Efficacy of a Diet Program on Body Weight in Overweight Americans: Open-Label Human Study

Submitted By: Blake Ebersole, NaturPro Scientific LLC. March 2, 2017

Introduction

The NIH reports that 68.8% of adults in the USA are considered to be overweight or obese (35.7% obese and 6.3% have extreme obesity). It is generally accepted that being overweight increases risk factors for chronic disease. According to the Centers for Disease Control, 29.1 million Americans live with type 2 diabetes and 86 million with pre-diabetes. According to the U.S. National Institutes of Health, including the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), high body weight and inadequate physical activity are two primary causes of insulin resistance and pre-diabetes. For many overweight people, changing dietary habits is key to maintaining a healthy body weight.

This report summarizes a pilot study performed in the USA to evaluate the safety and efficacy of a weight loss system originally developed and tested in South Africa by physicians at the Medical Nutritional Institute (MNI)in Johannesburg, South Africa, to provide a more effective weight loss solution.

Background

MNI was started in 2002 to focus on weight management and healthcare training services. MNI developed the weight loss system to address previous limitations of corporate wellness programs to deliver sustainable weight loss and measurable health benefits. Conrad Smith M.D. and Mariaan Du Plessis (registered pharmacist) developed an approach to improve insulin management during weight loss programs.MNI developed a 3-tiered solution centered on insulin management in conjunction with caloric control and intervention with a plant and mineral based dietary supplement, containing ingredients researched to address insulin performance.MNI implemented two studies within corporate wellness programs in 2009 and 2010 and an additional three studies from 2011 through 2014.

In 2010, MNI partnered with GOLO, LLC in the USA (Newark, Delaware), and GOLO implemented a pilot study in 2011 to understand whether the initial results in South Africa could be replicated in a separate population of subjects.

Methods

A 26-week, open-label pilot study of 35 overweight/obese human subjects was conducted in Delaware in the United States by the marketer GOLO to determine the efficacy of a weight loss program “GOLO for Life”. The study was conducted in the U.S. in 2010-2011 and recruited 49 subjects. Study participants were recruited through local newspaper ads and local postings. The study was comprised of weekly study visits with key data collected at baseline, 30 days, 90 days, and 26 weeks (Study 1), with an option for subjects to continue with the study for an additional 26 weeks (Study 1a). At study completion after 26 weeks, 23 subjects opted to continue on the program as a maintenance study for an additional 26 weeks. Each subject’s baseline values were recorded and served as the basis by which the program’s efficacy was measured.

Study #	Location	N	Weeks
1	United States	35	26
1a	United States	23	52

Table 1. Overview of studies on diet program. N is the number of subjects completing the study. Study #1a is the continuation of study #1 after an additional 26-week follow-up.

The Diet Program

The diet program included behavior modification guidance in the form of booklets that included a self-assessment, an eating plan based on food groups, portion control and caloric restriction, and a dietary supplement as three capsules, three times per day. The supplement contained a blend of plant-derived ingredients and minerals consisting of banaba leaf, barberry bark extract, apple fruit extract, salacia bark extract, gardenia fruit extract, rhodiola root, inositol, chromium, zinc and magnesium. The diet program used in this study may be best categorized as self-directed, with counseling and support available online, by email communications, or through a toll-free phone number. Subjects were provided with written handouts for the meal plan that included guidance on serving recommendations from the major food groups, with portion control and a self-assessment behavioral handout. Subjects were also provided with food and exercise logs. Subjects were directed to attempt 15 minutes of exercise per day or 105 minutes per week and to preferably exercise using high intensity workouts (HIT) such as walking with 30 second bursts and 30 second rest periods. Optional exercise classes were made available to the subjects twice per week.

Study Criteria

Adults older than 20 years old, with a body mass index >25 kg/m^2 were included in the study. Subjects were required to be healthy overweight or obese. Excluded were type 2 diabetics, pregnant or lactating subjects, determined by questionnaire, and individuals with known allergies to the dietary supplement or any of its ingredients. Subjects were instructed to continue to take all medications that they were taking at the time that the study began. Any subsequent changes in medication were made under supervision of the subjects' personal physician. Subjects were not compensated to join the trial or for participating in the trial.

Subjects were requested to visit the study center weekly with a minimum monthly visit to remain in the study. At each visit, body weight, body mass index (BMI), visceral fat, body fat, muscle loss and metabolic age as measured by a Tanita Body Composition Analyzer SC-331S were measured.

Body circumference measurements were taken at the waist, shoulders, chest, bicep, hips and thighs, and blood pressure (mmHg) and heart rate were also measured. Subjects provided completed food and exercise logs at the visit and their feedback on the Program. Subjects self-reported changes in dress and pants sizes. Front and side pictures of all subjects were taken at baseline and various intervals and at end points to verify results. Medication history and reduction or elimination of medications was also recorded.

At baseline, 3 months, and 6 months, blood work was taken and fasting blood glucose (mg/dL), HbA1c (% DCCT) and blood lipids (triglycerides, total cholesterol, LDL, HDL) were measured using LabCorp or equivalent clinical chemistry providers.

Compliance

Compliance was measured at each weekly visit and at least monthly through exercise logs and food logs kept by subjects, and a count of supplement capsules remaining during each study visit. A minimum average compliance of 50% was required for inclusion in the data analysis. Compliance was based on level of adherence to diet, supplementation and exercise recommendations.

Ethical Requirements

Informed consent was obtained for all subjects. Study subjects were not compensated for participation. No institutional review board was used.

Data Analysis

Blake Ebersole (NaturPro Scientific LLC, Carmel, Indiana) reviewed all data provided by GOLO, LLC, evaluated the apparent integrity and completeness of the data, conducted statistical analysis, and wrote the report. All data from subjects completing the study were analyzed based on changes in endpoints from baseline using means, standard deviation and single-factor ANOVA using Microsoft Excel.

Results

Out of 49 subjects entering the study, 35 completed the full 26 week study. Of the 14 subjects who left the study, none were due to adverse events (Figure 8). Data from dropouts were not included in the analysis of group results if they did not reach the 26 week mark and complete blood work. All drop out subjects lost weight, with data and reason for dropping out stated in Figure 8 below.

After 7 days, body weight in 34 subjects was reduced by an average of 3.4 lbs., and after 30 days, an average of 7.7 lbs. weight loss was observed (Figure 1). One subject did not report data at 7 days and 30 days. After 90 days, average body weight was reduced by 20 pounds, and waist circumference was reduced by an average of four inches. After 26 weeks, the average weight loss was 30.9 pounds, which was significant from baseline ($p<0.005$) (Figure 2). The average decrease in BMI at 26 weeks was 4.8 units (Figure 3).

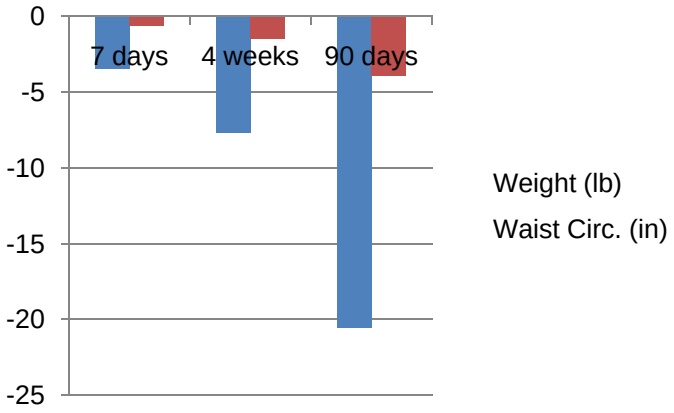

Figure 1. Change in average body weight (lb) and waist circumference after 7 days,30 days and 90 days (n=35, except for one subject at 7 and 30 days whose data was not reported).

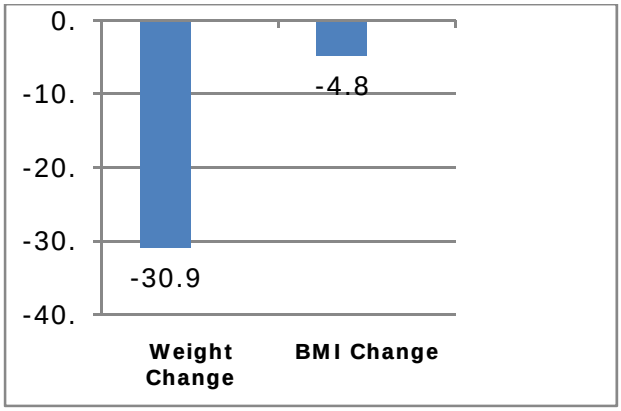

Figure 2. Change in average body weight (lb) and BMI after 26 weeks

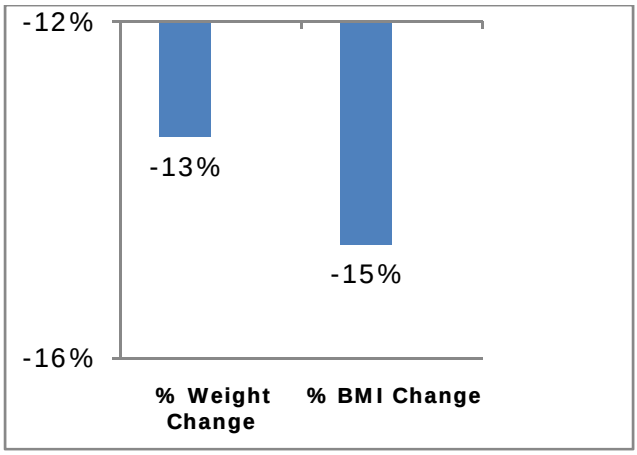

Figure 3. Change in average body weight and BMI after 26 weeks as a percentage of baseline values.

Average waist circumference, pants and dress size, fat percentage, total cholesterol, and triglycerides all decreased significantly from baseline after 26 weeks (Figure 4). Muscle loss did not significantly decrease, suggesting the diet program reduced body fat without significant loss of muscle mass. For the subjects who remained in the study for an additional 26 weeks, all measures continued to be a significant reduction from baseline, except for total cholesterol.

	Baseline	90 Day	26 Weeks (n=35)	1 Year (n=23)
Weight (lbs)	210.8	191.4 -19.3 ± 8.86 (*p* = 0.069)	178.8 -30.9 ± 11.1 (*p*= 0.0024)	167.8 -36.6 ± 14.7 (*p* =0.000049)
Waist Circumference (in)	42.1	39.0 -3.09 ± 1.70 (*p* =0.02)	35.7 -5.48 ± 1.75 (*p* =0.000031)	34.5 -6.94 ± 2.52 (*p*= 0.0000016)
BMI	32.9		28.1 -4.8 ± 1.8 (*p* =0.00084)	25.9 -6.1 ± 3.0 (*p* =0.0000025)
Dress Size	16.2		9.33 -7 ± 2 (*p* =0.000024)	7.3 -8 ± 2 (*p*= 0.0000049)
Pants Sizes (waist inches)	40.7		35.5 -5.27 ± 1.01 (*p*= 0.00025)	33.6 -7.6 ± 2.6 (*p* =0.00078)
Muscle (lbs)	129.7		122.7 -7.1 ± 5.1 (*p* =0.24)	127.3 -2.3 ± 7.0 (*p* =0.75)
% Muscle	62.30%		69.20% 6.9% ± 4.3% (*p* =0.00067)	75.90% 12.5% ± 4.6% (*p* =0.0000017)
Fat (lbs)	80.0		56.2 -23.8 ± 11.7 (*p* =0.00074)	40.4 -34.3 ± 12.6 (*p* =0.000000017)
% Fat	37.60%		30.80% -6.9% ± 4.3% (*p* =0.00068)	24.10% -12.5% ± 4.6% (*p*= 0.0000017)
Cholesterol	184.5		166.9 -17.6 ± 33.9 (*p* =0.041)	174.7 -7 ± 38 (*p* =0.50)
LDL	105.5		91.5 -13.9 ± 29.1 (*p* =0.69)	94.4 -8 ± 31 (*p* =0.38)
HDL	57.4		60.5 3.11 ± 9.93 (*p* =0.41)	64.8 9 ± 16 (*p* =0.064)
Triglyceride	108.3		74.4 -33.9 ± 48.1 (*p=0.0037)*	76.9 -37 ± 55 (*p* =0.0067)
CHL/HDL ratio	3.51		2.88 -0.63 ± 0.90 (*p=0.020)*	2.88 -0.64 ± 1.23 (*p* =0.07)
HDL/LDL ratio	2.05		1.61 -0.44 ± .070 (*p* =0.035)	1.61 -0.42 ± 0.98 (*p* =0.13)

Figure 4. Summary of data in the U.S. diet study, based on average values. Values in red were not significant (P>0.05).

According to the NIDDK, fasting blood glucose and hemoglobin A1c (HbA1c) are primary indicators of blood sugar health and insulin resistance. At 26 weeks fasting blood glucose was reduced by an average of 8.5% (p<0.01) and HbA1c was reduced by an average of 3.9% (5.79 to 5.56, p=0.011) (Figure 5). In a subset of 24 healthy pre-diabetic subjects with baseline HbA1c levels between 5.7 and 7.1, an average 6.9% decrease was found at 90 days (p<0.0001). A 4% average reduction was observed after 26 weeks, which was significant (p=0.002).At 52 weeks, an average 7.3% decrease was found in these subjects (p<0.001).

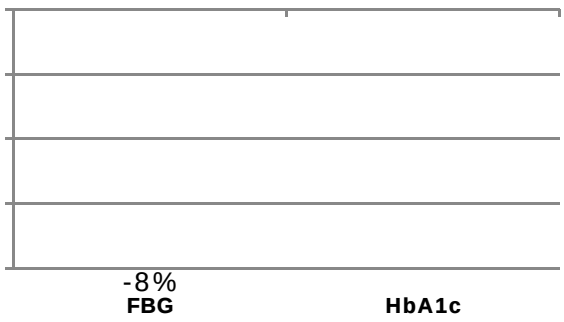

Figure 5. Change in average fasting blood glucose (FBG) and hemoglobin A1c from baseline to 26 weeks (n=35).

In all subjects, average systolic and diastolic blood pressure was reduced by 12.5% ($p<0.001$) and 6.0% ($p<0.05$), respectively after 26 weeks (Figure 6).

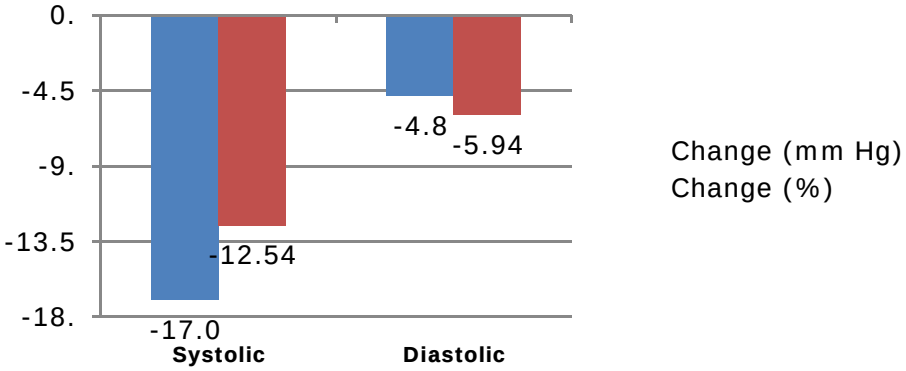

Figure 6. Change in average blood pressure from baseline to 26 weeks (n=35).

Visceral fat was significantly reduced over 26 weeks by an average of 28% (from 10.00% to 7.19%, p=0.005, Figure 7)and by an average of 37%in subjects who continued for 39-55 weeks (from 10.00% to 6.32%, $p<0.0001$).Of the 35 subjects, 11 had a visceral fat percentage greater than 13% at the start (average 15.82%). At 26 weeks, the average visceral fat percentage for these 11 subjects was 11.45%.

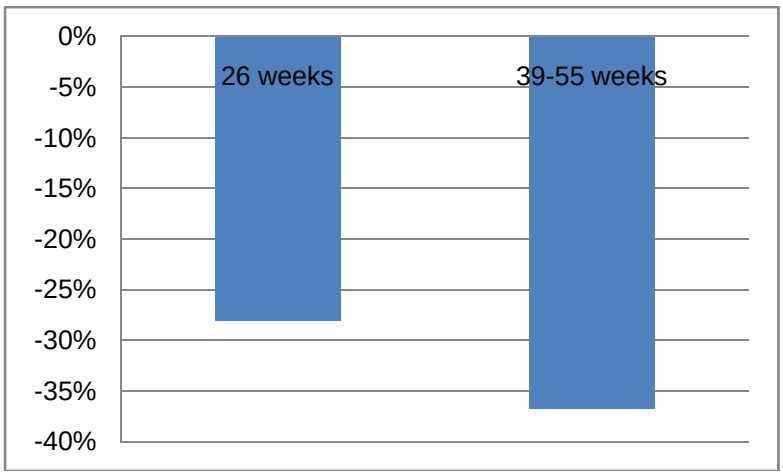

Figure 7. Change in average visceral fat (%) over 26 weeks (p=0.005) and over 39-55 weeks ($p<0.00001$) (n=35)).

Metabolic age, calculated from body composition analysis, also decreased from an average of 56.3 to 43.2 years of age ($p<0.0001$) at 26 weeks. Although metabolic age is an estimated value, it can be used as supportive data with respect to the number of other improvements observed in this study on primary biomarkers such as body weight.

Fourteen (14) of the USA study participants had been prescribed a total of 35 medications at the start of the study. After 26 weeks, more than half (18) prescription medications were eliminated, and 6 were prescribed at a lower dosage, all under the supervision of the subjects' personal physician. 14 subjects left the study before 26 weeks due to various factors (Figure 8). No dropouts were due to adverse events. All dropouts showed a reduction in weight.

Baseline (lb)	End (lb)	Difference (lb)	Weeks in Study	Reasons
227	212.6	-14.4	16	Family issues
205	191.6	-13.4	12	Unknown
173.4	165.6	-7.8	10	Moved away
225.8	221.6	-4.2	9	Husband made her stop
140.4	135.6	-4.8	7	Work
240.4	229.6	-10.8	5	Drug problem
210.4	199.8	-10.6	5	Mother sick
274.6	268.2	-6.4	8	Health issues
168.8	155.6	-13.2	14	Travelling time
151.2	123.2	-28	14	Time issues
184.6	177.2	-7.4	7	Scheduling conflicts
165.4	145.2	-20.2	20	Time issues
151.4	139.6	-11.8	15	Pregnancy
232.4	218	-14.4	13	Changed jobs-too far

Figure 8. Body weight changes from subjects who discontinued the 26-week study. No dropouts were due to study or treatment related issues.

Discussion

The diet program used in this study combines diet, exercise and nutritional supplementation together into a self-directed program. A number of studies have been performed using similar diet programs. A recent meta-analysis was performed that categorized randomized controlled human trials on diet programs into three categories: 1) "market leaders" such as Nutri-system and Weight Watchers, 2) very-low-calorie meal replacements, and 3) self-directed programs such as Atkins and SlimFast[1]. Most of the diet plans studied combine face-to-face and group counseling, medical supervision, packaged foods or diet plans, and exercise recommendations.

The range of weight loss in 6-month studies on market leaders was between 3.6 and 8.1% of total body weight. Meanwhile, weight loss for very-low-calorie meal replacement programs ranged between 1.9 and 22% for study durations between 3 and 9 months, with most studies reporting an average reduction lower than 8%. For self-directed programs, studies ranging from 3-12 months demonstrated a range of average weight loss between 0 and 8.7%, with the predominant number of studies averaging less than 5% weight loss. The diet program used in this study may be best categorized as self-directed, with counseling and support available online, by email communications, or through a toll-free phone number. In this study, an average weight loss of 13% was observed in 26 weeks, which compares favorably

[1] *Ann Intern Med. 2015 Apr 7;162(7):501-12. Efficacy of commercial weight-loss programs: an updated systematic review. Gudzune KA et al.*

to previous studies on self-directed programs. In addition to improvements in body weight and BMI, a number of blood markers associated with poor diet, cardiometabolic syndromes, and insulin resistance, including fasting blood sugar and HbA1c, were also improved compared to baseline values.

Glycated hemoglobin A1c (HbA1c) is a marker long used by physicians to determine a patient's average blood glucose levels over the previous 8-12 weeks. For this reason, HbA1c is generally considered a more reliable marker than fasting blood glucose to reflect average levels of blood glucose. Insulin resistance occurs when cells in the body are less responsive to insulin, which can lead to increases in blood sugar reflected in HbA1c and FBG levels. Thus, a reduction in HbA1c levels, along with improvements in body weight, together may indicate an improvement in insulin resistance. For example, changes in insulin resistance and HbA1c can be caused by exercise-mediated changes in body composition in older adults with type-2 diabetes[2]. Other diet programs have also measured improvements in HbA1c and body weight. A 2016 study on Weight Watcher's showed a significant 6-month weight loss of 5.5%, and a significant decrease in HbA1c in pre-diabetic subjects following the program[3]. A health coaching program in diabetics with a low socioeconomic status was also shown to reduce body weight, waist circumference and HbA1c[4].

The diet program used in the current study appeared to improve body weight favorably, consistent with previous studies on other similar diet programs. The diet program used in this study was affordable and did not require office visits, or food to be purchased, aside from an included dietary supplement requiring the consumption of three capsules per day. These factors could help to contribute to long-term compliance for a broader spectrum of people, as well as for those who have more weight to lose and need a long-term weight loss plan.

As with any study, dropouts and side effects can be a concern for weight loss plans. However dropouts from the studies all had reduced body weight at the time of withdrawal, and no withdrawals were due to treatment or study-related effects. Based on this early data, the diet program in this study may be an effective program that can be self-directed and also easily monitored by health coaches or physicians.

Although subjects were used as their own controls in this study, data from control groups in studies of other diet programs allow for some meaningful comparisons to be made. The amount and percentage of weight loss observed in this study was consistent with data reported by similar programs such as Weight Watchers and Nutrisystem. Despite the lack of a separate control group, an abundance of control data has been published. Further, the high degree of clinical relevance and supporting evidence on the individual elements of the intervention in this study adds a considerable degree of strength to the results observed. Larger studies are planned on the program to determine whether the effects observed can be repeated in other populations, and in larger sample sizes over longer durations.

Overall, subjects in this study showed significant reductions in body weight and BMI, and also experienced improvements in several markers of metabolic function. The data is consistent with previous results from the program, and with published data supporting the elements of the program. Thus, the effects observed in this study on a combination of dietary and behavioral interventions support the effectiveness of the GOLO for Life program for weight loss and several related clinical endpoints.

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[2] *Diabetes Care. 2013 Aug;36(8):2372-9.Changes in insulin resistance and HbA1c are related to exercise-mediated changes in body composition in older adults with type 2 diabetes: interim outcomes from the GREAT2DO trial. Mavros Y et al.*

[3] *Am J Public Health. 2016 May;106(5):949-56. Comparison of Commercial and Self-Initiated Weight Loss Programs in People With Prediabetes: A Randomized Control Trial. Marrero DG.*

[4] *J Med Internet Res. 2015 Oct 5;17(10). Health Coaching Reduces HbA1c in Type 2 Diabetic Patients From a Lower-Socioeconomic Status Community: A Randomized Controlled Trial. Wayne N*

Appendix – Summary of Individual Subject Weights at 26 weeks

Subject #	Baseline (lb)	26 weeks (lb)	Difference (lb)	Difference (%)
1	205.8	174.6	-31.2	-15%
2	220.8	189.2	-31.6	-14%
3	238.0	203.6	-34.4	-14%
4	205.0	189.0	-16.0	-8%
5	155.6	143.0	-12.6	-8%
6	177.8	152.6	-25.2	-14%
7	238.0	185.2	-52.8	-22%
8	192.6	156.0	-36.6	-19%
9	246.0	206.0	-40.0	-16%
10	220.2	184.4	-35.8	-16%
11	156.8	135.8	-21.0	-13%
12	197.0	153.4	-43.6	-22%
13	182.6	152.6	-30.0	-16%
14	213.8	183.0	-30.8	-14%
15	233.0	190.6	-42.4	-18%
16	182.6	163.6	-19.0	-10%
17	375.4	332.4	-43.0	-11%
18	188.0	162.8	-25.2	-13%
19	201.4	161.8	-39.6	-20%
20	250.2	221.6	-28.6	-11%
21	173.2	144.0	-29.2	-17%
22	172.0	157.2	-14.8	-9%
23	183.2	152.8	-30.4	-17%
24	206.4	160.4	-46.0	-22%
25	173.4	139.6	-33.8	-19%
26	240.2	188.6	-51.6	-21%
27	273.8	241.2	-32.6	-12%
28	265.0	226.0	-39.0	-15%
29	237.4	198.2	-39.2	-17%
30	248.8	239.6	-9.2	-4%
31	162.2	141.0	-21.2	-13%
32	183.4	160.8	-22.6	-12%
33	189.2	151.0	-38.2	-20%
34	172.4	161.0	-11.4	-7%
35	180.0	157.0	-23.0	-13%
Average	**209.7**	**178.8**	**-30.9**	**-15%**

Appendix Table 1. Individual weight loss after 26 weeks.

26 Week USA Summary				
Participants	#		**35**	
Trial Length	weeks		**26**	
Average Weight	lb		**-30.9**	
Average Weight Change Per Week	lb		**-1.2**	
% Body Weight	%		**-13.4**	
Muscle Mass	lb		**-7.1**	
Fat	lb		**-23.8**	
BMI	%		**-14.6**	
Visceral Fat	%		**-27.9**	
Total Inches	inches		**-23.3**	
Waist Size	inches		**-6.0**	
Dress Size	Sizes		**-3.4**	
Pants Size	Sizes		**-5.3**	
Food Compliance	%		**73.9**	
Exercise Compliance	%		**73.2**	
Blood Pressure Systolic	%		**-12.5**	
Blood Pressure Diastolic	%		**-5.9**	
Total Cholesterol	%		**-9.6**	
LDL	%		**-13.2%**	
HDL	%		**5.4%**	
Triglycerides	%		**-31.3%**	
Glucose	%		**-8.5%**	
A1C	%		**-3.9%**	
Cholesterol/HDL Ratio	%		**-14.2%**	
LDL/HDL Ratio	%		**-17.7%**	
Metabolic Syndrome Risk Factors	Baseline		**114**	
Metabolic Syndrome Risk Factors	26 wks.		**50**	
Metabolic Syndrome	Baseline		**24**	
Metabolic Syndrome	26 wks.		**5**	
Pre Diabetic	Baseline		**23**	
Pre Diabetic	26 wks.		**12**	

Appendix Table 2. Summary of results after 26 weeks.