMR. According to literature, RMR is modulated by the number of calories consumed in the diet

relative to energy expenditure. Excessive consumption of calories appears to increase resting metabolic rate while fasting and very low-calorie dieting causes resting metabolic rate to decrease.^[26] The results from the present study did not replicate those findings from previous studies that assessed the thermogenic effects involving p-synephrine from (*Citrus aurantium*) alone and in conjunction with the flavonoids in a double-blinded, randomized, placebo-controlled study where increases in RMR were reported.^[18] These inconsistent results of RMR might be attributed to factors influencing RMR energy expenditure, such as age, gender and BMI. Menopause also can affect metabolism in such a way as reducing RMR.^[27]

In the present study, TC did not increase thermal imaging of Brown Adipose Tissue (BAT) in the supraclavicular region, no statistically significant results were found on any measures evaluated. These findings are not consistent with the pre-clinical

study in mice where a thermogenic blend containing the same ingredients increased thermal imaging of BAT.^[21] This could be attributed to the lack of a controlled environment and variability in the procedure or measurement inherent to the present human study. Although no significant changes were observed in body weight, the reported significant reduction in percent body fat among participants is supportive of the positive effect of TC on body composition.

Hunger cravings, desire to eat and appetite showed a significant reduction and feelings of fullness showed significant improvement. Previous clinical and preclinical studies have demonstrated that bitter orange reduces hunger cravings,^[18] *I. gabonensis* and capsinoids reduce blood leptin levels,^[12,28] and *Coleus forskohlii* reduces food intake.^[29,30] No statistically significant changes were observed in energy levels, however, there is an uptrend over the 12 weeks study.

TC was well-tolerated throughout the study and did not negatively impact physical health parameters such as heart rate, blood pressure, cholesterol and glucose. This study shows that TC has a good safety and tolerability profile and can be used as a daily nutritional supplement. According to previous studies, the safety of p-synephrine and bitter orange extract has been reviewed and it has been concluded that when taken orally and in recommended amounts both are safe for daily use.^[18] The good safety and tolerability profile of TC is a positive option in comparison with the current anti-obesity and costly medications that have been approved by the FDA for chronic weight management. Many promising weight-loss drugs have been withdrawn from the market due to their life-threatening side effects.^[2]

The present study had several limitations. The participants were employees, family, or friends of 4Life employees and, as such, this may present a bias towards the study product that could have influenced their responses and adherence to the intervention. It was an open-label clinical trial which may unconsciously influence the outcomes from participants and lacked a formal placebo-controlled group that needs to be considered when attributing observed changes specifically to the TC, as opposed to other external factors or placebo effects. Limitations related to the lack of a controlled environment could affect results from thermal imaging of BAT. Study participants were asked to maintain a consistent diet and exercise regimen throughout the study and therefore there was no control for confounding variables, such as variations in physical activity, diet and other lifestyles factors that could affect the results. The number of participants in the study may be small or not representative of the population of interest. Having a larger number of participants could help to understand better the effects of TC in the two different gender groups, age category, ethnicity category and improve the generalizability of the findings.

CONCLUSION

Oral administration of TC led to significant reductions in percent body fat and WHR. TC supplementation also improved feelings of hunger and satiety over the course of the entire study. Resting metabolic rate results further suggested that participants decreased their calorie intake due to feelings of fullness and reduced desire to eat. TC further demonstrated a good safety and tolerability profile and thus can be safely used as a daily nutritional supplement. Although not definitive, this study supported the daily use for weight management and body composition.

A larger, longer, placebo-controlled and double-blinded study will likely provide more conclusive answers to specifics of TC supplementation efficacy.

CONFLICT OF INTEREST

M.P., D.V. and X.H. were employees of 4 Life Research, LLC (Sandy, Utah), the manufacturer of the studied product Thermogenic Composition (TC).

AUTHORS' CONTRIBUTIONS

Dr. David Vollmer designed and managed the study, reviewed and edited the manuscript. Millerlandy Popayan Jaramillo wrote, analyzed the data and edited the manuscript. Dr. Lawry Xuesheng Han analyzed the data, edited and reviewed the manuscript. Dr. Dennis Eggett conducted the statistical data analysis.

FUNDING SOURCES

Funding for this project was provided by 4Life Holdings, LLC.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was reviewed and approved by 4Life Research Ethics Committee before its commencement. The study has been registered on clinicaltrials.gov (NCT06092840). At the beginning of the study, a participant number was assigned and asked to fill out an Information Form and Informed Consent.

ABBREVIATIONS

TC: Thermogenic Composition; **WHR:** Waist to Hip Ratio; **BMI:** Body Mass Index; **FDA:** Food and Drug Administration; **BAT:** Brown Adipose Tissue; **RMR:** Resting Metabolic Rate; **VAS:** Visual Analog Scale; **FFM:** Fat Free Mass; **FM:** Fat Mass.

SUMMARY

A 12-week oral administration to healthy adults of a thermogenic composition containing dihydrocapsiate, red pepper (*Capsicum annuum*), citrus (*Citrus* spp) peel extract, *Coleus forskohlii* and african mango (*Irvingia gabonensis*) reduced percent body fat, waist to hip ratio and improved feelings of hunger and satiety

over the course of the entire study. Furthermore, this study demonstrated a good safety and tolerability profile and thus can be safely used as a daily nutritional supplement for weight management and body composition.

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