ORIGINAL INVESTIGATION

Coaching patients On Achieving Cardiovascular Health (COACH)

A Multicenter Randomized Trial in Patients With Coronary Heart Disease

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Background: Disease management programs in which drugs are prescribed by dietitians or nurses have been shown to improve the coronary risk factor profile in patients with coronary heart disease. However, those disease management programs in which drugs are not prescribed by allied health professionals have not improved coronary risk factor status. The objective of the Coaching patients On Achieving Cardiovascular Health (COACH) study was to determine whether dietitians or nurses who did not prescribe medications could coach patients with coronary heart disease to work with their physicians to achieve the target levels for their total cholesterol (TC) and other risk factors.

Methods: Multicenter randomized controlled trial in which 792 patients from 6 university teaching hospitals underwent a stratified randomization by cardiac diagnosis within each hospital: 398 were assigned to usual care plus The COACH Program and 394 to usual care alone. Patients in The COACH Program group received regular personal coaching via telephone and mailings to achieve the target levels for their particular coronary risk factors. There was one coach per hospital. The primary outcome was the change in TC (ΔTC) from baseline (in hospital) to 6 months after randomization. Secondary outcomes included measurement of a wide range of physical, nutritional, and psychological factors. The analysis was performed by intention to treat.

Results: The COACH Program achieved a significantly greater ΔTC than usual care alone: the mean ΔTC was 21 mg/dL (0.54 mmol/L) (95% confidence interval [CI], 16-25 mg/dL [0.42-0.65 mmol/L]) in The COACH Program vs 7 mg/dL (0.18 mmol/L) (95% CI, 3-11 mg/dL [0.07-0.29 mmol/L]) in the usual care group ($P<.0001$). Thus, the reduction in TC from baseline to 6 months after randomization was 14 mg/dL (0.36 mmol/L) (95% CI, 8-20 mg/dL [0.20-0.52 mmol/L]) greater in The COACH Program group than in the usual care group. Coaching produced substantial improvements in most of the other coronary risk factors and in patient quality of life.

Conclusions: Coaching, delivered as The COACH Program, is a highly effective strategy in reducing TC and many other coronary risk factors in patients with coronary heart disease. Coaching has potential effectiveness in the whole area of chronic disease management.

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CLINICAL TRIALS have shown that the reduction of total cholesterol (TC) and low-density lipoprotein cholesterol (LDL-C),[1-3] the treatment of hypertension,[4] and the performance of regular exercise[5] have reduced mortality in patients with coronary heart disease (CHD). However, evidence from all over the world has shown that these advances are only being partially applied in clinical practice.[6-10] The concept has arisen of a treatment gap in CHD—the difference between evidence-based medicine and the real world.[11]

Strategies to address the treatment gap have been usually aimed at the physician, and these have often been ineffective.[12,13] Strategies that target the patient have become known as disease management programs.[14] A systematic review performed by McAlister et al[14] concluded that these programs are effective in improving coronary risk factors. However, closer inspection of these disease management programs reveals that there are 2 distinct types of programs, which, until now, have been inappropriately grouped together: (1) those in which dietitians or nurses prescribe medication (usually lipid-lowering agents) directly to patients and (2) those in which dietitians or nurses do not have prescribing rights. Published work shows that all of the effective programs involved the prescription of medication(s) directly to patients.[15-18] Not surprisingly, the effectiveness of these

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interventions was attributable to progressive titration of lipid-lowering drug therapy with monitoring of the risk factor level until the target was achieved. On the other hand, none of the programs in which drugs were not prescribed by allied health professionals was effective in improving the coronary risk factor profile in patients with CHD, despite improving health behaviors.[19-24]

Although programs that involve the direct prescription of medication to patients are clearly effective, they may be seen as competitive with usual medical care in some environments and may thus be counterproductive by alienating the usual treating physician. There is a role for a program that can achieve risk factor reduction in patients with CHD without involving support staff directly in the prescribing of drugs to patients. This has been the rationale for our development of the Coaching patients On Achieving Cardiovascular Health (COACH) Program to bridge the treatment gap in patients with CHD.

The COACH Program intervention was not founded on the application of theoretical principles. It is an empirical technique based on the head coach's experience as a secondary school teacher. The COACH Program is a training program for patients with CHD in which a health professional coach trains patients to aggressively pursue the target levels for their particular coronary risk factors while working in partnership with their own physician(s). The coach is hospital based and uses the telephone and mailings to provide regular coaching sessions to patients after discharge from the hospital. Coaching is directed at the patient and not at the treating physician. Patients are coached to know their risk factor levels, the target level for their risk factors, and how to achieve the target levels for their risk factors. Patients are persuaded to see their physician and ask for appropriate prescription of medication(s). Coaching also trains patients to follow appropriate lifestyle measures. Coaching aims to enable patients to drive the process of achieving and maintaining the target levels for their risk factors.

In a pilot study, we showed that one coach at a single institution reduced serum TC levels by 21 mg/dL (0.54 mmol/L) compared with usual medical care by using this simple approach.[25] The beneficial effect of the coaching seemed to be due to the patient's better adherence to the nutritional advice given by the coach and to the patient's better adherence of the treatment prescribed by the usual medical practitioner.[25] The current study was designed to test whether The COACH Program could achieve similar results in a much larger sample of patients spread over 6 university teaching hospitals, with a different coach in each hospital. In addition, we also determined the impact of coaching on a wide range of other modifiable coronary risk factors.

METHODS

PATIENT SELECTION

This randomized, multiple risk factor clinical intervention took place in 6 university teaching hospitals in Melbourne, Australia. There was one coach based in the cardiology department of each hospital. There were thus a total of 6 coaches. Coaches consecutively screened patients for enrollment into the study using cardiology department admission summaries and by attending ward rounds. Coaches approached patients at the bedside and invited them to participate in The COACH Program intervention study. Patients were included if they had been hospitalized for (1) coronary artery bypass graft surgery, (2) percutaneous coronary intervention, (3) acute myocardial infarction or unstable angina and then discharged on medical therapy, or (4) coronary angiography with planned (elective) revascularization. Patients were excluded if they were not able to be contacted by telephone, could not speak or read English, had no fasting blood sample taken within 24 hours of hospitalization, were participating in another study involving lipids, lived too far from or were unwilling to travel to the hospital for follow-up visits, were too ill in the hospital to interview, or would not provide signed consent.

Coaches obtained baseline clinical and demographic characteristics (before randomization) for recruited patients by interview at the bedside and from the medical record. The baseline dietary and psychological questionnaires were completed by the patients as inpatients. Recruitment continued until the target number of 140 patients in each hospital had been achieved. The study protocol was approved by the human research ethics committees within each hospital.

THE COACHES

The coaches were 2 dietitians and 4 nurses (see list of coaches of The COACH Study Group on page 2782). Coaches were trained by one of the dietitians and the head coach (M.J.V.), who was formerly a teacher and who was the coach in the original study.[25] This coach repeated the intervention in the original study center. The other dietitian was a recent graduate. Of the nurses, 2 were experienced in coronary care, 1 in intensive care, and 1 in research. The research nurse was replaced midstudy with a research assistant (scientist) who had previous experience in conducting a coronary risk factor trial.

TRAINING PROGRAM FOR COACHES

Immediately before commencement of the study, the 5 new coaches underwent a part-time training program for 2 weeks on conducting The COACH Program. Coaches were trained in the technique applied in the original pilot study.[25] Training also included the use of The COACH Program software package, developed specifically for the COACH study.

RANDOMIZATION

Patients were allocated to The COACH Program intervention and usual care groups on the basis of random numbers in blocks of 10 and stratified by cardiac procedure: coronary artery bypass graft surgery, percutaneous coronary intervention, post–acute myocardial infarction or unstable angina discharged on medical therapy, or coronary angiography for planned revascularization. The allocation sequence was computer generated by an assistant from the Department of Epidemiology and Preventive Medicine, Monash University Medical School, Alfred Hospital. Recruited patients were randomized within 24 hours after discharge from the hospital. The coaches communicated with the assistant via telephone, facsimile, or e-mail.

THE COACH PROGRAM INTERVENTION

The COACH Program package was mailed to patients within 24 hours of the coach being notified of group allocation. This package included information on their in-hospital lipid and other coronary risk factor levels and a 1-page chart of risk factor targets for the secondary prevention of CHD. In addition, the hos-

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pital sent the usual medical caregiver the same 1-page chart of risk factor targets together with the discharge summary.

Coaching Sessions Delivered by Telephone

The coach initiated contact with the patient by telephone within 2 weeks after randomization for the first coaching session. A further 3 telephone coaching sessions followed at 6-week intervals. A fifth call at 24 weeks was made to patients in The COACH Program group to arrange a 6-month assessment of risk factors.

Patients were coached according to the COACH model, which has been described in detail in a previous publication.[25] In essence, The COACH Program intervention consists of a process of continuous improvement, which involves coaching the patient to go to their physician and obtain measurement of their coronary risk factors and to be informed of the results of these measurements, education regarding targets, negotiation of a plan of action to achieve the target, and subsequent monitoring of the patient's progress toward the achievement of the target level. This quality improvement cycle, which indicates that each coaching session is used as the foundation for the next coaching session, is a key feature of The COACH Program. There was no preset time frame for coaching sessions. The length of the calls was determined by the length of time the coach needed to establish a plan of action with the patient to be achieved by the next coaching session. Patients were invited to contact their coach between coaching sessions for questions and additional information as required.

Patients were coached to achieve the following Australian target levels for modifiable coronary risk factors: TC less than 155 mg/dL (<4.0 mmol/L),[26] complete smoking cessation, blood pressure less than 140/90 mm Hg,[27] fasting glucose level less than 110 mg/dL (6.1 mmol/L),[28] body mass index (BMI) (calculated as weight in kilograms divided by the square of height in meters) less than 25,[29] saturated fat intake of 10% or less of total energy intake,[27] and 30 minutes or more of moderate-intensity activity on most or all days of the week.[27]

Coaching Sessions in Writing

The COACH Program software package was used in conjunction with the telephone coaching sessions. This package was developed as part of The COACH Program to generate written reports that were a summary of each verbal coaching session. Each report covered 7 modifiable risk factors: cholesterol, smoking, blood pressure, glucose level, body weight, dietary saturated fat intake, and physical activity. Patients were mailed a copy of the report for reference and reinforcement of expected progress by the next coaching session. The reports provided the coach with a record of patient progress as a reference for the next coaching session.

USUAL CARE

Together with the hospital discharge summary, the hospital sent to the usual medical caregiver of the patient a 1-page chart of risk factor targets for the secondary prevention of CHD, identical to that mailed to The COACH Program patients and also sent to their usual medical caregivers. Patients were contacted only once after discharge, at 24 weeks, to arrange a follow-up assessment within the next 2 weeks.

OUTCOME MEASURES

The primary outcome was the change in fasting serum TC (ΔTC) level from baseline (in hospital) to 6 months after randomization. The secondary outcomes were the change from baseline to 6 months after randomization of fasting triglyceride; high-density lipoprotein cholesterol (HDL-C) and LDL-C; systolic blood pressure; diastolic blood pressure; body weight; BMI; fasting glucose level; dietary intake of total fat, saturated fat, cholesterol, and fiber by means of a validated food frequency questionnaire[30]; smoking behavior (verified by serum cotinine level in self-reported smokers at baseline); walking for exercise; cardiac depression score (CDS) for depressed mood[31]; and anxiety score by means of the State-Trait Anxiety Inventory (STAI).[32] The secondary outcomes measured only at 6 months after randomization included self-reported patient perceptions of general health, mood, and cardiac symptoms.

LABORATORY METHODS AND MEASURING INSTRUMENTS

The biochemical analyses for TC, triglyceride, HDL-C, and fasting glucose were performed within the pathology department of each hospital. Cotinine analyses were performed in the laboratory of the Alfred Hospital. The hospital laboratories are accredited by the National Association of Testing Authorities of Australia and by the International Standards Organisation. The laboratory personnel performing the biochemical measurements were not aware of group assignment.

Venous blood was drawn for biochemical measurements by pathology collectors not involved with the study. Both TC and triglyceride were measured by enzymatic colorimetric methods. The HDL-C was measured directly using a homogeneous method or after precipitation of non–HDL-C. The LDL-C was calculated by the Friedewald equation, except when triglyceride levels exceeded 400 mg/dL (4.5 mmol/L).[33] Fasting glucose was measured by the glucose oxidase method. Cotinine was measured by gas chromatography–mass spectroscopy.

Blood pressure was measured in a sitting position by the use of an automatic digital sphygmomanometer (Omron T3; OMRON Corp, Kyoto, Japan). Two measurements were taken, and the lower systolic and diastolic measurements were used. Weight was measured on electronic scales with the patient dressed in light indoor clothing without shoes. The height used for calculation of BMI was recorded from the patient's medical history. The questionnaires for dietary intake, depression, and anxiety were completed by the patients.

SAMPLE SIZE

Based on an estimated mean difference in TC between the 2 groups of 9 mg/dL (SD, 32 mg/dL) (mean, 0.22 mmol/L; SD, 0.83 mmol/L), we estimated that to achieve a power of 0.90 with α being .05, we would require a total of 300 subjects to complete the study in each group. Allowing for a dropout rate of up to 30%, the target recruitment number was 140 patients in each study center (70 in The COACH Program group and 70 in the usual care group).

STATISTICAL ANALYSIS

Statistical analyses were performed with Stata statistical software.[34] Results are expressed as mean (95% confidence intervals) for normal data and median (range) for skewed data. The 2-tailed, unpaired *t* test and Kruskal-Wallis test were used to compare normal and skewed continuous variables, respectively. The χ^2 test was used to compare categorical variables. Factors that influence the ΔTC were assessed by stepwise forward regression analysis. The variables were entered into this analysis if univariate analysis found them to be significant at $P<.05$. The comparison of the effects of the coaches on TC was evaluated by using analysis of variance. The analyses were performed by intention to treat.

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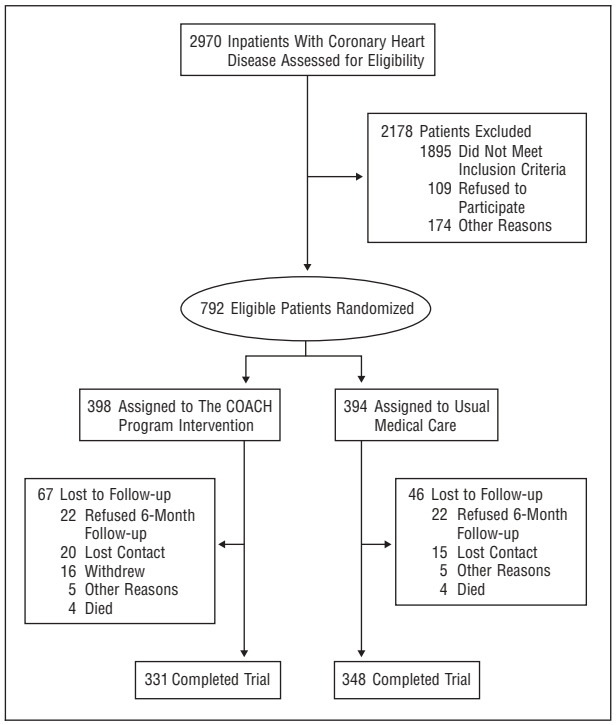

Flow of patients through the trial.

RESULTS

PARTICIPANT FLOW AND FOLLOW-UP

From May 28, 1999, to April 12, 2000, 792 patients (610 men, 182 women) were randomized. The **Figure** shows the number of patients screened and randomly assigned and those who completed the study protocol. Of the 398 patients randomized to The COACH Program, 331 (83%) completed the trial, compared with 348 (88%) of the 394 usual care patients. Follow-up ended on November 30, 2000.

Patients remained in their original groups throughout the study, and analysis was performed by intention to treat. The primary outcome was the reduction in TC level from baseline to 6 months after randomization. Thus, for 113 dropout patients, it was assumed that their 6-month measure of TC was the same level as at baseline.

The baseline characteristics of those patients randomized but failing to have a 6-month lipid estimation (dropout, n=113) were contrasted with the baseline characteristics of those completing the study (n=679). The only significant differences in the baseline characteristics of the patients who completed the study from those who did not complete the study were an excess of patients in the dropout group who stated an intention not to attend a cardiac rehabilitation program after hospitalization ($P<.0001$), were not married ($P=.001$), were participants in study center 2 ($P=.002$), had a higher CDS for depressed mood ($P=.005$), were living alone ($P=.006$), had prior knowledge of what is a normal blood pressure reading ($P=.006$), were living rurally ($P=.02$), had self-reported high blood pressure ($P=.03$), and were assigned to coaching ($P=.04$).

The 2 groups of randomized study participants were similar in all respects (**Table 1**). Table 1 shows that 77% of the participants were men, with a median age of 58.5 years. Most patients were hospitalized for management of acute coronary syndromes and/or percutaneous coronary intervention, 17% had diabetes, 48% were hypertensive, 32% were current smokers at the time of the acute event, and 80% were discharged with a prescription for lipid-lowering medication. The mean laboratory values were as follows: TC, 192 mg/dL (4.96 mmol/L); triglyceride, 142 mg/dL (1.60 mmol/L); HDL-C, 43 mg/dL (1.11 mmol/L); LDL-C, 117 mg/dL (3.02 mmol/L); fasting glucose, 105 mg/dL (5.9 mmol/L); blood pressure, 130/76 mm Hg; and BMI, 28.

LENGTH OF COACHING SESSIONS

The time spent on the telephone was longest for the first coaching session, with a median duration of 30 minutes (range, 6-200 minutes). The median duration of subsequent calls was 20 minutes (range, 5-50 minutes).

PRIMARY OUTCOME

Based on intention to treat, The COACH Program group achieved a mean reduction in TC from baseline to 6 months after randomization of 21 mg/dL (0.54 mmol/L) (95% CI, 16-25 mg/dL [0.42-0.65 mmol/L]) compared with 7 mg/dL (0.18 mmol/L) (95% CI, 3-11 mg/dL [0.07-0.29 mmol/L]) in the usual care group ($P<.0001$). Thus, the reduction in TC from baseline to 6 months after randomization was 14 mg/dL (0.36 mmol/L) (95% CI, 8-20 mg/dL [0.20-0.52 mmol/L]) greater in The COACH Program group than in the usual care group (**Table 2**). Based on intention to treat, the mean TC at 6 months in The COACH Program group was 173 mg/dL (4.48 mmol/L) (95% CI, 166-177 mg/dL [4.29-4.57 mmol/L]) and 183 mg/dL (4.72 mmol/L) (95% CI, 178-186 mg/dL [4.61-4.82 mmol/L]) in the usual care group ($P<.001$). When the analysis was performed excluding the patients for whom there was no 6-month measurement of TC, the differences described under intention to treat were magnified. The level of significance was unaltered.

LIPID-LOWERING MEDICATION AT 6 MONTHS AFTER RANDOMIZATION

Patient self-reported lipid-lowering medication at 6 months was only available for the 679 patients who completed the trial. There were more patients taking lipid-lowering drug therapy in The COACH Program than in the usual care group: 311 (94%) of 331 vs 302 (87%) of 348, respectively ($P=.002$). There was no difference in the class of drug prescribed between The COACH Program and the usual care groups ($P=.24$). Of the 613 patients undergoing lipid-lowering drug therapy, 41% were taking simvastatin, 39% were taking atorvastatin calcium, 17% were taking pravastatin sodium, and 3% were taking other agents.

The median dose of simvastatin used was 20 mg (range, 5-80 mg) in both The COACH Program and usual care groups; for pravastatin sodium, doses were 40 mg

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Table 1. Baseline Clinical Characteristics (Before Randomization) of Patients in The COACH Program and Usual Care Groups

Characteristic	The COACH Program (n = 398)	Usual Care (n = 394)
Sex, No. (%)		
Male	313 (79)	297 (75)
Female	85 (21)	97 (25)
Age, y		
Mean (SD)	58.6 (10.6)	58.3 (10.6)
Median (range)	59 (24-86)	58 (32-87)
Cardiac procedure, No. (%)		
Coronary artery bypass graft surgery	42 (11)	36 (9)
Percutaneous coronary intervention	158 (40)	160 (41)
Post-AMI/post–unstable angina while undergoing medical therapy	149 (37)	150 (38)
Angiography for planned revascularization	49 (12)	48 (12)
Past cardiovascular history, No. (%)		
Angina	141 (35)	159 (40)
Acute myocardial infarction	129 (32)	134 (34)
Percutaneous coronary intervention	63 (16)	73 (19)
Coronary artery bypass graft surgery	32 (8)	48 (12)
Fasting lipids in-hospital, mg/dL [mmol/L]*		
Triglyceride, median (range)	142 (35-1329) [1.6 (0.4-15.0)]	142 (35-1249) [1.6 (0.4-14.1)]
Cholesterol, mean (SD)		
Total	194 (46) [5.02 (1.18)]	189 (44) [4.90 (1.13)]
HDL	43 (13) [1.10 (0.33)] (n = 396)	43 (12) [1.11 (0.32)] (n = 393)
LDL	119 (38) [3.09 (0.97)] (n = 380)	114 (38) [2.94 (0.97)] (n = 380)
Fasting glucose, median (range), mg/dL [mmol/L]	104 (58-331) [5.8 (3.2-18.4)] (n = 396)	106 (59-404) [5.9 (3.3-22.4)] (n = 392)
Blood pressure, mean (SD), mm Hg		
Systolic	130.3 (18.1)	129.9 (19.5)
Diastolic	76.0 (11.2)	75.9 (11.6)
Family history coronary heart disease, No. (%)†	63 (16)	79 (20)
Known diabetes (type 1 and type 2), No. (%)	63 (16)	70 (18)
Hypertension (patient's self-report), No./Total No. (%)	191/395 (48)	185/390 (47)
Body mass index, mean (SD), kg/m^2	28.2 (4.6)	28.4 (4.7)
Smoking status (patient's self-report), No. (%)		
Current (≥1 cigarette per day during 3 mo before hospitalization)	136 (34)	120 (31)
Stopped >3 mo ago	159 (40)	179 (45)
Never (smoked <3 mo at any stage during life)	103 (26)	95 (24)
Walking regularly (patient's self-report), No. (%)	225 (57)	247 (63)
Lipid-lowering medication on discharge, No. (%)	320 (80)	320 (81)

Abbreviations: AMI, acute myocardial infarction; COACH, Coaching patients On Achieving Cardiovascular Health; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

*Three patients did not have a measurement of HDL-C at baseline; LDL-C measurements were taken only for patients with triglyceride levels less than 400 mg/dL (4.5 mmol/L).

†First-degree relative who died of coronary heart disease when younger than 60 years.

(range, 20-40 mg) for The COACH Program group and 40 mg (range, 10-80 mg) for the usual care group; and for atorvastatin calcium, doses were 20 mg (range, 10-80 mg) for both groups. Atorvastatin was the only drug for which there was a greater number of patients prescribed a higher dose (≥20 mg) in The COACH Program group than the usual care group ($P = .02$).

FACTORS INFLUENCING CHANGE IN TC LEVEL

Stepwise forward regression analysis revealed that the following factors were associated with a greater reduction in TC (in order of decreasing contribution): being prescribed lipid-lowering medication at 6 months, a higher baseline TC level, a higher baseline fasting glucose level, reduction in saturated fat intake, being coached (all $P < .0001$), and reduction in body weight ($P < .003$). In particular, age, sex, the performance of cardiac rehabilitation, and psychological characteristics (CDS and STAI) had no significant impact on the reduction in TC from baseline to 6 months after randomization.

SECONDARY OUTCOMES

The secondary outcomes were also analyzed by intention to treat (baseline values being substituted for missing data), except for self-reported measures of general health, mood, and symptoms, which were only obtained from patients at the 6-month stage. As shown in Table 2, The COACH Program achieved a significantly greater reduction in the calculated LDL-C from baseline to 6 months after randomization than did usual medical care. However, coaching had no significant impact on the change in triglyceride or HDL-C. There was a rise in systolic blood pressure and diastolic blood pressure in both The COACH Program and usual care groups, but there was a significantly lesser rise in levels in The COACH Program patients. The COACH Program resulted in a sig-

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Table 2. Outcome Variables in The COACH Program Intervention and Usual Care Groups*

Variable	The COACH Program (n = 398)	Usual Care (n = 394)	*P* Value
Primary end point			
ΔTotal cholesterol, mg/dL [mmol/L]	↓21 (16 to 25) [↓0.54 (0.42 to 0.65)]	↓7 (3 to 11) [↓0.18 (0.07 to 0.29)]	<.0001
Secondary end points			
Lipids, mg/dL [mmol/L]			
ΔTriglyceride	↓15 (6 to 24) [↓0.17 (0.07 to 0.27)]	↓12 (4 to 22) [↓0.14 (0.04 to 0.25)]	.76
ΔHDL-C	↑3 (2 to 4) [↑0.08 {0.05 to 0.10}]	↑4 (3 to 5) [↑0.10 (0.07 to 0.13)]	.20
ΔLDL-C	↓21 (17 to 25) [↓0.55 (0.45 to 0.65)] (n = 376)	↓8 (4 to 12) [↓0.21 (0.11 to 0.31)] (n = 375)	<.0001
Blood pressure, mm Hg			
ΔSystolic	↑0.1 (–1.5 to 1.7)	↑4.5 (2.5 to 6.5)	.001
ΔDiastolic	↑0.4 (–0.7 to 1.5)	↑2.8 (1.5 to 4.0)	.005
Body weight and body mass index			
ΔBody weight, kg	↓1.3 (0.9 to 1.8)	↓0.4 (–0.03 to 0.8)	<.001
ΔBody mass index, kg/m^2	↓0.5 (0.3 to 0.6)	↓0.1 (–0.01 to 0.3)	.001
ΔFasting glucose, mg/dL [mmol/L]	↓4 (0.05 to 7) [↓0.2 (–0.003 to 0.4)]	↓4 (0.2 to 7) [↓0.2 (0.01 to 0.4)]	.76
Nutrient intake			
ΔTotal fat, g	↓15.3 (12.2 to 18.3)	↓10.5 (7.2 to 13.7)	.04
ΔSaturated fat, g	↓8.0 (6.6 to 9.4)	↓4.9 (3.6 to 6.3)	.002
ΔCholesterol, mg	↓36 (25 to 46)	↓20 (10 to 30)	.04
ΔFiber, g	↑0.5 (–1.3 to 0.2)	↓0.7 (–0.1 to 1.5)	.02
Depression and anxiety score			
ΔCardiac depression scale	↓4.9 (2.9 to 7.0)	↓2.8 (0.8 to 4.7)	.14
ΔState-Trait Anxiety Inventory	↓2.2 (1.5 to 3.0)	↓1.1 (0.3 to 1.8)	.03
Patient's self-report, No./Total No. (%)			
Gave up smoking since discharge	53/106 (50)	41/97 (42)	.27
Taken up walking since discharge	120/173 (69)	64/147 (44)	<.0001
Self-perception of excellent health†	107/331 (32)	61/348 (18)	<.0001
Self-perception of excellent mood†	104/331 (31)	53/348 (15)	<.0001
Symptoms of dyspnea†	56/331 (17)	93/348 (27)	.002
Symptoms of chest pain†	51/331 (15)	84/348 (24)	.004

Abbreviations: Δ, baseline level minus 6-mo level; ↓, reduction; ↑, increase; COACH, Coaching patients On Achieving Cardiovascular Health; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

*Variables are given as mean (95% confidence interval) unless stated otherwise.

†Measured at 6 mo only; LDL-C measurements were obtained only for patients with triglyceride levels less than 400 mg/dL (4.5 mmol/L).

nificantly greater reduction in body weight; BMI; dietary intake of total fat, saturated fat, and cholesterol; and anxiety level as measured by STAI. The dietary fiber intake increased in coached patients and decreased in usual care patients. More coached patients reported taking up regular walking than noncoached patients. Of those who reported regular walking for exercise, there was no impact of The COACH Program on the duration of walking, which was a median of 30 minutes per day. Fewer coached patients reported symptoms of breathlessness and chest pain at 6 months. More coached patients reported better general health and mood at 6 months. There was no impact of The COACH Program on fasting glucose, smoking behavior, or depression (CDS) score. It was interesting that 17 (42%) of 41 of The COACH Program patients and 14 (40%) of 35 of the usual care patients who claimed to have stopped smoking since their index event had high levels of cotinine detected in their blood at 6 months (P=.90).

ATTENDANCE AT AN OUTPATIENT CARDIAC REHABILITATION PROGRAM

There was no significant difference between the 2 groups in the attendance at a cardiac rehabilitation program. Of the patients who were coached, 176 (53%) attended a cardiac rehabilitation program compared with 199 (57%) of usual care patients.

COMPARISON OF CENTERS

Coaching achieved a greater ΔTC than did usual care at each center. Differences in the coaching effect on ΔTC between centers did not achieve statistical significance (P=.095).

COMMENT

Coaching delivered according to The COACH Program by hospital-based coaches resulted in a 14-mg/dL (0.36-mmol/L) greater reduction in TC levels than did usual care. In addition, The COACH Program achieved substantial improvements in blood pressure; body weight; BMI; dietary intake of total fat, saturated fat, cholesterol, and fiber; and self-reported walking for exercise, well-being, mood, symptoms of chest pain, and breathlessness in patients with CHD 6 months after hospitalization. Multivariate analysis has indicated that the major factors that enable coaching to achieve the lower TC levels were better adherence to dietary advice and lipid-lowering medication. Additional possible factors were a slightly higher percentage of coached patients pre-

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scribed lipid-lowering drugs and the slightly higher proportion of patients prescribed higher doses of atorvastatin in The COACH Program group.

So why has The COACH Program succeeded in achieving significantly reduced risk factor levels despite the coaches not being able to prescribe medication? Until now, the programs that did not involve the direct prescription of medication(s) have targeted education, health behaviors, and health practices (eg, more health checks and more blood tests). Despite the patients reporting better adherence to health behaviors, which should have improved risk factors, these interventions failed to have an effect on cholesterol level, blood pressure level, and smoking habit.[19-24] A specific example illustrating that education and empowerment alone, without monitoring of the impact of an intervention and providing feedback, are insufficient to improve lipid outcomes is shown in the study by Holt et al.[23] This study tested an intervention that involved empowering patients with CHD to obtain measurement of their cholesterol level. It was expected that if patients had more cholesterol checks, this would necessarily translate into reduced TC levels. Although this empowerment was successful in increasing the number of cholesterol checks among patients, the subsequent action taken by health care professionals as a result of these checks was poor. This outcome suggests that education alone to improve the process toward risk reduction, without any attempt to monitor patient progress toward the treatment goal, is insufficient to achieve risk factor reduction.

On the other hand, the strategy used to influence behavior change in the approaches in which drugs are prescribed differs from that used in the previously published approaches in which drugs were not prescribed. Those interventions in which drugs were prescribed showed that case management by nurses[15,18] and secondary prevention clinics[16,17] achieved substantially lower serum TC levels in patients than did usual medical care. The approaches in which drugs were prescribed involved the selection of a therapeutic lipid goal with the aggressive pursuit of this goal. Therefore, the objective of these studies was to achieve a clearly defined end point. As part of this approach, patient progress toward achievement of the target risk factor levels was constantly evaluated. By their competitive nature, these interventions outperformed usual medical care. Indeed, the effectiveness of these interventions was attributable to progressive titration of lipid-lowering drug therapy with monitoring of the risk factor level until the target was achieved.[15-18]

The characteristics of The COACH Program intervention are similar to those of the strategies with prescribing rights. Common features include the aggressive pursuit of the target level for a particular risk factor (in the case of The COACH Program, the primary target for TC was less than 4.0 mmol/L), monitoring the patient's progress toward achievement of the target level (in this case, checking that patient action had taken place since the previous coaching session), and revising the plan of action and providing further monitoring until the target risk factor level was achieved. The only difference between The COACH Program intervention and strategies that have prescribing rights is that in The COACH Program the actual prescription of medication is left in the hands of the usual physician. The coach does not have prescribing rights. The coach urges the patient to make appropriate requests for treatment from their own physician(s).

There seems to be a need for interventions that go beyond the simple transfer of information and reminders. Education should be followed by empowerment and monitoring, with iteration of this process until the target risk factor level is achieved. This is a key feature of The COACH Program.

STUDY LIMITATIONS

This study was a randomized controlled trial that examined the risk factor levels achieved at 6 months in coached patients vs usual care patients. The dropout rate of 14% has been accounted for by analyzing by intention to treat. This analysis has assumed that the TC and other coronary risk factor levels of the patients lost to follow-up were identical at 6 months to the levels measured at baseline. This approach did not alter the significance of any of the study end points but only reduced the magnitude of their impact. The 14% dropout rate observed in the COACH study is almost identical to the dropout rate reported in 5 comparable randomized trials reported in this article[15-16,19,21,24] (mean dropout rate, 18%; range, 10%-28%).

The sample size calculations, the primary end point, and the multivariate analysis were derived from the change in TC from baseline to 6 months after randomization. This end point was measured on blood taken by collectors from laboratories all blinded to the group allocation. The study thus has met CONSORT guidelines.[35]

The laboratory measurement of all lipid levels, glucose levels, and cotinine estimation was also performed double-blind. We recognize a possibility of bias in the self-reported secondary end points, such as perception of general health, mood, fitness, and cardiac symptoms. It was of interest that the serum cotinine blood measurement of self-reported ex-smokers showed a 40% prevalence of high cotinine levels in both coached and usual care patients. This lack of difference between the 2 groups suggests that the self-reported results may not have been heavily influenced by the coached patients' wish to please their coach.

In the initial pilot study[25] (conducted in 1996-1998), 60% of the patients in the usual care group were prescribed lipid-lowering medication and the mean TC level was 214 mg/dL (5.54 mmol/L) at 6 months after hospitalization. In this COACH study (conducted in 1999-2000), 87% of patients in the usual care group reported taking lipid-lowering medication at 6 months, and the corresponding mean TC level was 183 mg/dL (4.72 mmol/L). This increase in the prescription of lipid-lowering drug therapy and the consequent reduction in TC levels in usual care patients between these 2 periods could have resulted from better uptake of lipid management guidelines by clinicians. In the case of the usual care group in the COACH study, it may also have been influenced by the 1-page chart of secondary prevention goals given to all treating physicians on discharge of the pa-

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The COACH Study Group

The structure of the administrative organization is as follows: *Scientific Committee*: M. V. Jelinek (St Vincent's Hospital Melbourne, chairman). *Members*: M. J. Vale (St Vincent's Hospital Melbourne, head coach, coordinator), J. D. Best (St Vincent's Hospital Melbourne), A. M. Dart (Alfred Hospital), L. E. Grigg (The Royal Melbourne Hospital), D. L. Hare (Austin and Repatriation Medical Centre), B. P. Ho (Monash Medical Centre), R. W. Newman (Western Hospital Footscray), J. J. McNeil (Department of Epidemiology and Preventive Medicine, Monash University Medical School, Alfred Hospital); *Writing Committee*: M. J. Vale, M. V. Jelinek, J. D. Best; *Coaches*: M. J. Vale, dietitian (St Vincent's Hospital Melbourne), J. Ferguson, nurse, and F. Stewart, scientist (Alfred Hospital), L. McGuigan, nurse (Austin and Repatriation Medical Centre), A. Egan, nurse (Monash Medical Centre), R. Vincent, nurse (The Royal Melbourne Hospital), C. Biviano, dietitian (Western Hospital Footscray); *Coordinating and Data Management*: L. V. Di Giulio, data manager, St Vincent's Hospital Melbourne; *Computer Support*: N. J. Doherty, programmer, Department of Epidemiology and Preventive Medicine, Monash University Medical School, Alfred Hospital; *Randomization Center*: A. Peeters, Department of Epidemiology and Preventive Medicine, Monash University Medical School, Alfred Hospital; *Statistical Advice*: J. J. McNeil (Department of Epidemiology and Preventive Medicine, Monash University Medical School, Alfred Hospital), J. D. Santamaria (St Vincent's Hospital Melbourne), S. Vidmar, research assistant (Clinical Epidemiology and Biostatistics Unit, Murdoch Children's Research Institute).

tients from hospital. Providing this chart was not usual practice and may have had an enhancing effect on usual care. Despite this potential effect, coaching was more effective than usual care in all of the hospitals.

STUDY IMPLICATIONS

The COACH Program resulted in an improvement in a wide array of coronary risk factors when compared with usual care. This improvement should translate into substantial reductions in total mortality, CHD deaths, acute coronary syndromes, coronary revascularization, and stroke.[36]

As with all randomized trials, the generalizability of the findings may be questioned. The major exclusions from this study were in patients living remotely from the study center and thus not being able to be reassessed at 6 months, patients with major language problems, and patients with other serious illnesses in which secondary prevention of CHD may not have been relevant. Our pilot study proved that The COACH Program was effective in patients remote from the study center.[25] We therefore have confidence that The COACH Program is applicable to most patients with CHD in whom secondary prevention is appropriate. Clearly, The COACH Program would have to be adapted for patients with specific language or cultural differences.

The COACH Program has been designed to assist the usual care providers to improve the coronary risk factor profile of their patients. In this regard, The COACH Program could be seen to overlap with conventional cardiac rehabilitation programs. In this study, 55% of the patients also underwent a cardiac rehabilitation program. In our prespecified multivariate analysis of factors that affect the change in TC, the attendance at a cardiac rehabilitation program did not influence the change in TC. A retrospective analysis of the study has compared the impact of The COACH Program and cardiac rehabilitation together and separately on the secondary end points in this study.[37] We have found that both The COACH Program and cardiac rehabilitation were highly effective in improving risk factor status.[37] It was concluded that The COACH Program was an alternative approach to cardiac rehabilitation for those patients unable or unwilling to attend cardiac rehabilitation. In addition, it may be an appropriate method for continuing care of those patients who have completed a convalescent cardiac rehabilitation program.

The COACH Program is a patient-targeted strategy that has been successful in significantly reducing risk factor levels in patients with CHD without involving dietitians or nurses in prescribing medication directly to patients. Thus, this straightforward approach represents an attractive adjunct to the current management of CHD and has the potential to integrate fully into any existing system of health care delivery.

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