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Original Article

The Effect of an Innovative Supplement Compound on Fat Burning and Weight Management for Obese People

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ABSTRACT

In summary, obesity represents a significant public health concern on a global scale. The objective of this study is to evaluate the effect of regular consumption of nutritional supplements on body weight and its impact on overweight or obese individuals. The study employed a randomized, placebo-controlled trial design. A randomized, placebo-controlled trial was conducted with male and female participants with a body mass index (BMI) between 25 and 40 kg/m². All subjects underwent a comprehensive six-week weight-loss program, which included an individualized diet devoid of any physical activity recommendations and once-daily consumption of the complex supplement or placebo. The body weight, BMI, and body composition were measured at the beginning and end of the proposed duration (180 days). The results of the study are as follows: A total of 150 participants were randomized, and 120 participants aged 44.16 ± 5.87 years and with a body weight of 80.53 ± 12.51 kg completed the treatment. At the conclusion of the study, there was a discernible trend towards a reduction in body weight, BMI, and waist circumference in the treatment group. Notably, individuals with type III obesity in the experimental group exhibited a significant reduction in body weight (four individuals at the commencement of treatment versus zero individuals at the conclusion of six months) and BMI (25 and 39.9). In contrast, the placebo group did not exhibit any notable changes in their bodies. Conclusions: The regular consumption of the nutritional supplement resulted in a reduction in body weight and BMI in obese individuals after 24 weeks, with the greatest effect observed in those with type III obesity.

Keywords: Innovative supplement, Obesity, Overweight, Body weight changes, Waist circumference

INTRODUCTION

Obesity contributes to various chronic diseases, such as diabetes, hypertension, cancers, as well as heart diseases. The management of obesity is always difficult and challenging. The conservative management, dietary restriction, and physical activities are often ineffective, and therefore many obese individuals must resort to surgical intervention. Surgical intervention has now become more effective with the introduction of laparoscopic technique. However, the type of surgery causes several problems and side effects.

The issue of obesity has become a significant concern in the field of public health, with alarming rates of prevalence reaching epidemic levels [1]. The growing

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prevalence of obesity, affecting millions worldwide, underscores the urgent need for novel approaches to weight management. One potential approach is the use of innovative supplements designed to enhance fat burning and support weight management in obese individuals. Body fat is divided into two categories: essential and non-essential. Essential fats are essential for normal bodily functions, such as providing insulation and facilitating metabolic processes. These components represent approximately 3% and 12% of total body weight in men and women, respectively [2]. Non-essential fat is stored within adipose tissues, which are located beneath the skin and surrounding major organs. The accumulation of non-essential fat occurs when the body experiences a prolonged energy surplus, whereby energy intake exceeds expenditure. The accumulation of non-essential fat in excess of that required for normal bodily functions leads to overweight and obesity [3]. Recent data, derived from population studies across 195 countries, indicates that in 2015, approximately 603.7 million adults and 107.7 million children worldwide were affected by obesity [4]. Furthermore, it has been observed that the average body mass index (BMI) tends to increase by 0.4 points in men and 0.5 points in women with each passing decade [5]. The metabolic consequences of obesity encompass a range of dysfunctions in vital processes, including blood glucose regulation, lipid metabolism, and blood pressure control.

Previous studies have demonstrated the efficacy of certain dietary compounds in achieving favorable outcomes in weight management and reducing excess adipose tissue. For instance, Barrea, *et al.* [6] demonstrated that the utilization of a specific dietary compound resulted in a notable reduction in body weight over a specified period. Allison, *et al.* [7] underscored the potential of combining several nutritional components to achieve significant improvements in body composition and effective weight management outcomes.

Innovative supplement compounds have demonstrated encouraging outcomes in fat burning and weight management among individuals with obesity. Research indicates that supplements such as Calebin A, derived from Curcuma caesia [7], a combination dietary supplement comprising various nutrients [8], and a newly developed multi-ingredient supplement rich in polyphenol antioxidants and compounds enhancing metabolic function [9], have resulted in noteworthy reductions in body weight, body fat percentage, and improvements in lipid profiles. Moreover, novel lipid derivatives of α-lipoic acid have demonstrated potential in combating obesity by boosting energy expenditure through beta-oxidation while suppressing lipogenesis. Furthermore, nutraceuticals containing chitosan and α-lipoic acid have demonstrated efficacy in reducing weight, BMI, and enhancing lipid profiles and inflammatory markers in obese individuals [10]. These findings collectively demonstrate the potential of innovative supplement compounds in addressing fat burning and weight management challenges among those grappling with obesity.

Obese individuals are not satisfied with their body shape and weight; therefore, they may resort to various supplements in the market which claim to reduce weight. Most of the claims are not substantiated and are sometimes fraudulent. Evidence on the effectiveness and safety of these supplements is often not available. It is therefore our interest to find a safe method of weight reduction for obese individuals. This could be a steppingstone for the development of a more effective and less invasive method for the treatment of obesity. The objective of this research is to demonstrate the efficacy of the proposed nutritional complex in promoting fat burning and weight management. This nutritional complex has the potential to serve as a promising alternative to pharmaceutical products currently used in the treatment of obesity.

MATERIALS AND METHODS

Study Subjects

A total of 120 individuals were selected as subjects for this randomized pilot study. Inclusion criteria were as follows: age between 35 and 55 years, body mass index (BMI) ≥25 and <42 kg/m^2, willingness to participate in the study for 180 days, and signature of the informed consent. The participants in the study were not subjected to any dietary or exercise regimen throughout the duration of the research. They were required to demonstrate a good understanding of the scientific trial. Individuals who met any of the following criteria were excluded from the study: treatment for cardiovascular risk factors (e.g., hypertension, diabetes mellitus, and others), severe mental, liver, or kidney disease, cancer, breastfeeding, or pregnancy, as well as subjects who consumed alcohol frequently.

Additionally, subjects had to have not participated in a weight-control program within the last six months.

The participants were randomly divided into two groups:

- Group 1: Received the proposed nutritional complex for 180 days.
- Group 2 received an alternative dietary supplement as a placebo for 180 days.

Prior to initiating evaluations, this study received full approval from the Ethics Committee of the Tunisian National Center for Sports Medicine and Sciences (approval number LR09SEP01) in accordance with the International Conference on Harmonization Guidelines on Good Clinical Practice and the ethical standards of the Declaration of Helsinki [11]. Prior to the commencement of the study, each participant provided written informed consent. Participation in the study was entirely voluntary. To ensure the utmost confidentiality, all data collected from participants were analyzed with discretion.

Study Design

This randomized, two-group, parallel-group, and innovative oral nutritional supplement-controlled study was conducted in accordance with the relevant ethical standards. The total duration of the intervention was 36 weeks (180 days). The intervention was examined over a six-month period. One weight-loss group (Group 1) consumed the proposed nutritional complex for the entire duration of the study. The other controlled group (Group 2) received another nutritional supplement as a placebo for the entire period. The participants were randomly assigned to receive either a placebo or the nutritional complex once a day, with a single morning dose of 15 grams.

Treatments

The participants did not adhere to any specific dietary or exercise regimen throughout the course of the study. The dietary program, which was designed to be followed daily, was prescribed individually to all participants. The nutritional complex was designed to provide a reduction in body weight of 20% relative to the baseline, with a 20% reduction in lipid intake being the lower limit of the restriction. The participants were instructed to ingest their supplement once daily at 8 a.m., with a dosage of 15 grams. The dietary program was prescribed for a period of 180 days. The participants were provided with a one-week dietary supplement consumption plan as an illustration of an individualized food program designed for each of them. Furthermore, no alterations were made to the food list, allowing for the creation of personalized dietary plans according to individual preferences while ensuring that the resulting menu would meet the necessary nutritional requirements. All participants underwent weight measurement and received no information regarding nutritional supplements. Moreover, nutrition education and motivational sessions were given by the researchers.

This nutritional complex is based on a unique blend of natural ingredients with scientifically proven properties to promote fat burning and improve overall health.

The ingredients and their quantities are as follows: Psyllium Husk: 13.5 grams; Garcinia cambogia: 500 milligrams; Magnesium glycinate: 230 milligrams; Caffeine: 200 milligrams; Capsaicin: 5 milligrams; Vitamin B6: 2 milligrams; Chromium picolinate: 0.2 milligrams.

Components of a Nutritional Complex

Table 1 presents the benefits of the ingredients and their effect on weight management.

a. Psyllium husk: Psyllium husk is a rich source of natural fiber that improves digestive function and promotes feelings of fullness. It reduces the absorption of fat in the body.
b. Garcinia cambogia: Inhibits the storage of new fat in the body. It also has an appetite-suppressing effect.
c. Magnesium glycinate: It facilitates the metabolic process and stimulates the burning of calories. It has been demonstrated that this supplement improves sleep quality and reduces stress levels.
d. Caffeine, in particular, has been shown to stimulate the metabolism and promote fat burning. It enhances energy and focus.
e. Capsaicin: It is theorized that the supplement promotes fat burning by increasing body temperature and stimulating the metabolism. It has been demonstrated that this substance reduces appetite.
f. Vitamin B6 has been demonstrated to improve metabolic efficiency, with a role in regulating blood sugar levels.
g. Chromium: It regulates blood sugar levels and reduces sugar cravings.

Table 1: Components of the nutritional complex

	Quantity	Function
Psyllium husk	13.5 g	– A rich source of natural fiber, it has been demonstrated to improve digestion and promote satiety. – It has been demonstrated that this substance reduces the absorption of fat in the body.
Garcinia cambogia	500 mg	– It inhibits the storage of new fat in the body. – It has been demonstrated that this substance has the effect of reducing appetite.
Magnesium glycinate	230 mg	– It facilitates the metabolic process and stimulates the burning of calories. – It has been demonstrated that this product improves sleep quality and reduces stress levels.
Caffeine	200 mg	– It stimulates the metabolism and promotes the burning of fat. – It enhances energy and focus.
Capsaicin	5 mg	– This product is designed to promote the burning of fat by increasing the body's temperature and stimulating its metabolism. – It has been demonstrated that this substance reduces appetite.
Vitamin B6	2 mg	– This product is designed to promote the burning of fat by increasing the body's temperature and stimulating its metabolism. – It has been demonstrated that this substance reduces appetite.
Chromium	0.2 mg	– Regulates blood sugar levels and reduces sugar cravings.

Endpoints

The following analyses and measurements were conducted:

General health variables

During this period, data pertaining to specific medical conditions and medication use were collected. Furthermore, blood pressure and heart rate were calculated at each interval (three measurements were taken at 5-minute intervals, and the averages recorded). Furthermore, a blood sample was collected for analysis of the lipid profile, including total and LDL cholesterol, at the beginning and end of the study period.

Anthropometric and body composition

Variables were assessed at the outset and conclusion of the study period. These measurements were conducted in accordance with standard procedures and in alignment with the World Health Organization (WHO) guidelines [12]. All measurements were conducted by trained personnel in the morning, with the participant barefoot and wearing only underwear. Body weight was utilized as the metric of interest. Body mass index (BMI) was calculated as body weight (kg) divided by the square of height (m^2). Based on their BMI, participants were divided into four groups: underweight (BMI <18.5 kg/m^2), normal weight (BMI 18.5-24.9 kg/m^2), overweight (BMI 25.0-29.9 kg/m^2), obesity level I (BMI 30.0-34.9 kg/m^2), obesity level II (BMI 34.9-39.9 kg/m^2), and obesity level III (BMI $>$ 40kg/m^2) (Table 2). The waist circumference was measured using a steel tape.

Table 2: BMI and Body Weight Status by Implications

BMI	Implications to the weight status
Less than 18.5	Underweight
18.5-24.9	Normal weight
25.0-29.9	Overweight
30.0-34.9	Obesity level I
34.9-39.9	Obesity level II
Greater than 40	Obesity level III

Source: Gavin (2005) and Sharkey (1997)

The researchers advised that all participants should minimize the use of diuretics and avoid any adverse health effects. The participants had fasted for a minimum of three hours prior to the blood sampling procedure.

Statistical Analysis

The sample size was duly considered. The total sample size estimated for the present study was 120 participants. The population analyzed included all subjects who completed the entire treatment period. The data are presented as mean ± standard deviation (SD) or percentage (%) and N. The Kolmogorov-Smirnov test was employed to verify the normal distribution of the data. The two analysis groups were established according to the presence of overweight or obesity at baseline. The significance level was set at a two-tailed p-value of less than 0.05. All calculations were conducted using the SPSS Inc. software version 28.0.0.0 (190).

RESULTS

Recruitment and Study Population

The study was conducted between September 2022 and August 2023. A total of 120 healthy participants (66 men [55%], 54 women [45%]) were included in the study. Subjects were randomly assigned to either the control or experimental group, stratified by sex. A total of ten individuals withdrew from the control group, while eight individuals did so from the experimental group. At the conclusion of the study, 30 individuals were excluded for personal reasons (n = 30), health issues (n = 8), loss to follow-up (n = 10), and non-compliance with treatment instructions (n = 12). Consequently, 120 participants completed the six-month study (see figure 1), with their results included in subsequent analyses. The distribution of values was found to be normal. All tests were conducted with a two-tailed hypothesis. The two analysis groups were conducted according to the presence of overweight or obesity at baseline. The significance level was set at a two-tailed *p*-value of less than 0.05.

Body Composition Variables and Anthropometric Measurements

The experimental group exhibited a reduction in body weight, BMI, and waist circumference at the conclusion of the six-month study period. In contrast, the control group, which did not consume the complex nutritional supplement, demonstrated a slight decrease in anthropometric variables and body composition. The relationship map between the initial and final variables of Group 2 BMI demonstrates the complete disappearance of the Obesity Level III group, indicating that the food supplement exerts an effect on weight (see Table 4 and Figure 2).

Compliance and Adverse Effects

In the compliance analysis, 94% of participants demonstrated good adherence to treatment. No serious adverse effects were observed during the consumption of complex nutritional supplements. Diarrhea, constipation, bloating, and heartburn were documented as adverse events in study. No serious effects were detected between treatment groups throughout the study.

DISCUSSION

Despite the existence of efficacious, safe, and cost-effective thermogenic agents in weight loss supplements, there is still a demand for more efficacious, safe, and cost-effective thermogenic agents. This leads us to the current study. This is the first randomized study conducted over a six-month period (180 days) to investigate the effect of a combination of compounds obtained from a complex nutritional supplement on weight loss after a 24-week weight-loss program. No specific dietary or exercise program was imposed upon the participants during the study period. The study indicates that consumption of one stick per day of a fraction rich in nutritional components is beneficial (The supplement contained the following ingredients: psyllium husk (13.5 grams), garcinia cambogia (500 milligrams), magnesium glycinate (230 milligrams), caffeine (200 milligrams), capsaicin (5 milligrams), vitamin B6 (2 milligrams), and chromium picolinate (0.2 milligrams)). A reduction

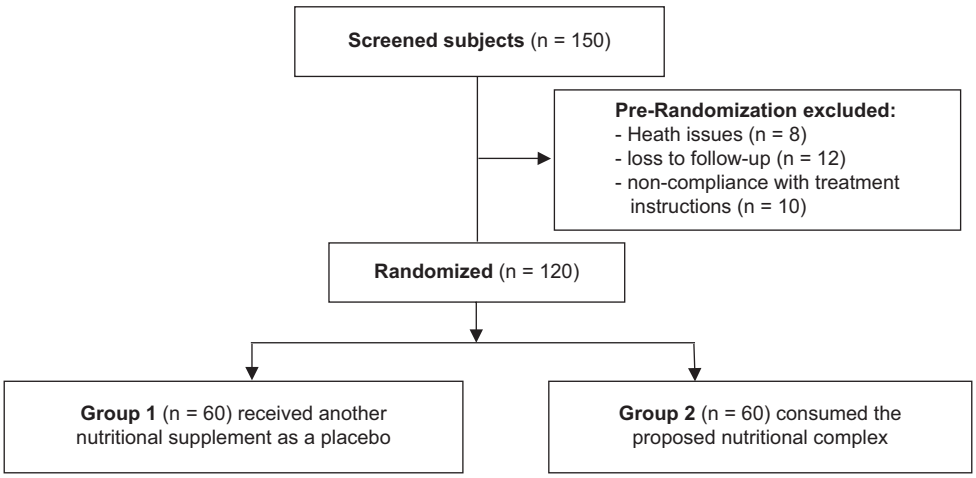

Figure 1: Consort diagram

in body weight and BMI was observed in group 2 participants following the implementation of a weight loss program. In the final body weight measurement classification, obesity type III was not observed (Figure 2). Furthermore, there was a slight reduction in body weight and waist circumference in the control group, while these characteristics exhibited a significant decrease in the group consuming the natural nutritional supplement. Innovative supplement compounds have demonstrated encouraging outcomes in fat burning and weight management among individuals with obesity.

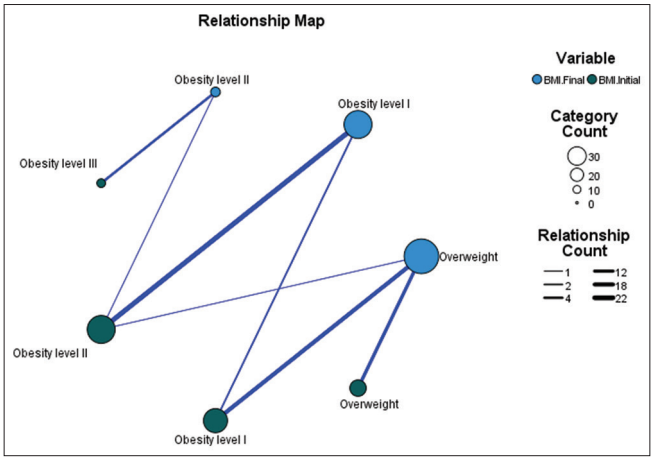

Figure 2: Relationship map of initial and final BMI variables

Table 3: Basic characteristics (BMI and gender) of the sample population

		Frequency	Percent (%)
Gendre	Male	66	55
	Female	54	45
BMI	Overweight	25	20.8
	Obesity level I	42	35.0
	Obesity level II	46	38.3
	Obesity level III	7	5.8

BMI: body mass index

The results of our study on the reduction of body weight and waist circumference demonstrate the effectiveness of the nutritional supplement, even in the absence of dietary restrictions or limitations on physical activity. The initial group to conduct a randomized, placebo-controlled trial provided data on BMI and body weight in subjects with a high body mass index (BMI) following the ingestion of fiber [13]. Nevertheless, their findings indicated that a daily intake of 1 g of chitin-chitosan fiber had no significant effect on body weight or BMI reduction after four weeks of treatment. A study of obese adults aged between 20 and 50, with a BMI ≥30 kg/m^2, was conducted in which the subjects were randomized into two groups: one treated with a dietary supplement and a placebo group receiving rice flour. Both groups demonstrated no significant alterations in their total calorie intake, macronutrient consumption, or activity levels. Nevertheless, the treated group exhibited notable reductions in body weight, body fat percentage, absolute fat mass, upper abdominal, waist, and hip circumferences in comparison to the placebo group. The supplement was well tolerated by participants, with no significant changes observed in heart rate or blood pressure. The occurrence of adverse events was minimal and unrelated to the treatment, indicating the safety of the supplement for weight loss in this study. The results indicate that this stimulant-free supplement may be a promising option for promoting weight and fat loss in obese individuals. It offers a potentially effective and tolerable alternative to stimulant-based products [14]. Nevertheless, the subjects in the previous studies were subjected to the same dietary and physical activity programs as those in the present study (6 months).

A study was conducted to assess the impact of a dietary supplement on weight loss, body fat percentage, cholesterol, and triglycerides in obese subjects over

Table 4: Anthropometric and body composition variables throughout the study for both groups

	Group 1				Group 2			
	BMI initial		BMI final		BMI initial		BMI final	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
Overweight	14	18	15	16	12	20	31	51.7
Obesity level I	18	35	34	33	20	33.3	24	40.0
Obesity level II	10	7.1	10	7.1	24	40	5	8.3
Obesity level III	20	39.9	20	39.9	4	6.7	0	0
Waist circumference (cm; SD)	97.35 ± 11.6		95.35 ± 11.92		98.20 ± 11		93.41 ± 10.36	
body weight (Kg; SD)	88.25 ± 14.61		86.8 ± 13.82		83.25 ± 11.61		76.78 ± 8.52	

a six-week period. The results indicated a significant reduction in weight, a decrease in the body fat percentage, and lower cholesterol and triglyceride levels. These findings support the supplement's efficacy and safety for weight management [15].

The present study also demonstrated a reduction in body weight. This result was maintained following the ingestion of complex carbohydrates, with no recommendations for either a controlled diet or physical activity. Significant weight loss was also achieved in other studies that offered a controlled diet but did not provide any guidance on physical activity [16,17]. However, the duration of the treatment period in these studies ranged from two to six months.

The European Society of Parenteral and Enteral Nutrition (ESPEN) recommends the use of bioelectrical impedance analysis (BIA) to assess body composition in healthy and diseased individuals (including those who are overweight or obese). This approach employs a BIA equation that is tailored to the specific characteristics of the individual, including race, sex, and age [18].

It is recommended that further research be conducted in the following areas:

The findings of this study substantiate the efficacy of the proposed nutritional complex in facilitating fat burning and weight management, thereby establishing it as a promising alternative to conventional pharmaceuticals employed in the treatment of obesity.

The study indicates the importance of continued use of this compound as part of a healthy and balanced lifestyle, with an emphasis on a proper diet and regular exercise.

It should be noted that:

Long-term studies are essential for a comprehensive understanding of the dietary complex's safety and overall health effects.

The impact of nutrition and exercise on health outcomes is a key area of interest. The study posits that the optimal approach to achieving weight loss and improved overall health is to combine the use of the dietary complex with a healthy diet and regular exercise.

- The necessity for further research: The study indicates a need for further research to elucidate the mechanisms by which the dietary complex functions and its effects on fat burning and overall health.

The results of this study indicate that a new dietary compound may be an effective means of fat burning and weight management.

The results of this study are highly promising, indicating the effectiveness of a novel dietary compound in fat burning and weight management.

The study, however, highlights the necessity for further investigation to evaluate the safety and long-term effects of this compound as well as to elucidate its mechanism of action in greater detail.

In conclusion, the results of this study confirm the efficacy of nutritional supplementation in reducing body weight as a treatment option for individuals who do not have access to a controlled diet or regular physical activity. Future studies on the nutritional supplement will aim to study all age groups and to share this supplement in different regions, given that each region has its own diet.

CONCLUSIONS

The results demonstrated that regular intake of the nutritional supplement had an effective effect on body weight loss following an individualized strategy, without controlled dieting or physical activity. In particular, the greatest reduction in body weight was observed in Group 2 participants who had taken the nutritional complex. Moreover, in this group, the intake of the nutritional supplement resulted in a reduction in weight and BMI after six months. These sustained results indicate that the use of the nutritional complement component mix may be an effective product in weight control programs for the obese.

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Institutional Review Board Statement: Prior to initiating evaluations, this study received full approval from the Ethics Committee of the Tunisian National Center for Sports Medicine and Sciences (approval number LR09SEP01, 12/09/2022).

Informed Consent Statement: Each participant provided written informed consent before commencement of the study. Participation was

entirely voluntary. To ensure utmost confidentiality, all data collected from participants were analyzed with discretion.

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Conflicts of Interest: The authors declare no conflicts of interest.

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