A Randomized Trial of the IMPACT Worksite Cholesterol Reduction Program

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To evaluate the incremental effectiveness of a worksite cholesterol control management program when added to an established, comprehensive health promotion program at the worksite, we conducted a randomized, controlled trial including both blue- and white-collar employees at four geographically dispersed worksites. One hundred twenty-seven employees with serum cholesterol levels of 240 mg/dL or greater were assigned to receive an enhanced intervention program (the IMPACT program) while 125 were assigned to a regular screening and referral group, which included a comprehensive worksite health promotion program. One hundred eighteen program and 116 control subjects had one-year follow-up measures recorded. We used venipuncture specimens to obtain standardized baseline and follow-up cholesterol measures. Program subjects experienced a mean decline of 16.6 mg/dL as compared to a decline of 10.0 mg/dL in control subjects. The crude intergroup difference was 6.6 mg/dL (95% confidence internal [CI] = 1.1, 14.3), while the adjusted difference was 6.9 mg/dL (95% CI = 0.5, 14.3). Neither difference was significant at the .05 level. The percentage of program subjects who reduced their cholesterol level to below 240 mg/dL (36%) was significantly greater than the corresponding percentage among control subjects (21%). The enhanced worksite cholesterol control program provided incremental benefit in the percentage of individuals with elevated cholesterol in a population already exposed to a comprehensive worksite health promotion program that includes regular cholesterol screening, referral, and education activities. [Am J Prev Med 1995;11:120–3]

The association between high blood cholesterol and cardiovascular disease has been well documented.[1,2] The second National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP II) recommends using population-based strategies and complementary approaches targeting high-risk individuals as cornerstones of reduction efforts.[3] Recommendations include screening all adults for elevated blood cholesterol at least once every five years, with appropriate nonpharmacologic, and in some cases pharmacologic, interventions directed at those found at risk.

Data from the third National Health and Nutrition Examination Survey indicate that, following NCEP guidelines, approximately 52 million U.S. adults need dietary therapy to reduce their blood cholesterol. Of these, 12.7 million might also require pharmacologic therapy.[4] A substantial percentage of such individuals have been counseled to change their diet to reduce their low-density lipoprotein (LDL) cholesterol levels.[1]

Worksite health promotion and disease prevention programs offer a valuable opportunity to improve control of high blood cholesterol in working adults. Results from the 1992 survey of worksite health promotion activities indicate that 20% of private U.S. worksites with 50 or more employees offered cholesterol screening, with 28% of these offering follow-up or tracking of individuals found at risk.[5] A study from a large corporation estimated that, for each employee with a total cholesterol over 221 mg/dL, excess costs to the corporation, including compensation, health care and nonhealth care benefits costs, were $370 annually versus costs of employees with total cholesterol levels below that cut-off point.[6]

The U.S. Department of Health and Human Services Year 2000 National Health Promotion Objectives for the Nation set the goal of blood pressure and cholesterol control programs available at 50% of U.S. worksites with 50 or more employees.[7] Substantial progress toward meeting this objective has already been achieved, with offerings for blood pressure or cholesterol reduction, or both, available at an estimated 35% of such worksites in 1992, compared to 17% in 1985.[5,8]

Despite their popularity, relatively little is known about the effectiveness of worksite cholesterol reduction programs. Most

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published worksite studies are limited by use of nonexperimental designs, lack of selection for study based solely on elevated cholesterol, small numbers, or limited time of follow-up.[9] Three randomized trials of worksite programs, which vary with regard to inclusion criteria, type of intervention, and length of follow-up, have yielded estimates of program effects ranging from 0% to 8% reductions in serum total cholesterol.[10–12] The effect of programs targeting high-risk individuals who already have access to a comprehensive health promotion program at the worksite has not been evaluated. The purpose of our study is to evaluate one such program using a randomized, controlled design.

METHODS

Subjects were recruited from five worksites selected based upon the presence of an on-site health promotion program coordinated by Johnson & Johnson Health Management, Inc., offer of cholesterol screening (usually as part of the administration of a health risk assessment), management interest and agreement to follow study protocols covering recruitment of subjects, and delivery of the study intervention. Four sites met all criteria and were included in the study. Populations from which subjects were drawn had access to a comprehensive worksite-based health promotion/disease prevention program covering, at a minimum, fitness, cholesterol, blood pressure, smoking cessation, nutrition, and weight control for at least two years prior to this study. Industries represented by sites selected were automobile manufacturing, defense contracting, medical products, and other light manufacturing. Sites included one each in California, Florida, Georgia, and Texas. The worksite populations included both white- and blue-collar groups.

Individuals with total serum cholesterol levels of at least 240 mg/dL obtained from previous screenings were invited for remeasurement to determine study eligibility. Eligible individuals, those whose remeasured nonfasting total cholesterol was 240 mg/dL or greater, received information on the nature of the study intervention and the study design and had any additional questions answered before being asked to sign a consent form. High-density lipoprotein (HDL) cholesterol measurements were obtained on most subjects, with a few exceptions due to technical factors, and were used to eliminate from eligibility those individuals whose non-HDL cholesterol levels were less than 190 mg/dL.

All eligible individuals were referred to their physician or given an appropriate referral if they indicated no usual source of primary health care. We randomized subjects who agreed to participate and who signed a consent form in approximately equal numbers to enhanced intervention and screening and referral groups, using a table of random numbers accessed at a central coordinating office remote from all study sites. All study subjects completed a questionnaire covering basic demographic information and medication use at baseline and one-year follow-up. Screening and referral subjects received no further contacts by study personnel until they were contacted for follow-up measures at the end of the one-year study period.

Subjects assigned to the IMPACT enhanced intervention group received monthly 10-minute individual sessions at the worksite with a counselor that included assessment of current dietary fat content, behaviors, readiness to change, and perceived vulnerability for negative effects due to the risk factor, using validated instruments according to predetermined protocols. Also assessed were the degree to which prior goals were reached and reasons for not reaching them, compliance with any physician-prescribed medication, and goal setting for the next month. A key goal of the enhanced intervention program was to encourage subjects to seek appropriate medical care for their elevated cholesterol and to comply with their physician-prescribed treatment. In addition, a monthly package mailed to the home address contained a personalized cover letter, information on cholesterol/lipids including behavioral challenges (among these were limiting amount of butter eaten in a day, amount of high-fat snacks eaten in a week, and walking 20 minutes three times a week). Program recipients were offered an opportunity to have their cholesterol level measured approximately six months after enrollment.

Incentives such as coupons toward low-fat cookbooks or athletic equipment were offered after each challenge had been met. In addition, participants received priority enrollment in relevant programming offered as part of the overall worksite health promotion program. Sites were required to offer at least six classes or demonstrations (such as a display of common foods with test tubes of fat to indicate the fat content of each) related to cholesterol control during the 12-month intervention period.

Counselors were either nutritionists or health educators with a minimum of three years of experience in counseling for this risk area in comparable settings. Each had successfully completed a 16-hour IMPACT training program, which included review of relevant literature, practice in effective counseling techniques, role playing, use of materials, and quality assurance efforts. Counselors were supervised by the on-site health promotion program coordinator, and conformance with protocol was monitored centrally through review of notes in standardized form from all counseling sessions and participant reports of satisfaction with counselors and content of sessions.

We obtained cholesterol measurements (total and HDL) at baseline and at the one-year follow-up (as well as six-month measures for program recipients), using nonfasting venipuncture specimens shipped using a standardized protocol. Determinations on all specimens were performed by Metpath, Inc. at their Teterboro, New Jersey, facility, which participates in a quarterly standardization program managed by the Centers for Disease Control and Prevention for the National Heart, Lung, and Blood Institute.

We compared changes from baseline total cholesterol for enhanced intervention subjects with corresponding changes for screening and referral subjects with 95% confidence intervals (CIs). Change scores were adjusted for age, sex, and baseline total cholesterol using a regression model. The difference in proportions was tested using the Mantel-Haenszel summary chi-square statistic.

RESULTS

A total of 490 individuals had baseline cholesterol measurements performed to determine eligibility for inclusion in the study (Figure 1). Of these, a total of 238 were excluded (201 as a result of total cholesterol less than 240 mg/dL, 26 as a result of non-HDL cholesterol less than 190 mg/dL, and 11 as a result of refusal to participate). The sizes of initial enhanced intervention and screening and referral groups and follow-up numbers and rates are as follows: in the intervention group, 127 were enrolled and 118

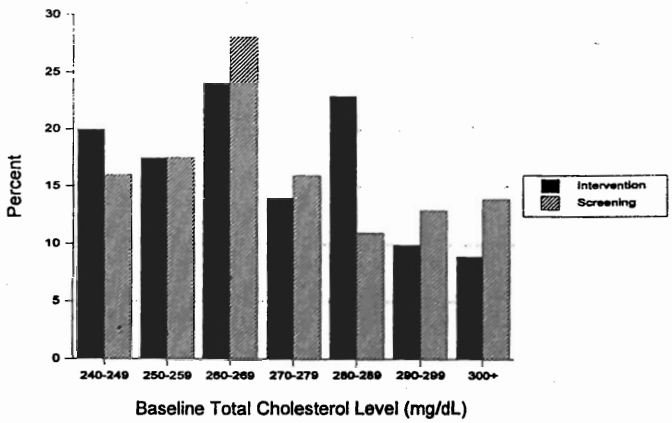

Figure 1. Distribution of baseline total cholesterol values.

Table 2. Cholesterol below 240 mg/dL at follow-up

	n	Number (%) with cholesterol below 240 mg/dL at follow-up
Not taking medication at follow-up		
Intervention group	98	32 (33%)
Screening group	103	20 (19%)
Taking medication at follow-up		
Intervention group	20	10 (50%)
Screening group	13	4 (31%)

Mantel-Haenszel summary chi-square = 5.03, $P = .02$.

(92.9%) were followed; in the screening group, 125 were enrolled and 116 (92.8%) were followed. Reasons for those not followed up included leaving company, remaining with company but moving out of area, and refusing to return for follow-up cholesterol determination despite at least two written and two telephonic or person-to-person attempts.

Baseline characteristics of the final study groups are provided in Table 1. No significant intergroup differences were found. Very small percentages of both groups were taking cholesterol control medication at baseline.

Changes in the total serum cholesterol were −16.6 mg/dL for the intervention group and −10.0 mg/dL for the screening group; crude difference = 6.6 (CI = −1.1, 14.3); difference adjusted for age, sex, and baseline total cholesterol = 6.9 (CI = −0.5, 14.3); and difference adjusted for age, sex, baseline total cholesterol, and medication use = 6.2 (CI = −1.1, 13.4). Comparison of the difference adjusted for medication use with differences not adjusted for this factor indicates that medication use explains little of the intergroup difference. Table 2 lists numbers of individuals in each group whose cholesterol decreased to below 240 mg/dL at follow-up, stratified by medication use at follow-up. Although the average decrease in total cholesterol was about 50% greater in the enhanced intervention than the screening and referral group, 95% CIs for both the crude and adjusted differences extend slightly beyond the null value, indicating that the difference between groups was not statistically significant at the .05 level. However, as shown in Table 2, a significantly greater percentage of enhanced intervention subjects achieved a postprogram cholesterol level below 240 mg/dL than screening and referral subjects.

Interim cholesterol results were obtained approximately six months after the initiation of the intervention for 106 of the 118 final enhanced intervention subjects, demonstrating an average decline of 21.1 mg/dL at the approximate midpoint of the program year. The one-year average decline in total cholesterol for these 106 individuals was 15.8 mg/dL.

Among subjects not initially reporting cholesterol medication use, 15/113 enhanced intervention subjects and 10/112 screening and referral subjects reported taking such medication at the one-year follow-up evaluation ($P = .30$).

Eighty-nine of the 118 subjects enrolled in the enhanced intervention group reported seeing a physician during the study period. Information on physician visits was not collected for screening and referral subjects.

Table 1. Description of study groups

	Intervention group	Screening group
Number	118	116
Percentage female	21.2%	20.7%
Mean age (years)	48.7	48.0
Percentage on cholesterol medication	4.2%	3.4%
Baseline total cholesterol (mg/dL) (SD)	270.9 (22.2)	272.0 (21.0)

DISCUSSION

IMPACT was developed in response to demand from employers for programs that better targeted those at highest risk. The results reported here are the first from a cholesterol reduction component added to a preexisting comprehensive worksite health promotion program. In this context, the results, when taken together, suggest that an additional effect was achieved and can be considered promising. While the adjusted change scores did not reach statistical significance ($\alpha = .05$) using a two-tailed test, the more conservative approach to considering intergroup differences, a greater percentage of the treatment group was successful at reducing serum cholesterol levels to below 240 mg/dL.

The underlying program, in this case LIVE FOR LIFE, has shown significant effects on employee risk factors and costs for the entire worksite population.[13] Thus, the study was a conservative test for the IMPACT program. Future studies should address its effectiveness at worksites with less prior health promotion programming.

What accounted for the change in the total cholesterol of the screening and referral groups? Regression to the mean may have

been observed despite limiting eligibility to those with two elevated readings. Referral of all participants (including screening and referral subjects) to a physician may have led to improved control, even though the screening and referral groups had been referred previously in a similar manner. Modest increases in cholesterol medication use occurred in both groups. The knowledge that remeasurement would occur at one year may also have influenced behavior of the screening and referral groups. Additionally, the continued presence of an underlying health promotion program that addressed not only cholesterol but promoted exercise, weight management, and improved nutrition for a variety of reasons, including but not limited to improvement in blood cholesterol, may also have contributed to the screening and referral groups' improvement.

The small effect size may be due in part to the low intensity of the IMPACT intervention versus that for most previously reported studies. Also, the at-risk population identified may be more refractory to change efforts than a population without prior exposure to an underlying worksite health promotion program. However, a cholesterol change of 10 mg/dL in the entire population with elevated cholesterol would achieve a significant reduction in overall cardiovascular morbidity and mortality, if sustained.

The greater reduction in total cholesterol in the enhanced intervention group six months after program initiation, as compared to the final one-year results, may reflect waning enthusiasm for suggested behavior modifications. Seasonal variation in cholesterol values may have also affected results, since baseline measures were taken in the fall and winter.[14]

Since a significant percentage of those with elevated cholesterol levels can lower them with behavioral interventions alone, a worksite behavioral change program for those at high risk could be a useful complement to physician management. Follow-up was limited to one year. Based on a large number of behavior change studies, particularly those dealing with nutritional factors, a continuing intervention, although perhaps of lower intensity, may be required to extend or maintain reductions in total cholesterol. Although clinical programs integrated into primary care delivery may be more effective, they tend to be more intensive, incur higher costs, and rely on medication to a greater extent.

Monitoring, feedback, and reinforcement are important components of most behavioral interventions. Feedback on changes in cholesterol was offered only once because of cost constraints. Future interventions should assess the impact of more frequent measurement and feedback of cholesterol levels, the key outcome variable.

Although all counselors received identical training including the use of a detailed protocol, counselor notes and monthly challenge results show considerable variability in emphasis for participants with similar problems. An interactive software management tool to guide counselors to cover all required areas and to choose appropriate challenges could increase consistency and improve results.

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