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COMPREHENSIVE LIFESTYLE INTERVENTIONS IN THE COMMUNITY: A PRELIMINARY ANALYSIS

Gary Null[1] and **Martin Feldman***[2]
[1] Center for Postgraduate and Continuing Education
New York College of Chiropractic.
[2] 132 East 76th Street, Suite 1A
New York, NY 10021
Phone: (212) 744-4413
Fax: (212) 472-5139

ABSTRACT

In a 6-month prospective study designed to retard the aging process, we examined the effects of comprehensive lifestyle modifications in 52 participants aged 31 to 78 years, who were free of clinically overt disease. The group adhered to a low-fat vegetarian diet supplemented with antioxidant nutrients, engaged in regular aerobic exercise (power-walking or jogging), and received motivational support. Statistical analysis of objective data shows a trend of optimization of weight and lipid values. Overall, the group lost an average of 2.95 kg, or 4.4% of starting weight; total cholesterol (TC) decreased 7.7%; LDL-C, 12%; and TC/HDL-C ratio, 9%. Analysis by age and gender shows no significant differences in trends. When grouped by objective parameter, maximal effect is found in those with greatest deviation from a normal value at baseline. Subjective assessments showed significant improvement in energy levels and physiological functioning. Although more well-defined studies are needed, we conclude that lifestyle modifications can optimize health status and level of physiologic functioning, and may be instituted by adults of all age groups with prior medical approval.

INTRODUCTION

The most effective strategy for preventing chronic diseases is clearly the population-based approach, which shifts the distribution of risk factors by alterations in health-related behaviors that may contribute to aging (1, 2). Specific lifestyle interventions have been shown to prevent disease and reduce morbidity and mortality among adults of all age groups (3, 4). For example, suboptimal cholesterol values, which are associated with a significant risk for coronary heart disease (CHD), can be avoided or corrected by diets that are low in saturated fat, weight control, and regular exercise programs (1). Oxidation of low density lipoprotein cholesterol (LDL-C) appears to play an important role in CHD, and recent studies support a protective function for antioxidant nutrients, such as vitamin E and beta-carotene (5-8). Although perhaps most widely acknowledged for their contribution to the recent decline in cardiovascular mortality (1, 2, 4), appropriate lifestyle interventions may also prevent a significant percentage of cancer-related deaths and diabetic complications (9).

The following study was designed to optimize health and prevent disease in the population at large, regardless of individual age, rather than to treat specific disease states in afflicted individuals. It reflects the public health approach to preventive medicine and is based on a definition of "health" that surpasses the absence of disease. Unlike controlled clinical trials, this study was not designed to assess the effect of one or more interventions in a specific population either at high risk for, or diagnosed with, a clinically defined disease. Rather, it examines the effect of multiple lifestyle interventions in a cross-section of individuals with absence of clinically overt disease, and explores the degree to which these interventions may be sustained in a noncontrolled environment. A secondary objective of this study was to investigate the effects of age and gender on outcome, and to determine whether individuals who undertake comprehensive lifestyle modifications can achieve measurable improvements in health regardless of age. A recognized pilot study, this program extended for a 6 month duration, entailed a relatively small sample size, and did not include detailed medical data on the participants throughout various phases.

METHODS

Selection of Study Population

Persons with an interest in improving their health by means of diet, exercise, and attitudinal changes volunteered to participate in the study. They adhered to a lifestyle program consisting of a low-fat vegetarian diet high in vitamins A, C, and E, aerobic exercise according to schedule, and other activities designed to develop enhanced compliance with these lifestyle changes. Participants met the following criteria: over 30 years of age, male or female gender, residence in the greater New York area, absence of life-threatening illnesses, and not currently receiving lipid-lowering drugs. Because the program was designed to maximize health rather than treat disease, individuals with previously diagnosed cardiovascular disease or cancer were excluded from the analysis. Otherwise, all persons who

*To whom all correspondence should be addressed were eligible and volunteered were accepted into the study. The study population represented a cross-section of age, gender, race, ethnic group, socioeconomic status, and educational level. Each participant was informed in detail of the comprehensive nature of the program.

Study Population

Of 109 participants who completed the study regimen, the statistical analysis includes 52 individuals who met the entry criteria and completely followed the program regarding data collection, blood testing, and meeting attendance. The data were rigorously collected; even minor omissions of the administrative process resulted in exclusion from the statistical analysis. Thus, the study population consisted of 23 males and 29 females, ranging from 31 to 78 years, with an average age of 51.5 ± 12.3 years (Table 1).

Table 1: Baseline characteristics

	All Cases	< 50 Years	> 50 Years
No. of Enrollments	52 (100%)	25 (48.1%)	27 (51.9%)
Females	29 (55.8%)	13 (25.0%)	16 (30.8%)
Males	23 (44.2%)	12 (23.1%)	11 (21.1%)
Age (years)			
Mean/Avg	51.5	40.9	61.0
S.D.	12.3	6.2	7.6
Range	31 - 78	31 - 49	51 - 78
Weight (kg)			
Mean/Avg	66.9	66.7	67.1
S.D.	14.9	16.2	13.3
Range	42.6 - 113.4	45.4 - 113.4	42.6 - 97.5

Complete blood chemistries (SMA-24 Chemical Profile), complete blood count (CBC) with differential, serum ferritin, thyroid hormone (T-4), sedimentation rate, and urinalysis were obtained at the start and the end of the program. The laboratory samples were drawn following a 7 hour fast. TC, high-density-lipoprotein cholesterol (HDL-C), and triglyceride levels were measured by National Health Laboratories, using the Olympus AU 5200 analyzer (Olympus Corp., New Hyde Park, NY). LDL-C was calculated as [(TC minus HDL-C) minus (triglycerides/5)] (10). Body weights were obtained at the beginning and end of the program. Systolic and diastolic blood pressure measurements were also recorded, but are not included in the statistical analysis because of the small number of high or low pressure samples.

Diet

The participants were asked to eat a low-fat vegetarian diet consisting of fruits, vegetables, legumes, grains, soy and sea products, eggs, and fresh fish. The caloric intake was not restricted, and was assumed to be comparable to that consumed prior to the study. The diet consisted of approximately 60-65% carbohydrates, 15-20% fat, and 15-20% protein. All foods were eaten on a 4 day rotational basis; the same food could be eaten throughout a given day, but not again until 4 days later. Caffeine, refined sugars, yeast, chemical preservatives, canned and salted foods, and dried fruits were eliminated. Participants kept a food diary and were encouraged to eliminate any foods that produced an unfavorable reaction. See Table 2 for sample dietary menus.

Table 2: Sample menus

Day 1:

Breakfast: Eggs poached organic with rice cakes and fresh cantaloupes

Lunch: Bowel of lentil soup, steamed vegetables over brown rice (broccoli, cauliflower, brussels sprouts)

Dinner: 1 cup of vegetable broth; chinese vegetables stir fry with brown rice and salmon

Day 2:

Breakfast: 6 oz oatmeal, with soy mild and strawberries

Lunch: Cup of minestrone soup; chinese vegetable salad with bok choy; daikon radish, pea pods, sunflower seeds, bean sprouts, and sea vegetables with falx seed oil and lemon dressing.

Dinner: Avocado salad with a fresh arugula, walnuts, onions, zucchini, and sprouts with olive oil/lime dressing. Kale with tofu curry, sweet potatoes and sea vegetables and sesame seeds.

Day 3:

Breakfast: 6 oz millet cooked, with almond mild and blueberries.

Lunch: Cup of split pea soup.

Dinner: Buckwheat and spelt pasta dinner with three bean salad.

Day 4:

Breakfast: 6 oz barley cooked hot cereal with potato milk and frozen cherries.

Lunch: Pumpkin seeds and cous cous stuffed into a large green pepper; red leaf lettuce with scallions, garlic, and yellow squash, with poppy seed dressing.

Dinner: Broiled red snapper with roasted potatoes, cauliflower, and red leaf salad with flax seed oil and lemon dressing.

Rotation Diet: If oats, barley, rice, rye are eaten on day 1, 2, 3, 4 then that grain would not be put back in the diet until the fifth day.

The recommended dietary regimen included up to eight servings daily of (preferably organic) fruits and vegetables, resulting in a fiber intake of at least 35 grams daily. The diet consisted largely of raw produce, including five to six servings of steamed, juiced, or raw vegetables, and one serving of sea vegetables daily. From one to three 8 oz glasses of fresh fruit or vegetable juices were consumed daily.

Of total calories, approximately 20% were supplied by oil or fat, most of which came from mono- and polyunsaturated fats. The participants were given lists of unsaturated oils that were permitted for cooking, including sesame, canola, walnut, safflower, sesame, flax seed, and olive oil. To minimize exposure to trans-fatty acids, foods containing partially hydrogenated fats were eliminated from the diet.

Protein intake approximated 0.9 mg/kg per day, and was supplied from vegetarian sources, including beans, nuts, seed, and tofu, as well as non-vegetable sources, including certain types of fish and eggs. Salmon, fluke, flounder, bass and fresh water fish were permitted, as were from one to three (preferably organic) soft or poached eggs per week. No other animal proteins or products were allowed. One serving of soy-based food was recommended daily. Participants were encouraged to supplement their diet with a rice-based protein mix containing branched-chain amino acids and complex carbohydrates, and providing 116 calories and less than 1 gram of fat or 12 grams of complete protein.

Antioxidant Nutrients

The high dietary intake of fruits and vegetables provided maximal sources of beta carotene, as well as vitamins A, C, and E. A water soluble antioxidant, vitamin C has been shown to enhance the body's resistance to disease and to contribute to the biosynthesis of various tissues.(11) Furthermore, elderly individuals have been known to be lacking in Vitamin C.(12) Thus, supplementation included three dosages of vitamin C throughout the day, totaling approximately 5,000 mg daily.(12, 13) Vitamin E, another free radical scavenger, guards the lipids of the cell membrane from oxidation, augments oxygenation and enhances several aspects of the immune response. Indeed, vitamin E has been shown to enhance the immunity of elderly people by warding off lipid peroxides. (14) Thus, additional supplementation was provided in the form of 400 U of d-alpha-tocopherol. (vitamin E);(15) The regimen also provided each participant with approximately 10,000 U beta carotene daily, which has been cited a potentially less toxic form of vitamin A. (11) A general supplement supplying 200% of the Recommended Daily Allowance (RDA) of vitamins and minerals was also recommended.

Because selenium has been shown to be a necessary cofactor for glutathione peroxidase and an enhancer of immune function, a supplement of 150 ìg selenomethionine daily was recommended. (11,16) Additional supplementation included 15 mg zinc of a picolinate or amino-acid chelated formula, (17) and 800 mg calcium/magnesium daily. The participants were supplied with the sources of N-acetyl-cysteine and glutathione,(17) endogenous antioxidants that diminish with age, as well as pycnogenol and quercitin, two powerful bioflavonoids.(18-20)

Exercise

Aerobic exercise was performed for at least 5 days a week according to schedule. Most participants began with moderate exercise, at a level and duration with which they were comfortable. Over time, all achieved the ability to perform aerobic exercise for 30 to 45 minutes a day at a target heart rate derived according to formula [(220 - age) x 75%]. In addition, the group monitored their recovery heart rate, which was taken 5 minutes after cessation of exercise, and curbed their activity level accordingly. Participants under 50 years of age were instructed not to exceed a recovery rate of 120 beats per minute, and those over 50 years, 130 beats per minute. Approximately 80% of the study group participated in power walking, and 20% continued running or jogging, as these were activities to which they were accustomed. About half of the group met in Central Park on Sunday mornings. The remainder performed similar exercise in their own neighborhood, watching a videotape for instruction in proper walking technique. For 2 days a week, the participants exercised with light weights for one-half hour in order to affect muscle groups minimally involved in the primary exercise of power-walking, running, or jogging.

Attitudinal Change

Because attitudinal changes were perceived as key to sustaining the comprehensive lifestyle interventions introduced by the study, the regimen required participants to focus on personal goal identification and attainment. The study intervention required adherence to comprehensive lifestyle changes over a relatively short time (6 months); thus, motivation was perceived to be a key factor in both the sport- and long-term success of the program. The study began with a seminar during which the participants learned of the requirements for successful completion of the program. This experience became a very powerful motivator when the individuals returned to their home environments and daily routines, where the required diet and exercise regimens might be judged as aberrant. Subsequently, the group attended monthly lectures devoted to specific means to successfully change various aspects of their lives to maximize health. They also were provided with reading materials concerning fulfillment of personal goals (15, 21). Some of these materials included aids to identification of potential obstacles to growth and fulfillment and suggestions for overcoming these obstacles.[11]

All participants devoted 10-15 minutes daily to journal writing in which they explored their personal goals, including improved health. This experience was included in the regimen as an aid to recognition of life-affirming goals, development of a plan for achieving these goals, and addressing self-imposed barriers to success. Writing clarified resolution of their inner conflicts and helped strengthen personal conviction to complete the program. Additional support for adherence to the dramatic lifestyle changes of program was obtained from group meetings and individual telephone conversations with the study leaders. As a result of these interventions, the free-living study population gained an enhanced awareness of and a sense of responsibility for personal health.

RESULTS

The 52 participants included in this statistical analysis adhered to the study regimen, including required data collection, for 6 months. Compliance with the dietary, exercise, and attitudinal components of the program was excellent, and surpassed our expectations.

In order to assess the effects of age on outcome, we arbitrarily divided the study population into those participants under vs over 50 years of age (Table 1). This cut-off point approximates the average age of the study population (51.5 $\pm$ 12.3 years), and reflects epidemiologic data concerning age-related predictability of lipid risk factors for CHD (22). The analysis also considers the effects of gender on outcome. When appropriate, the sample population is further analyzed according to relative risk of disease at the time of study entry.

The study findings were divided into objective vs. subjective data. Objective data included measurable factors that are commonly associated with risk for CHD, including body weight and certain laboratory values. Subjective data were provided by the participants.

Because of the wide variability in baseline laboratory values in the study population, the relatively short duration of the study, and the influence of multiple parameters on outcome, the results are presented as trends (percent increase or decrease in average values) rather than absolute changes. The participants served as their own controls, and the observed changes were interpreted not to represent random trends.

I. Objective Data

Changes in weight, lipid values, and the ratio of total blood cholesterol to high- density-lipoprotein cholesterol (TC/HDL-C) were obtained for the entire study population (Table 3). Further analysis of subsets grouped according to relative ranking is provided for each of these parameters. The mean values of each parameter from the population at the start of the study and at the end of the study were compared for equality using the paired t-test. The hypothesis that the sample means were equal was rejected if the computed t-values were greater than the critical t-values.

Weight: The trend of the entire study population was one of weight loss, which averaged 2.95 lbs, or 4.4% of the starting weight of 66.9 ± 14.9 kg (Table 3). Weight loss following the intervention was significant (p=0.0001).

The five heaviest participants lost an average of 10.7 kg or 10.0% of starting weight, and the 4 lightest participants gained an average of 3.2 kg or 6.9% starting weight. In general, those tending toward obesity lost more weight than those who were slightly overweight, and those who were underweight gained weight.

When analyzed according to age, a greater percentage of weight was lost by the participants over 50 years of age compared with those under 50 years (4.9% vs 3.9%, respectively). Of those over 50 years of age, females lost twice as much weight as males (6.2% vs 3.1% of starting weight).

In order to analyze weight loss according to CHD risk at time of study entry, the participants were grouped into subsets based on initial TC level. The 19 participants with an initial TC of 200 mg/dL or greater lost from 0 to 15 kg, (5.6% of starting weight). No one in this group gained weight. The 33 participants with an initial TC less than 200 mg/dL lost an average 2.28 kg (3.6% of initial weight).

Total blood cholesterol: The TC of the entire group decreased 7.7%, from an average of 177.2 mg/dL to

Table 3: Change in risk factors by age/gender (trends represented as % decline)

	All Cases			≤ 50 Years			≥ 50 Years		
	Start	End	Decrease	Start	End	Decrease	Start	End	Decrease
Weight (lbs)									
Total Population - Avg.	66.9	63.96	4.4%	66.7	64.1	3.9%	148.0	140.7	4.9%
St. Dev.	14.8	12.3		15.9	13.1		29.9	24.4	
Females - Avg. 62.9	59.3	5.7%	60.8	57.7	5.1%	64.5	60.5	6.2%	
St. Dev.	12.9	9.3		11.4	7.9		14.2	10.4	
Males - Avg.	72.0	69.85	3.0%	72.6	70.4	2.9%	71.3	69.1	3.1%
St. Dev.	15.4	12.6		17.5	25.5		12.0	10.4	
TC (mg/dL)	Start	End	Decrease	Start	End	Decrease	Start	End	Decrease
Total Population - Avg.	177.2	163.5	7.7%	166.0	154.1	7.2%	188.3	172.9	8.2%
St. Dev.	47.7	38.0		50.9	40.7		41.4	32.1	
Females	188.8	173.1	8.3%	173.7	160.2	7.8%	201.1	183.5	8.8%
St. Dev.	41.1	32.9		40.7	32.5		31.7	26.8	
Males	162.4	151.4	6.8%	158.4	147.9	6.6%	167.7	156.0	7.0%
St. Dev.	51.3	40.2		58.4	11.7		39.5	28.9	
LDL-C (mg/dL) Start	End	Decrease	Start	End	Decrease	Start	End	Decrease	
Total Poplation - Avg.	110.9	97.3	12.0%	103.7	91.7	11.6%	118.1	102.8	13.0%
St. Dev.	41.6	33.7		46.3	39.3		34.8	25.5	
Females	116.9	100.6	14.0%	108.3	93.5	13.7%	123.9	106.3	14.2%
St. Dev.	34.6	28.7		32.9	31.4		29.4	22.2	
Males	103.4	93.1	10.0%	99.1	90.0	9.2%	108.9	97.1	10.8%
St. Dev.	47.9	38.4		56.2	45.7		33.6	25.4	
HDL-C (mg/dL) Start	End	Increase	Start	End	Increase	Start	End	Increase	
Total Population - Avg.	52.2	53.0	1.5%	50.5	51.0	0.9%	53.9	54.9	1.8%
St. Dev.	14.6	13.7		12.8	10.5		16.0	16.1	
Females	57.6	59.1	2.6%	54.2	56.1	3.4%	60.4	61.5	1.9%
St. Dev.	15.5	13.8		12.7	8.4		17.4	17.0	
Males	45.4	45.3	-0.2%	46.8	45.9	-2.0%	43.6	44.4	1.8%
St. Dev.	9.8	8.9		11.7	9.9		6.1	7.4	
TBC/HDL-C Ratio Start	End	Decrease	Start	End	Decrease	Start	End	Decrease	
Total Population - Avg.	3.39	3.09	9.0%	3.29	3.02	6.7%	3.49	3.15	9.8%
Females	3.28	2.93	10.6%	3.20	2.86	10.8%	3.33	2.98	10.4%
Males	3.58	3.35	6.4%	3.38	3.22	4.7%	3.85	3.51	8.7%

163.5 mg/dL (Table 3). The results from the paired t-test showed that the hypothesis that the mean TC level at study start was equal to the mean TC level at study end could be rejected. The computed t-value was 4.07 (p = 0.0001), and the critical value for the tailed test was 1.675.

Because the study population evidenced a broad distribution of initial TC levels (range: 75-308 mg/dL), more meaningful trends may be discerned when analyzed by subsets (Figure I). The greatest effect (20.3% reduction) is seen in the 6 participants with an initial TC over 240 mg/dL, a range considered to be at high risk; the least effect (2.5% increase) occurred in the 18 individuals with initial TC levels below 158 mg/dL.

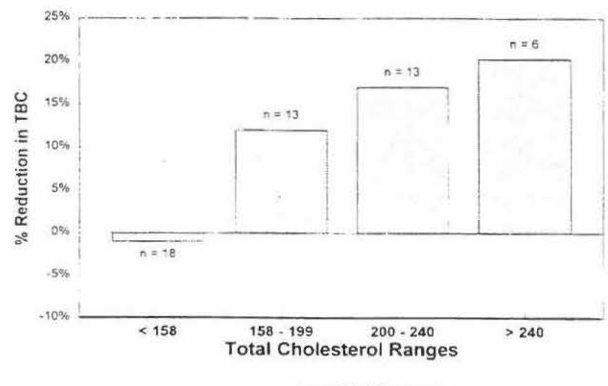

Figure 1. Percent reduction in total cholesterol (TC) by subset.

When analyzed according to age, a greater percent decrease in TC occurred in those participants over 50 years of age compared with those under 50 years (8.2% vs 7.2% from starting levels). Of those individuals over 50 years of age, a significantly greater decrease in TC occurred in females vs. males (8.8% vs 7.0%, respectively).

Low density lipoprotein cholesterol: The study group averaged a 12% reduction in LDL-C over the 6 month study from an average of 110.9 mg/dL to 97.3 mg/dL. The hypothesis of equality in mean values was rejected at t = 4.78 (p = 0.0001). The critical t-value for one tailed test was 1.675.

When analyzed by age and gender, there is a notable consistency in the percent reduction of LDL-C (Table 3). With further subset analysis, the findings are dramatic (Figure 2). The participants with the highest initial levels (LDL-C > 160 mg/dL), a range considered to be at high risk of CHD, evidenced a significantly greater decrease in LDL-C than those with lower initial LDL-C levels. The five participants with initial LDL-C levels less than 60 mg/dL had an average 18.6% increase in LDL-C, compared with a 19% decrease in the 5 individuals with an initial LDL-C over 160 mg/dL.

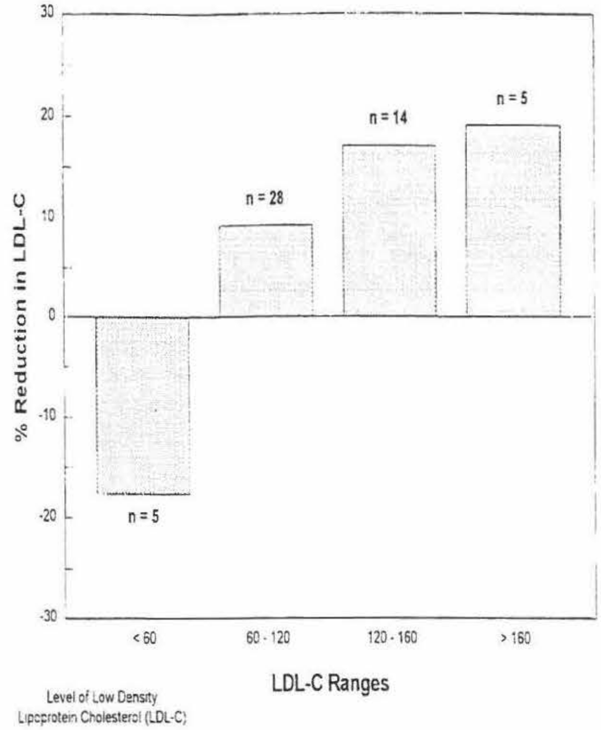

Figure 2. Percent reduction in low density lipoprotein cholesterol (LDL-C) by subset.

High density lipoprotein cholesterol: Over the study duration, the group showed a 1.5% increase in HDL-C. The mean HDL-C level at the start of the study was 52.2 mg/dL, whereas at the end of the study it was 53.0 mg/dL. The paired t=test results suggested that the hypothesis of equality in mean values cannot be rejected. The computed t-value was -0/71 (p = 0.24) whereas the critical value for the one tailed test was 1.675.

The HDL-C was reduced by 2% in younger males following the intervention, whereas older subjects showed a 1.8% increase in this lipid value. Both younger and older females showed an increase in HDL-C of 3.4% and 1.9%, respectively.

Total cholesterol/HDL-C Ratio: When compared with baseline, the TC/HDL-C ratio of the group decreased 10%, from 3.65 to 3.27. The hypothesis of equality in mean values was reported at t = 3.9 (P = 0.0001). The critical value of one tailed t-test is 1.67. As with other objective parameters assessed in the study, a greater decrease in TC/HDL-C ratio was observed in those individuals over 50 years of age compared with the younger group (9.8% vs 6.7%, respectively). Of those individuals over 50 years of age, females showed a significantly greater percentage decrease in TC than did males (8.8% vs 7.0%, respectively).

The average initial TC/HDL-C ratio for women was 3.3, well below 4.4, a nationally-based calculated average for women (23). For men, the average ratio was 3.6, again well below the 4.97, a nationally-based calculated average risk for men.

Analysis was performed on the basis of initial TC levels. Of the 33 participants (64% of total population) with a TC under 200 mg/dL, the TC/HDL-C ratio dropped 6.1%, compared with a 15.5% decrease in the 19 participants (36% of total) with a TC of 200 mg/dL or greater. When analysis was performed on the basis of initial LDL-C levels, the greatest decline occurred in the subsets with the highest initial LDL-C levels. The 33 (63.5%) participants with initial LDL-C levels less than 130 mg/dL evidenced a 6.7% decrease in TC/HDL-C ratio (3.0 to 2.8); the 14 (26.8%) in the 130-159 mg/dL range, a 12.5% decrease (4.0 to 3.5); and five (9.6%) in the range of 160 mg/dL and above, a 20.5% decrease (7.3 to 5.8).

Four of 5 participants with an initial TC/HDL-C ratio of 5.0 or greater evidenced significant improvements in the lipid ratio. A 39 year-old male who lost 10.8% body weight (113.4 to 101.15 kg), evidenced a 28% improvement in ratio, from 12.3 to 8.9. A 61-year old female who lost 9.6% of body weight (61.2 to 55.3 kg) improved 30%, from 7.9 to 5.5. A 78-year old male who lost 25% body weight (82.5 to 62.1 kg), decreased 17%, from 5.9 to 4.9. A 39 year-old female who lost 21% body weight (68 to 54 kg), evidenced a 25.5% improvement, from 5.1 to 3.8. The fifth participant in this category, a 59-year old female decreased from an initial TC/HDL-C ratio of 6.6 to 6.4. As may be inferred from this data and further illustrated in Figure 3, an association can be drawn between weight loss and change in TC/HDL-C ratios. The participants who lost 4.5 kg or more of weight had significantly greater improvements in the TC/HDL-C ratio. Age and gender did not appear to exert a significant influence on the effects of the study regimen on this parameter.

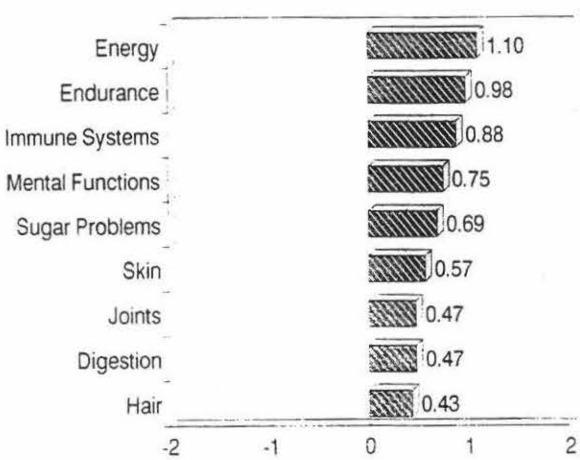

Figure 3. Scatter plot illustrating relationship between change in weight and change in the ratio of total cholesterol/high density lipoprotein cholesterol (TC/HDL-C).

II. Subjective Data

Subjective data was gleaned from personal diaries composed in essay format and from questionnaires regarding changes in the number of upper respiratory infections, energy levels, and other parameters described below. The participants reported that they had less viral upper respiratory infections, cold sores and fever blisters. Awareness of increased energy and vitality accompanied the increase in cardiovascular and aerobic endurance. Improved endurance was not limited by age or gender.

The questionnaires required the participants to rank changes of function in various categories as much worse (-2), worse (-1), no change (0), better (+1), or much better (+2). The categories included energy, endurance, carbohydrate metabolism, mental function, immune status, digestion, joints, skin hair, and premenstrual syndrome. In addition, the participants ranked the function as very low (-2), moderately low (-1), acceptable (0), moderately high (+1), or optimal (+2). The results of the questionnaires are summarized in Figures 4A and 4B. The

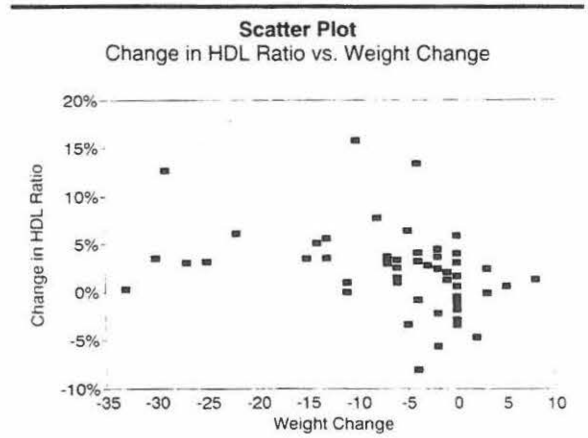

Fig ure 4A. Subjective assessments of changes in parameters of health by category.

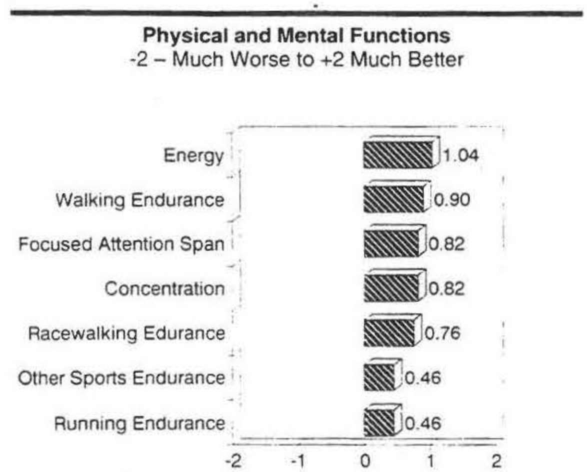

Figure 4B. Subjective assessments of changes in physical and mental functions.

study group perceived good improvement in energy levels and immune status. Participants with and without previous symptoms of bone and/or joint disease reported limited general improvement in these areas. The least improvement was reported for the digestive system as participants adjusted to a vegetarian diet. However, bowel transit time increased and constipation, the most frequently reported digestive symptom at study onset, responded well to the regimen.

The participants' personal diaries contained daily notations of food and activities. In addition, each individual regularly recorded their perceived life goals, means of achieving these goals, and obstacles to achievement. At study termination, the diaries of many participants were collected and the data was reviewed for an assessment of the processes experienced. This data revealed that the participants themselves perceived that their personal change in attitude was a major outcome of the study. Many participants verbalized an awareness of the need to stop procrastinating and start taking control of their lives.

DISCUSSION

We found the high number of individuals who voluntarily completed this rigorous regimen to be remarkable. Compliance with the comprehensive lifestyle interventions entailed in this study was exhibited by all participants included in the statistical analysis, regardless of age or sex. This population included women in the seventh decade of life as well as men up to 78 years of age.

All participants were required to adhere to a low-fat vegetarian diet, which for many members of the group, constituted a radical deviation from their standard diet. Although it was necessary for some individuals to work up to the required level of aerobic activity, all ultimately engaged in a program of rigorous exercise. The results clearly demonstrate that when a rigorous interactive program is employed, improvements in objective parameters (weight and lipid levels) may be achieved regardless of age, and that multiple lifestyle interventions are possible and practical for adults over age 50. Indeed, those individuals over 50 years of age demonstrated a greater rate of change in these parameters than those under 50 years.

Over the past 25 years, several controlled clinical trials have demonstrated that reducing the TC decreases the risk of developing clinically manifest CHD (24, 25). The results of primary and secondary prevention trials indicate that lowering cholesterol by either diet or drug therapy will reduce the rate of occurrence of CHD events 2% for each 1% reduction of cholesterol (1). Generalizing the results obtained in our cross-sectional population requires extrapolation from data derived from primary and secondary studies of specific populations, which is beyond the scope of this paper. Thus, we cannot make assumptions concerning the reduced risk of CHD in our participants.

The results of our study reveal trends also observed in controlled clinical trials which have demonstrated the benefits of lipid-lowering approaches. For example, regardless of the CHD risk factor examined — ie, weight, lipid value, or lipid ratio — the same effect is repeatedly found in these trials and in our study. The greater the initial level of cardiovascular risk, the greater the improvement or magnitude of change toward an optimal level (Figures 1 and 2). Additionally, as with previously conducted clinical trials, the overall percentage reduction in LDL-C observed in our study is greater than that of the total serum cholesterol. Unlike lipid-lowering trials, however, the results of our multifactorial regimen indicate an innate "normalization" process rather than a unidirectional effect. With adherence to the study protocol, those individuals who had very low levels of TC and/or LDL-C at study entry exhibited a trend toward elevation of these lipid levels, while those with very high levels at study entry showed a trend toward reduction. Analysis of the parameters which required subjective assessment (Figures 4A and 4B) clearly indicate a trend of increase in energy and improvement in physiological function. On the basis of both the objective and subjective data derived from this study, therefore, the participants evidenced a significant overall improvement in health.

The optimization of quantifiable parameters and subjective assessments of physiological functioning that were observed in this study cannot be attributed to any one factor of this comprehensive program. Previous studies have found that when used separately, exercise and diet are about equally effective in reducing cardiac risk in individuals with mildly to moderately elevated cardiovascular risk factors (26) and in overweight subjects (27). Regular aerobic exercise has significant cardiovascular benefits, including a reduction in incidence of and mortality from coronary artery disease (28-30), which may be attributed to positive effects on blood lipid levels (31) and blood pressure (32). Current data indicate that a threshold of approximately 15 miles per week of jogging may be required to induce beneficial change in lipoprotein concentrations and subclass distribution (32). With the substitution of power-walking for jogging, this limit was met by our study regimen. In addition, regular exercise has positive mental benefits (31), optimizes micro-nutrient intake, and assures a maximum quality-adjusted life-expectancy (34).

The goal of our program was optimization of health. For some participants, weight loss was a by-product of the regimen, and, in general, weight loss and exercise levels were well correlated (Fig 3). This finding agrees with previously reported data (35), and is further borne out by an informal follow-up conducted 3 months after study termination. At that time, we contacted 14 participants who had lost 2.7 or more kg over the duration of the study. Of those individuals who continued to exercise, five had no change in weight from time of study end, and four had lost additional weight. The five individuals who had regained some of the weight lost during the study had reduced their exercise level, while maintaining the eating patterns established during the study.

Because the oxidative modification of LDL-C appears to increase its atherogenicity (5), interest has focused on the lipid-lowering potential of dietary antioxidants. In vitro, oxidation of LDL-C can be prevented by naturally occurring antioxidants, including vitamin C, vitamin E, and beta carotene (36). Recent evidence suggests that these dietary anti-oxidants may influence the rate of progression of coronary atherosclerosis in vivo (36-38). In addition, it has been shown that plasma antioxidant capacity rises in response to exercise and that the contribution of individual antioxidants to this change can be influenced by vitamin supplementation (39).

Due to differences in study populations as well as in study duration and parameters, the results of our pilot study cannot be strictly compared with findings of previous clinical trials, including the Lifestyle Heart Trial (40). That year-long trial entailed the use of a very-low-fat vegetarian diet plus moderate exercise and relaxation techniques in patients with angiographically documented CAD and an average initial TC/HDL-C ratio of 6.33 (SD 2.14). Although both the Lifestyle Heart Trial and our pilot study focused on the effects of lifestyle modifications, the populations differed significantly. Similarly, the overall results of our cross-sectional study cannot be compared with primary (24, 25) or secondary (41-43) prevention trials of lipid-lowering agents in populations with primary dyslipidemia or documented CHD.

Examination of the effects of our study regimen on those participants at greatest risk of CHD — ie, those with the highest weights and non HDL-C lipid values at study entry — reveals improvements in CHD risk factors that rank favorably with the results of certain clinical trials. For example, the four participants in our study who also met the requirements for entry into the Helsinki Heart Trial (non-HDL-C$\geq$ 200 mg/dL) averaged a 22.7% reduction in LDL-C, which rates favorably with the 11% decrease in LDL-C observed over 5 years of gemfibrozil therapy in 4,081 participants in the Helsinki Trial (24). Similarly, the 19.8% reduction in LDL-C observed in the five study participants with initial LDL-C values of 150 mg/dL or more also compares favorably with the 15% reductions observed in over 70% of patients with comparable LDL-C values who were administered 20 mg fluvastatin daily (44).

Cost-effectiveness analyses of lipid-lowering drug therapies for primary prevention must take into consideration the avoidance of CHD and its associated costs, as well as the costs of drugs and drug-related effects, including non-CHD morbidity and mortality (45, 46). Unlike lipid-lowering drugs, dietary therapy has not been found to be associated with increased non-CHD mortality (10). Overall, our study participants did not find out-of-pocket expenditures to be excessive. Their costs included organic vegetarian food sources, a juicer, laboratory tests as described above, and membership in a health club or similar facility for exercise in winter. Longer-term studies are necessary to assess the effect of our study regimen on overall morbidity and its associated costs.

CONCLUSIONS

According to current Adult Treatment Panel (ATP) Guidelines, dietary therapy is indicated as primary prevention for individuals with an LDL-C of 160 mg/dL or greater and with less than 2 risk factors, and for those with an LDL-C of 130 mg/dL or greater and more than 2 risk factors (10). More specifically, the Step I diet is recommended initially, to be followed by the Step II diet as needed to progressively reduce intake of saturated fatty acids and cholesterol and to promote weight loss in overweight individuals. Concomitantly, the appropriate use of physical activity is considered essential in the nonpharmacologic therapy of elevated serum cholesterol. Review of the literature indicates that such interventions may have little effect on serum cholesterol in free-living subjects (47). In fact, trials of such dietary interventions in high risk subjects have resulted in TC reductions averaging about 2% over 6 months to 6 years (48). This minimal response has largely been attributed to an insufficiently rigorous diet, and recommendations have been made for further reduction in fat.

We propose that rather than focusing on content of diet alone, consideration be given to a more comprehensive program of lifestyle interventions. Just as multiple factors interact to influence the health of all free-living individuals, so comprehensive lifestyle interventions may result in an improved health status of the population at large. As demonstrated in this study, a multifactorial regimen of diet, exercise, supplementation, and attitudinal support can successfully reduce risk for CHD and apparently enhance health. Weight control, a by-product of this regimen, improves other major risk factors, including elevated blood pressure, uric acid and glucose intolerance (49). We realize that the subjective assessments of energy, endurance, and immune function that were analyzed in this study constitute less rigorous data than that which can be reproducibly measured. Nonetheless, we believe that the improvements in these categories as determined by the study participants are indeed noteworthy. Because we believe that the assessment of health status in free-living individuals should encompass parameters beyond the absence of disease, we suggest that more consideration be given to physiological parameters of functioning and performance. These parameters may be especially important to mature age groups.

Respondents to our call for study entry clearly wanted to improve their health status, and therefore may represent a segment of the population more motivated to comply with lifestyle interventions than other individuals. We cannot, therefore, claim that the rigorous and comprehensive approach employed in our study would be practicable for the populace at large or any subset thereof. We do, however, believe that even with 75% adherence to the study regimen, beneficial effects on health status would be evident. Thus, although the findings of this preliminary analysis support the benefits of a comprehensive and rigorous regimen of lifestyle interventions, a larger patient population, more detailed data, and a longer duration of study and follow-up are needed to yield more definitive information concerning the effects on morbidity and mortality.

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