Standard Process
WHOLE FOOD NUTRIENT SOLUTIONS

Standard Process Purification Research

Sold Through Health Care Professionals

STANDARDPROCESS.COM

Standard Process
WHOLE FOOD NUTRIENT SOLUTIONS

Standard Process 21-Day Purification Program Supports Cardiovascular Health

Study Finds Standard Process Purification Program Supports Cardiovascular Health

Open-label, prospective outcomes study
Six weeks (three week control/21-day purification)

40 subjects: 18-65 years of age (22 men, 18 women)
Four with BMI < 25, 16 with BMI 25-29.9, 20 with BMI ≥ than 30

Decrease in blood pressure

Improvement in lipid measures

Modest weight and BMI reduction

In this study, healthy adults were recruited from the campus of Logan College of Chiropractic and included based on weight and a total cholesterol level equal to or greater than 180 mg/dl.

During the first three weeks, participants didn't change their diet, and their food intake was logged in a diet journal (collected by the researchers each week). Data collected include height, weight, blood pressure, and heart-rate variability data, as well as a 12-hour fasting **blood sample** when participants entered the study (baseline) and at week 3.

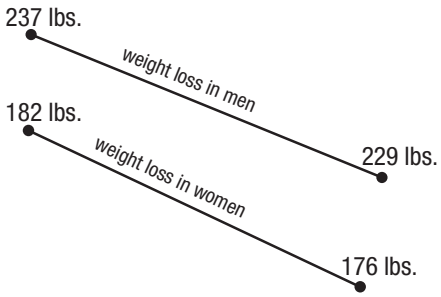
At the beginning of week 4, participants received their purification program instructions and supplements, and a final blood sample was collected on day 42.

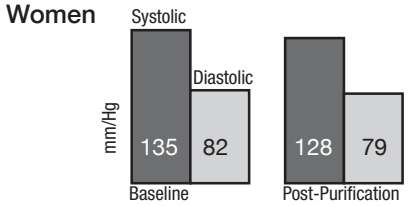
Blood samples examined for:

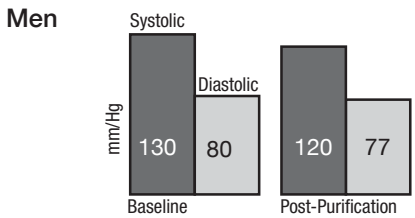
- Total cholesterol **(TC)**
- High-density lipoprotein **(HDL)** cholesterol
- Triglycerides **(TRI)**
- Low-density lipoprotein **(LDL)** cholesterol
- Homocysteine
- High-sensitivity C-reactive protein **(CRP)**

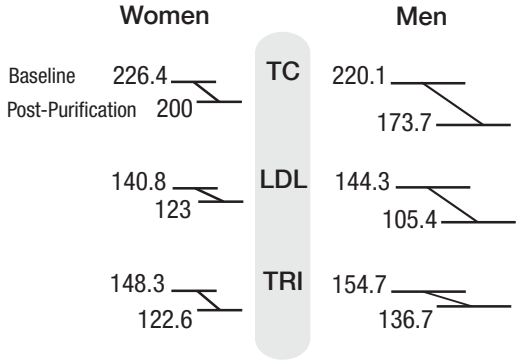
Results

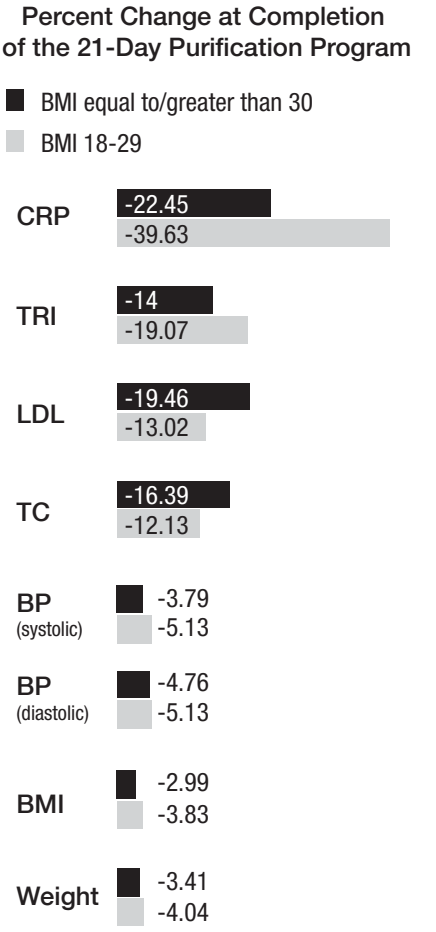
- For the group as a whole, statistically significant **weight loss** (8 lbs. for men, 6 lbs. for women) occurred from baseline to post-purification (p = <0.0001). This led to a statistically significant decline in BMI for the group (p = <0.0001).
- A statistically significant reduction in both systolic and diastolic **blood pressure** was seen for both the group as a whole (p = <0.0001, p = 0.008 respectively) as well as men and women (p = <0.0001 for both).











1. *J Chiropr Med.* 2008. Sep;7(3):94-100.
Retrospective study: 26 subjects
Reported reduction in weight, total cholesterol, triglycerides, low-density lipoprotein, very low-density lipoprotein

› A statistically significant reduction in **total cholesterol** (p = <0.0001), and **LDL cholesterol** (p = <0.0001) **triglycerides** (p = 0.069), was found for all subjects, as well as a reduction in HDL cholesterol (p = 0.019).

In men, the decrease in total cholesterol and LDL from baseline to post-purification was statistically significant (p = 0.0001 and p = 0.0003 respectively).

In women statistically significant drops in total cholesterol and LDL were reported (p = 0.0052 and p = 0.0141), and a strong trend was found for decrease in triglycerides (p = 0.0585).

› A statistically significant reduction in **C-reactive protein** was reported in the group as a whole (p = 0.0009), as well as in both women (p = 0.0224) and men (p = 0.0160).

› The subjects of greater than normal weight had similar changes (reported as a **percent change**) from week 3 to the end of the study. While both groups experienced similar results in general, the overweight group changed more in regard to C-reactive protein, triglycerides, and systolic blood pressure; while the group with a BMI equal to or greater than 30 saw a greater reduction in total cholesterol and LDL cholesterol.

› Statistically non-significant findings: The heart-rate variability (measurement of difference between heartbeats and the difference between a series of consecutive heart rates) was not statistically significant for the group as a whole. Likewise, in the group as a whole, homocysteine levels did not show a statistically significant change.

Expanding on the results reported by Powell and Leonard,[1] the Logan study supports the finding of improved lipid profiles in patients who have completed the purification program and provides more information on how the purification program can impact blood pressure and C-reactive protein as well.

This study shows that the 21-day Standard Process Purification Program can support cardiovascular health.*

More study is needed to examine:

› Decrease in high-density lipoprotein
› Mixed findings for heart-rate-variability parameters
› Compliance
› Generalizability to populations with BMI less than 25
› Effect of exercise on intervention

*These statements have not been evaluated by the Food & Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

Standard Process®
WHOLE FOOD NUTRIENT SOLUTIONS

Prospective Case Series Study

Journal of Chiropractic Medicine (2013) 12, 30–38

ELSEVIER

JCM Journal of Chiropractic Medicine

www.journalchiromed.com

Case reports

Changes in weight loss and lipid profiles after a dietary purification program: a prospective case series

Erica Callahan DC, MSACN*

Assistant Professor, Clinic, New York Chiropractic College, Seneca Falls, NY

Received 12 June 2012; received in revised form 31 October 2012; accepted 15 November 2012

Key indexing terms:
Weight reduction programs;
Overweight;
Obesity

Abstract

Objective: The purpose of this case series was to describe immediate changes to weight and lipid profiles after a 21-day Standard Process whole food supplement and dietary modification program.

Methods: Changes in weight and lipid profiles were measured for 7 participants (6 men and 1 woman) participating in a 21-day program. The dietary modifications throughout the Standard Process program were consumption of (1) unlimited fresh or frozen vegetables and fruits and preferably twice as many vegetables as fruits, (2) ½ to 1 cup of cooked lentils or brown rice each day, (3) 4 to 7 teaspoons of cold pressed oils per day, and (4) at least 64 oz of water a day. After day 10 of the program, participants were allowed to consume 1 to 2 servings of baked, broiled, or braised poultry or fish per day. Participants consumed a whey protein–based shake as meal replacement 2 times per day. Nutritional supplementation included a cleanse product on days 1 to 7, soluble fiber supplementation including oat bran concentrate and apple pectin on all days, and "green food" supplementation on days 8 to 21.

Results: Weight loss ranged between 5.2 (2.4 kg) and 19.9 lb (9.0 kg) (average, 11.7 lb; 5.3 kg). Total cholesterol levels decreased with ranges between 11 and 77 mg/dL, and low-density lipoprotein cholesterol levels decreased in a range between 7 and 67 mg/dL.

Conclusion: After participating in a dietary program, the 7 participants demonstrated short-term weight loss and improvements in their lipid profiles.

Introduction

National statistics indicate that 33% to 36% of the US population is obese.[1] Diets emphasizing caloric restriction, without malnutrition of essential nutrients and regardless of dietary macronutrients, are promoting healthy weight loss, improving lipid profiles and fasting insulin levels, inducing metabolic adaptations, and reducing oxidative stress.[2-6] In addition, commercially available meal replacement products, such as Medifast (Medifast Inc., Owings Mills, MD),[7] NutriSystem (Nutrisystem, Fort Washington, PA),[8] Healthy Solutions (Healthy Solutions LLC, Scottsdale, AZ),[9]

* Corresponding author. New York Chiropractic College, 2360 State Route 89, Seneca Falls, NY 13148. Tel.: +1 315 568 3293; fax: +1 315 568 3204.
E-mail address: ecallahan@nycc.edu.

1556-3707/$ – see front matter © 2013 National University of Health Sciences.
http://dx.doi.org/10.1016/j.jcm.2012.11.004

Ultra-Slim Fast (Unilever Slim Fast, London, UK),[10] and Isagenix 28-Day Program (Isagenix International LLC, Chandler, AZ),[11] are safe and effective weight loss products. With so many weight management programs available, how can a health care provider recommend the most appropriate evidence-based intervention for each of their patients?

Adherence to the diet plan is the critical factor for weight loss, weight maintenance, and health benefits. Evidence-based commercially available programs and products require minimal professional intervention and address the individualized eating habits of a diverse patient population. However, the development of nutrient profiling systems with an emphasis on whole foods philosophy and patient education may induce behavioral changes in eating habits.[12]

Consequently, a better quality diet characterized by increased consumption of more fruits, vegetables, whole foods, and decreased consumption of saturated fats, sugar, sodium, and processed foods may allow individuals to maintain a healthy weight and prevent chronic diseases associated with being overweight and obese to include cardiovascular disease, type II diabetes, and certain types of cancers.[13,14]

The Standard Process Purification Program (SPPP) (Standard Process Inc, Palmyra, WI) is used by some chiropractors as a nutritional intervention for their patients.[15] The 21-day SPPP is a holistic therapy designed to create a synergistic effect of whole food supplementation and dietary modifications with energy restriction.[15] The dietary modifications with energy restriction emphasize consuming controlled portion sizes of low–energy-density foods, for example, fruits, vegetables, and whole grain products, and have been fully described by Powell and Leonard.[15] The program includes 2 meal replacement shakes and introduces moderate amounts of protein from vegetable and whey sources on days 11 through 21 while restricting or eliminating meat, refined oils, and refined carbohydrates.[15] In addition to the whey protein–based shake, the nutritional supplementation program includes a cleanse product on days 1 to 7, soluble fiber supplementation including oat bran concentrate and apple pectin on all days, and "green food" supplementation on days 8 to 21.[15] Based upon a retrospective medical record review, Powell and Leonard[15] reported that SPPP improved lipid profiles and weight status of 28 chiropractic patients.

As summarized by Rolls,[16,17] low–energy-density diets and portion size control are 2 critical attributes underlying nutritional interventions in both the prevention and treatment of obesity. The dietary component of the SPPP incorporates both of these attributes. The attributes of regimented nutritional supplementation program are consistent with the evidence for improvements in lipid profiles and weight loss. Dietary fiber intake of more than or 22 g/d has been associated with reduction in total cholesterol and low-density lipoprotein (LDL) cholesterol in premenopausal women.[18] Phytosterols are cholesterol-like substances found in plants such as oat bran. A diet high in soluble fiber pectin and phytosterols has been found to significantly reduce total cholesterol levels[19] and exert a modest triglyceride-lowering effect.[20] Probiotics and prebiotics may have significant health benefits on lipid metabolism, mineral absorption, and immune function via their beneficial influences on microbial ecology of the gut.[21-26] Although there are limited clinical data on the role of microflora management interventions on weight loss and improved health status,[27-29] probiotic and/or prebiotic nutritional supplementation and colon-cleansing products are being promoted as critical elements for initiating and maintaining weight loss.

The development of the SPPP incorporated theoretical concepts underlying effective nutritional interventions for improvements in lipid profiles and weight status associated with reducing chronic disease risk factors. However, at present, the only published evidence on its effectiveness is a retrospective medical record review of a nonrandom series of 28 chiropractic patients who "successfully" completed the SPPP; and their patient records included pre-post lipid profiles and weight measurements.[15] Thus, the purpose of this case series was to describe prospectively any changes to weight and lipid profiles after a 21-day SP whole food supplement and dietary modification program.

Methods

Study population

Participants were recruited from faculty, staff, and students at a chiropractic college (20-60 years of age) who were participating in a college-sponsored "Cleanse Event." For approximately 1 month (April 2011), general campus announcements were used to advertise a "Cleanse Event"; and individuals inquiring about the "Cleanse Event" were made aware of the concurrent research study. The "Cleanse Event" was a 21-day weight management program in which volunteer participants completed the SPPP, attended weekly "Lunch and Learn" nutritional educational seminars,

and received lifestyle and nutritional advice from the supervising clinician. The participants were responsible for purchasing their SPPP kits (Standard Process Inc) at a discounted price of 40% of retail. Of the 32 participants screened for the program, 7 individuals agreed to participate in the research study. All 7 participants provided written informed consent to participate in this study. The New York Chiropractic College Institutional Review Board approved all measurement and intervention procedures for the study.

During May 2011, the supervising clinician screened 32 individuals to participate in the program. During the screening visits, participants completed a health history questionnaire and were interviewed about potential food allergies. The participants self-reported any previous participation in purification or detoxification programs and any adverse effects that they experienced. The participants self-reported any known food intolerances or allergies, digestive complaints, and thyroid complaints or previous thyroid-related conditions. They also self-reported any medications, herbal remedies, or nutritional supplements that they were currently using. In addition, screenings of blood pressure and body mass index (BMI) occurred. Measurements of sitting blood pressure were from both arms using the standard clinic procedure of mercury sphygmomanometer with the Korotkoff sound technique according to the recommendations for blood pressure measurements in humans.[31] Body mass index was calculated from the measured body weight and height (kilograms per square meter). To participate in this prospective case series, the BMI inclusion criterion was 25 to 34.99 kg/m^2.

The exclusion criteria for participating were as follows: (1) taking any prescription medication including birth control medications; (2) *hypertension* and *borderline hypertension* defined as systolic blood pressure of at least 135 mm Hg and/or diastolic blood pressure of at least 85 mm Hg; (3) neurological disorders including peripheral neuropathy; (4) diabetes; (5) thyroid disorders; (6) irritable bowel disease or colitis; (7) eating disorders; and (8) food sensitivities/allergies to the ingredients found within the nutritional supplements (including lactose- and gluten-intolerant individuals). According to the American Heart Association, at-home and ambulatory measurements of systolic blood pressure should be at least 135 mm Hg and/or diastolic blood pressure should be at least 85 mm Hg in assessing possible hypertension risk.[32] This selected upper limit for screening participants may also account for any possible "white coat hypertension" phenomenon as described by the American Heart Association. If the participants did not satisfy any of these exclusion criteria for the program, then the inclusion criterion for participating in the case series analysis was a BMI from 25 to 34.99 kg/m^2 to meet the classifications of overweight or class I obesity.

Intervention

On the first morning of the program and on the morning following the completion of the 21-day program, pre-post measurements on the research participants occurred.

As previously described by Powell and Leonard,[15] participants were instructed to increase vegetable and fruit consumption while restricting or eliminating meat, sugar, caffeine, nuts, alcohol, *trans* fats, and refined carbohydrates during the 21-day SPPP. The specific dietary modifications throughout the 21-day SPPP were consumption of (1) unlimited fresh or frozen vegetables and fruits and preferably twice as many vegetables as fruits, (2) ½ to 1 cup of cooked lentils or brown rice each day, (3) 4 to 7 teaspoons of cold pressed oils per day (eg, flaxseed oil, fish oil, coconut oil), and (4) at least 64 oz of spring water a day. After day 10 of the SPPP, participants were allowed to consume 1 to 2 servings (3 oz) of baked, broiled, or braised poultry or fish per day. Furthermore, as previously described by Powell and Leonard,[15] the SPPP included whole food nutritional supplementation. In addition to the whey protein–based shake as meal replacement 2 times per day, the nutritional supplementation program included a cleanse product on days 1 to 7, soluble fiber supplementation including oat bran concentrate and apple pectin on all days, and "green food" supplementation on days 8 to 21.[15]

As part of the program, there were weekly luncheons for the participants. At the weekly luncheons, the supervising clinician answered questions from the participants; and the participants shared recipes and provided peer encouragement to each other. Difficulties with adhering to the dietary modifications and adverse effects were discussed.

Data collection

Anthropometric measurements included body weight, height, BMI, and waist and hip circumferences. Anthropometric assessments were conducted with the participants wearing light clothing (gown and shorts) and barefoot. Weight was measured using a high-precision digital scale (DI-10, DIGI Matex, Inc, Singapore; 0.1-kg gradations; 225-kg capacity). Height was measured using a high-precision digital stadiometer

(seca 242, Hamburg,·Germany; 1-mm gradations; measuring range, 62-210 cm). Body mass index was calculated from the measured body weight and height (kilograms per square meter). A standard cloth tape marked with inches and centimeters was used to measure waist and hip circumferences. Each site was measured 3 times and the 3 most consistent measurements were averaged to enhance reliability. Body landmarks of the umbilicus and greater trochanters were used to standardize measurements of pre-post waist and hip circumferences, respectively, to enhance reliability and validity. The waist-to-hip ratio and waist-to-height ratio were calculated.

A fasting lipid profile was obtained from each participant, pre-postintervention. Professional services were obtained from a local hospital to perform venipuncture and analyze the venous plasma samples. Venous plasma (lithium heparin) was collected by standard venipuncture technique from the antecubital vein. Venous plasma samples were analyzed using routine clinical chemistry methods to measure total cholesterol, LDL cholesterol, high-density lipoproteins (HDL cholesterol), and triglycerides.

A visual analog scale was used to assess perceived energy level, weight management control, and gastrointestinal health. The context of administrating the 10-cm visual analog scale required that the participants rate their energy level with anchors set at "no energy at all" to "full of energy," weight management control with anchors set at "always worrying about my weight" to "no problems with weight control," and gastrointestinal health with anchors set at "daily gastrointestinal symptoms" to "no symptoms at all." Gastrointestinal symptoms included bloating, belching, flatulence, diarrhea or constipation, heartburn, and nausea.

Participants kept a daily diary of any adverse effects that they experienced. The participants were instructed to write "none" or "no adverse effects" if they did not experience any adverse effects on a given day. The diaries were collected weekly, and the participants had the contact information of the principal investigator to ensure adequate safety monitoring during the 21-day intervention. The participants also completed a daily checklist regarding their supplementation schedule adherence.

The diary allowed us to monitor any adverse effects, and the completed checklist allowed us to monitor participant compliance to the recommended supplementation schedule. The participants were not asked to record dietary food intake during the 21 days. Compliance to the dietary recommendations was gauged using verbal reports by each participant during the weekly luncheons as part of the program.

Data analyses

The primary outcome measures were weight and lipid profiles pr-e and postintervention. Secondary outcomes were BMI; waist and hip circumferences; waist-to-hip and waist-to-height ratios; and perceived changes in energy level, weight management control, and gastrointestinal health. Pre-post data from each of the cases in the series were presented in Tables 1 to 3. Interpretations of the data findings were based upon meaningful clinical differences for each of the outcome measures.

Results

Study population

Of the 32 individuals screened and enrolled in the program, 6 men and 1 woman (n = 7; 26 ± 2.1 years)

Table 1 Anthropometric measurements

	Preintervention						Postintervention					
	Weight	BMI	Waist	Hip	Waist/hip	Waist/height	Weight	BMI	Waist	Hip	Waist/hip	Waist/height
Participants	lb (kg)	kg/m^2	in	in	Ratio	Ratio	lb (kg)	kg/m^2	in	in	Ratio	Ratio
1 (M)	193.7 (87.9)	27.8	36.5	41.0	0.89	0.52	182.9 (83.0)	24.8	35.8	39.8	0.90	0.51
2 (M)	250.8 (113.8)	33.9	43.5	47.0	0.93	0.60	234.8 (106.5)	31.7	40.5	44.0	0.92	0.56
3 (M)	231.3 (104.9)	31.3	41.5	44.0	0.94	0.58	216.6 (98.2)	29.4	40.5	42.5	0.95	0.56
4 (M)	179.9 (81.6)	26.3	33.5	38.5	0.87	0.48	174.7 (79.2)	24.7	33.5	39.5	0.85	0.48
5 (M)	179.6 (81.5)	27.3	33.0	40.0	0.83	0.49	171.5 (77.8)	26.0	32.0	39.0	0.82	0.47
6 (F)	163.4 (74.1)	30.7	35.0	41.0	0.85	0.57	156.0 (70.8)	29.4	34.0	40.5	0.84	0.56
7 (M)	260.0 (117.9)	33.8	42.0	45.5	0.92	0.57	240.1 (108.9)	29.6	39.6	44.0	0.90	0.54
Mean values	208.4 (94.5)	30.2	37.9	42.4	0.89	0.54	196.7 (89.2)	27.9	36.6	41.3	0.88	0.53

F, female; *M*, male.

Table 2 Fasting lipid profiles (milligrams per deciliter)

	Preintervention				Postintervention			
Participants	Total cholesterol	HDL	LDL	TAG	Total cholesterol	HDL	LDL	TAG
1 (M)	176	32	113	153	144	34	93	84
2 (M)	213	29	118	331	177	26	111	200
3 (M)	177	41	97	195	123	35	66	110
4 (M)	260	29	185	228	183	23	118	208
5 (M)	129	44	68	83	118	38	59	105
6 (F)	148	57	81	50	101	35	55	54
7 (M)	143	49	67	133	116	37	58	103
Mean values	178	40	104	168	137	33	80	123

TAG, triglycerides; *F*, female; *M*, male.

qualified for the analysis according to the inclusion and exclusion criteria. Twenty-three individuals did not meet the BMI inclusion criterion of 25 to 34.99 kg/m^2. Two individuals were currently taking prescription medications. The 7 participants enrolled in the case series analysis reported that they engaged in an exercise routine (either aerobic exercise or resistance training) at least 3 times per week, and they were instructed to maintain their levels of physical activities and exercise during the SPPP.

Compliance

During the weekly luncheons during the program, the 7 participants reported that they followed the dietary recommendations. Overall, the 7 participants were compliant with consuming 2 whey protein–based shakes as meal replacements and following the nutritional supplementation program. On days 12 and 21, 1 participant reported not consuming *SP Complete* shakes as meal replacements. On day 5, 1 participant reported having 1 less *SP Cleanse* serving than recommended (14 *SP Cleanse* pills instead of 21 *SP Cleanse* pills per day). On days 18 and 20, 1 participant reported having 1 less *SP Green Food* serving than recommended (5 *SP Green Food* pills instead of 10 *SP Green Food* pills). On days 6 and 16, 1 participant reported consuming only 1 *SP Complete* shake. In summary, there were 7 reported days in which 1 participant did not fully comply with treatment recommendations. The estimated compliance with the allocated treatment was 95% (7 participants × 21 days = 147 compliance days; minus the 7 reported noncompliance days; 140/147 = 95%).

Outcome measures

Table 1 summarizes the anthropometric measurements. Weight loss was between 5.2 lb (2.4 kg) and 19.9 lb (9.0 kg) with an average weight loss of 11.7 lb (5.3 kg). Decreases in BMI were between 1.3 and 4.2 kg/m^2 with an average decrease of 2.3 kg/m^2 pre-post intervention. Pre-post intervention, the average decrease in waist circumferences was 1.3 in with a concomitant decrease of 0.01 in the waist/height ratio. Participant 4, with the least amount of weight loss, did not experience decreases in waist circumference or waist/height ratio. With the exception of participant 4, hip circumferences decreased between 0.5 and 3.0 in. There were no systematic changes among the participants for the waist-hip ratio pre-post intervention.

Table 3 Visual analog scale data (0-10 cm): ratings of energy level, weight management control, and gastrointestinal health

		Preintervention			Postintervention		
Participants	Age (y)	Energy level	Weight control	Gastrointestinal	Energy level	Weight control	Gastrointestinal
1 (M)	27	2.3	5.9	4.3	6.3	6.3	7.0
2 (M)	30	1.2	2.5	7.0	6.7	6.9	7.6
3 (M)	27	5.9	1.0	2.5	7.2	5.5	6.6
4 (M)	27	3.2	1.0	2.4	6.5	6.5	7.9
5 (M)	24	3.0	5.6	7.2	6.2	6.9	7.4
6 (F)	24	5.7	0.5	3.8	4.9	4.9	6.0
7 (M)	25	2.4	2.3	4.4	6.4	7.8	6.3
Mean values	26	3.4	2.7	4.5	6.3	6.4	7.0

F, female; *M*, male.

Table 2 summarizes the lipid profiles. Pre-post intervention, decreases in total cholesterol levels and LDL cholesterol levels were between 11 and 77 mg/dL and between 7 and 67 mg/dL, respectively. Total cholesterol levels decreased on average from 178 mg/dL preintervention to 134 mg/dL postintervention with a concomitant decrease in LDL levels from 104 mg/dL preintervention to 80 mg/dL postintervention. With the exception of participant 1, HDL levels decreased between 3 and 22 mg/dL with an average decrease of 7 mg/dL. The LDL to HDL ratios decreased on average 0.27 point. There were no systematic changes among participants for triglyceride levels pre-post intervention.

In general, participants reported improvements in energy levels, weight management control, and gastrointestinal health postintervention (Table 3).

Adverse effects

There were a total of 169 recordings in the adverse effects logs (7 participants recording symptoms for 21 days each, with some participants reporting more than 1 symptom per day). The percentages of adverse effects were calculated for 5 different categories: (1) no adverse effects at a frequency of 58%, (2) headaches at a frequency of 13.6%, (3) gastrointestinal symptoms at a frequency of 14.2%, (4) fatigue and muscle soreness at a frequency of 8.3%, and (5) hunger and food cravings at a frequency of 5.9%. With the exception of gastrointestinal symptoms reported by only 1 participant throughout week 3, all other adverse effects subsided after week 2.

Discussion

The findings of this case series showed similar results to the retrospective medical record review by Powell and Leonard[15] that the SPPP is a nutritional intervention that may assist with short-term weight loss and lipid profile improvement. Clinically meaningful decreases occurred for weight loss (11.2 vs 9.0 lb; 5.1 vs. 4.1 kg), total cholesterol levels (44 vs 47 mg/dL), and LDL cholesterol levels (24 vs 35 mg/dL) in both the current study and the retrospective medical record review by Powell and Leonard,[15] respectively. The dietary component of the SPPP is consistent with the findings that low–energy-density diets and portion size control are 2 critical attributes underlying weight loss.[16,17] The whole food properties of the regimented nutritional supplementation program to include whey-based protein meal replacement shakes, fiber, phytosterols, prebiotics and probiotics, and 1 to 2 servings of lean meat (days 11-21) are consistent with the evidence for improvements in lipid profiles and weight loss ("Introduction" and below). The weekly luncheons by providing patient education on the benefits of low–energy-density diets, that is, whole foods philosophy of healthy eating, mostly likely contributed to our findings on the SPPP.[12]

For overweight and obese adults, that is, BMI from 25 to 34.99 kg/m^2, a rapid weight loss of 3.3 to 5.5 lb/wk (1.5 to 2.5 kg/wk) or approximately 2% to 3% of initial body weight per week is deemed safe under the supervision of a health care provider.[9,33-35] Weight loss for all individuals in the case series met this safety criterion for rapid weight loss. There were improvements in the secondary anthropometric outcome measures, but the pre-post changes were not clinically meaningful differences with the exception of BMI. On average, BMI shifted from obese category to the overweight category, with 5 of the 7 participants changing from being classified as obese to overweight or overweight to normal weight. Waist-to-height ratios less than 0.50[36,37] and waist-to-hip ratios less than 0.83 for women and less than 0.90 for men[38] are associated with a decreased risk for cardiovascular disease. Reducing the risk of cardiovascular disease as defined by these anthropometric indices was not observed.

Although total cholesterol levels were less than 200 mg/dL at preintervention (178 mg/dL), the pre-post intervention decrease of 44 mg/dL was still deemed clinically meaningful, as a total cholesterol level of 131 mg/dL after the SPPP reflects a more favorable lipid profile.[39,40] In the current study and previously,[15] participants with total cholesterol levels greater than 200 mg/dL experienced clinically meaningful decreases. For LDL cholesterol levels, a target of 100 mg/dL is ideal for reducing the risk of cardiovascular disease, with the most recent recommendation to change the ideal target to less than 70 mg/dL.[39,40] The SPPP reduced LDL cholesterol levels from an average of 104 to 80 mg/dL (inducing decreases in all 7 participants). However, 2 participants still demonstrated post-SPPP total LDL cholesterol levels greater than 100 mg/dL, which do not achieve the ideal target of decreased cardiovascular disease risk. This was also previously demonstrated by the Powell and Leonard study in which all patients showed a reduction in LDL cholesterol levels, but the average total LDL cholesterol was 110 mg/dL.[15]

The impact of the program on optimal levels of triglycerides, less than 150 mg/dL,[39,40] was inconclusive in the current study, with Powell and Leonard[15]

reporting a decrease from 116 to 89 mg/dL. Neither the current study nor the previous study[15] detected increases in HDL cholesterol levels to greater than 60 mg/dL.[39,40] A decrease in HDL cholesterol is expected when participants are participating in a calorie-restricted, low–energy(calorie)-density dietary intervention.[41,42] In addition, weight loss achieved through exercise is more effective at raising HDL cholesterol levels than dieting.[43] Similarly, exercise, independent of weight loss and dietary changes, is an effective intervention for decreasing triglycerides.[44,45] However, there is evidence that high-protein and moderate-protein weight loss diets are effective at decreasing triglycerides and increasing HDL cholesterol levels.[46-49] Although HDL cholesterol levels decreased in patients, the pre and post LDL/HDL cholesterol ratio levels also decreased from an average of 2.95 preintervention to 2.68 postintervention. According to recommendations by the National Cholesterol Education Program Adult Treatment Panel III, an LDL/HDL cholesterol ratio of around 2.5 is optimal for decreased cardiovascular disease risk.[50]

Low-calorie, protein-rich weight loss diets reduce fat mass while maintaining lean body mass and enhancing satiety.[47,51-54] Short-term, high-protein diets reduced total cholesterol levels and LDL cholesterol levels in overweight and obese individuals.[46,51,55] The inclusion of whey protein sources into a low-calorie dietary intervention may be more effective than soy protein toward enhancing weight loss, reducing total cholesterol levels, and maintaining lean body mass.[54,56,57] In addition, increases in protein intake during weight maintenance stimulate fat oxidation, which results in decreases in fat mass.[58,59] Perceptions of improvements in energy levels, weight management control, and gastrointestinal health were also consistent with low-calorie, protein-rich weight loss diets.[53]

Limitations and future studies

Although the case series analysis was prospective, participant selection bias limits the generalizability of the results. Sample size and sex bias (6 men and 1 woman) limit the generalizability of the results. This was a short-term study; thus, long-term effects of the dietary modifications and whole food supplementation with respect to adherence, weight control, and health benefits are unknown. The SPPP is designed to work synergistically using both dietary modifications and whole food supplementation. However, the multicomponent nature of the program and the inclusion of weekly patient education preclude any conclusions on the independent effects of dietary modifications and whole food supplementation on weight loss and improvements in lipid profiles.

Future studies should be performed including randomized controlled trials to compare the SPPP with other dietary supplements and programs. When planning these trials, their validity depends upon adequately defining (1) hypotheses; (2) recruitment strategies; (3) sampling of patient populations to include eligibility criteria, sample size, and randomization procedures; (4) therapeutic and control interventions with procedures to monitor treatment adherence and adverse events; (5) blinding; (6) primary and secondary outcome measures; and (7) appropriate statistical procedures.[30] The randomized trial needs to address the sustainability of dietary modifications after the 21-day "detoxification" phase and the long-term benefits on weight management and chronic disease risk factors.[3,13,14,60-62] Given the current obesity epidemic and diversity of patient populations and their eating behaviors, there is a critical need for a vast array of evidence-based weight management programs that health care professionals can offer to their patients to promote long-term weight control and health.[3,60-62]

Conclusions

After participating in the short-term SPPP, which included dietary modification and whole food supplementation, the 7 participants experienced weight loss and improvements in their lipid profiles. Participants in this study showed overall compliance and reported only a few mild adverse effects. The findings have practical implications from the perspective of offering nutritional interventions within a primary care setting such as a chiropractic office.

Funding sources and potential conflicts of interest

No funding sources or conflicts of interest were reported for this study.

References

1. Austin GL, Ogden LG, Hill JO. Trends in carbohydrate, fat, and protein intakes and association with energy intake in

normal-weight, overweight, and obese individuals: 1971-2006. Am J Clin Nutr 2011;93:836–43.
2. Civitarese AE, Carling S, Heilbronn LK, Hulver MH, Ukropcova B, Deutsch WA, et al. Calorie restriction increases muscle mitochondrial biogenesis in healthy humans. PLoS Med 2007;4:e76.
3. Dansinger ML, Gleason JA, Griffith JL, Selker HP, Schaefer EJ. Comparison of the Atkins, Ornish, Weight Watchers, and Zone diets for weight loss and heart disease risk reduction: a randomized trial. JAMA 2005;293:43–53.
4. Das SK, Gilhooly CH, Golden JK, Pittas AG, Fuss PJ, Cheatham RA, et al. Long-term effects of 2 energy-restricted diets differing in glycemic load on dietary adherence, body composition, and metabolism in CALERIE: a 1-y randomized controlled trial. Am J Clin Nutr 2007;85:1023–30.
5. Heilbronn LK, de Jonge L, Frisard MI, Delany JP, Larson-Meyer DE, Rood J, et al. Effect of 6-month calorie restriction on biomarkers of longevity, metabolic adaptation, and oxidative stress in overweight individuals: a randomized controlled trial. JAMA 2006;295:1539–48.
6. Sacks FM, Bray GA, Carey VJ, Smith SR, Ryan DH, Anton SD, et al. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. N Engl J Med 2009;360:859–73.
7. Davis LM, Coleman C, Kiel J, Rampolla J, Hutchisen T, Ford L, et al. Efficacy of a meal replacement diet plan compared to a food-based diet plan after a period of weight loss and weight maintenance: a randomized controlled trial. Nutr J 2010;9:11.
8. Foster GD, Borradaile KE, Vander Veur SS, Leh SK, Dilks RJ, Goldbacher EM, et al. The effects of a commercially available weight loss program among obese patients with type 2 diabetes: a randomized study. Postgrad Med 2009;121:113–8.
9. Furlow EA, Anderson JW. A systematic review of targeted outcomes associated with a medically supervised commercial weight-loss program. J Am Diet Assoc 2009;109:1417–21.
10. Bowerman S, Bellman M, Saltsman P, Garvey D, Pimstone K, Skootsky S, et al. Implementation of a primary care physician network obesity management program. Obes Res 2001;9(Suppl 4):321S–5S.
11. Balliett M, Rasmussen O, Burke J. Effects of tea combined with high-protein meal replacement shakes on anthropometric measurements, lipid profiles, cellular biochemistry, neurochemistry, and microbial metabolism: a prospective observational study. Journal of Chiropractic Medicine 2011;10: 272–82.
12. Glanz K, Hersey J, Cates S, Muth M, Creel D, Nicholls J, et al. Effect of a nutrient rich foods consumer education program: results from the nutrition advice study. J Acad Nutr Diet 2012;112:56–63.
13. Gil A, Ortega RM, Maldonado J. Wholegrain cereals and bread: a duet of the Mediterranean diet for the prevention of chronic diseases. Public Health Nutr 2011;14:2316–22.
14. Raynor HA, Van Walleghen EL, Bachman JL, Looney SM, Phelan S, Wing RR. Dietary energy density and successful weight loss maintenance. Eat Behav 2011;12:119–25.
15. Powell JP, Leonard JS. A nutritional program improved lipid profiles and weight in 28 chiropractic patients: a retrospective case series. J Chiropr Med 2008;7:94–100.
16. Rolls BJ. The relationship between dietary energy density and energy intake. Physiol Behav 2009;97:609–15.
17. Rolls BJ. Plenary lecture 1: dietary strategies for the prevention and treatment of obesity. Proc Nutr Soc 2010;69:70–9.
18. Mumford SL, Schisterman EF, Siega-Riz AM, Gaskins AJ, Wactawski-Wende J, Vanderweele TJ. Effect of dietary fiber intake on lipoprotein cholesterol levels independent of estradiol in healthy premenopausal women. Am J Epidemiol 2011;173: 145–56.
19. Metzger BT, Barnes DM, Reed JD. A comparison of pectin, polyphenols, and phytosterols, alone or in combination, to lovastatin for reduction of serum lipids in familial hypercholesterolemic swine. J Med Food 2009;12:854–60.
20. Demonty I, Ras RT, van der Knaap HC, Meijer L, Zock PL, Geleijnse JM, et al. The effect of plant sterols on serum triglyceride concentrations is dependent on baseline concentrations: a pooled analysis of 12 randomised controlled trials. Eur J Nutr 2012;52:153–60.
21. Delzenne NM, Cani PD. Interaction between obesity and the gut microbiota: relevance in nutrition. Annu Rev Nutr 2011;31:15–31.
22. Delzenne NM, Neyrinck AM, Backhed F, Cani PD. Targeting gut microbiota in obesity: effects of prebiotics and probiotics. Nat Rev Endocrinol 2011;7:639–46.
23. de Vrese M, Schrezenmeir J. Probiotics, prebiotics, and synbiotics. Adv Biochem Eng Biotechnol 2008;111:1–66.
24. Macfarlane GT, Steed H, Macfarlane S. Bacterial metabolism and health-related effects of galacto-oligosaccharides and other prebiotics. J Appl Microbiol 2008;104:305–44.
25. Pereira DI, Gibson GR. Effects of consumption of probiotics and prebiotics on serum lipid levels in humans. Crit Rev Biochem Mol Biol 2002;37:259–81.
26. Roberfroid M, Gibson GR, Hoyles L, McCartney AL, Rastall R, Rowland I, et al. Prebiotic effects: metabolic and health benefits. Br J Nutr 2010;104(Suppl 2):S1–S63.
27. Cani PD, Delzenne NM. The role of the gut microbiota in energy metabolism and metabolic disease. Curr Pharm Des 2009;15:1546–58.
28. Parnell JA, Reimer RA. Weight loss during oligofructose supplementation is associated with decreased ghrelin and increased peptide YY in overweight and obese adults. Am J Clin Nutr 2009;89:1751–9.
29. Wong JM, Kendall CW, de Souza R, Emam A, Marchie A, Vidgen E, et al. The effect on the blood lipid profile of soy foods combined with a prebiotic: a randomized controlled trial. Metabolism 2010;59:1331–40.
30. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol 2010;63:e1–e37.
31. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. Circulation 2005;111: 697–716.
32. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the

American Heart Association Council on High Blood Pressure Research. Hypertension 2005;45:142–61.
33. National Task Force on the Prevention and Treatment of Obesity, National Institutes of Health. Very low-calorie diets. JAMA 1993;270:967–74.
34. Munro IA, Garg ML. Weight loss and metabolic profiles in obese individuals using two different approaches. Food Funct 2011;2:611–6.
35. Tsai AG, Wadden TA. The evolution of very-low-calorie diets: an update and meta-analysis. Obesity (Silver Spring) 2006;14:1283–93.
36. Lee CM, Huxley RR, Wildman RP, Woodward M. Indices of abdominal obesity are better discriminators of cardiovascular risk factors than BMI: a meta-analysis. J Clin Epidemiol 2008;61:646–53.
37. Schneider HJ, Friedrich N, Klotsche J, Pieper L, Nauck M, John U, et al. The predictive value of different measures of obesity for incident cardiovascular events and mortality. J Clin Endocrinol Metab 2010;95:1777–85.
38. Yusuf S, Hawken S, Ounpuu S, Bautista L, Franzosi MG, Commerford P, et al. Obesity and the risk of myocardial infarction in 27,000 participants from 52 countries: a case-control study. Lancet 2005;366:1640–9.
39. Third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation 2002;106:3143–421.
40. Martin SS, Metkus TS, Horne A, Blaha MJ, Hasan R, Campbell CY, et al. Waiting for the National Cholesterol Education Program Adult Treatment Panel IV guidelines, and in the meantime, some challenges and recommendations. Am J Cardiol 2012;110:307–13.
41. Aicher BO, Haser EK, Freeman LA, Carnie AV, Stonik JA, Wang X, et al. Diet-induced weight loss in overweight or obese women and changes in high-density lipoprotein levels and function. Obesity (Silver Spring) 2012;20:2057–62.
42. Mooradian AD, Haas MJ, Wehmeier KR, Wong NC. Obesity-related changes in high-density lipoprotein metabolism. Obesity (Silver Spring) 2008;16:1152–60.
43. Rashid S, Genest J. Effect of obesity on high-density lipoprotein metabolism. Obesity (Silver Spring) 2007;15:2875–88.
44. Gerhard GT, Ahmann A, Meeuws K, McMurry MP, Duell PB, Connor WE. Effects of a low-fat diet compared with those of a high-monounsaturated fat diet on body weight, plasma lipids and lipoproteins, and glycemic control in type 2 diabetes. Am J Clin Nutr 2004;80:668–73.
45. Shaw K, Gennat H, O'Rourke P, Del Mar C. Exercise for overweight or obesity. Cochrane Database Syst Rev 2006: CD003817.
46. Clifton PM, Bastiaans K, Keogh JB. High protein diets decrease total and abdominal fat and improve CVD risk profile in overweight and obese men and women with elevated triacylglycerol. Nutr Metab Cardiovasc Dis 2009;19:548–54.
47. Lasker DA, Evans EM, Layman DK. Moderate carbohydrate, moderate protein weight loss diet reduces cardiovascular disease risk compared to high carbohydrate, low protein diet in obese adults: a randomized clinical trial. Nutr Metab (Lond) 2008;5:30.
48. Layman DK, Evans EM, Erickson D, Seyler J, Weber J, Bagshaw D, et al. A moderate-protein diet produces sustained weight loss and long-term changes in body composition and blood lipids in obese adults. J Nutr 2009;139:514–21.
49. Noakes M, Keogh JB, Foster PR, Clifton PM. Effect of an energy-restricted, high- protein, low-fat diet relative to a conventional high-carbohydrate, low-fat diet on weight loss, body composition, nutritional status, and markers of cardiovascular health in obese women. Am J Clin Nutr 2005;81:1298–306.
50. Fernandez ML, Webb D. The LDL to HDL cholesterol ratio as a valuable tool to evaluate coronary heart disease risk. J Am Coll Nutr 2008;27:1–5.
51. Brehm BJ, D'Alessio DA. Benefits of high-protein weight loss diets: enough evidence for practice? Curr Opin Endocrinol Diabetes Obes 2008;15:416–21.
52. Mettler S, Mitchell N, Tipton KD. Increased protein intake reduces lean body mass loss during weight loss in athletes. Med Sci Sports Exerc 2010;42:326–37.
53. Leidy HJ, Carnell NS, Mattes RD, Campbell WW. Higher protein intake preserves lean mass and satiety with weight loss in pre-obese and obese women. Obesity (Silver Spring) 2007;15:421–9.
54. Paddon-Jones D, Westman E, Mattes RD, Wolfe RR, Astrup A, Westerterp-Plantenga M. Protein, weight management, and satiety. Am J Clin Nutr 2008;87:1558S–61S.
55. Meckling KA, Sherfey R. A randomized trial of a hypocaloric high-protein diet, with and without exercise, on weight loss, fitness, and markers of the metabolic syndrome in overweight and obese women. Appl Physiol Nutr Metab 2007;32:743–52.
56. Baer DJ, Stote KS, Paul DR, Harris GK, Rumpler WV, Clevidence BA. Whey protein but not soy protein supplementation alters body weight and composition in free-living overweight and obese adults. J Nutr 2011;141:1489–94.
57. St-Onge MP, Claps N, Wolper C, Heymsfield SB. Supplementation with soy-protein-rich foods does not enhance weight loss. J Am Diet Assoc 2007;107:500–5.
58. Lejeune MP, Kovacs EM, Westerterp-Plantenga MS. Additional protein intake limits weight regain after weight loss in humans. Br J Nutr 2005;93:281–9.
59. Soenen S, Plasqui G, Smeets AJ, Westerterp-Plantenga MS. Protein intake induced an increase in exercise stimulated fat oxidation during stable body weight. Physiol Behav 2010;101: 770–4.
60. Malik VS, Hu FB. Popular weight-loss diets: from evidence to practice. Nat Clin Pract Cardiovasc Med 2007;4:34–41.
61. Scholl J. Traditional dietary recommendations for the prevention of cardiovascular disease: do they meet the needs of our patients? Cholesterol 2012;2012:367898.
62. Shai I, Schwarzfuchs D, Henkin Y, Shahar DR, Witkow S, Greenberg I, et al. Weight loss with a low-carbohydrate, Mediterranean, or low-fat diet. N Engl J Med 2008;359:229–41.

Standard Process®
WHOLE FOOD NUTRIENT SOLUTIONS

Retrospective Case Series Study

Journal of Chiropractic Medicine (2008) 7, 94–100

ELSEVIER

JCM Journal of Chiropractic Medicine

www.journalchiromed.com

A nutritional program improved lipid profiles and weight in 28 chiropractic patients: a retrospective case series☆

James P. Powell DC[a], Joseph S. Leonard MS[b,*]

[a] *Director, Powell Chiropractic Clinic Inc, Canton, OH 44718*
[b] *Manager of Outcomes Research, Department of Research and Development, Standard Process Inc, Palmyra, WI 53156*

Received 31 October 2007; received in revised form 16 April 2008; accepted 4 May 2008

Key indexing terms:
Cholesterol;
Diet therapy;
Metabolic detoxication, phase II;
Metabolic detoxication, phase I;
Chiropractic;
Nutrition therapy;
Lipids

Abstract

Objective: This study retrospectively examined the effects of a 21-day nutritional intervention program, which included fruit and vegetable consumption, energy restriction, and nutritional supplements, on serum lipid measures in 28 chiropractic patients.

Methods: Medical records were reviewed for 28 chiropractic patients who had completed a commercially available 21-day nutritional intervention program between April 2005 and August 2007 and for whom complete serum lipid and weight measures immediately pre- and postintervention were available. The primary outcome was change in serum lipids, and change in body weight was a secondary outcome variable.

Results: Significant reductions in total, low-density lipoprotein, very low-density lipoprotein, and high-density lipoprotein cholesterol, and triglycerides were observed. Serum triglycerides decreased from 116.3 ± 54.6 (mean ± SD) to 88.6 ± 40.5 mg/dL ($P < .01$). Total cholesterol decreased from 223.3 ± 40.7 to 176.2 ± 30.0 mg/dL ($P < .0001$). Low-density lipoprotein cholesterol decreased from 145.7 ± 36.8 to 110.9 ± 25.3 mg/dL ($P < .0001$). High-density lipoprotein cholesterol decreased from 54.3 ± 14.6 to 47.6 ± 10.5 mg/dL ($P < .001$). Weight for patients decreased from 191.2 ± 38.8 to 182.2 ± 36.3 lb ($P < .0001$).

Conclusions: This retrospective case series supports the hypothesis that a nutritional purification intervention program emphasizing fruit and vegetable consumption, energy restriction, and nutritional supplements reduces serum lipids and weight.

Introduction

Chiropractors regularly provide preventive health interventions based on lifestyle and nutritional factors (smoking, exercise, diet, etc) to promote the health of their patients, to prevent disease conditions, to provide

☆ Competing interests: JL is employed by Standard Process Inc as the Manager of Outcomes Research, Department of Research and Development. JP sells Standard Process products in his practice and earns income from the sale of these products.

* Corresponding author. Standard Process Inc., 1200 W Royal Lee Dr., Palmyra, WI 53156. Tel.: +1 262 495 6439; fax: +1 262 495 2512.

E-mail address: jleonard@standardprocess.com (J.S. Leonard).

1556-3707/$ – see front matter © 2008 National University of Health Sciences.
doi:10.1016/j.jcm.2008.05.002

symptomatic relief, and to reduce the recurrence of disease conditions.[1] Patients seeking chiropractic care may present with health conditions that put them at higher risk for chronic diseases. For example, high cholesterol and overweight are 2 known risk factors for cardiovascular disease (CVD).

A nutrient-dense diet with energy restriction has been hypothesized to slow aging and extend life span in humans based on experiments in primates and other animals.[2] In addition, it is well established that a diet rich in fruits and vegetables reduces risk for chronic disease, particularly CVD risk.[3-6] The mechanisms are still being explored, but longitudinal dietary studies show that individuals consuming a whole food diet consisting of unprocessed fruit and vegetables, lean meat, nuts, and healthy oils—as with the Mediterranean diet—have lower rates of all-cause and cause-specific (CVD, cancer) mortality.[7,8] Conversely, research shows that the modern Western dietary pattern (saturated and *trans*-fat, refined grains, sugar, salt, etc) is associated with increases in CVD mortality.[9,10]

Nutritional purification refers to optimizing the general health and wellness of patients in certain clinical settings using nutrition as the primary therapeutic modality. It takes many forms and may incorporate several integrative and alternative therapies. Anecdotal reports from practitioners using the Standard Process (SP) Purification Program (Standard Process Inc, Palmyra, WI) for nutritional support have indicated a possible beneficial effect of the program on serum lipid measures. To further investigate potential effects on serum lipids, we conducted a retrospective chart review on 28 chiropractic patients (9 male and 19 female) who had received the 21-day purification program between April 2005 and August 2007 while receiving chiropractic care at our clinic. Primary end points of interest were serum cholesterol and triglyceride measures. Weight reduction was examined as a secondary outcome. The purpose of this study was to retrospectively examine the effects of a 21-day nutritional intervention program on serum lipid measures in 28 chiropractic patients.

Methods

Deidentified case reports for 28 patients were reviewed and analyzed for this case series. The records of patients were selected for inclusion in the chart review if they had recorded lipid panel and weight measures pre- and posttherapy. Patients were selected without regard for body mass index, age, or sex. Nineteen of the 28 patients were female, and patient age ranged from 25 to 77 years (mean age = 50 ± 11.7). Patients received chiropractic care from our clinic for a variety of musculoskeletal problems while on the nutritional program.

Patients included in the study were not taking any pharmaceutical lipid-lowering or cholesterol medications before or during the 21 days of the nutritional program. Patients who were taking other prescription pharmaceutical medications when they began the nutritional program continued using these medications during the 21 days of the intervention.

A serum lipid panel had been obtained from each patient before starting the nutritional program and was repeated at the conclusion of the 21-day program (between 21-23 days after starting the program). Patient charts were deidentified according to the Health Insurance Portability and Accountability Act Privacy Rule.

Dietary modification in the purification program included an increased intake of raw fruits and vegetables and restriction or elimination of meat, refined oils, and refined carbohydrates (energy reduction) for the duration of the program. Patients were asked to comply with the following dietary modifications for the 21 days of the program: (1) eat vegetables and fruit only; (2) do not eat any salad dressing; (3) drink only water as a beverage, eight 12-oz glasses per day; (4) salads can have unlimited fresh vegetables (red, yellow, and green peppers; onions; tomatoes; mushrooms; spinach; broccoli; mixed greens; etc); (5) no nuts, seeds, beans, or starchy root vegetables (potatoes, yams, turnips, etc); and (6) steamed vegetables are recommended along with salad at dinner (kale, broccoli, Swiss chard, Brussels sprouts, asparagus, red beets, etc).

In addition to dietary modifications with energy restriction, a specific nutritional supplementation regimen was also prescribed for patients. SP Cleanse, GastroFiber, SP Complete (a whey protein–based shake), and SP Green Food, nutritional supplements from Standard Process Inc, were provided to these patients during the 21-day program as described in Table 1 in accordance with dosages described on product labels. Refer to Appendix A for a description of these products.

Because this study was a retrospective chart review on a nonrandom series of selected cases, data were analyzed qualitatively and statistical tests were performed only to document statistically significant change in the selected sample as a whole for serum lipid parameters and weight. A paired *t* test was used to

Table 1 Supplementation regimen during the 21-day purification program

Baseline	Days 1-7	Days 8-14	Days 14-21	Follow-up
Serum Lipid Measures	SP Cleanse: 7 Capsules 3×/d Without Food	GastroFiber: 3 Capsules 3×/d Without Food	GastroFiber: 3 Capsules 3×/d Without Food	Serum Lipid Measures Weight
	GastroFiber: 3 Capsules 3×/d Without Food	SP Green Food: 5 Capsules 2×/d With Food	SP Green Food: 5 Capsules 2×/d With Food	
	SP Complete Nutritional Shakes: 2-3 Shakes/d as Needed; 2 Rounded Scoops of SP Complete Powder + 1 to 1 1/2 cups of fruit + 1/2 to 1 cup of water + 1 TBSP Flaxseed Oil (Suggested)	Continue With SP Complete Shakes: 2-3 Shakes/d as Needed	Continue With SP Complete Shakes: 2-3 Shakes/d as Needed	

See Appendix A for a description of the supplements used. Serum lipids were measured at baseline before patients commenced the purification program. *TBSP*, Tablespoon.

analyze the changes in relevant measures pre- and posttherapy ($\alpha = .01$).

Results

Pre- and postintervention serum lipid measures for these patients were extracted from their medical charts and analyzed. Total cholesterol, triglycerides, high-density lipoprotein (HDL), low-density lipoprotein (LDL), and very low-density lipoprotein (VLDL) decreased significantly ($P \leq .01$) on average for these patients (Fig 1 and Table 2).

Individually, all patients showed beneficial changes in serum lipids, although the magnitude of the response varied. Average serum triglycerides decreased from 116.3 ± 54.6 mg/dL preintervention to 88.6 ± 40.5 mg/dL postintervention ($P < .01$). Total cholesterol decreased for all patients, as shown in Fig 2. The average total cholesterol for these patients preintervention was 223.3 ± 40.7 mg/dL (mean ± SD). This decreased to 176.2 ± 30.0 mg/dL postintervention, a 47-point drop on average ($P < .0001$). Low-density lipoprotein cholesterol also decreased for all patients in a similar fashion (data not shown). The average LDL cholesterol decreased from 145.7 ± 36.8 mg/dL preintervention to 110.9 ± 25.3 mg/dL postintervention ($P < .0001$), a 35-point drop. Average HDL cholesterol ("good cholesterol") decreased from 54.3 ± 14.6 mg/dL preintervention to 47.6 ± 10.5 mg/dL postintervention ($P < .001$), a 7-point drop. Twenty-two patients had decreased HDL postintervention, whereas 4 had slight increases and 2 were unchanged (Fig 3). In addition, the LDL/HDL ratio and the total cholesterol–HDL ratio both decreased significantly for these patients. The LDL/HDL ratio decreased from 2.9 ± 1.2 to 2.5 ± 0.9 ($P \leq .001$), and the total cholesterol–HDL ratio decreased from 4.4 ± 1.4 to 3.9 ± 1.2 ($P \leq .001$). The statistically significant decrease in the total cholesterol–HDL ratio and the LDL/HDL ratio suggests that the reductions in total and LDL cholesterol contribute most to the hypolipidemic effects of the purification program than do reductions in HDL. The average weight for patients was 191.2 ± 38.8 lb preintervention. This decreased to 182.2 ± 36.3 lb

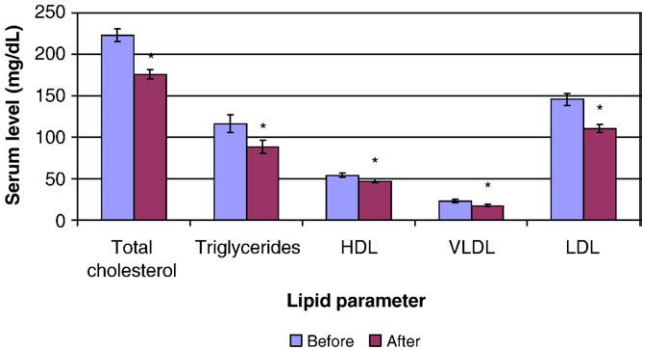


Fig 1. Change in serum lipids for 28 chiropractic patients after administration of a nutritional purification protocol for 21 days. Serum total cholesterol, triglycerides, HDL, LDL, and VLDL all decreased significantly on average for 28 patients who completed the 21-day purification program ($P < .0001$). A *t* test was used to analyze the change in lipid parameters ($\alpha = .01$). Asterisk indicates significant difference between pre- and posttherapy values.

Table 2 Change in average lipid parameters for 28 chiropractic patients after 21 days on the purification program

Total Cholesterol (mg/dL) Mean ± SD		Triglycerides (mg/dL) Mean ± SD		HDL (mg/dL) Mean ± SD		VLDL (mg/dL) Mean ± SD		LDL (mg/dL) Mean ± SD	
Before	After	Before	After	Before	After	Before	After	Before	After
223.3 ± 40.7	176.2 ± 30 *	116.3 ± 54.6	88.6 ± 40.5 *	54.3 ± 14.6	47.6 ± 10.5 *	23.3 ± 10.9	17.8 ± 8.1 *	145.7 ± 36.8	110.9 ± 25.3 *

Patients who completed the 21-day purification program showed significant reductions in all lipid parameters measured, including LDL, HDL, and total cholesterol, and triglycerides.

* $P \leq .01$.

postintervention ($P < .0001$) (Fig 4). Weight decreased for all patients.

Discussion

Our results are comparable with those found in several other studies. O'Dea[11] observed temporary reversal of the effects of a Western diet and lifestyle in diabetic Aboriginals who returned to a hunter-gatherer lifestyle for 7 weeks. The 10 individuals showed improvements in several aspects of their carbohydrate and lipid metabolism linked to insulin resistance, including glucose tolerance, fasting glucose and insulin levels, and serum triglycerides. Triglyceride levels that were highly elevated before the intervention (356 ± 40.7 mg/dL) decreased to normal levels postintervention (101.8 ± 8.6 mg/dL). This parallels our observations for changes in serum triglycerides in response to nutritional purification. Weight loss, a low-fat diet, and increased physical activity all contributed to the observed normalization or near-normalization of end points in these individuals, according to the author.[11]

Gardner et al[12] compared the hypolipidemic effects of 2 low-fat dietary interventions in normocholesterolemic subjects. Both diets were typical of a low-fat

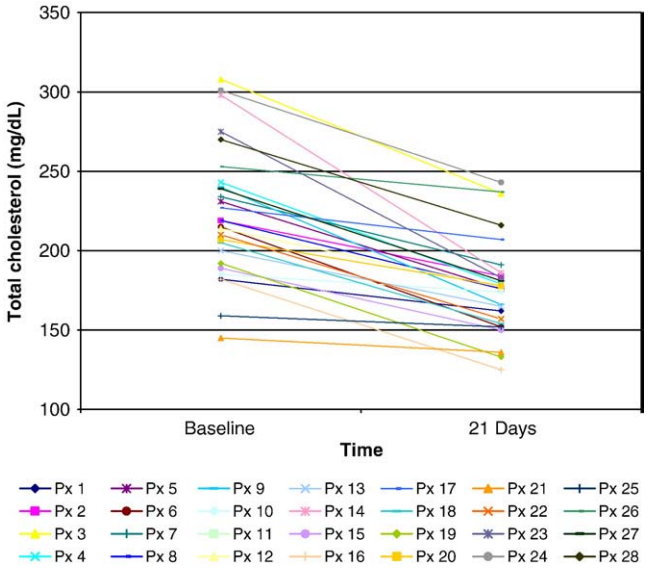


Fig 2. Change in total cholesterol for 28 chiropractic patients after administration of a nutritional purification protocol for 21 days. Total cholesterol decreased for all 28 patients who completed the 21-day purification program. Total cholesterol decreased an average of 47 points in these patients ($P < .0001$). A t test was used to analyze the change in total cholesterol ($\alpha = 0.01$). Several individual patients with the highest total cholesterol at the start of the program showed the sharpest reductions after completing the program.

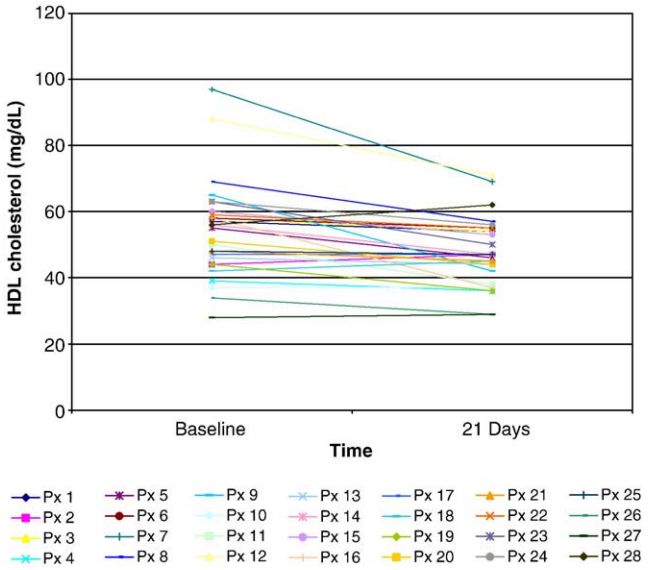


Fig 3. Change in HDL cholesterol for 28 chiropractic patients after administration of a nutritional purification protocol for 21 days. High-density lipoprotein cholesterol decreased for 22 of the 28 patients who completed the 21-day purification program. High-density lipoprotein decreased an average of 7 points in these patients ($P < .001$). A t test was used to analyze the change in HDL cholesterol ($\alpha = .01$).

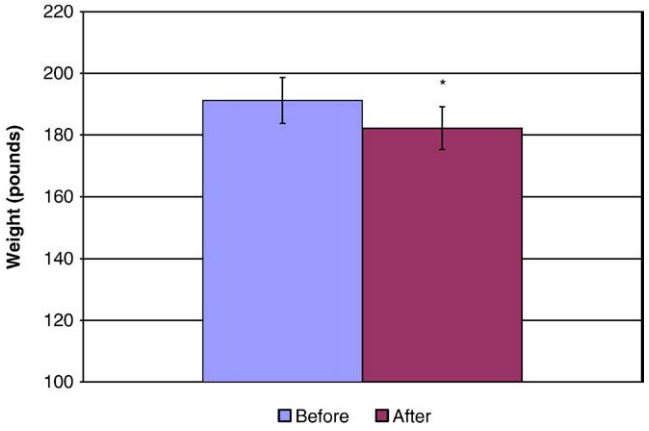


Fig 4. Change in weight for 28 chiropractic patients after administration of a nutritional purification protocol for 21 days. Weight decreased for all 28 patients who completed the 21-day purification program. The average weight for these patients before the program was 191.2 ± 38.8 lb. This decreased significantly to 182.2 ± 36.3 lb ($P < .0001$) after 21 days on the program. A t test was used to analyze the change in weight ($\alpha = .01$).

American diet, but 1 intervention emphasized increased fruit and vegetable consumption. Subjects eating the latter diet had significantly decreased LDL and total cholesterol compared with subjects on the basic low-fat diet, supporting the concept that inclusion of nutrient-dense plant-based foods in the diet favorably affects serum lipids. After 4 weeks, the low-fat–only group had a total cholesterol reduction of −9.2 mg/dL vs −17.6 mg/dL for the low-fat plus fruit/vegetables group ($P = .01$). The LDL cholesterol reductions were −7.0 mg/dL for the low-fat–only group and −13.8 mg/dL for the low-fat–plus group ($P = .02$). These trends parallel the results of our retrospective analysis, with similar magnitude. However, the 2 diet groups did not differ significantly in HDL cholesterol and triglyceride level reduction, which differs from our findings.

Jenkins et al[13] found that a 1-month dietary intervention containing foods and food constituents known to decrease cholesterol (plant sterols, viscous fiber, soy protein, and nuts) was just as effective as statin drugs in lowering cholesterol in 46 healthy, hypercholesterolemic subjects. The randomized controlled trial provided all foods except fruits and vegetables to the participants, allowing the researchers to monitor the amount and type of foods being eaten and subject compliance. The statin drug was double blinded with a placebo. Dietary compliance was estimated at 93% to 95% for all 3 intervention groups. The experimental diet group showed a 28.6% decrease in LDL cholesterol and a 23.5% decrease in LDL/HDL ratio after 4 weeks, significantly greater than the control diet group (8% decrease in LDL cholesterol; 3% increase in LDL/HDL ratio), but essentially equal to the control diet plus statin drug group (30.9% decrease in LDL cholesterol; 28.4% decrease in LDL/HDL ratio). Total cholesterol decreased from 268.0 mg/dL at baseline to 208.9 mg/dL after 4 weeks in the experimental diet group, significantly more than in the control group ($P < .005$). In the statin drug group, total cholesterol decreased similarly, from 256.4 mg/dL at baseline to 196.5 mg/dL after 4 weeks, compared with control group ($P < .005$). The serum cholesterol reductions were not significantly different between the statin drug and experimental diet groups. Again, triglycerides did not change significantly in this study, contrary to our findings. However, the trend was for an increase in triglycerides for the control group and a decrease in both the experimental diet and statin drug groups; so these authors may simply have not had sufficient power to resolve statistically significant effects. C-reactive protein and 10-year coronary heart disease risk estimates also significantly decreased in the statin drug and experimental diet intervention groups, but not in the control diet group. The magnitude of total cholesterol decrease in this study was greater than what we observed, but our nutritional intervention did not focus on specific lipid-lowering foods. The increase in dietary fruits and vegetables in our patients during the intervention should have increased intake of such foods overall, as many of them are plant-based. The magnitude of effect of specific food types on serum lipids is an area for further examination.

This retrospective case series adds to the sparse but accumulating data on the short-term effectiveness of energy-restricted nutritional interventions for lowering serum lipids in hyperlipidemic patients. The high consumption of nutrient-dense fruits and vegetables appears to contribute to the hypolipidemic effects observed in the current study. Because of the retrospective nature of this analysis and the holistic, intent-to-treat approach of the clinician, we were not able to elucidate the independent effects of the nutritional and supplemental intervention components on the outcome measures. This is a limitation of the current study and a valid question to be addressed in future investigations. It should be noted that the purification program used in this study is marketed as a holistic, integrative therapy with synergy between the diet and supplement components. Thus, a reductionist analysis of the individual

intervention components may lack external validity from a clinical perspective.

A recent meta-analysis of studies of cholesterol and CVD risk, with a combined total of 97861 human participants, estimated that a 39-mg/dL decrease in LDL cholesterol reduced risk for several CVD end points (coronary mortality, nonfatal myocardial infarction, the combination of coronary mortality and nonfatal myocardial infarction, stroke, and any vascular event) between 22% and 27%.[14] Our participants achieved an average 35-point drop in LDL cholesterol, suggesting that this intervention could substantially decrease patient risk for CVD if LDL reductions were maintained over time. However, our analysis did not examine long-term compliance of patients with program diet and supplement components after completion of the 21-day intervention. This is a limitation of the current study. Although it does not negate the observed effects of the acute intervention, the long-term compliance of patients is an important question with respect to health outcomes and warrants further study. It should be noted that the patients in this study were well aware of the changes in their lipid and weight measures after the intervention and it was educational for many of them. Nonetheless, the diet and lifestyle modifications required by the intervention are stringent; and it is reasonable to question whether such behavior changes are lasting.

This intervention was given to patients in a chiropractic care setting. The advantage of a nutritional intervention in this setting is that patients often present with risk factors for chronic diseases before such diseases are manifest and when nutritional and lifestyle interventions can slow or possibly even reverse progression toward overt disease. Future chronic disease incidence in populations can be predicted by the prevalence of certain risk factors such as elevated serum lipids, overweight, or other measures. Another advantage of interventions targeting risk factors is that it is possible to observe changes in these risk factors over very short time intervals as a result of therapy, whereas chronic diseases may take months or years to manifest.

High-density lipoprotein cholesterol decreased in these patients as a result of the intervention, along with other measured lipid parameters. Because HDL cholesterol level is inversely correlated to CVD risk,[15] we were concerned that significant decreases in HDL might negate the protective effects of lowering LDL cholesterol and triglyceride levels during the intervention. However, both LDL/HDL and total cholesterol–HDL ratios decreased significantly in these subjects, indicating that reductions in total and LDL cholesterol were of greater magnitude than that of HDL cholesterol. In addition, it has been shown that the total cholesterol–HDL ratio may be a better predictor of cardiovascular morbidity and mortality than absolute lipid parameter values alone.[15,16] Thus, the overall effect of this intervention on lipid measures of CVD risk appears to be positive.

Another limitation of this case series is the small sample size. The 28 subjects were selected from among all patients in the care of the Powell Chiropractic Clinic on the basis of specific inclusion criteria—they completed the purification program, and they had pre- and postintervention serum lipid measures recorded in their medical records. Compliance with the purification program was gauged qualitatively with verbal self-reporting by patients. Future analyses of this type should examine compliance with greater stringency. Nonetheless, this case review is relevant to generating hypotheses for future studies and for recommending nutritional purification in patients with elevated serum lipids. An additional limitation is that the reduction of blood lipids may have been the result of other factors or other components of the overall chiropractic treatment that could not be controlled.

Conclusions

In this retrospective case review, 28 patients who completed a commercially available 21-day purification program for nutritional support while receiving chiropractic care showed secondary beneficial changes in their serum lipids and weight. The observed effect was similar to that observed in previous reports and was comparable with what is observed with statin treatment. Whether these beneficial changes can be sustained over time remains to be determined.

Because serum total and LDL cholesterol levels and serum triglycerides are independent risk factors for CVD, nutritional interventions that show beneficial effects on these markers may help reduce the risk for CVD later in life. This is relevant to chronic disease prevention efforts in chiropractic care and warrants further study. Randomized, double-blind, controlled clinical trials of such interventions are required before any conclusive treatment recommendations can be considered.

Appendix A

The nutritional supplements used in this trial are described below.

SP Complete shake contains whey protein powder, flax meal powder, brown rice protein powder, calcium citrate, magnesium citrate, buckwheat juice powder, Brussels sprouts (whole plant), kale, choline bitartrate, inositol, barley grass, alfalfa juice powder, soybean lecithin powder, grape seed extract (includes Masquelier OPC-85, with 98% total phenolic compounds, and 65% proanthocyanidins), carrot powder, and red wine extract (95% total phenolics). A serving size is 2 rounded tablespoons, and contains 377 J. Containing unrefined, dehydrated whole foods, this supplemental shake mix supports the energy-restricted diet by providing bioavailable protein as well as phytochemical micronutrients, vitamins, and minerals (particularly calcium).

SP Cleanse contains juniper berry powder, red clover powder, collinsonia root powder, apple pectin, burdock root powder, barley grass powder, dandelion leaf, Spanish black radish root, Oregon grape root powder, cayenne pepper powder, fenugreek seed powder, choline bitartrate, inositol, globe artichoke leaf, fennel seed, oat flour, beet leaf juice powder, beet root powder, milk thistle (80% silymarin), wildcrafted tillandsia powder, carrot powder, broccoli powder, and kale powder. A serving size is 7 capsules.

This product contains 20 different whole food and botanical ingredients (dehydrated) intended to help the human body eliminate metabolic and environmental toxins via the liver, kidneys, gastrointestinal (GI) tract, skin, and lymph system.

GastroFiber contains psyllium husk powder, collinsonia root powder, apple pectin, fennel seed, and fenugreek seed powder. A serving size is 3 capsules.

This product supplies significant dietary fiber to support healthy GI function. The ingredients are intended to help cleanse and lubricate the GI tract, while promoting proper pH and the growth of beneficial gut flora.

SP Green Food contains Brussels sprout powder (whole plant), kale powder, alfalfa sprout powder, buckwheat juice powder, and barley grass juice powder. A serving size is 2 capsules.

This product is rich in cruciferous vegetables (dehydrated kale and Brussels sprouts) intended to support liver phase I and phase II detoxification systems, while also providing some important phytochemical micronutrients and trace minerals.

References

1. Rupert RL. A survey of practice patterns and the health promotion and prevention attitudes of US chiropractors. Maintenance care: part I. J Manipulative Physiol Ther 2000;23:1-9.
2. Wanagat J, Allison DB, Weindruch R. Caloric intake and aging: mechanisms in rodents and a study in nonhuman primates. Toxicol Sci 1999;52:35-40.
3. Esmaillzadeh A, Kimiagar M, Mehrabi Y, Azadbakht L, Hu FB, Willett WC. Fruit and vegetable intakes, C-reactive protein, and the metabolic syndrome. Am J Clin Nutr 2006;84:1489-97.
4. Joshipura KJ, Hu FB, Manson JE, et al. The effect of fruit and vegetable intake on risk for coronary heart disease. Ann Intern Med 2001;134:1106-14.
5. Feskanich D, Ziegler RG, Michaud DS, et al. Prospective study of fruit and vegetable consumption and risk of lung cancer among men and women. J Natl Cancer Inst 2000;92:1812-23.
6. Michels KB, Giovannucci E, Chan AT, Singhania R, Fuchs CS, Willett WC. Fruit and vegetable consumption and colorectal adenomas in the Nurses' Health Study. Cancer Res 2006;66: 3942-53.
7. Knoops KTB, de Groot LC, Kromhout D, et al. Mediterranean diet, lifestyle factors, and 10-year mortality in elderly European men and women: the HALE Project. JAMA 2004;292:1433-9.
8. Trichopoulou A, Orfanos P, Norat T, et al. Modified Mediterranean diet and survival: EPIC–elderly prospective cohort study. Bmj 2005;330:991.
9. Kesteloot H, Sans S, Kromhout D. Dynamics of cardiovascular and all-cause mortality in Western and Eastern Europe between 1970 and 2000. Eur Heart J 2006;27:107-13.
10. Critchley J, Liu J, Zhao D, Wei W, Capewell S. Explaining the increase in coronary heart disease mortality in Beijing between 1984 and 1999. Circulation 2004;110:1236-44.
11. O'Dea K. Marked improvement in carbohydrate and lipid metabolism in diabetic Australian aborigines after temporary reversion to traditional lifestyle. Diabetes 1984;33:596-603.
12. Gardner CD, Coulston A, Chatterjee L, Rigby A, Spiller G, Farquhar JW. The effect of a plant-based diet on plasma lipids in hypercholesterolemic adults: a randomized trial. Ann Intern Med 2005;142:725-33.
13. Jenkins DJ, Kendall CW, Marchie A, et al. Effects of a dietary portfolio of cholesterol-lowering foods vs lovastatin on serum lipids and C-reactive protein. JAMA 2003;290:502-10.
14. Genser B, Marz W. Low density lipoprotein cholesterol, statins and cardiovascular events: a meta-analysis. Clin Res Cardiol 2006;95:393-404.
15. Criqui MH, Golomb BA. Epidemiologic aspects of lipid abnormalities. Am J Med 1998;105:48S-57S.
16. Kannel WB. Incidence and epidemiology of heart failure. Heart Fail Rev 2000;5:167-73.