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Comparing the Benefits of Diet and Exercise in the Treatment of Dyslipidemia[1]

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Background. **Lifestyle changes are advocated as a first line of treatment for dyslipidemia. However, few studies have directly compared various combinations of diets and exercise.**

Methods. **In a randomized controlled pilot study, we compared the standard lifestyle recommendations (NCEP step I diet with regular exercise) and more intense interventions including the NCEP step I diet with a supervised aerobic exercise program and the step II diet with and without a supervised aerobic exercise program. We measured risk factors, dietary intake, time on treadmill, and health-related quality of life at baseline and after 3 months.**

Results. **Out of 198 eligible subjects, 47 (24%) were willing to participate and 41 completed the study. No significant change were observed with standard lifestyle recommendations. In contrast, participants in the more intense interventions lost weight (−1.7 to −3.7 kg) and reduced their total cholesterol (−4% to −6%), low-density lipoprotein cholesterol (−6%), and systolic blood pressure (−7.3 to −8.8 mmHg). Participants in the exercise program significantly increased their exercise capacity (1.6 to 1.9 METS). Overall, each 10% reduction in body weight was associated with a 7.6% reduction in low-density lipoprotein cholesterol.**

Conclusion. **Standard lifestyle recommendations had little effect on blood lipid levels but more intense lifestyle interventions may be effective at improving blood lipids, other risk factors, and quality of life.**

Key Words: **dyslipidemia; cardiovascular disease prevention; diet; exercise; quality of life; preference; SF-36 Health Survey; randomized controlled trial.**

INTRODUCTION

Lifestyle changes are widely advocated as a first line of treatment for dyslipidemia. The Canadian [*1,2*] and the American [*3*] lipid guidelines recommend dietary changes and regular physical activity for all individuals with dyslipidemia. Despite the fact that diets and exercise are currently prescribed to treat dyslipidemia, very few studies have directly compared the impact of various combinations of diets and exercise on cardiovascular risk factors and the quality of life of participants.

It has been demonstrated that National Cholesterol Education Program (NCEP) step I or step II diet alone, in free-living people, reduces serum total cholesterol and LDL cholesterol (LDL-C) by 5 to 13% [*4–12*]. However, a drop in the high-density lipoprotein cholesterol (HDL-C) level is also often reported [*4–6,10,12*]. As a low HDL-C is associated with increased cardiovascular risk [*3*], this may minimize the overall impact of diet on the risk of cardiovascular disease. On the other hand, exercise is associated with an increase in the HDL-C level [*4,11,13–15*]. For this reason, a combination of diet and exercise may be the optimal approach to control dyslipidemia. In four randomized controlled trials, a combination of exercise and diet did favorably affect LDL-C and HDL-C as well as enhance the reduction in weight loss and blood pressure [*4,10,11,15*].

Diet and exercise may also have a differential impact

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on the health-related quality of life (HRQOL). Observational studies have shown that the level of physical activity is positively associated with general well-being, a positive mood, self-perceived quality of life, as well as lower levels of anxiety, stress, and depression [*16–19*]. The impact of diets on HRQOL may vary according to the type of diet. Positive changes in HRQOL were observed with a weight reduction diet [*20,21*]. On the other hand, patients on a low-sodium and high-potassium diet for the treatment of hypertension reported lower HRQOL [*20*]. To our knowledge, only one randomized controlled trial has directly compared the single and joint effects of diet and exercise among sedentary people with high cholesterol level but free of symptomatic cardiovascular disease [*22*]. After 1 year, exercise improved the participants' mental health, perceived competence/self-esteem, as well as coping. In contrast, no significant changes were associated with the dietary intervention.

In a 2 × 2 factorial design, we compared the changes in cardiovascular risk factors and in HRQOL of participants randomized to receive the NCEP step I or step II diet with or without a supervised aerobic exercise training program. We performed this pilot study to (a) assess the feasibility of implementing these lifestyle interventions in primary care prevention; (b) evaluate the change in cardiovascular disease risk factors and the HRQOL associated with each intervention; and (c) identify the determinants of changes in lipid profile.

METHODS

Design of the Study

Between January 1999 and May 1999, study participants were recruited through announcements in newspapers, radio, and television and notice boards at four McGill teaching hospitals. Participants could also be referred by their treating physician. Approval from the institutional review board was obtained from the Faculty of Medicine of McGill University and each participating hospital.

People were invited to contact the research coordinator and a telephone eligibility questionnaire was administered to all interested candidates. Eligible subjects included men and women between 40 and 60 years of age, free of established cardiovascular disease, with a body mass index between 22 and 36 kg/m^2. All participants also had a diagnosis of dyslipidemia documented by a blood result in the past 3 months. For men, dyslipidemia was defined as a total cholesterol/HDL-C ratio ≥4.5 if LDL-C was >5.0 mmol/L or a total cholesterol/HDL-C ratio ≥5.0 if LDL-C varied between 4.0 and 5.0 mmol/L, inclusively. For women, it was defined as a total cholesterol/HDL-C ratio ≥4.0 if LDL-C was >5.0 mmol/L or a total cholesterol/HDL-C ratio ≥4.5 if LDL-C varied between 4.0 and 5.0 mmol/L, inclusively.

We excluded subjects on lipid-lowering drugs. Those taking drugs that could affect lipid profiles, such as antihypertensives (i.e., thiazide, β blocker), thyroid medication, or hormonal replacement therapy, were excluded if the dosage had been changed over the last 3 months. In addition, we excluded subjects who reported depression, psychiatric problems, diabetes, nephrotic syndrome, uncontrolled hypertension (≥170/95 mmHg), as well as current smokers and previous smokers who had stopped smoking for less than 6 months, pregnant or lactating women, women who were planning a pregnancy, and subjects who had gained or lost 5 kg or more in the past 3 months. We excluded physically active subjects, defined as those currently doing recreational, occupational, and household activities equivalent to 6 METS or more for at least 30 min three times a week.

Subjects who met the eligibility criteria had a fasting blood test, after providing informed consent. Those with dyslipidemia as previously described had a complete medical examination and a treadmill exercise test to confirm their eligibility and to rule out any contraindication to exercise. Thereafter, subjects were randomly assigned to one of four groups: the NCEP step I diet with information on exercise (step I diet); the NCEP step II diet with information on exercise (step II diet); the NCEP step I diet with a supervised aerobic exercise training program (step I diet with exercise); and the NCEP step II diet with a supervised aerobic exercise training program (step II diet with exercise). Randomization was stratified by gender and body mass index (≥27 kg/m^2, <27 kg/m^2); a body mass index ≥27 kg/m^2 is associated with an increased risk of hypertension, hypercholesterolemia, and diabetes [*23*]. Randomization numbers were allocated to the study participants in sequential order. All study interventions were offered to participants free of charge.

A registered dietitian met all participants individually for 1 h to give information on the benefits of regular exercise and to explain the NCEP step I or step II diet [*3*]. The step I diet consists of approximately 55% of total energy derived from carbohydrates and ≤30% from fat. Saturated fat is reduced to less than 10% of total calories and dietary cholesterol is reduced to less than 300 mg per day. The NCEP step II diet consists of approximately 55% of total energy derived from carbohydrates and ≤30% from total fat. Saturated fat is reduced to less than 7% of total calories and dietary cholesterol is reduced to less than 200 mg per day. Participants with a body mass index ≥27 kg/m^2 also received a hypocaloric diet to lose no more than 250 g per week. In addition, participants allocated in the NCEP step II diet were invited to attend eight group lectures given by a registered dietitian to develop skills to help implement dietary lifestyle changes. Each group lecture included interactive activities to help participants elaborate personal goals, read food labels, plan menus, modify recipes, and sample low-fat foods and recipes. Participants' partners were invited to attend. After 1 month, the dietitian met all participants individually for 15 min to review the dietary and exercise instructions and answer any questions.

All participants received a two-page summary of information about exercise prepared by an exercise physiologist. It included a list of the general health benefits of regular exercise as well as various recommendations and precautions about exercise. An exercise prescription specifying the duration, frequency, and intensity of exercise, based on the participant's maximal heart rate during the stress test, was also provided. This information was given and reviewed by the dietitian.

Participants randomized to the aerobic exercise training program attended supervised exercise classes three times a week for a total of 12 weeks (36 classes). Classes were supervised by exercise physiologists at the McGill Cardiovascular Health Improvement Program. Each class accommodated 6 to 10 participants and consisted of 45 min of cardiovascular exercise (walking, cycling, stepping) and 10 min of stretching. The intensity of the aerobic exercise varied between 65 and 85% of the participant's symptom-limited maximal heart rate on the baseline treadmill test.

Clinical and Laboratory Procedures

At baseline and at the end of the 12-week study, each participant underwent a complete medical examination, a symptom-limited maximal exercise stress test (Bruce protocol), measurements of body weight and height, as well as two supine blood pressure (after lying 5 min) and two standing blood pressure (after standing 3 min) measurements. All subjects also completed the quality of life questionnaires.

Fasting venous blood was collected once at baseline and twice at the 12-week visit. Specimens were analyzed at the Clinical Chemistry Laboratory of the Royal Victoria Hospital, Montreal, Canada. Total cholesterol and triglyceride analyses were performed on a DAX 96 chemistry analyser (Bayer Diagnostics, Canada) using Bayer reagents. HDL-C was also analyzed on the DAX 96 using direct HDL reagent from Roche Diagnostics, Canada. LDL-C was calculated using the Friedewald equation [*24*].

Cardiovascular Disease Risk

The Cardiovascular Disease Life Expectancy Model was used to estimate the 10-year cardiovascular risk based on the participants' cardiovascular risk profile including age (year), gender, HDL-C and LDL-C (mmol/L), systolic and diastolic blood pressure (mmHg), smoking status (yes or no), cardiovascular disease (yes or no), and glucose intolerance (yes or no) [*25*].

Dietary Assessment

Dietary intake was measured by a dietitian using the mean of three 24-h recalls at baseline and again at Week 12. At baseline, the first interview was done in-person using food portion models and the other two recalls were done by telephone. At Week 12, all three recalls were done by telephone. Recalls included 2 weekdays and 1 weekend day. Nutrient intake was calculated using the Candat program (Godin London Inc., London, Ontario, 1991) and the most recent Canadian Nutrient File (Health Canada, Ottawa, Canada, 1997).

Health-Related Quality of Life

HRQOL questionnaires were administered in the following sequence: (1) SF-36 Health Survey; (2) Rating Scale; (3) transition question; and (4) Standard Gamble. The SF-36 was self-administered and other instruments were administered in face-to-face interviews by one of two trained interviewers who were blinded to the participant's study group.

The SF-36 Health Survey [*26–28*] describes eight domains of the participants' HRQOL over the past month. In addition, two overall scores, the Physical Component Summary (PCS) and the Mental Component Summary (MCS) scores, were calculated [*29*]. At the 12-week evaluation, we also modified the SF-36 transition question and asked participants the following question "Compared to before the program, how would you rate your current health in general now?" They answered using a 5-point Likert scale.

Participants also valued their current health using the Rating Scale and the Standard Gamble. For the Rating Scale, we used a 30-cm feeling thermometer with 100 graduations [*30*]. *Perfect health* and *Immediate death* were placed by the interviewer at the top (score = 100) and bottom (score = 0) of the scale, respectively. Participants were asked to place their *Current health* on the thermometer. All Rating Scale scores varied from 0 to 100, representing the worst and the best health, respectively. Standard Gamble consisted of a set of questions where participants were asked to choose between their *Current health* and a hypothetical alternative with a probability P of *Perfect health* and a probability $(1 - p)$ of *Immediate death*. Using a visual aid, the probabilities were changed [*31*], until the participants were unable to choose between their *Current health* and the hypothetical alternative. At this point, the Standard Gamble score was equal to the probability of *Perfect health*. Standard Gamble scores vary between 0 and 100, where 100 is equivalent to *Perfect health* and 0 is equivalent to *Immediate death*.

TABLE 1

Mean (SD) Baseline Values for the Anthropometric Measures, Cardiovascular Fitness, and Cardiovascular Risk Factors

	Step I diet (n = 9)	Step I diet with exercise (n = 10)	Step II diet (n = 12)	Step II diet with exercise (n = 10)
Male gender (n)	1	4	6	4
Anthropometry				
Weight, kg	76.1 (13.0)	81.6 (10.5)	76.6 (12.2)	79.0 (15.1)
Body mass index, kg/m^2	29.1 (3.9)	28.6 (1.9)	27.9 (3.2)	28.9 (3.3)
Proportion with body mass index n (%)				
<27 kg/m^2	4 (44)	1 (10)	4 (33)	3 (30)
≥27 kg/m^2	5 (55)	9 (90)	8 (67)	7 (70)
Treadmill exercise test (min)	9.1 (2.4)	9.0 (2.3)	10.2 (1.8)	9.7 (1.6)
Serum lipids				
Total cholesterol (mmol/L)	7.31 (0.58)	7.17 (0.64)	7.30 (0.62)	7.17 (0.71)
LDL-C (mmol/L)	5.13 (0.53)	4.90 (0.58)	5.09 (0.66)	4.96 (0.44)
HDL-C (mmol/L)	1.33 (0.15)	1.19 (0.17)	1.15 (0.18)	1.26 (0.14)
LDL-C/HDL-C ratio	3.88 (0.34)	4.17 (0.46)	4.51 (0.70)	3.98 (0.48)
Triglycerides (mmol/L)	1.89 (0.57)	2.49 (1.08)	2.33 (0.79)	2.12 (0.79)
Blood pressure				
Systolic (mmHg)	129 (8)	139 (20)	127 (10)	135 (14)
Diastolic (mmHg)	83 (7)	86 (9)	81 (6)	86 (8)
10-year cardiovascular risk (%)	11.3 (4.1)	23.2 (13.2)	20.6 (12.5)	19.1 (14.7)

Statistical Analysis

Analysis of variance (two-tailed) was used to compare the mean scores and the mean change scores between the study groups. Adjusted (age, gender, and body mass index) and unadjusted point estimates were similar. Therefore, we reported only the unadjusted estimates. We computed the 95% confidence interval (CI) around the mean change in outcome variables for each study group. A χ^2 test was used to test the statistical significance for proportions.

To identify the determinants of favorable lipid changes, we computed the Pearson correlation coefficients between the relative percentage change in HDL, LDL, and LDL/HDL from baseline (([final value − baseline value]/baseline value) * 100) and the relative percentage change in body weight, percentage energy from total fat intake, and time on treadmill. Significant variables were thereafter entered in a multivariate linear model.

RESULTS

Study Population

A total of 598 people responded to the study announcement. After a brief description of the study and the administration of an eligibility questionnaire, 151 people decided not to participate and 400 were not eligible. The most frequent exclusion criteria were: cholesterol levels outside the study range (165), a high level of physical activity (68), age outside the study range (47), currently on lipid-lowering medication (40), diagnosis of cardiovascular disease (18), and smoking status (11). Forty-seven subjects were randomized and 41 (87%) completed the study. Participants who did not complete the study were mostly men (5 men, 1 woman). Their mean age was 46 years. Three participants were lost to follow-up in the step I diet group, one in the step II diet group, and two in the step II diet with exercise group. No adverse events related to the study intervention were reported during the study.

The four study groups were similar in terms of sociodemographic characteristics with 40–50% males except for the step I diet group, where only one man came back for the final assessment. Overall participants were mostly middle-aged, married, English-speaking, well educated, and employed, and reported a large range of household income.

Adherence to Study Intervention

All participants (41) attended the 1-h and 15-min dietitian visits. The average attendance at the 8-h dietary lectures was 76%. Sixteen (73%) participants randomized to the step II diet attended at least six of eight dietary lectures. One participant did not attend a single class. The average attendance at the exercise classes was 97%. All participants allocated to the supervised exercise training exercise attended at least 24 of 36 exercise classes and 16 (80%) came to all 36 exercise classes.

Anthropometry, Treadmill Test Duration, and Cardiovascular Risk Factors

At baseline, the four study groups were comparable in terms of treadmill test duration, blood pressure, and lipids including total cholesterol, HDL-C, and LDL-C levels (Table 1). The proportion of participants with a body mass index ≥27 kg/m^2 was larger in the step I

TABLE 2

Mean Changes (95% Confidence Interval[a]) in Anthropometric Measures, Cardiovascular Fitness, and Cardiovascular Risk

	Step I diet (n = 9)	Step I diet with exercise (n = 10)	Step II diet (n = 12)	Step II diet with exercise (n = 10)
Anthropometry, weight, kg[b]	0.0 (−1.1, 1.1)	−3.7 (−6.1, −1.3)	−1.7 (−3.1, −0.2)	−2.9 (−5.5, −0.3)
Treadmill exercise test, min[c]	−0.02 (−0.9, 0.8)	1.9 (1.1, 2.6)	0.6 (−0.3, 1.5)	1.6 (0.5, 2.7)
Serum lipids				
Total cholesterol (mmol/L)	−0.16 (−0.49, 0.16)	−0.41 (−0.90, 0.07)	−0.41 (−0.81, −0.01)	−0.3 (−0.7, 0.1)
LDL-C (mmol/L)	−0.11 (−0.47, 0.24)	−0.31 (−0.65, 0.04)	−0.34 (−0.63, −0.05)	−0.3 (−0.5, −0.1)
HDL-C (mmol/L)	−0.04 (−0.12, 0.05)	0.04 (−0.03, 0.11)	0.04 (−0.04, 0.12)	0.00 (−0.07, 0.07)
LDL-C/HDL-C ratio	0.04 (−0.23, 0.31)	−0.39 (−0.79, 0.00)	−0.42 (−0.81, −0.04)	−0.2 (−0.4, −0.04)
Triglycerides (mmol/L)	−0.02 (−0.58, 0.53)	−0.43 (−1.15, 0.29)	−0.33 (−0.72, 0.07)	−0.02 (−0.69, 0.66)
Blood pressure				
Systolic (mmHg)	−5.7 (−14.1, 2.7)	−8.8 (−16.7, −0.8)	−7.3 (−11.4, −3.1)	−8.0 (−14.7, −1.3)
Diastolic (mmHg)	−2.4 (−8.9, 4.1)	−2.4 (−6.2, 1.4)	−2.2 (−6.7, 2.4)	−1.8 (−5.7, 2.1)
10-year cardiovascular risk (%)	−0.69 (−3.54, 2.15)	−6.16 (−11.0, −1.28)	−3.07 (−5.76, −0.38)	−3.04 (−6.09, 0.02)

[a] Confidence interval that does not include the value zero indicates significant change within group.
[b] P value = 0.04 (analysis of variance for the overall significance of difference between the four study groups).
[c] P value = 0.01 (analysis of variance for the overall significance of difference between the four study groups).

diet with exercise group (90%) compared with the other study groups, where the proportion varied from 55 to 70%.

Compared with the participants who received the standard lifestyle recommendation, those in the step I diet with exercise lost significantly more weight (−3.7 kg vs 0 kg) and had a greater improvement in their treadmill test duration (change in total exercise time: +1.9 min vs −0.02 min) (Table 2). Similar improvements were observed in the step II diet with exercise; participants lost a mean of −2.9 kg and improved their total exercise time by +1.6 min. On average, participants in the step II diet group lost −1.7 kg (−3.1, −0.2) but did not improve their treadmill test duration.

No significant changes in lipid values and blood pressure were observed in the standard lifestyle recommendation group, while consistent and significant reductions were observed among the more intense intervention groups (Table 2). The mean systolic blood pressure dropped significantly (between −7.3 and −8.8 mmHg) in all groups except the step I diet group, where it remained stable. As seen in Fig. 1, in the more intense intervention groups, the total cholesterol level decreased by 4 to 6% while LDL-C decreased by 6%. In the step I diet group, the mean total cholesterol and LDL-C decreased by only 3 and 2%, respectively. Finally, modest increases in HDL-C were observed in all groups except the step I diet group. These improvements in cardiovascular disease risk factors in the more intense groups translated into a 3 to 6% absolute reduction of the estimated 10-year cardiovascular disease risk, whereas this risk remained stable in the step I group (−0.69%). This represents a relative risk reduction varying from 15 to 27% over baseline for the more intense interventions, compared with only 6% for the step I diet group.

Dietary Assessment

At baseline, the dietary assessment revealed no significant differences between the study groups and the mean (95% CI) daily energy intake was equal to 2,081 calories (1,911, 2,250). No significant changes were observed between the study groups. However, within each group, we observed a significant decrease in the mean (95% CI) energy intake: step I diet: 433 calories (−78, −788); step I diet with exercise: −484 calories (−111, −857); step II diet: −547 calories (−221, −872); step II diet with exercise: −784 calories (−517, −1,051).

As seen in Fig. 2, before dietary intervention, the average consumption of fat and cholesterol was already consistent with the NCEP step I diet; cholesterol intake was less than 300 mg per day, and the percentages of energy from total fat and saturated fat were close to 30 and 10%, respectively. Consequently, no significant within-group changes in the intake of fat and cholesterol were observed for participants assigned to the NCEP step I diet with or without exercise. At the end of the study, the diet of the participants assigned to the step II diet with or without exercise groups was consistent with the NCEP step II diet; cholesterol intake was less than 200 mg per day, the percentage of energy from carbohydrates was close or superior to 55%, and the percentage of energy from total fat was less than 30%. However, only those in the exercise training program have decreased their mean percentage of energy from saturated fat to less than 7%. Furthermore, only those in the most intense intervention (step II diet with exercise) have seen their percentages of total energy from carbohydrates, total fat, and saturated fat and daily intake of cholesterol reduced significantly during the course of the study. This suggests that the addition of an exercise compo-

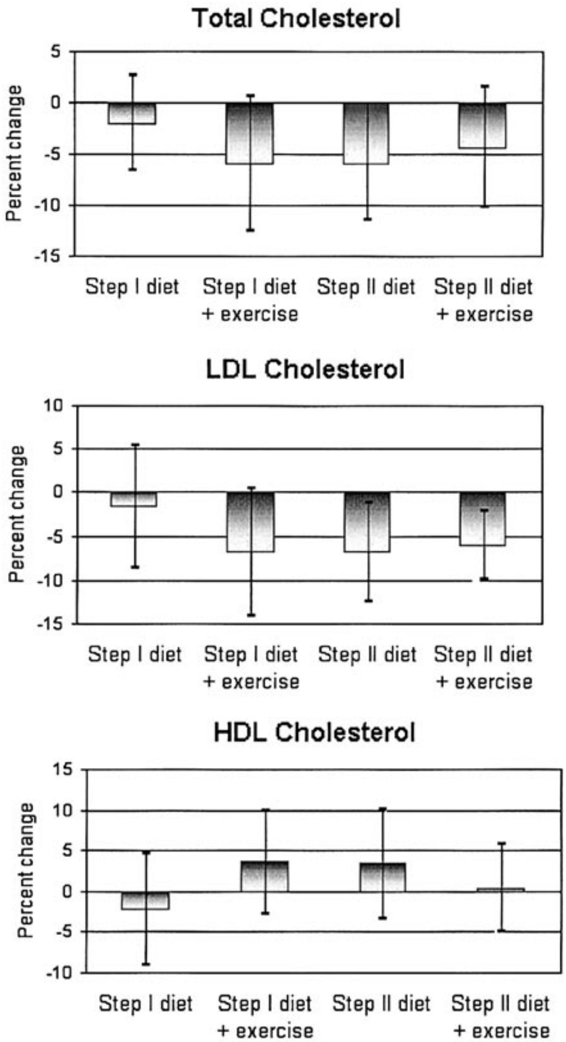

FIG. 1. Mean percentage change from baseline in lipid values for each study group. The vertical lines represent the 95% confidence interval around the mean.

nent to the NCEP step II diet may have maximized the dietary changes.

Health-Related Quality of Life

At baseline, no health-related quality of life differences were observed across the study groups on the SF-36 Health Survey. On average, participants reported very good HRQOL at baseline (Table 3). The mean Mental and Physical Component Summary scores, representing an overall evaluation of the participants' mental and physical health, were above 50, which indicates a better quality of life than the average general U.S. population. During the study, participants' HRQOL was preserved with no significant change on any of the SF-36 scales.

At Week 12, participants allocated to the supervised exercise program reported significantly greater improvement in their perceived health compared with those who received only the information on exercise. Twenty participants (100%) allocated to the step I or step II diet with exercise rated their health as either "much better" or "somewhat better" at the end of the study (Table 3) compared with 15 participants (71%)

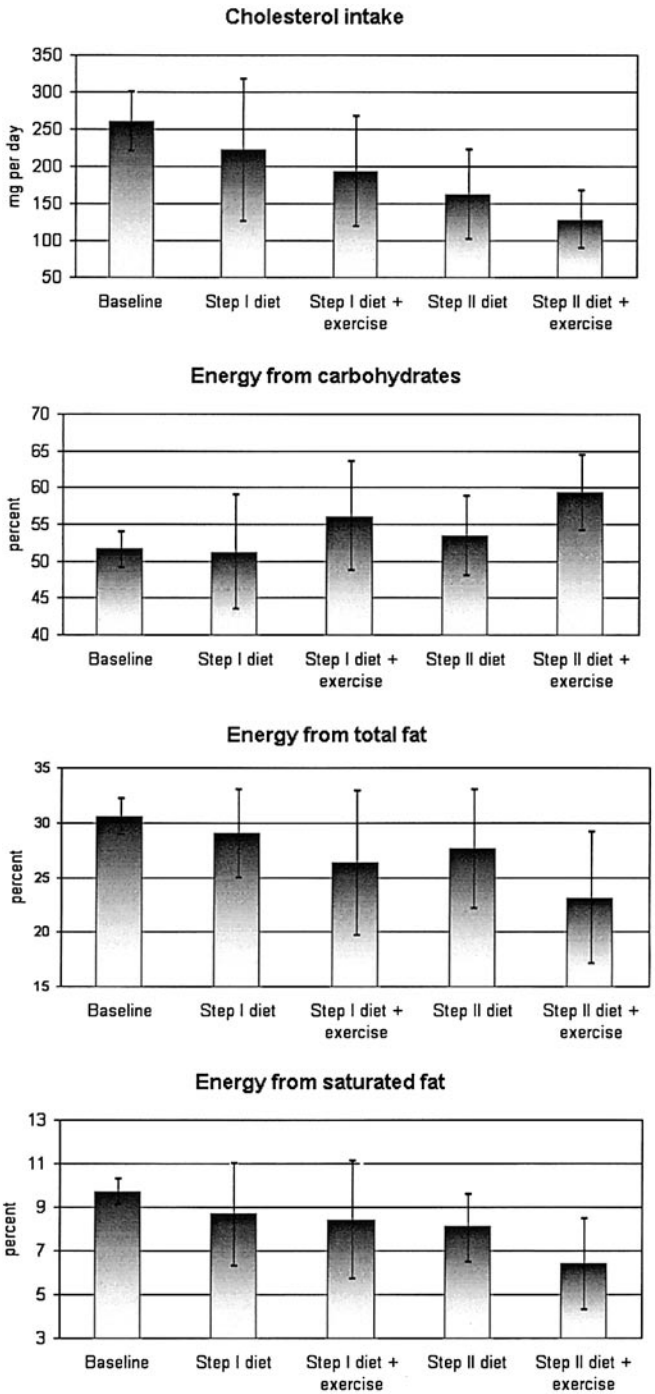

FIG. 2. Mean dietary intake at baseline for all participants (n = 41) and mean dietary intake at Week 12 for each study group. The vertical lines represent the 95% confidence interval around the mean.

TABLE 3

Mean (95% Confidence Interval[a]) Baseline Values and Changes in Health-Related Quality of Life Measures

	Baseline (n = 41)	Step I diet (n = 9)	Step I diet with exercise (n = 10)	Step II diet (n = 12)	Step II diet with exercise (n = 10)
SF-36 Health Survey					
Mental Component Summary	52.2 (49.7, 54.7)	1.8 (−2.5, 6.1)	3.5 (−4.9, 12.0)	3.1 (−2.1, 8.3)	1.9 (−4.4, 8.1)
Physical Component Summary	53.2 (51.6, 54.9)	−1.4 (−6.6, 3.7)	−0.4 (−2.5, 1.6)	−2.0 (−5.6, 1.7)	−3.8 (−10.0, 2.5)
Transition question					
Much better/somewhat better		6 (67%)	10 (100%)	9 (75%)	10 (100%)
About the same	NA[b]	3 (33%)	0 (0%)	2 (17%)	0 (0%)
Somewhat worse/much worse		0 (0%)	0 (0%)	1 (8%)	0 (0%)
Preference measures					
Rating Scale	75.9 (72.4, 79.3)	2.3 (−2.7, 7.4)	8.5 (2.3, 14.7)	5.3 (2.0, 8.6)	7.6 (−1.2, 16.4)
Standard Gamble	87.8 (83.1, 92.5)	−4.4 (−11.3, 2.4)	3.8 (−11.4, 18.9)	3.0 (−4.7, 10.7)	4.7 (−8.8, 18.2)

[a] Confidence interval that does not include the value zero indicates significant change within group.
[b] This question was asked at Week 12 only.

among the participants in the step I or step II diet without the exercise training program (mean difference: 29%; 95% CI: 10–48%).

On the Rating Scale and Standard Gamble, participants reported similar average preferences for their present health at baseline and no significant changes were observed across the study groups. However, a consistent trend was observed; in contrast to the participants in the step I diet group, those in the more intense interventions reported greater positive changes. On the Rating Scale, participants allocated to the more intense intervention groups reported significant improvement; the mean increase in the Rating Scale scores varied between +5.3 and +8.5 points. In the step I group, the mean change in Rating Scale score was equal to +2.3 points. On the Standard Gamble, the mean improvement varied from +3.0 to +4.7 points in each study group except in the step I diet group where the mean change was equal to −4.4 points. Compared with prior to the study, participants assigned to the more intense interventions attributed more value to their health at the end of the study.

Determinants of Changes in Lipid Profile

In univariate models (Table 4), the percentage change relative to baseline in body weight, percentage of energy from total fat intake, and time on treadmill were not correlated with a relative change in HDL-C. However, a relative reduction in LDL-C was associated with a relative reduction in body weight (Pearson coefficient = 0.34, P = 0.03) and in percentage of energy from total fat intake (Pearson coefficient = 0.30, P = 0.06). The relative reduction in LDL/HDL was also associated with a reduction in weight (Pearson coefficient = 0.36, P = 0.02) and marginally associated with an increase in treadmill time (Pearson coefficient = −0.28, P = 0.08) but not with a change in energy from total fat intake (Pearson coefficient = 0.15, P = 0.34). The association between LDL/HDL and weight change was significant among overweight individuals (body mass index ≥27 kg/m^2: Pearson coefficient = 0.40, P = 0.03; body mass index <27 kg/m^2: Pearson coefficient = 0.56, P = 0.06). The relative change in body weight was negatively correlated with the relative change in total exercise time on treadmill (Pearson coefficient = −0.31, P = 0.05). This association remained significant even after adjusting for the change in caloric intake. Finally, over a 3-month period, after adjusting for the observed relative change in total energy from fat, each 10% reduction in body weight was associated with a mean (95% CI) reduction in LDL cholesterol of 7.6% (0.9–14.3%). These analyses suggest that cardiovascular risk reduction, as estimated by a reduction in the LDL/HDL ratio, may be most effectively reduced by a reduction in weight, especially among overweight individuals. In our study, improvement in exercise capacity, as estimated by the time on treadmill, was associated with weight reduction. Dietary fat restriction did not correlate with either LDL/HDL or weight reduction.

TABLE 4

Pearson Correlation Coefficients between the Percentage Change in Cholesterol Values Relative to Baseline and the Percentage Change in Body Weight, Total Fat Intake, and Time on Treadmill Relative to Baseline

	Change (%) from baseline			
Change	HDL-C	LDL-C	LDL/HDL ratio	Weight
Weight	−0.20 (P = 0.21)	0.34 (P = 0.03)	0.36 (P = 0.02)	1.0
Energy from fat	0.08 (P = 0.61)	0.30 (P = 0.06)	0.15 (P = 0.34)	0.01 (P = 0.94)
Time on treadmill	0.24 (P = 0.13)	−0.15 (P = 0.34)	−0.28 (P = 0.08)	−0.31 (P = 0.05)

DISCUSSION

The first objective of this pilot study was to assess the feasibility of implementing the NCEP step I and step II diets with information on exercise or with a supervised aerobic exercise training program for people with high LDL-C levels and without evidence of cardiovascular disease. Participants allocated to the NCEP step I diet with information on exercise received the "usual care" treatment currently offered to patients with hypercholesterolemia in primary prevention. Those randomized to the other groups received more intense interventions. Our results suggest that although it is feasible to implement more intense lifestyle interventions in the primary prevention of cardiovascular disease, a large proportion of people may not be ready or able to participate in such intensive programs. In fact, of 198 eligible subjects, only 47 (24%) were willing to participate despite the fact that all study interventions were offered free of charge with convenient schedules including early morning, day, and evening times.

Among our highly selected group, however, the attendance was very high and each intervention produced its expected effect. Participants assigned to the supervised exercise program improved their treadmill exercise test duration and lost weight. In addition, after 12 weeks, the average participant's diet was consistent with the assigned step I or step II diet. At the end of the study, participants were asked to evaluate their intervention. Sixty-eight percent of the participants in the more intense interventions reported that the most difficult aspect of the intervention was to find the time to come to the exercise and dietary classes. Although intense preventive interventions can be successfully implemented among highly motivated people, it would be important to evaluate more flexible and less time-consuming approaches to reach a larger proportion of the target population.

The second objective of this pilot study was to evaluate the changes in cardiovascular risk factors and HRQOL with each intervention. Our results suggest that, overall, more intense interventions may produce more important positive changes in lipid profile, blood pressure, and health perception. In multivariate analysis, weight reduction was the most important factor associated with the lowering of LDL-C. However, the size of our study did not allow us to determine which intervention produced the optimal changes in cardiovascular risk factors. Despite these limitations, important observations can be made.

First, our results did not provide evidence that the "standard lifestyle recommendations" with a visit to a dietitian and information on exercise may improve cardiovascular fitness, dietary intake, and cardiovascular risk factors. Similar findings were reported in the Swedish study [*10*] where advice on diet and exercise was given to 158 healthy middle-aged men with raised cardiovascular risk factors in a 6-month controlled randomized study. The exercise intervention did not include any supervised exercise training program and the dietary intervention consisted of meeting a dietitian once. Eighteen months after the intervention, the observed changes in total cholesterol, LDL-C, and blood pressure in the intervention groups were not different from those in the control group. In contrast, studies evaluating more intense interventions have found that combining dietary changes with a supervised aerobic exercise program is the most efficient lifestyle intervention to improve lipoprotein profile. The effect of a prudent weight-reducing diet with and without a supervised aerobic exercise program on cardiovascular disease risk factors in overweight men and women has also been studied in a large ($n = 264$) randomized controlled trial by Wood *et al.* [*4*]. They have shown that a combined program was the most effective in improving the lipoprotein profile and was associated with a rise in HDL-C and a drop in LDL-C. Stefanick *et al.* [*15*] have shown that the NCEP step II diet failed to lower LDL-C levels in men ($n = 197$) or postmenopausal women ($n = 180$) who did not engage in aerobic exercise. In the Oslo diet and exercise study ($n = 219$), after 1 year of intervention, the lipid profile changes in the combined interventions were superior to those for exercise or diet alone [*11*]. A recent meta-analysis reported that the combined approach potentiates the reduction in LDL-C and triglyceride cholesterol but attenuates the increase in HDL-C, when compared with exercise alone [*32*]. These results suggest that for patients who truly wish to avoid taking lipid-lowering medication, the NCEP step I diet alone is not a realistic alternative.

The second observation concerns the impact of the preventive intervention on HRQOL. Despite the fact that participants reported very high HRQOL at the beginning of the study, those involved in the exercise training program reported a significantly greater improvement in health status perception than those without exercise. In addition, participants in the more intense interventions tended to report greater positive changes on the preference-based measures. Other prospective studies should be done to better document the impact of diets and exercise programs on preference measures and to determine to what extent these effects are maintained over time.

CONCLUSION

More intense lifestyle interventions may be associated with improvement in cardiovascular health and quality of life. Further studies should be done to identify interventions that are both effective and attractive for the majority.

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