

## Food Allergen Eliminations for Obesity Reduction: A Comparison Study with Therapeutic Exercise

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Received: 11 August 2018; Accepted: 04 September 2018

**Citation:** Buck Willis F, Ram Shanmugam, Sarah A Curran. Food Allergen Eliminations for Obesity Reduction: A Comparison Study with Therapeutic Exercise. Food Sci Nutr Res. 2018; 1(1): 1-6.

### ABSTRACT

*It has been estimated that over 75% of the US population have hidden food allergies which may be a contributing cause to the obesity epidemic. The purpose of the comparison, study was to compare changes from removing food allergens (alone) versus food allergen elimination combined with proven multi-discipline protocols for obesity reduction.*

**Methods:** Seventeen subjects had food allergen identification performed (leukocyte reactions, ALCAT tests) and these foods were eliminated. Ten subjects chose to also employ proven Combined Treatment protocols (Eating natural foods 5/day in "Single-portion" sizes and performing brief "Aerobic-surge" exercises 5/day). The duration of this study was 90 days.

**Results:** There was a significant change in weight for all subjects ( $P < 0.0001$ ) and there was also a statistically significant difference between groups ( $P < 0.0001$ ). In comparison, the Combined Treatment showed a 75% greater weight loss (-12.4Kg), 80% greater fat percentage reduction (-5.4%), and 70% greater BMI reduction (3.6).

**Conclusion:** Food allergen elimination was beneficial for obesity reduction in this comparison study and use of food allergen elimination with therapeutic protocols was even more effective.

### Keywords

Aerobic-surge Exercise, ALCAT testing, Weight loss, Immunoglobulin.

### Introduction

Obesity in the United States, currently affects over 118 million adults (36.5%), based on Body Mass Index (BMI)  $> 30$  (1-39). This Disease costs over \$150 Billion dollars in the USA each year, and the CDC states that "The (annual) medical costs for people who have obesity were \$1,429 higher" (than non-obese adults). Currently the demographics of this disease show that the largest ethnic group is among Black Americans (non-hispanic) and the greatest age group is 40-59 [1] (Figure 1).

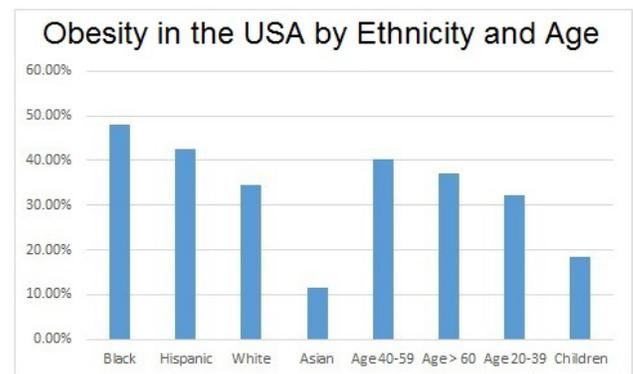


Figure 1: Ethnic Obesity Demographics.

Food allergies are estimated to affect up to 75% of the US population [2-5]. While food allergy testing and elimination have been studied for reduction of migraine headaches [7,8] and intestinal disorders [9,10], the research has not been extensive in determining the efficacy of food allergy elimination in obesity reduction. Many weight loss protocols have been examined [4,10-25,26,27] but only a few studies have investigated identifying and eliminating the causes of obesity.

Lewis et al examined food allergen elimination in a study for weight reduction [5]. They tested 120 overweight subjects (mean age 45.5, BMI = 29) for IgG food allergens and foods that had a positive reaction were removed from experimental subjects diet for 90 days. These subjects saw significant changes in weight and waist/hip circumferences. The mean value changes are as follows: Weight (-5kg, P<0.01) and Waist circumference (-5.4cm, P<0.01). However that particular study did not test for other Ig reactions nor did they include other proven protocols for weight reduction in obese subjects [5].

“PAN-5” is an effective combination of separately proven protocols and the acronym means: Portion sized meals eaten more frequently (< 2 cups, 5/d) [10,11] Aerobic-surge Exercise (brief, high intensity) for 2-minutes, 5/d [14,16,18-21,25,29], and Natural foods which must be eaten 5 times/day within the <2 cup maximum serving [11,12,28,30-33].

A portion-sized study was completed by Kesman et al. who examined 65 obese adults (Mean age 55.8 and BMI > 30 to 40) and their intervention included a Portion-size plate (2 cups) with separations for food groups [11]. After six months there was a significant change between experimental vs control groups (P=0.41) and the mean changes were -2.4% Δ body weight for Portion Plate vs +2.2% Δ body weight for the control group [11].

A key study by Iwao et al was conducted on Olympic boxing athletes and they examined both frequency of eating and portion size on weight loss in a two week study [13]. Twelve boxers were separated into two categories, one group ate 6 meals/day (6M) and one group ate 2 meals/day (2M). The same daily food quantities were divided into six meals or two meals, and all boxers had similar exercise and training regime. Both groups lost weight and while there was not significant difference in the weight change, the 6M group had a 90% greater change in body fat than the 2M group. This study showed that eating smaller portions sizes, more frequently, yielded a far greater fat reduction for the 6M group [13].

Brief duration, High Intensity exercises have been a recent addition to the protocols used in weight loss [14-16,19-21]. A study by Fisher examined using High Intensity Interval Training (HIIT) vs. Moderate Intensity Training (MIT) for Improving Cardio metabolic Health in Overweight or Obese Males [14]. This study examined 28 healthy, overweight or obese males, (age 20, BMI 25 - 35) and this study lasted 6 weeks.

The HIIT exercise intervention included 20-minute, interval

training on a cycle ergometer at 15% of max anaerobic power (four minutes), followed by 85% of max anaerobic power (30 seconds). The interval cycle was completed four times per exercise session, on three training rides were completed each week. In comparison the MIT group trained at 55% of peak VO<sub>2</sub> for 45-60 minutes of continual cycling, five days/week. The total time training over the 6-week study duration was as follows: HIIT = 360 minutes vs. MIT = 1,350 minutes. Even with a 3.75 times lesser duration in training, difference between groups was only seen in one of eight variables.

The mean change in peak VO<sub>2</sub> was greater for MIT (MIT 11% vs HIIT 2.3%, P=0.0185), however there was no significant difference in all of the other six outcome measures: weight, total cholesterol, triglycerides, HDL, LDL, and insulin sensitivity (p>0.05). HIIT only required 27% of the time dedicated to exercise, and this time duration could heighten compliance for daily use.

A new, brief Aerobic-surge protocol includes exercising at ≥ 75% of a deconditioned person’s estimated maximum heart rate for only two minutes, and this formula is (220-age) x .75 = target Aerobic-surge heart rate [15]. This brief 2-minute bout was performed five times/day and was tested in a randomized, controlled, multi-centre trial by Willis et al. Forty-six obese subjects (mean age 39, mean BMI = 34) completed participation at three sites in this 60-day trial. The Aerobic-surge subjects (N=23) were taught how to elevate their HR to the target heart rate (≥ 75% of max HR) and measure this from their carotid pulse. The exercises included stationary bicycling, stair climbing, vigorous scissor kicks, and other similar exercises to elevate their HR to the target rate. In comparison the Control subjects (N=23) were simply told to “exercise more” which is a common instruction given in primary care.

The dependent variables in that study were changes in weight (pounds) and ‘Body Summation’ of 10 girth measurements. A 2x2 ANOVA was used to calculate differences. There was a significant difference between groups (P<0.0001), and the mean changes were as follows: EXP = -8.2Kg and -47cm vs. Control +0.6Kg and +4.3cm [15].

Eating natural, unprocessed foods was examined in a study testing the ‘New Nordic Diet’ by Polsen et al. [27]. They compared the ‘Average’ diet (control) to the New Nordic Diet (NND) which removed the processed foods and substituted with natural foods (high in fruits, vegetables, fish, and whole grains). In that study 181 obese subjects (mean age 42) were randomly selected for either the NND group or the Average diet for 26-weeks.

The dependent variable was change in weight and there was a significant difference for the NND vs Average group. The NND subjects showed a mean change of -4.7 kg vs the Average diet group lost only a mean -1.5kg (P < 0.001). There were also significant differences seen in Fat change (1.87% difference, P < 0.001), Waist circumference (-2.94cm difference, P < 0.001), and in Systolic blood pressure (-5.13 mm Hg difference, P < 0.001) [27].

These studies showed the combined benefits from reducing Portion sizes (with greater meal frequency), Aerobic-surge or high intensity exercise, and the benefits of eating Natural foods. The purpose of the comparison study was to compare changes from removing food allergens (alone) versus food allergen elimination combined with multi-discipline protocols for obesity reduction.

## Methods

Twenty obese adults were recruited (mean age 50) and all had a Body Mass Index rating > 30 (mean BMI = 34). After signing informed consent (as approved by the IRB), all subjects were screened to eliminate other pathologies such as cardiovascular disease, and three subjects were excluded because of arrhythmia, and history of MI. All enrolled subjects (7 men, 10 women) had at least a 6-month wash out period from any other weight loss protocol or product(s).

Six blood vials were drawn from each subject for food allergen testing (leucocyte reactions) and this ALCAT test of 237 foods was completed by the Cell Science System laboratory (Deerfield Beach, FL). Within one week the results were returned and the Principle Investigator (PI) who explained the results to each subject. Any foods that had any leucocyte reactions were eliminated from their diet and the duration of this study was 90 days. (The mean number of foods eliminated was 26 of 237 tested.)

Subjects were then tested for body weight and the body fat percentage using the Omron electrostatic body composition testing equipment. (One Omron body fat test reading was validated with both caliper testing and BodPod testing in one subject.) All patients resided in different cities in Texas and were tested in their location.

Control subjects only chose to remove the food allergens (N=7). Other subjects volunteered to also employ the combined treatment system (N=10) which includes the following:

- Portion-size meal control (consuming < 2 cups), five times per day.
- Aerobic-surge exercise (HR elevated  $\geq$  75% max for 2 minutes), performed 5/day.
- Natural Foods eaten five times per day (included within the < 2cup portion size).

PAN5 subjects were taught these protocols and sent daily accountability text messages to the PI stating their "Count" of Portion-sized meals/Aerobic-surge exercises/Natural foods, (i.e. 5/5/5). The PI sent encouraging text messages daily and spoke with each subject weekly, with Tele-medicine meetings monthly. The dependent variables in this comparative study were changes in body weight, body fat percentage, and BMI. Subjects were given the results of their participation during the 90-day follow up and testing session. (Subjects were not involved in the design of the trial but determine their own choice of protocols and exercises if a PAN-5 subject.)

## Results

In comparison, Combined Treatment subjects showed a 75%

greater weight loss, 80% greater fat percentage reduction, and 70% greater BMI reduction than subjects (Figure 2).

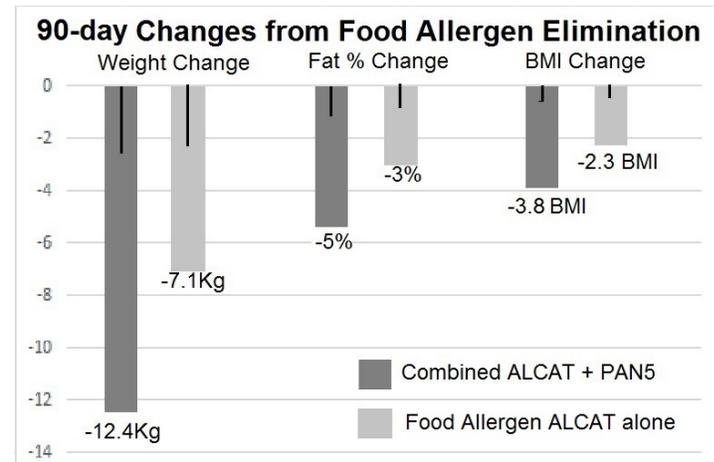


Figure 2: Study Results.

The data are analyzed in three comparisons: 1) Food Allergen Elimination Only, Pre/Post. 2) Combined Treatment (Food Allergen Elimination + PAN5), Pre/Post. 3) Food Allergen only group vs Combined Treatment group.

### Category 1: Food Allergen Elimination Only

There were seven participants with an average age of 49.8 years, whose average changes in weight (Kg), fat %, and BMI were respectively -7.11, -3.02 and -2.31 with the standard deviation (a measure of homogeneity) 4.6, 1.2 And 0.62. They were more homogeneous with respect to BMI change but less homogenous with respect to fat change and more heterogenous with respect to weight change. Because of the smaller sample size, we did not capture meaningful comparisons with respect to the ages in years. However, we notice that the weight changes are more heterogenous among males, fat changes are more heterogenous among females, and BMI changes are more heterogeneous among females.

The interaction between the gender and age is not estimable for lack of enough replications. By controlling the gender factor, only partial correlation between the weight change and the fat change is significant (corr = -0.963, p value = 0.002). By controlling the impact of age factor, only the partial correlation between the fat change and the weight change is significant (corr = -0.906, p value = 0.013). By performing a factor analysis with a 91.15% of the total variations into consideration, we note the proximities among the variables the age, gender, weight, fat, and BMI changes.

### Category 2: Combined Treatment (Food Allergen Elimination + Pan-5)

There were ten participants with an average age of 50.4 years, whose average changes in weight (Kg), fat %, and BMI were respectively -12.44, -5.4, and -3.8 with the standard deviation (a measure of homogeneity) 2.5, 1.6, and 0.81. They were more homogeneous with respect to BMI change but less homogenous with respect to fat change and more heterogenous with respect to

weight change. The comparisons of weight change, fat change and BMI change across the ages in years indicate that a heterogeneous weight change exists at 48 years rather than in other ages; fat changes are heterogeneous at 52 years rather than in other ages, and BMI changes are heterogeneous at 48 years rather than in other ages.

Likewise, we notice that the weight changes were more heterogenous among females, also fat changes were more heterogeneous among females, and BMI changes are more heterogeneous among males. The trend of weight changes over the age in years is seen in the Figure 3. An analysis of variance (AOV), with an adjusted R-square = 99.9%, indicates that there is a significant interaction between the gender and age ( $F = 150.275$ ,  $p$ -value = 0.003). By controlling the gender factor, the partial correlation between the weight change and the BMI change is significant ( $\text{corr} = -0.631$ ,  $p$  value = 0.068) but between the weight change and fat change is insignificant ( $\text{corr} = 0.176$ ,  $p$  value = 0.65).

By controlling the impact of age factor, only the partial correlation between the fat change and the BMI change is somewhat significant ( $\text{corr} = -0.583$ ,  $p$  value = 0.09) while the weight change is insignificant with fat change or BMI change. By performing a factor analysis with an 85% of the total variations into consideration, we note proximities among the variables the age, gender, weight, fat, and BMI changes.

### Category 3: food allergen elimination vs. combined treatment

Here, we notice a two-way design layout for the changes with three rows ( $i=1$  for kilo gram,  $i=2$  for fat and  $i=3$  for BMI) and the two columns ( $j=1$  for Combined Treatment and  $j=2$  for elimination only). By performing a two-way AOV with an adjusted R-square = 92% on the dependent variable change, we notice that not only their row and column factors have a significant interaction ( $F = 18.72$ ,  $p=0.001$ ) but also their rows are significantly different from each other ( $F = 233.16$ ,  $p = 0.001$ ) as much as their columns are also significantly different from each other ( $F = 51.66$ ,  $p = 0.001$ ). Multiple comparisons were necessary in this analytic situation. The 95% confidence intervals are computed for the changes and they are  $-7.01 < \text{Kg} - \text{fat} < -4.6$ ,  $-14.6 < \text{Kg} - \text{BMI} < -12.29$ , and  $-8.84 < \text{fat} - \text{BMI} < -6.47$ . Because zero is not contained in these brackets, everyone in the pair is significantly different from its companion. Lastly, the impact of combined food allergen elimination is significantly different from the impact of food elimination only with  $F = 17.63$  and  $p = 0.001$ .

### Discussion

The overall changes in weight by age were broad (Figure 3), however the changes by gender were homogenous, (Figure 4). Food allergen testing has been shown beneficial in reducing other diseases. Ali et al used the same ALCAT leucocyte reaction test (Cell Science Systems Laboratory, Deerfield Beach, FL) for food allergen elimination in a double-blind study for treating Irritable Bowel Syndrome (IBS) [9]. They tested 58 subjects for reactions to 237 foods and randomly assigned subjects to either a Food Allergen elimination 4-week diet (Experimental) or a sham diet

that did not reduce the allergens (control).

### Trend of Weight Change by Age Group

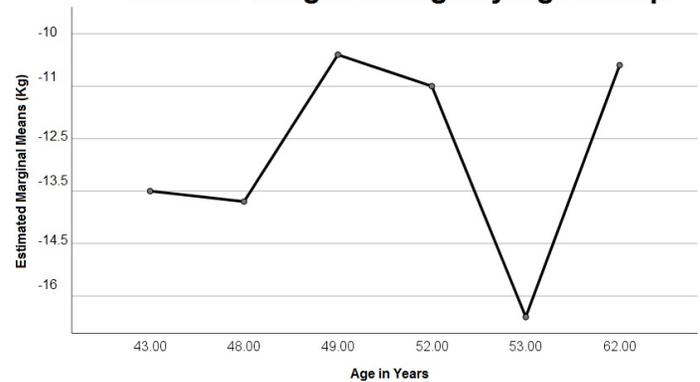


Figure 3: Trend of Weight Change by Age Group.

### Changes in BMI by Gender

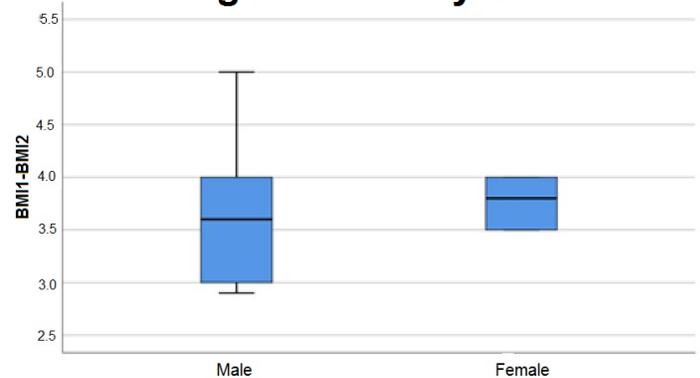


Figure 4: Changes in BMI by Gender.

The primary outcome measure in that study was difference in the IBS Global Improvement Scale (GIS). The experimental group showed significant improvement in the GIS scores at four weeks ( $p = 0.04$ ) and following eight weeks ( $p = 0.02$ ). The control group did not experience such changes ( $p > 0.05$ ) [9]. Eliminating the food allergens reduced inflammation which benefited those patients by reduced symptom scores. This is similar to how food allergen elimination benefitted obese subjects in our study.

The combined PAN-5 system works to increase daily metabolic rates which move beyond the old adage of “energy in vs energy out,” and in this study has been shown to increase basal metabolic rates anecdotally with changes in resting energy expenditure. The strategy of eating more frequently in smaller portion sizes is in agreement with several studies [5,12,13], and our comparison study showed the similar result as seen in Iwao’s study because the vast majority of weight lost was from the reduction of fat [13].

High intensity interval training has shown to reduce fat and Bagley et al examining the effects of sprint interval training in 41 subjects (mean age 39, BMI = 24.6) in a 12 week study [16]. The sprints were four, 20-second sprints (3/week) above the Peak VO<sub>2</sub> aerobic threshold on cycle ergometer. There was a significant

change in Total Body Fat ( $P < 0.001$ ) which is interesting because this protocol required just 4 minutes of exercise per week. This is comparable to the Willis et al Aerobic-surge study which included only 70-minutes per week in the 2-minute Aerobic-surge exercise (5/day) was effective in reducing fat [15]. This also confirms the results in brief, high intensity training by Fisher et al [14].

In a pediatric study, Torbahn et al showed efficacy of both portion control and natural foods for treating childhood obesity [17]. In their study of 279 pediatric patients, a preliminary nutritional assessment was completed from forms that were given to the parents, (Subject ages 8 – 16, with BMI  $\geq$  90% percentile to 97th percentile). Their interventions including portion-sized controls, reduced “eating rate” (speed), and frequency of eating “red, green, and yellow” natural foods (as opposed to packaged snack foods that were previously eaten). A significant change was noted in BMI for those patients at both one and two years ( $P < 0.01$ ) [17].

Obesity continues to rise [1,2-6,11-27] and the causes of this disease must be identified in hopes of a lifetime cure. Once the causes such as food allergens are eliminated, this disease can be reversed with interdisciplinary protocols. The purpose of the comparison study was to Evaluate changes from removing food allergens (alone) versus food allergen elimination combined with multi-discipline protocols (PAN-5) for obesity reduction.

## Conclusion

There is significant evidence that hidden food allergies may be one meaningful cause of the growing obesity epidemic and eliminating food allergens will begin by decreasing daily weight gains, to empower weight loss. The combination of the protocols in PAN-5 system have shown even greater changes (improvement) by eating smaller portion sizes more frequently, participating in a brief, high intensity Aerobic-surge exercise for two minutes (5/day), and eating natural foods five times a day (within the portion size).

A future randomized, controlled trial should examine differences between food allergen elimination vs. PAN-5 in a cross-over examination, with longitudinal outcomes to evaluate if food allergen elimination with combined treatment plans can become a cure for the obesity disease.

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