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EVALUATION OF EFFICACY AND SAFETY OF NUTRICHARGE®S&F (AN NATURAL SUPPLEMENT) ON WEIGHT MAINTENANCE: A RANDOMIZED, PROSPECTIVE, DOUBLE BLIND, PLACEBO CONTROLLED STUDY

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ABSTRACT

Aim: The aim of the present investigation is to evaluate the efficacy of Nutricharge® S&F on weight maintenance in obese subjects by monitoring the changes in Body Weight, Body Mass Index (BMI), Body fat analysis and Waist circumference. The study was conducted for assessing the safety and tolerability of Nutricharge® S&F. As a secondary objective the quality of life was assessed by using the Moorehead Ardelt questionare.

Methodology: The study was designed in 6 phases comprising of screening, treatment period, telephonic survey and end of the visit. A total of 117 subjects were enrolled based on the inclusion and exclusion criteria. Eligible subjects were randomly assigned either to Nutricharge® S&F (investigational arm) or to matching placebo (placebo arm) in the ratio of 4:1. The general physical examination including measurement of pulse, respiratory rate, temperature, blood pressure, and systemic examination of major systems namely cardiovascular system (CVS), central nervous system (CNS), gastrointestinal (GI) and respiratory system were measured and monitored during the study. The anthropometric measurements such as Height, weight, BMI, Body fat analysis and waist circumference were also assessed. The change in the anthropometric measurements (Body Mass Index (BMI), body fat analysis and waist circumference) from baseline visit (Phase 2) to after Day 90 ± 3 (Phase 5) of treatment were determined. Safety of the investigational product was assessed from the number of adverse events occurred and judging their causal relationship to the study drug.

Results and Conclusion: It was found that by using the Nutricharge the weight and BMI in the treatment groups were significantly decreased showing the potentiality of the Nutricharge S & F towards the obesity disorders. It can be concluded that the Nutricharge S & F is an excellent product for reducing obesity and is safe for use.

Key Words: Obesity, Metabolic disorder, Nutritional supplement

INTRODUCTION

Obesity is a result of a positive energy balance and is a serious health problem throughout the world and a major concern in the individual life style. According to the World Health Organization (WHO) currently more than 1.5 billion adults worldwide are overweight, of which at least 500 million are prone to be obese [1]. Obesity is usually linked to several health disorders such as cardiovascular disease, hypertension, diabetes mellitus, and hyperlipidemia, which are collectively known as "metabolic syndrome". The number is expected to increase over the next 10 years. It is also predicted that by the end of year 2020, 3 billion adults would be overweight and more than 700 million of them would lead to a condition called as obese.

The growing prevalence of obesity is associated with significant metabolic complications like type 2 diabetes, hyperlipidemia, hypertension, and cardiovascular disease (CVD)

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causing substantial socioeconomic and physical burden on society [2, 3].

Obesity leads to chronic, excessive adipose tissue expansion resulting in an increase in the risk for cardiovascular disease, type 2 diabetes mellitus, and other metabolic abnormalities. This is primarily thought to stem from the low-grade, systemic inflammatory response syndrome that characterizes adipose tissue in obesity. With a global increase in the prevalence of obesity, nutrition and exercise play a vital role in its prevention and treatment. Natural product (neutraceuticals) interventions are currently being investigated on a large-scale basis as potential treatments for obesity and weight management. Apart from taking care of the imbalance between energy intake and energy output neutraceuticals should have the potential to ameliorate the development of oxidative stress and inflammation in obesity, thereby limiting the onset of obesity complications. Although research efforts in the past have focused individually on either the physiological or the behavioral factors involved but most contemporary research has viewed obesity as multiply determined [4].

Metabolic syndromes such as diabetes mellitus, obesity are rapidly increasing in the westernized world because of poor lifestyle habits favoring fat and sucrose enriched meals and low physical activity or sedentariness. Medical nutritional therapy is an integral component of diabetes mellitus, obesity and metabolic syndrome management. Pharmacological intervention is taken into consideration when diet associated physical exercise and healthy lifestyle is insufficient for controlling blood glucose, body weight and metabolic profile. In contrast, neutraceuticals with potential towards pharmacological action and intervention for obesity are still remains a controversial issue because of only modest long term efficacy and also concern about safety. The worldwide incidence of obesity has been rapidly increasing in the last two decades. According to WHO report, obesity has been classified as a growing epidemic, and if immediate action is not taken, millions of people will suffer from serious weight related disorders [5]. The overweight is mainly arises when there is an imbalance between energy intake, principally stored as triglycerides (food consumption), and energy expenditure (basal metabolic rate and biochemical processes).

The excess energy is primarily stored in adipose tissue in the form of triglycerides. When adipose tissue function is compromised during obesity, the excessive fat accumulation in adipose tissue, liver, and other organs predisposes the individual to the development of metabolic changes that increase overall morbidity risks [6]. Hence, the recent recognition of metabolic syndrome and its influence on health has led the researchers to consider the potential drug-food or nutrient drug interactions. This fact is due to nutrition therapy and pharmacological intervention are the major components in managing metabolic. Natural product (neutraceuticals) interventions are currently being investigated on a large-scale basis as potential treatments for obesity and weight management. Functional, health-enhancing foods, or neutraceuticals, are food-type products that influence specific physiological functions in the body. This function provides benefits to health, well-being, or performance beyond regular nutrition, and products of this nature are marketed and consumed for these value- added properties [7]. A convergence of public events on a global scale has placed obesity in the forefront of food policies and corporate strategies. While it has generated innumerable conferences and an entire low carbohydrate food passion in the short run. Its real promise is in long term proven product development of foods that are demonstrated to functionally impact obesity or neutraceuticals for obesity control.

It is a condition that includes a cluster of disorders such as obesity, diabetes, hypertension, hyperlipidemia etc. mainly due to poor nutrition. In order to deal with this syndrome, researchers have made various interventions in the treatment methods as well in terms of nutrition. The term neutraceuticals include nutritional and pharmaceutical aspects that work for the prevention and treatment of diseases and provide health and medicinal benefits. Thus, in the field of metabolic disorders where nutrition plays a major role in the overall treatment, the potential influence of food and nutrient intake on drug therapeutic effect may be crucial [8].

Efforts are made to provide a solution to the problem may be in the form of nutritional supplements which will help in combating the obesity problem. Nutricharge helps in bringing the behavioral and neutraceuticals treatments alone to improve the situation. Rather, we also suggest that such measures as regulating obesity problem aimed at all the individuals of different age groups, taxing unhealthy foods and providing resources for physical activity, among others, may be the best way to address the issue before it can become a more serious concern. Regardless of which methods are most successful, there are a variety of options already available to assist overweight and obese individuals with the weight loss process. Because identifying effective interventions for weight loss has proven to be so difficult in the past, it is not surprising that there are many different professional approaches targeted at better understanding. The purpose of this article is to explain the rationale for the development of neutraceuticals product i.e., Nutricharge S &F products that can be used adjunct to available current therapies. The ingredients in the product are described in terms of their clinical efficacy. The current article aims to examine current research on neutraceuticals and their role in the management of obesity and body composition.

MATERIAL AND METHODS

In Nutricharge S & F study the drug administration will be started after 1 month, all subjects will be fulfilling the diet plan that is Screening Visit (Day 31). All subjects' informed consent, demographics and medical history will be obtained

at screen visit and also clinical (i.e. pulse, BP, temp, respiratory rate, CVS, CNS, GI) examinations and anthropometric (i.e. Height, Weight, BMI, Body Fat Analysis, waist circumference) measurements will be performed to evaluate the subject health status to participate in the study. All the subjects, who satisfy the inclusion and exclusion criteria, will be enrolled in to the study. The distribution of males and females towards the treatment and age wise are clearly tabulated in Table 1.

During the pre screening study period (Day -30 to Day 0). The enrolled subjects will be advised to follow restricted diet advised by the medical Investigator, to assess the diet compliance to the advised diet plan. During this period, compliance to the diet plan and quality of life questionnaire will be checked at Day -21, Day - 15 and Day -7 through telephonic conversation. Subjects complying with the diet plan will be carried forward for the main study. Based on the results from screening and diet compliance during the pre screening period, a total of 117 male and female obese subjects, who satisfy the inclusion and exclusion criteria, will be enrolled into the study. Baseline visit will be performed on Day 1. The subjects will undergo treatment / drug administration assessments at the site. The age distribution in the groups included in the trail was between 19 and 60 years with average age of 31.4 years in Nutricharge S & F and 34 years in placebo respectively. The average height for both groups was same with 1.6 mts. Their body weight are between 63 and 119 Kgs with average weight of 81.7 Kgs in Nutricharge S & F and 80 Kgs in placebo respectively. Next coming to BMI of between 30 to 45 with an average BMI of 33.2 Kgs/m^2 in Nutricharge S & F and 31.9. Kgs/m^2 in placebo.

Inclusion criteria

1. Male and female subjects aged between 18 and 65 Years.
2. BMI $\geq$ 30 and $\leq$ 47
3. Subjects able to communicate effectively.
4. In the judgment of the Principal Investigator, able to comply with protocol requirements

Exclusion Criteria:

1. Contraindications or Hypersensitivity to study product or placebo.
2. History or presence of any medical condition or disease according to the discretion of the Investigator.
3. Clinically relevant conditions expected to preclude achievement of exercise recommendation.
4. Current use of vitamin or mineral supplements, nutritional supplements and or medical foods within 30 days prior to the beginning of the study and for the duration of the study.
5. Use of prescription medications and/or nonprescription medications for acute medical conditions, semi-acute medical conditions, and weight loss.
6. Use of medications known to result in significant weight gain (e.g., oral steroids or second generation anti-psychotics)
7. Hepatic, renal, gastrointestinal, respiratory, cardiovascular, endocrinology, neurologic, immunologic, or hematologic disease.
8. Diabetes mellitus, irritable bowel syndrome, Gastro-esophageal reflux disease, HIV, hepatitis B or C, malignancy, sleep apnea, insomnia (requiring use of sleeping medication more than once weekly), night eating syndrome, Anorexia nervosa, bulimia, of non-specific eating disorder, and serious psychiatric illness
9. Female subjects who are currently pregnant and breast feeding
10. Current diagnosis or history of alcoholism or drug dependence.
11. Currently taking any medication on a regular basis
12. Use of any experimental medication within 1 month prior to screening or as concomitant medications.

Subjects will undergo an evaluation to determine eligibility to participate in this study based on the assessment of the investigator. At Phase 0, for all subjects' informed consent, demographics and medical history will be obtained. A diet instructional presentation will be given followed by a meeting with Investigator to establish review, motivate and document the diet plan. In Phase 0, the following clinical examinations and anthropometric measurements will be performed to evaluate the subject health status to participate in the study. Clinical Examination: General physical examination including measurement of pulse, respiratory rate, temperature, blood pressure, and systemic examination of major systems namely cardiovascular system (CVS), central nervous system (CNS), gastrointestinal (GI) and respiratory system. Simultaneously the anthropometric measurements - Height, weight, BMI, Body fat analysis and waist circumference will be analyzed by using standard procedures.

For determining the body fat analysis the fat percentage will be measured using a commercially available digital weight scale incorporating a bioelectric impedance analyzer (HBF-375, Omron Health care Co., Kyoto, Japan). The instrument is portable and easy to use in epidemiological field surveys. Body fat percentage will be measured to the nearest 0.1 per cent. The digital weight scale includes a hand grip and foot plate, each of which is equipped with two electrodes. The two electrodes between the left and right grip were short circuited, along with those for the left and right feet. Upon measurement, the study subjects will stand on the foot plate and gently grasped the two handgrips with arms held straight forward. During the measurement, the instrument records impedance from the hands to the feet, which corresponds to the whole body impedance, by applying an electric alternating current flux of 500 µA at an operating frequency of 50 kHz.

Consequently, Body fat percentage will be calculated from the impedance value and the pre entered personal data. Total body water will be predicted from the impedance index (height2/impedance). From the total body water, the Body fat percentage will be calculated as 100 x [weight-(total body water)]/ weight. The calculation will be done by software program based on algorithm developed and patented by Omron Health Care Co., Kyoto, Japan. Impedance measured and predicted total body water, which is not displayed to user, is automatically fed to algorithm along with pre entered data and the software calculates the body fat percentage. Finally for assessing the quality of life the subjects will be questioned by using Moorehead Ardelt Quality of Life Questionnaire II: Quality of life questionnaires will be performed every day to all subjects The scores and interpretations of tests administered will be documented in the source and as well as in Case Report Forms (CRF).

RESULTS

The use of nutrition supplement has a potential effect in the evaluated parameters i.e., both physical and also the quality of life. The results of SBP, DBP and Pulse rate was not significantly changed during 90 days of treatment in both the groups and found to be negligible. The average weight of the treatment group was decreased by 6.05 (i.e. 7.4 percent) in 90 days. During the study we have observed that the weight was decreasing in the order of 1.23, 2.34, 4.18 and 6.05 during 15, 30, 60 and 90 days respectively. Over all in 90 days of exposure period a maximum of 11.1 kgs decreased was observed using the investigational product Nutricharge S&F. Similarly, using placebo, Weight also decreased by 1.35 (i.e. 1.67 percent) in 90 days which was found to be very negligible (Figure-1).

The body mass index was decreased by 2.47 (i.e. 7.4 percent) in 90 days of treatment period by using Nutricharge S & F supplement. During the study BMI was found to be decreased from 0.5, 0.95, 1.7 and 2.47 with 15, 30, 60 and 90 days respectively. A maximum 4.2 BMI decreases (i.e. 1.6 percent) was achieved in 90 days of exposure period using the nutricharge S&F. On the other hand using placebo a negligible difference of 0.51 was observed (Figure-2).

The measurement of waist is also an important parameter for assessing the obesity. During the study the waist size was measured and found that a decrease of 1.63 (42%) was observed by using the Nutricharge during the exposure period. The order of decrease of the waist size was 0.22, 0.63, 1.11 and 1.63 with treatment periods of 15, 30, 60 and 90 days respectively. A maximum of 4 inches was observed by using Nutricharge S & F. Similarly, using placebo, Waist of Size (in) also decreases 0.03 (i.e. 0.07 %) in 90 days (Figure 3). The percent fat content was analyzed and found that a decrease of 2.43 (6.46 %) in 90 days by using Nutricharge S & F. The trend of percent fat decreasing 0.44, 0.87, 1.52 and 2.43 during 15, 30, 60 and 90 days of exposure. A maximum extent of 7.6% fat content was observed using Nutricharge and placebo showed only 0.79 (i.e. 20.2 percent) in 90 days of treatment period (Figure-4).

The fat mass content was also analyzed during the study and found that a decrease of 4.12 (13.45%) in 90 days by using Nutricharge S & F. The scope of FAT Mass decreasing 0.82, 1.57, 2.75 and 4.12 with 15, 30, 60 and 90 days respectively. Finally it was found that a maximum of 7.74% FAT MASS decreases was observed by using Nutricharge supplement. A decrease of 1.03 (3.59%) was observed in placebo during 90 days of exposure period (Figure-5). Free FAT MASS content was analyzed and the results showed a decreasing 1.92(i.e. 3.76 percent) in 90 days by using Nutricharge S & F (Figure-6). It was found that the scope of Free FAT Mass was decreased from 0.42, 0.77, 1.43 and 1.92 with 15 days, 30 days, 60 days and 90 days respectively. On an average a maximum of 4.39 Free FAT MASS decreases was observed using Nutricharge S & F compared to that of placebo 0.32 (0.61 p%) in 90 days (Figure-7). The Moorehead Ardelt Quality of Life questionnaire was prepared and questioned to the subjects. The results of the feedback found to be satisfactory and maximum extent of satisfaction was observed.

DISCUSSIONS:

Obese individuals have a 50 percent to 100 percent increased risk of death from all causes, compared with normal-weight individuals. Most of the increased risk is due to cardiovascular causes. Almost 80 percent of obese adults have diabetes, high blood pressure, coronary heart disease, high blood cholesterol levels, or osteoarthritis. As the authors note, while the past decade has yielded remarkable discoveries in the regulation of body weight, this same period has also witnessed an unparalleled increase in the prevalence of obesity making it one of the nation's most pressing health problems. More recent data suggest that the situation is only worsening and that similar trends are being observed in other developed nations [4].

These startling findings have led the WHO to declare obesity a global epidemic (WHO, 1998). According to the authors, the etiology of the obesity epidemic is multiply determined. Genetics are currently thought to explain 25%-40% of the variance in BMI [4] and, while research into this area may hold promise for those with metabolic or other related abnormalities, it is unlikely to solve India's obesity epidemic, they explain High blood pressure is the most common overweight- and obesity-related health condition in men and women. For example, obese men and women are more than twice as likely, compared with men and women who are not overweight, to have hypertension. And the findings for high blood cholesterol among obese individuals compared

with those not overweight, paints the same picture. Obese and overweight persons also represent 67 percent of those with type 2 diabetes [9]. Increases in weight gain, whether modest or large, can increase one's risk of illness and death. For example, individuals who have gained 11 to 18 pounds double their risk of developing type 2 diabetes [10], while those who gain 44 pounds or more have four times the risk of type 2 diabetes. Strong evidence suggests short-term weight loss (as modest as 5 percent to 15 percent of excess total body weight) in overweight and obese individuals reduces risk factors for diabetes and cardiovascular disease.

The adverse effects of obesity are not only medical. They can also affect quality of life for individuals, limiting mobility and decreasing physical endurance. In addition, negative attitudes toward the obese still exist and often result in social, academic, and job discrimination.

In general, community-based studies in the india have not found a strong link between psychological disorders and obesity [11]. Many studies specifically examining the relationship between depression and obesity have been inconclusive [12]. However, recent studies in Europe have shown a link between obesity and depression, warranting further study in the United States.

Body image also plays a key role in individuals' emotional response to their size and appearance. People at greater risk for poor body image are most likely to be binge eaters, women, those who were obese during adolescence or with early onset of obesity, and those with emotional disturbances. Obese individuals, especially women, tend to overestimate their body size. However, body image perceptions have been known to differ among various ethnic and racial groups. For example, differences in body image and weight-related concerns between black and white girls and women have been observed. In general, black girls and women report less social pressure to be slim, fewer incidences of weight-related discrimination, less weight and body dissatisfaction, and greater acceptance of overweight than their white counterparts. These differences will have a profound effect in trying to address obesity in this country and need to be considered when discussing prevention interventions.

Although obesity-related diseases occur most frequently in adults, important consequences of excess weight occur in overweight children and adolescents as well. "Overweight adolescents have a 70 percent chance of becoming overweight or obese adults. This increases to 80 percent if one or more parent is overweight or obese [13]. Children with one obese parent face two times the risk of becoming obese adults, compared with children whose parents are not obese [14].

Moreover, many chronic conditions (for example, type 2 diabetes, high blood pressure, and high cholesterol) that were previously considered adult diseases are now seen more frequently in overweight and obese children and adolescents. For example, type 2 diabetes used to be so rare in children and adolescents that it was called "adult-onset diabetes." However, recent reports indicate that 8 percent to 45 percent of children with newly diagnosed diabetes have type 2 diabetes. The population is becoming increasingly overweight; researchers expect type 2 diabetes to appear more frequently in younger, prepubescent children.

Information that facilitates healthy food and lifestyle choices, public awareness levels regarding the importance of these choices, and behavioral and motivational programs to aid in weight control and management are critical components for an effective strategy to reduce obesity. Governmental action in this area includes a diverse range of activities, such as formal regulations related to food labeling to convey nutritional content, dietary guidelines to promote healthy eating habits, public awareness campaigns, curricula development, and model educational programs to facilitate behavioral change. Whether education is through labeling, mass media, professional guidelines, or community outreach programs, all these efforts represent population-based attempts to increase awareness and support healthy behaviors.

The Task Force on Community Preventive Services, an independent panel of scientific experts supported by the Centers for Disease Control and Prevention (CDC), conducted systematic reviews of community interventions to increase physical activity [15]. Based on available evidence, the task force recommended several interventions related to information dissemination and education to provide behavioral and social support for physical activity.

The task force found sufficient evidence to support the efficacy of community interventions involving:

- Comprehensive, high-visibility community campaigns to promote physical activity.
- Point-of-decision prompts to encourage stair walking.
- Behavior-change group programs.
- School-based physical education.
- Improved social support networks or "buddy programs" to encourage physical activity.

The task force found that the available evidence was insufficient to demonstrate the effectiveness of mass media campaigns, classroom-based education, and college-age physical education. Similar evidence reviews are currently being conducted for community interventions related to nutrition and dietary patterns.

In addition to sponsoring clinical trials that examine techniques for and health effects of obesity treatment, NIH [16] also supports research focused on identifying the external conditions that prevent obesity and facilitate obesity treatment. These studies examine the social, cultural, psychological, economic, environmental, and other determinants that

influence food intake and physical-activity patterns, as well as evaluating environmental and policy interventions seeking to modify these determinants.

STATISTICAL ANALYSIS

All baseline demographics and characteristics are performed by using SAS version 9.2 (SAS Institute Inc., Cary, NC, USA). P<0.05 were considered statistically significant. The descriptive statistics for continuous variables will be presented with number (n) of non-missing observations, Mean, Standard Deviation (SD), Median, Minimum and Maximum. For categorical data, descriptive statistics will be presented with number (n) and their percentages

CONCLUSION

In conclusion, the evidence on an average of weight decreases by 6.05 (i.e. 7.4 %), maximum 11.1 weights decreased and also on an average of BMI decreases by 2.47 (i.e. 7.4 %), maximum 4.2 BMI decreases in 90 days by using Nutricharge S & F. Similarly, using placebo, Weight decreased by 1.35 (i.e. 1.67 %), BMI also decreases 0.51 in 90 days since they follow diet plan first one month .The evidence on an average of Waist of Size decreasing 1.63 (i.e. 4.2 %), maximum 4 Waist of Size decreases and on an average of FAT % decreasing 2.43 (i.e. 6.46 %), maximum 7.6 FAT % decreases in 90 days by using Nutricharge S & F, Similarly, using placebo, Waist of Size decreases 0.03 (i.e. 0.07 %), FAT% also decreases 0.79 (i.e. 20.2 %) in 90 days. The evidence on an average of FAT MASS decreasing 4.12 (i.e. 13.45 %), maximum 7.74 FAT MASS decreases and on an average of Free FAT MASS decreasing 1.92(i.e. 3.76 %), maximum 4.39 Free FAT MASS decreases and also on an average of Free FAT MASS Index decreasing 0.78 (i.e. 3.76 percent), maximum 1.72 Free FAT MASS Index decreases in 90 days by using Nutricharge S & F. Similarly, using placebo, FAT MASS also decreases 1.03 (i.e. 3.59 %), FAT MASS also decreases 0.32 (i.e. 0.61 %), Free FAT MASS Index also decreases 0.10 (i.e. 0.48 %) in 90 days. The above results conclude that Nutricharge S & F is an excellent product for reducing obesity and is well tolerated and safe for use.

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Table 1: Summary of demographic characteristics with respect to age and gender.

Variable	Nutricharge S & F(N=80)	Placebo (N=20)
Gender		
Female	51(63.8%)	9 (45%)
Male	29(36.3)	11 (55%)
Age Group		
18-35	57(71.3%)	11(55.0%)
36-45	17(21.3%)	9(45.0%)
46-60	5(6.25%)	
61-65	1(1.25%)	

Note: The denominator for percentages is the total number of subjects in the treatment arm for a particular dose. Total of 100 subjects, 80 subjects were treated with Nutricharge S & F and 20 with matching placebo. The distribution of male and female in the study were 51 (63.8%) and 29 (36.3%) in Nutricharge S & F and 9 (45%), 11(55%) in placebo.

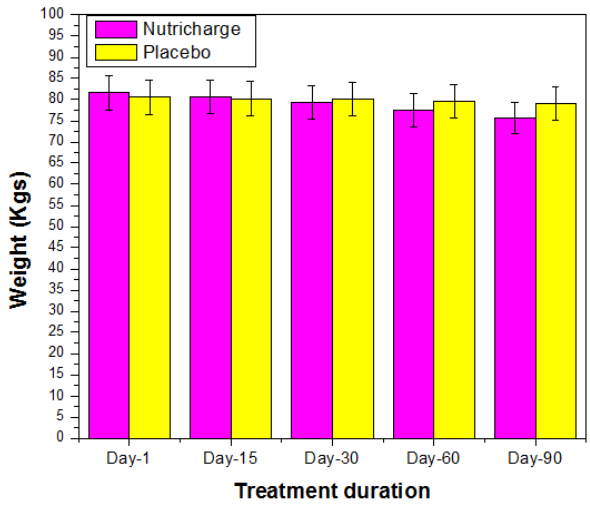

Figure 1: Graphical representation of the weight variation duration the treatment of nutricharge in comparision with placebo.

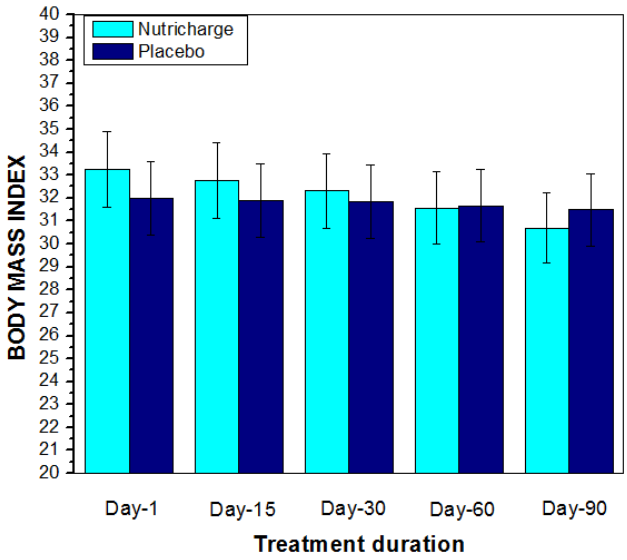

Figure 2: Graphical representation of the body mass index during the treatment of nutricharge in comparision with placebo for a priod of 90 days.

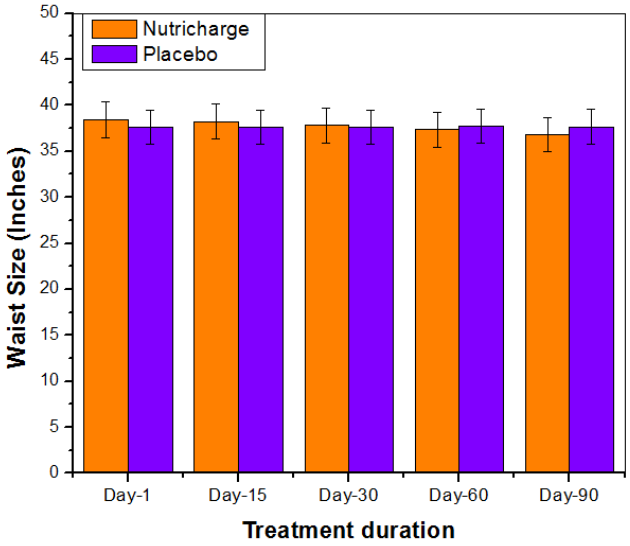

Figure 3: Differences in waist size during the treatment of nutricharge in comparision with placebo.

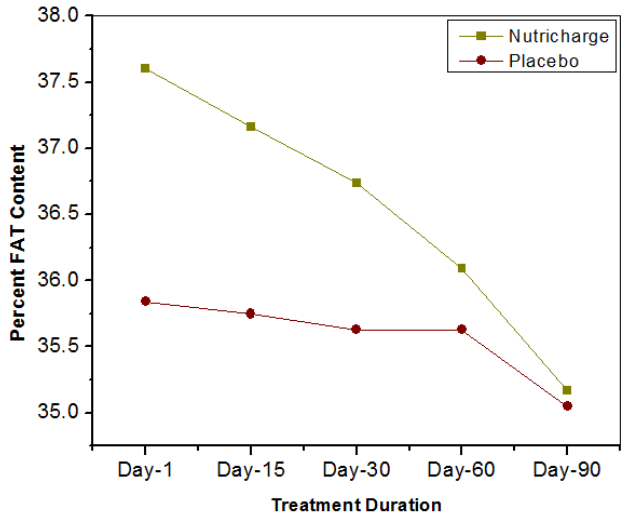

Figure 4: Percent fat content analyzed during the usage nutricharge in comparision with placebo.

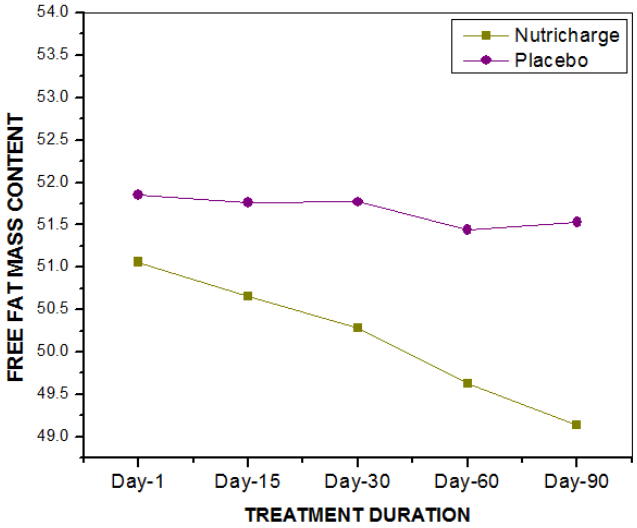

Figure 6: Variations in percent free fat mass content determined during treatment of nutricharge in comparision with placebo.

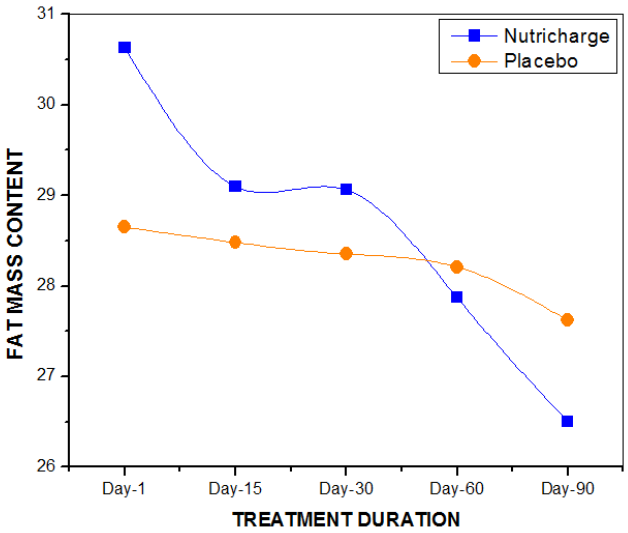

Figure 5: Graphical representation of the fat mass content analyzed during the exposure period of nutricharge in comparision with placebo.