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Eliminating Immunologically-Reactive Foods from the Diet and its Effect on Body Composition and Quality of Life in Overweight Persons

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Abstract

Background: Given the relationship between chronic disease and poor nutritional habits, using strategies to address the crisis of poor health in the U.S. is necessary. We explored if overweight people wanting to lose weight could benefit from having the Immuno Bloodprint, a proprietary IgG-mediated food sensitivity test to determine which foods to eliminate from the diet. IgG-mediated antibodies are thought to be causal in some food hypersensitivity and thus related to overweight status.

Objective: This study assessed the effect of an IgG-mediated food sensitivity test in combination with a food elimination diet on body composition and secondary outcomes in people who wanted to lose weight and/or were overweight.

Methods: A total of 120 subjects aged 18 and over took part in the study. Subjects had to eliminate all reactive foods from their diet for 90 days. Body composition, blood pressure and pulse, and quality of life were assessed at baseline and 30-, 60-, and 90-day follow-up.

Results: Subjects who eliminated IgG-mediated reactive foods from their diet had reductions in weight, body mass index, waist and hip circumferences, resting diastolic blood pressure and had improvements in all indicators of quality of life according to the SF-36 from baseline to 90-day follow-up.

Conclusions and Context: Subjects were able to improve their body composition and quality of life in response to eliminating IgG reactive foods from the diet. This test may represent a strategy to counteract the severe U.S. obesity epidemic.

Abbreviations: Body mass index (BMI), Immunoglobulin E (IgE), Immunoglobulin G (IgG), and Waist/hip ratio (WHR).

Keywords: Food Sensitivity Testing; Elimination Diet; Obesity

Introduction

Chronic diseases, such as cardiovascular/heart disease, obesity, and diabetes, account for the majority of deaths in the U.S. each year, and the care of these patients accounts for more than 75% of the nation's medical costs [1]. In addition, behavioral causes, such as poor diet and being sedentary, account for nearly 40% of all deaths [2]. Many recent studies have implicated dietary factors in the cause and prevention of significant diseases, including obesity and heart disease. Thus, the best strategy for improving the health of the nation and reducing the number and costs of premature deaths lies in changing behavior, such as eating better.

Chronic diseases are likely to be multi-factorial involving a number of different predispositions, although the degree of the effect of any factor may vary from person to person. Many people are aware that dietary habits contribute to their condition, and some also believe that dietary intolerance, allergy, or sensitivity causes their symptoms so removing reactive foods from the diet may be beneficial. Determining food intolerance is typically difficult due to its uncertain etiology, non-specific symptoms, and relative inaccessibility of the affected organ. Thus, many efforts to test for food intolerance, especially in sufferers of digestive disorders, have predominantly looked at food allergy due to the incidence of Immunoglobulin E (IgE)-mediated antibody responses, although these immediate type reactions appear to be rare [3].

Therefore, symptomatic reactions to food might be caused by another immunologic mechanism, rather than dietary allergy. Such reactions might be Immunoglobulin G (IgG)-mediated antibodies, which result in a delayed response following exposure to a particular antigen, compared to IgE [4] and are suggested to be causal in some food hypersensitivity [5-7]. However, this mechanistic explanation is not consistently believed and is considered by some to be physiological [8-10], due in part because IgG food antibodies have been found in apparently healthy persons [11-13]. Nonetheless, IgG food antibodies may play a role in certain conditions, such as irritable bowel syndrome [14], obesity [15], type I diabetes [16], and migraine [17]. Thus, the purpose of this study was to evaluate the effectiveness of a novel food sensitivity test, the Immuno Bloodprint, in combination with an elimination diet based on the presence of IgG antibodies to food in persons wanting to lose weight and/or who were overweight or obese according to body mass index (BMI).

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Materials and Methods

Subjects

Potential subjects (n=120) who were interested in losing weight were recruited, screened, and enrolled at the University of Miami Miller School of Medicine between 2008 and 2010. The study was conducted with the approval of the Institutional Review Board for human subjects research, and all participants signed informed consent before commencing in the study. The sample comprised of 16% males (n=19) and 84% females (n=101) with a mean age of 45.5 years (SD=12.2; R=20, 70). The racial/ethnic distribution of the sample was as follows: 51% Hispanic (n=61), 38% white, non-Hispanic (n=46), 6% black, non-Hispanic (n=7), and 5% of other types (n=6).

Sample size

Based on the results of Atkinson et al. (2004), who utilized an IgG-mediated test and subsequent 12-week elimination diet for GI symptoms, we estimated that our sample would achieve at least a 5% improvement in body weight at the end of the intervention period (from baseline to 90-day follow-up) [18]. We calculated that a sample size of 75 subjects (with at least 80% power and an alpha level = 0.05) would be necessary to detect this difference. Our goal was to enroll at least 100 subjects in the study, and we were able to enroll 120.

Study design

Potential study candidates were approached and screened among consecutive patients who were being treated at the Internal Medicine Clinics and at the Center for Complementary and Integrative Medicine. Potential subjects were being treated for a wide range of medical and mental health problems and were identified by the clinicians as potential candidates for needing to lose weight. Subjects were identified as individuals with BMI 20 and above and/or who expressed an interest in losing weight. Subjects were enrolled in the study if they were not: (1) less than 18 years of age; (2) currently participating in another research trial for weight loss; (3) suffering from serious medical complications that might limit their participation, such as recent heart attack, stroke, or chronic kidney disease; and/or (4) pregnant. Each subject agreed to eliminate the reactive foods from the diet for 90 days based on the results of the IgG-mediated test.

After fulfilling inclusion/exclusion criteria at screening, subjects made an appointment with study staff to have blood drawn. The tube of blood was sent to Immuno Laboratories, Inc. (Ft. Lauderdale, FL) for processing and analysis. Immuno Laboratories, Inc. is licensed federally and in several states, is accredited by the College of American Pathologists, and utilizes a proprietary test known as the Immuno Bloodprint. The test utilizes microtiter plates with tiny wells that hold antigens of 115 commonly eaten foods and ingredients (see Appendix 1), and the participant's blood is tested with each antigen. Laser-like light beamed on a micro plate reads precisely which foods are reactive to each participant's blood based on IgG reactions to each antigen.

The participant was scheduled to return to receive the results and complete the baseline assessment. Subjects were provided with the test results and an individualized dietary plan based on replacing reactive foods with non-reactive foods as replacements per the Immuno Bloodprint results. A rotation plan of the non-reactive foods and general information about healthy eating, food preparation, and shopping was given to each participant. No other behaviors were addressed in the recommendations for each participant. The primary advice to each participant was to focus as much as possible on eliminating the reactive foods from the diet for the entire 90-day period. All participants were encouraged to contact the study team with questions, as they implemented their elimination diet.

Outcomes and assessment schedule

Each participant completed a basic demographics and medical history questionnaire at baseline. They were also asked to note any changes in type or amount of their medications during the course of the study. Criteria used to select the assessment instruments included: a) appropriateness for the population; b) ease of administration and scoring; c) experience administering these measures; and d) employment of measures involving a multi-method (i.e., self-report and physical measures) approach to enhance the validity of the overall assessment.

The primary outcomes of this study were measures of body composition, including: height and weight to assess BMI and hip and waist circumference to calculate waist/hip ratio (WHR). Subjects completed a 3-day food record at each assessment to list all food and beverage consumption during that particular time. Subjects recorded their intake from two weekdays and one weekend day prior to the assessment appointment to allow for fluctuations over a normal weekly period. Participants were instructed on how to complete the 3-day food record using common portion sizes and household measures. The 3-day food record at each assessment was used to gauge compliance to the elimination diet based on a comparison of the foods eaten during those three days to the Immuno Bloodprint results of reactive foods for that subject. For example, if a subject ate 20 different foods during the 3-day period and one of the foods was IgG-reactive according to the Immuno Bloodprint results, then the subject was 95% compliant with the diet for that particular assessment. We also assessed resting blood pressure and heart rate and quality of life with the SF-36 Health Survey [19], which provides psychometrically-based physical and mental health summary measures and a preference-based health utility index. The SF-36 provides a t-score for each scale or domain ranging from 0-100 with higher scores representing better perceived quality of life. Subjects were assessed on all outcome variables at baseline and 30-, 60-, and 90-day follow-up.

Statistical analysis

Data were analyzed using SPSS 19 (SPSS Inc., Chicago, IL) for Windows. Frequency and descriptive statistics were calculated on all variables. We utilized Linear Mixed Modeling (LMM) to assess the fixed effect of time on changes in our outcome variables from baseline to the 90-day follow-up period. If the type III test of the fixed effect of time and the parameter estimate of the baseline to the 90-day fixed effect were significant, then we used pairwise comparisons to determine the unique differences between baseline and follow-up values at 30, 60, and 90 days. LMM allowed us to account for subject attrition, inter-correlated responses between time points, and non-constant variability. The criterion for statistical significance was $\alpha = 0.05$

Results

For all participants, the average number of IgG-reactive foods and ingredients was 14.8 (SD=7.2) with a range of 5 to 34. Average percent compliance to the diet was as follows: 30-day follow-up, 97.8%

(SD=4.4, R=85.7, 100); 60-day follow-up, 95.2% (SD=8.2, R=71.4, 100); and 90-day follow-up, 94.7% (SD=8.0, R=77.8, 100). The top 10 most frequently tested IgG-reactive foods and ingredients were: mushroom (25%), pinto bean (28.3%), tomato (30.8%), kidney bean (36.7%), cheese (42.5%), egg (60%), wheat (65%), cow's milk (66.7%), baker's yeast (87.5%), and brewer's yeast (94.2%).

Table 1 shows the descriptive values of body composition, systolic and diastolic blood pressure, and heart rate at baseline and 30-, 60-, and 90-day follow-up. For weight, a significant fixed effect was found for time (F[3,27.7]=17.1, p<0.001), and the parameter estimate between baseline and 90-day follow-up was also significant (t[34.6]=4.0, p<0.001). Pairwise comparisons revealed that weight at baseline was significantly higher than at 30 days (mean difference=3.7; SE=0.6; 95% CI: 2.1, 5.2; p<0.001), at 60 days (mean difference=5.1; SE=0.9; 95% CI: 2.6, 7.5; p<0.001), and at 90 days (mean difference=5.5; SE=1.4; 95% CI: 1.7, 9.4; p=0.002). For BMI, a significant fixed effect was found for time (F[3,30.5]=17.4, p<0.001), and the parameter estimate between baseline and 90-day follow-up was also significant (t[36.2]=4.9, p<0.001). Pairwise comparisons revealed that BMI at baseline was significantly higher than at 30 days (mean difference=0.65; SE=0.10; 95% CI: 0.38, 0.93; p<0.001), at 60 days (mean difference=0.97; SE=0.14; 95% CI: 0.57, 1.37; p<0.001), and at 90 days (mean difference=1.07; SE=0.22; 95% CI: 0.46, 1.67; p<0.001). For waist circumference, a significant fixed effect was found for time (F[3,40.7]=17.1, p<0.001), and the parameter estimate between baseline and 90-day follow-up was also significant (t[34.5]=6.8, p<0.001). Pairwise comparisons revealed that waist circumference at baseline was significantly higher than at 30 days (mean difference=2.07; SE=0.47; 95% CI: 0.78, 3.36; p<0.001), at 60 days (mean difference=1.85; SE=0.47; 95% CI: 0.56, 3.15; p=0.01), and at 90 days (mean difference=2.35; SE=0.35; 95% CI: 1.38, 3.33; p<0.001). For hip circumference, a significant fixed effect was found for time (F[3,32.0]=4.31, p=0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[20.5]=3.1, p=0.005). Pairwise comparisons revealed that hip circumference at baseline was significantly higher than at 90 days only (mean difference=1.33; SE=0.42; 95% CI: 0.10, 2.57; p=0.05). For waist-to-hip ratio, a marginally non-significant fixed effect was found for time (F[3,34.2]=2.76, p=0.06), but the parameter estimate between baseline and 90-day follow-up was significant (t[31.5]=2.8, p<0.01). Pairwise comparisons revealed that waist-to-hip ratio at baseline was marginally higher than at 90 days only (mean difference=0.04; SE=0.01; 95% CI: 0.01, 0.07; p=0.05).

For systolic blood pressure, the fixed effect for time was non-significant (F[3,41.2]=2.30, p=0.09), but the parameter estimate between baseline and 90-day follow-up was significant (t[51.9]=2.5, p<0.05). However, pairwise comparisons revealed that the difference in systolic blood pressure from baseline to 90 days was not significant (mean difference=6.05; SE=2.41; 95% CI: -0.56, 12.7; p=0.09). For diastolic blood pressure, a significant fixed effect was found for time (F[3,41.9]=3.0, p<0.05), and the parameter estimate between baseline and 90-day follow-up was also significant (t[40.9]=2.6, p<0.01). Pairwise comparisons revealed that diastolic blood pressure at baseline was slightly higher than at 60 days (mean difference=3.5; SE=1.4; 95% CI: -0.28, 7.23; p=0.08) and at 90 days (mean difference=3.7; SE=1.4; 95% CI: -0.29, 7.72; p=0.08). For heart rate, the fixed effect for time was non-significant (F[3,35.3]=0.3, p=0.83), and the parameter estimate between baseline and 90-day follow-up was also non-significant (t[27.2]=-0.1, p=0.91).

Table 2 shows the descriptive values of all eight scales on the SF-36 at baseline and 30-, 60-, and 90-day follow-up. For physical functioning, a significant fixed effect was found for time (F[3,30.2]=9.1, p<0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[56.5]=-5.0, p<0.01). Pairwise comparisons revealed

Measures	Baseline	30 Days	60 Days	90 Days	F (df), p value
Weight (kg)	80±17.2 (56, 142)	76.6±15.8 (56, 133)	74.7±16 (56, 131)	75±17.7 (56, 131)	17.1 (3, 27.7), p<0.01
BMI	29.0±5.5 (20, 46)	27.7±5.6 (19, 43)	27.4± 5.6 (21, 43)	27.2±5.6 (21, 43)	17.4 (3, 30.5), p<0.01
Waist circumference (cm)	91.7±14.5 (66, 142)	85.9±12.7 (58, 125)	85.1±11.7 (66, 117)	84.3±12.4 (64, 114)	17.1 (3, 40.7), p<0.01
Hip circumference (cm)	106.4±11.4 (81, 140)	103.1±12.4 (12, 135)	103.4±13.5 (79, 135)	102.9±11.2 (90, 137)	4.3 (3, 32.0), p<0.01
Waist-Hip Ratio	0.86±0.11 (0.7, 1.5)	0.84±0.12 (0.6, 1.3)	0.83±0.09 (0.7, 1.1)	0.82±0.08 (0.7, 1.0)	2.8 (3, 34.2), p=0.06
Systolic BP (mm Hg)	123.2±17.2 (90, 194)	119.0±12.7 (88, 144)	119.0±15.1 (96, 162)	115.7±13.7 (95, 142)	2.3 (3, 41.2), p=0.09
Diastolic BP (mm Hg)	79.0±12.1 (52, 118)	75.9±9.1 (54, 96)	75.0±9.6 (58, 102)	74.0±7.3 (60, 87)	3.0 (3, 41.9), p<0.05
Heart rate (bpm)	73.6±10.7 (52, 102)	72.1±9.9 (52, 96)	73.3±8.9 (60, 90)	72.5±8.4 (60, 94)	0.3 (3, 35.3), p=0.83

Note: Values are mean ± standard deviation (minimum, maximum). The F test is for the fixed effect for time for the overall model.

Table 1: Body Composition, Systolic and Diastolic BP, and HR at Baseline and 30, 60, and 90 Days.

Measures	Baseline	30 Days	60 Days	90 Days	F (df), p value
Physical Functioning	86.5±17.9 (0, 100)	91.8±11.5 (50, 100)	91.7±9.9 (65, 100)	93.8±7.0 (75, 100)	9.1 (3, 30.2), p<0.01
Physical Role Functioning	83.9±21.4 (0, 100)	91.6±16.5 (31, 100)	88.3±14.1 (56, 100)	95.6±6.1 (81, 100)	10.4 (3, 39.4), p<0.01
Emotional Role Functioning	85.9±19.2 (25, 100)	91.7±16.2 (33, 100)	95.5±9.5 (75, 100)	93.3±9.6 (75, 100)	6.2 (3, 29.8), p<0.01
Mental Health	75.6±15.9 (35, 100)	83.0±15.1 (40, 100)	81.7±12.7 (55, 100)	86.5±10.1 (55, 100)	9.6 (3, 30.3), p<0.01
Social Functioning	80.1±22.8 (25, 100)	87.5±20.3 (38, 100)	88.5±14.2 (63, 100)	94.4±10.3 (63, 100)	8.9 (3, 35.3), p=0.06
Vitality	57.7±17.8 (18, 94)	69.9±16.2 (25, 100)	68.0±13.7 (44, 88)	70.3±14.7 (44, 100)	8.7 (3, 29.4), p=0.09
Bodily Pain	67.3±22.3 (0, 90)	78.4±14.3 (32, 90)	79.4±9.6 (62, 90)	78.5±13.6 (51, 90)	9.6 (3, 31.2), p<0.05
General Health	70.9±19.6 (5, 100)	82.4±13.8 (52, 100)	79.3±13.4 (52, 100)	81.1±11.0(57, 100)	9.4 (3, 28.0), p=0.83

Note: Values are mean ± standard deviation (minimum, maximum). The F test is for the fixed effect for time for the overall model.

Table 2: Physical and Mental Functioning at Baseline and 30, 60, and 90 Days.

that physical functioning at baseline was significantly lower than at 60 days (mean difference=-5.6; SE=1.9; 95% CI: -10.8, -0.23; p=0.05) and at 90 days (mean difference=-8.4; SE=1.7; 95% CI: -13.0, -3.8; p<0.01). For physical role functioning, a significant fixed effect was found for time (F[3,39.4]=10.4, p<0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[72.0]=-5.5, p<0.01). Pairwise comparisons revealed that physical role functioning at baseline was marginally lower than at 30 days (mean difference=-7.5; SE=2.8; 95% CI: -15.3, 0.31; p=0.07), but significantly lower at 90 days (mean difference=-11.5; SE=2.1; 95% CI: -17.1, -5.9; p<0.001). For emotional role functioning, a significant fixed effect was found for time (F[3,29.8]=6.2, p<0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[31.3]=-3.2, p<0.01). Pairwise comparisons revealed that emotional role functioning at baseline was significantly lower than at 60 days (mean difference=-8.6; SE=2.1; 95% CI: -14.3, -2.8; p<0.01) and at 90 days (mean difference=-7.8; SE=2.4; 95% CI: -14.6, -1.0; p<0.05). For mental health, a significant fixed effect was found for time (F[3,30.3]=9.6, p<0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[23.8]=-5.1, p<0.01). Pairwise comparisons revealed that mental health at baseline was marginally lower than at 60 days (mean difference=-5.6; SE=2.1; 95% CI: -11.6, 0.30; p=0.07), but significantly lower at 90 days (mean difference=-8.2; SE=1.6; 95% CI: -12.7, -3.6; p<0.001). For social functioning, a significant fixed effect was found for time (F[3,35.3]=8.9, p<0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[39.7]=-5.1, p<0.01). Pairwise comparisons revealed that social functioning at baseline was marginally lower than at 60 days (mean difference=-9.2; SE=3.5; 95% CI: -19.0, 0.60; p=0.08), but significantly lower at 90 days (mean difference=-13.6; SE=2.7; 95% CI: -20.9, -6.2; p<0.01). For vitality, a significant fixed effect was found for time (F[3,29.4]=8.7, p<0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[28.6]=-4.7, p<0.01). Pairwise comparisons revealed that vitality at baseline was significantly lower than at 30 days (mean difference=-10.3; SE=2.8; 95% CI: -18.1, -2.5; p<0.01), at 60 days (mean difference=-8.7; SE=2.7; 95% CI: -16.2, -1.2; p<0.05), and at 90 days (mean difference=-13.9; SE=3.0; 95% CI: -22.3, -5.5; p<0.01). For bodily pain, a significant fixed effect was found for time (F[3,31.2]=9.6, p<0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[32.6]=-4.6, p<0.01). Pairwise comparisons revealed that bodily pain at baseline was significantly lower than at 30 days (mean difference=-10.8; SE=2.7; 95% CI: -18.3, -3.4; p<0.01), at 60 days (mean difference=-12.0; SE=2.6; 95% CI: -19.2, -4.7; p<0.01), and at 90 days (mean difference=-13.7; SE=3.0; 95% CI: -22.0, -5.4; p<0.01). For general health, a significant fixed effect was found for time (F[3,28.0]=9.4, p<0.01), and the parameter estimate between baseline and 90-day follow-up was also significant (t[28.6]=-3.9, p<0.01). Pairwise comparisons revealed that general health at baseline was significantly lower than at 30 days (mean difference=-9.0; SE=1.8; 95% CI: -14.0, -3.9; p<0.01) and at 90 days (mean difference=-9.1; SE=2.3; 95% CI: -15.7, -2.5; p<0.01).

Discussion

In this clinic-based study of persons wanting to lose weight, we assessed the effect of an IgG-mediated food sensitivity test, the Immuno Bloodprint, combined with a subsequent elimination diet for 90 days on measures of body composition, resting blood pressure and heart rate, and quality of life. Not only did participants lose weight, but they demonstrated improvements in their BMI, waist and hip circumferences, resting diastolic blood pressure, and all measures of quality of life according to the SF-36 from baseline to 90-day follow-up. We also noted that some anthropomorphic changes occurred within 30 and 60 days (e.g., weight, BMI, waist circumference), but the greatest differences happened at the 90-day follow-up assessment. The results of our physical measures are strengthened by the positive changes seen in our quality of life indicators utilizing the SF-36, particularly the scales of vitality, bodily pain, and general health, suggesting that not only were our participants making improvements, but that they were subjectively associating those changes with how they felt in various domains. Additionally, subjects reported a very high compliance to the diet (at least 95% average compliance) for each of the follow-up periods.

The results of our study provide useful information for persons who are interested in losing weight, but have found other attempts to be challenging. Multiple ways of losing weight are recommended in the mass media by many different organizations, e.g., DASH, the South Beach Diet, the Ornish Diet, the Mediterranean diet, Weight Watchers, Nutrisystem, gluten-free, vegetarian/vegan, and others. However, none of those plans recognizes the possibility that certain foods, even those considered as healthy, such as tomatoes or pinto beans, could be problematic for overweight individuals who are IgG-reactive to them. Thus, eliminating foods that are IgG-reactive, while replacing them with similar, non-reactive foods to ensure that nutrient deficiencies do not occur, is a novel strategy for addressing the epidemic of overweight/obesity. Given that disease symptoms can be reversed with lifestyle changes, particularly by adopting healthier eating habits [20,21], a focus on educating overweight people about the benefit of eliminating IgG-reactive foods from the diet could be an additional strategy to ensure that weight loss is long-lasting and perhaps permanent. In addition, this novel IgG-mediated food test offers overweight persons an additional layer of information to add to what is commonly accepted as necessary to lose weight, e.g., a negative balance of caloric consumption versus expenditure, a reduction in calorie-dense foods, and the need to limit portion sizes.

While the use of IgG-mediated testing is not universally-accepted as accurate or valid in identifying foods that are reactive or "allergenic" due to the occurrence of IgG antibodies in the blood of healthy individuals [13,22], others have suggested that non-IgE mechanisms are useful for individuals who may be symptomatic to certain foods [23]. Additionally, researchers in headaches and gastroenterological complaints and disorders have discovered improvements in symptoms by using IgG-mediated testing combined with a subsequent food elimination diet [18,24-28]. Furthermore, while IgE testing is the commonly-recognized method to determine food allergies [29,30], the use of IgG testing may continue to show utility, as IgG antibodies against food antigens were shown to be linked to intima media thickness in obese adolescents juveniles [15].

Despite the controversies surrounding the use of food antibody testing and their accuracies, to our knowledge this study is the first to assess the use of a novel IgG-mediated test and subsequent food elimination diet on weight loss, as other prior studies have primarily focused on headaches or stomach problems. Given our positive findings in body composition (body weight, BMI, and weight and hip circumference) and the ongoing epidemic in overweight/obesity, which is inherently linked to the other waves of cardiovascular disease, diabetes, cancer, and other diseases [31-33], a simple test that can be utilized by overweight persons to help them lose weight is sorely indicated. The results of our study showed that participants lost an average of almost 1 pound per week, which is just under the recommendation of what is considered safe, healthy, and potentially permanent weight loss of 1-2 pounds per week [34]. Additionally, participants lost nearly 3 inches from the waist, as opposed to just under 1.5 inches from the hip, providing support for improvements in central obesity, which is a strong risk factor for metabolic syndrome, cardiovascular disease, diabetes, and others [35-37].

In addition to the positive changes associated with body composition, our participants noted substantial subjective improvements in both physical and mental quality of life, as rated with the SF-36, one of the gold standards in this area. Thus, we surmise that the objective findings in body composition validate the subjective improvements noted by the participants, particularly in better vitality, bodily pain, and general health. Our results are consistent with other studies that have shown improvements in ratings of quality of life in parallel with weight loss [38,39]. Our findings extend prior work by showing improvements in both the mental and physical quality of life domains, whereas others typically have only noted improvements in the physical domain [40,41].

Limitations of this study include our lack of any additional biological markers of inflammation, e.g., C-reactive protein, cytokines, or growth factors, to be able to determine the possible relationship between changes in body composition to other indicators of chronic disease. The foods that were tested include those that have been linked to cardiovascular disease, obesity, cancer, and other diseases (e.g., beef and cow's milk [42,43]), but were not eliminated from the diet if the participant was not reactive to those foods. Thus, perhaps even additional body composition and/or quality of life improvements could be made by considering the elimination of certain high-risk foods altogether regardless of IgG reactivity. Participants were not re-assessed with another IgG test at 90 days to determine consistency across the study and/or to denote any changes in response to the intervention.

The results of our study suggest that overweight or obese (according to BMI) people who want to lose weight are able to significantly improve multiple indicators of body composition, while simultaneously reporting subjective enhancements in physical and mental quality of life, by complying with a food elimination diet based on the results of IgG-mediated testing. Thus, within the spectrum of the overweight/obesity epidemic, our study represents a first attempt to show that a novel IgG-mediated Immuno Bloodprint test combined with a subsequent elimination diet may offer the opportunity for these persons to improve their dietary behaviors and subsequent health status by utilizing a tailored, individualized-specific program. Continued efforts at improving the way we intervene with overweight and obese people are critically important for reducing the personal and national burden of this epidemic in the U.S.

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References

1. Centers for Disease Control and Prevention (2008) Chronic disease. Atlanta: US Department of Health and Human Services.
2. Mokdad AH, Marks JS, Stroup DF, Gerberding JL (2004) Actual causes of death in the United States, 2000. JAMA 291: 1238-1245.
3. Roussos A, Koursarakos P, Patsopoulos D, Gerogianni I, Philippou N (2003) Increased prevalence of irritable bowel syndrome in patients with bronchial asthma. Respir Med 97: 75-79.
4. Crowe SE, Perdue MH (1992) Gastrointestinal food hypersensitivity: basic mechanisms of pathophysiology. Gastroenterology 103: 1075-1095.
5. el Rafei A, Peters SM, Harris N, Bellanti JA (1989) Diagnostic value of IgG4 measurements in patients with food allergy. Ann Allergy 62: 94-99.
6. Host A, Husby S, Gjesing B, Larsen JN, Lowenstein H (1992) Prospective estimation of IgG, IgG subclass and IgE antibodies to dietary proteins in infants with cow milk allergy. Levels of antibodies to whole milk protein, BLG and ovalbumin in relation to repeated milk challenge and clinical course of cow milk allergy. Allergy 47: 218-229.
7. Awazuhara H, Kawai H, Maruchi N (1997) Major allergens in soybean and clinical significance of IgG4 antibodies investigated by IgE- and IgG4-immunoblotting with sera from soybean-sensitive patients. Clin Exp Allergy 27: 325-332.
8. Barnes RM, Johnson PM, Harvey MM, Blears J, Finn R (1988) Human serum antibodies reactive with dietary proteins. IgG subclass distribution. Int Arch Allergy Appl Immunol 87: 184-188.
9. Lessof MH, Kemeny DM, Price JF (1991) IgG antibodies to food in health and disease. Allergy Proc 12: 305-307.
10. Husby S, Mestecky J, Moldoveanu Z, Holland S, Elson CO (1994) Oral tolerance in humans. T cell but not B cell tolerance after antigen feeding. J Immunol 152: 4663-4670.
11. Haddad ZH, Vetter M, Friedmann J, Sainz C, Brunner E (1983) Detection and kinetics of antigen-specific IgE and IgG immune complexes in food allergy. Ann Allergy 51: 255.
12. Husby S, Oxelius VA, Teisner B, Jensenius JC, Svehag SE (1985) Humoral immunity to dietary antigens in healthy adults. Occurrence, isotype and IgG subclass distribution of serum antibodies to protein antigens. Int Arch Allergy Appl Immunol 77: 416-422.
13. Kruszewski J, Raczka A, Klos M, Wiktor-Jedrzejczak W (1994) High serum levels of allergen specific IgG-4 (asIgG-4) for common food allergens in healthy blood donors. Arch Immunol Ther Exp (Warsz) 42: 259-261.
14. Finn R, Smith MA, Youngs GR, Chew D, Johnson PM, et al. (1987) Immunological hypersensitivity to environmental antigens in the irritable bowel syndrome. Br J Clin Pract 41: 1041-1043.
15. Wilders-Truschnig M, Mangge H, Lieners C, Gruber H, Mayer C, et al. (2008) IgG antibodies against food antigens are correlated with inflammation and intima media thickness in obese juveniles. Exp Clin Endocrinol Diabetes 116: 241-245.
16. Kohno T, Kobashiri Y, Sugie Y, Takai S, Watabe K, et al. (2002) Antibodies to food antigens in Japanese patients with type 1 diabetes mellitus. Diabetes Res Clin Pract 55: 1-9.
17. Pacor ML, Nicolis F, Cortina P, Peroli P, Venturini G, et al. (1989) Migraine and food. Recenti Prog Med 80: 53-55.
18. Atkinson W, Sheldon TA, Shaath N, Whorwell PJ (2004) Food elimination based on IgG antibodies in irritable bowel syndrome: a randomised controlled trial. Gut 53: 1459-1464.
19. Ware JE, Kosinski M, Dewey J (2000) How to score version two of the sf-36 health survey. Lincoln, RI: QualityMetric Incorporated.
20. Shintani TT, Beckham S, Brown AC, O'Connor HK (2001) The Hawaii diet:

Ad libitum high carbohydrate, low fat multi-cultural diet for the reduction of chronic disease risk factors: obesity, hypertension, hypercholesterolemia, and hyperglycemia. Hawaii Med J 60: 69-73.

21. Ornish D, Scherwitz LW, Billings JH, Brown SE, Gould KL, et al. (1998) Intensive lifestyle changes for reversal of coronary heart disease. JAMA 280 : 2001-2007.

22. Husby S (1988) Dietary antigens: uptake and humoral immunity in man. APMIS 1: 1-40.

23. Halpern GM, Scott JR (1987) Non-IgE antibody mediated mechanisms in food allergy. Ann Allergy 58: 14-27.

24. Alpay K, Ertas M, Orhan EK, Ustay DK, Lieners C, et al. (2010) Diet restriction in migraine, based on IgG against foods: a clinical double-blind, randomised, cross-over trial. Cephalalgia 30: 829-837.

25. Zar S, Mincher L, Benson MJ, Kumar D (2005) Food-specific IgG4 antibody-guided exclusion diet improves symptoms and rectal compliance in irritable bowel syndrome. Scand J Gastroenterol 40: 800-807.

26. Drisko J, Bischoff B, Hall M, McCallum R (2006)Treating irritable bowel syndrome with a food elimination diet followed by food challenge and probiotics. J Am Coll Nutr 25: 514-522.

27. Zuo XL, Li YQ, Li WJ, Guo YT, Lu XF, et al. (2007) Alterations of food antigen-specific serum immunoglobulins G and E antibodies in patients with irritable bowel syndrome and functional dyspepsia. Clin Exp Allergy 37: 823-830.

28. Rees T, Watson D, Lipscombe S, Speight H, Cousins P, et al. (2005) A prospective audit of food intolerance among migraine patients in primary care clinical practice. Headache Care 2: 105-110.

29. Ortolani C, Bruijnzeel-Koomen C, Bengtsson U, Bindslev-Jensen C, Bjorksten B, et al. (1999) Controversial aspects of adverse reactions to food. European Academy of Allergology and Clinical Immunology (EAACI) Reactions to Food Subcommittee. Allergy 54: 27-45.

30. Asero R, Ballmer-Weber BK, Beyer K, Conti A, Dubakiene R, et al. (2007) IgE-mediated food allergy diagnosis: Current status and new perspectives. Mol Nutr Food Res 51: 135-147.

31. Centers for Disease Control and Prevention (2004) The Burden of Chronic Diseases and Their Risk Factors: National and State Perspectives 2004. Atlanta: US Department of Health and Human Services.

32. Mente A, de Koning L, Shannon HS, Anand SS (2009) A Systematic Review of the Evidence Supporting a Causal Link Between Dietary Factors and Coronary Heart Disease. Arch Intern Med 169: 659-669.

33. Sturm R, Ringel JS, Andreyeva T (2004) Increasing Obesity Rates and Disability Trends. Health Aff (Millwood) 23: 199-205.

34. American College of Sports Medicine (2005) ACSM's Guidelines for Exercise Testing and Prescription. Hagerstown, MD: Lippincott Williams & Wilkins.

35. Janssen I, Katzmarzyk PT, Ross R (2004) Waist circumference and not body mass index explains obesity-related health risk. Am J Clin Nutr 79: 379-384.

36. Romero-Corral A, Somers VK, Sierra-Johnson J, Korenfeld Y, Boarin S, et al. (2010) Normal weight obesity: a risk factor for cardiometabolic dysregulation and cardiovascular mortality. Eur Heart J 31: 737-746.

37. Duman BS, Turkoglu C, Gunay D, Cagatay P, Demiroglu C, et al. (2003) The interrelationship between insulin secretion and action in type 2 diabetes mellitus with different degrees of obesity: evidence supporting central obesity. Diabetes Nutr Metab 16: 243-250.

38. Fontaine KR, Barofsky I, Andersen RE, Bartlett SJ, Wiersema L, et al. (1999) Impact of weight loss on health-related quality of life. Qual Life Res 8: 275-277.

39. Kolotkin RL, Crosby RD, Williams GR, Hartley GG, Nicol S (2001) The relationship between health-related quality of life and weight loss. Obes Res 9: 564-571.

40. Fine JT, Colditz GA, Coakley EH, Moseley G, Manson JE, et al. (1999) A prospective study of weight change and health-related quality of life in women. JAMA 282: 2136-2142.

41. Rippe JM, Price JM, Hess SA, Kline G, DeMers KA, et al. (1998) Improved psychological well-being, quality of life, and health practices in moderately overweight women participating in a 12-week structured weight loss program. Obes Res 6: 208-218.

42. Melnik BC (2009) Milk--the promoter of chronic Western diseases. Med Hypotheses 72: 631-639.

43. Sinha R, Cross AJ, Graubard BI, Leitzmann MF, Schatzkin A (2009) Meat intake and mortality: a prospective study of over half a million people. Arch Intern Med 169: 562-571.