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Coaching patients with coronary heart disease to achieve the target cholesterol:

A method to bridge the gap between evidence-based medicine and the "real world"—randomized controlled trial

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Abstract

Community studies have demonstrated suboptimal achievement of lipid targets in the management of patients with coronary heart disease (CHD). An effective strategy is required for the application of evidence-based prevention therapy for CHD. The objective of this study was to test coaching as a technique to assist patients in achieving the target cholesterol level of <4.5 mmol/L. Patients with established CHD (n = 245) underwent a stratified randomization by cardiac procedure (coronary artery bypass graft surgery or percutaneous coronary intervention) to receive either the coaching intervention (n = 121) or usual medical care (n = 124). The primary outcome measure was fasting serum total cholesterol (TC), serum triglyceride (TG), high-density lipoprotein cholesterol (HDL-C), and calculated low-density lipoprotein cholesterol (LDL-C) level, measured at 6 months postrandomization. At 6 months, the serum TC and LDL-C levels were significantly lower in the coaching intervention group (n = 107) than the usual care group (n = 112): mean TC (95%CI) 5.00 (4.82–5.17) mmol/L versus 5.54 (5.36–5.72) mmol/L (P < .0001); mean LDL-C (95%CI) 3.11 (2.94–3.29) mmol/L versus 3.57 (3.39–3.75) mmol/L (P < .0004), respectively. Coaching had no impact on TG or on HDL-C levels. Multivariate analysis showed that being coached (P < .001) had an effect of equal magnitude to being prescribed lipid-lowering drug therapy (P < .001). The effectiveness of the coaching intervention is best explained by both adherence to drug therapy and to dietary advice given. Coaching may be an appropriate method to reduce the treatment gap in applying evidence-based medicine to the "real world." © 2002 Elsevier Science Inc. All rights reserved.

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1. Introduction

During the 1990s it was clearly established that lipidlowering drug therapy reduced the morbidity and mortality from coronary heart disease (CHD) [1–5]. In particular, the CARE [3] and LIPID [5] studies showed that reductions of total and low-density lipoprotein cholesterol from apparently normal levels in patients with CHD resulted in significant improvements in patient outcomes. However, parallel surveys in the UK [6–8], Europe [9], and the United States [10] have shown that the results of these studies have been inadequately applied in clinical practice. The difference between the treatment recommended on the basis of clinical

trials and the treatment that actually occurs has been referred to as "the treatment gap" [11]. Reasons for this gap include a focus on acute problems in hospitals, reluctance to initiate therapy in the ambulatory care setting, therapy not being titrated to therapeutic level to achieve target lipid levels, and noncompliance or discontinuation of medical therapy [12,13]. These surveys indicate that current systems of health care are delivering suboptimally in the area of secondary prevention of CHD.

Very few programs have been developed specifically

aimed at the treatment gap. The reported studies were con-

ducted by nurses [14-19]. Two of these were effective, and

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a distinguishing feature of the interventions was that they defined the targets for treatment [14,15]. The other four aimed to modify diet and other behaviour according to therapeutic guidelines and were not effective in modifying lipid * Corresponding author. Tel.: +613-9417-0177; fax: +613-9417-0180. levels [16-19].

We propose to solve the treatment gap problem by a program of coaching the patient via the telephone. Coaching has been used in clinical medicine to improve doctor patient interaction [20], to assist patients to cope with painful procedures [21], for exercise training of patients to improve medical conditions [22,23] and in staff teaching [24]. Thus far, coaching has not been applied and evaluated in chronic disease management such as for the achievement of specific secondary prevention goals. Coaching is a method of training patients to take responsibility for the achievement and maintenance of the target levels for their particular modifiable risk factors. The Heart Foundation of Australia has set a secondary prevention target of <4.5 mmol/L for TC level (http://www.heartfoundation.com.au). In this randomized controlled trial in patients with CHD, we compared the effectiveness of usual care supplemented with coaching to achieve the recommended target TC level, with that of usual medical care alone.

2. Methods

2.1. Study population

This randomized clinical intervention was undertaken in patients with CHD who had been hospitalized for revascularization procedures, either coronary artery bypass graft surgery (CABG) or percutaneous coronary intervention (PCI). Patients were excluded if they were over the age of 75 years or if they had chronic disease where intensive coaching to improve long-term prognosis may not have been appropriate. For example, patients immobilized by conditions such as class IV heart failure, multiple sclerosis, etc. No exclusions

Table 1
Patient demographic and medical characteristics (at randomization) of completed patients (defined by cholesterol level obtained at 6 months)

	Coaching intervention $(n = 107)$	Usual care $(n = 112)$	
Gender; n (%)			
Male	80 (75%)	84 (75%)	
Female	27 (25%)	28 (25%)	
Age			
Mean (SD)	61.5 (10.3)	60.6 (9.5)	
Median (range)	63 (35–75)	61 (40–75)	
Cardiac procedure; n (%)			
CABG	59 (55%)	62 (55%)	
PCI	48 (45%)	50 (45%)	
Past cardiovascular history; n (%)			
Angina pectoris	96 (90%)	96 (86%)	
Myocardial infarction	53 (50%)	48 (43%)	
PCI	10 (9%)	10 (9%)	
CABG	7 (7%)	8 (7%)	
Lipids ^a (in-hospital) mmol/L; mean (SD)			
TC	5.27 (1.06); n = 75	5.38(0.92); n = 71	
TG	1.90(1.06); n = 75	1.88(0.87); n = 69	
HDL-C	1.05(0.39); n = 55	0.98(0.23); n = 47	
LDL-C	3.43(0.94); n = 53	3.60(0.86); n = 47	
Family history CHD ^b n (%)	39 (37%)	40 (36%)	
Diabetes ^c ; n (%)	16 (15%)	20 (18%)	
Hypertension ^d ; <i>n</i> (%)	60 (56%)	52 (46%)	
Body mass index ^e			
BMI; mean (SD)	29.1 (4.8); n = 107	28.6(4.1); n = 110	
Normal (BMI ≤ 25); n (%)	12 (11%)	17 (16%)	
Overweight (BMI $>$ 25–29.9); n (%)	58 (54%)	51 (46%)	
Obese (BMI \geq 30); n (%)	37 (35%)	42 (38%)	
Smoking Status ^f ; <i>n</i> (%)			
Current	24 (22%)	23 (21%)	
Ceased > 4 months prior to hospitalization	56 (52%)	65 (58%)	
Never	27 (25%)	24 (21%)	
Lipid-lowering medication on discharge; n (%)	35 (33%)	37 (33%)	

^aLipids: the goal of treatment was to reduce serum total cholesterol level to <4.5 mmol/L (as recommended by the Heart Foundation of Australia: http://www.heartfoundation.com.au).

^bPositive family history of CHD: first-degree relative with onset of CHD <60 years of age. For five patients (two coaching intervention, three usual care) family history unknown ie patient orphaned or adopted.

^cDiabetes: includes patients with type 1 and type 2 diabetes.

^dHypertension: was defined as on treatment for hypertension or self-reported history of hypertension.

^eBody mass index (BMI): normal body weight was defined as BMI ≤25 kg/m², overweight as BMI >25–29.9 kg/m², obese as BMI ≥30 kg/m².

^fSmoking status: current smoker was defined as ≥1 cigarette/day during 4 months before hospitalization, exsmoker as ceased >4 months ago, never smoker if smoked for <3 months at any stage during life.

were based upon assessment of likely noncompliance. The clinical and demographic characteristics of the patients (Table 1) were obtained from the patient's medical history and from the first telephone session. Patients were consecutively recruited from hospital discharge lists, and were invited to participate by telephone. The study protocol was granted ethical approval by the Human Research Ethics Committee of St. Vincent's Hospital, Melbourne.

2.2. Coaching intervention

Coaching was performed by a dietitian with a background in education, who was experienced in working with patients with cardiovascular disease. The coach initiated contact with the patient by telephone at 2 weeks postrandomization for the first coaching session. A further three phone coaching sessions followed at 6-week intervals. A fifth call at 24 weeks was made to patients in the coaching group advising them to obtain the 6-month blood sample for serum lipid analysis. Patients were coached to take responsibility for the achievement and maintenance of the target cholesterol level of <4.5 mmol/L (The Coach Model). Coaching was directed at the patient and not at the treating doctor. The patient was expected to know their cholesterol level, know the target for their cholesterol level, know what factors influence cholesterol level, and then to visit their treating doctor and ask for medical therapy as appropriate. Patients were coached to follow appropriate nutritional guidelines. There was no set time frame for coaching sessions. The length of calls varied according to the length of time the coach needed to establish a plan of action with the patient to be achieved by the next coaching session.

2.3. The Coach Model; a continuous five-stage coaching cycle

Each coaching session follows a continuous quality improvement cycle (see Fig. 1)

Stage 1. Asking questions to establish patient's knowledge, attitude and beliefs about their risk factors. For serum cholesterol: the patient is interviewed for knowledge of their own cholesterol level, the target cholesterol level, factors influencing cholesterol level, and reasons for achieving and maintaining the target cholesterol level. Questions are asked about medication(s) for cholesterol: had medication(s) been prescribed, the type, dose, how many days a week they take their medication(s), reasons for not taking medication(s). Dietary intake is assessed for sources of dietary saturated fat, and understanding the influence of saturated fat and other fats on blood lipids.

Stage 2. Explanation and rationale. The patient is educated where appropriate on factors described in (1) above. Rationale is given for all advice so that any problems that may prevent achievement of goals are resolved.

Stage 3. Assertiveness training. The patient is trained to be assertive in the relationship with the treating doctor; to obtain the cholesterol level; to agree upon the target choles-

terol level; to ask the treating doctor to commence appropriate drug therapy; to alter doses if appropriate; to change to a stronger medication if maximal therapy on a particular drug failed to achieve the target TC level.

Stage 4. Goal setting. Negotiation of a plan of action and setting goals to be achieved by the next coaching session. Reinforcement of the likelihood of a better cardiac outcome if the target TC level is achieved.

Stage 5. Reassessment at next coaching session. Patient adherence to negotiated plan of action from previous coaching session is evaluated.

The Coaching Cycle (stages 1 to 5) is continued until the target level for the risk factor is achieved.

2.4. Usual care

Patients were contacted by telephone at 2 weeks postrandomization to ask how they were. All patients in the study (including patients in the coaching intervention group) were offered information about a cardiac rehabilitation program and were encouraged to attend. Patients in the usual care group were contacted at 24 weeks postrandomization to obtain a fasting serum lipid profile within the next 2 weeks.

2.5. Outcome measures

The primary outcome measure was fasting serum TC level, measured at 6 months postrandomization, analyzed in the one central commercial laboratory. Based on an estimated TC of 5.5 mmol/L (SD 1.0) within the Australian population [25] and a clinically significant change of 0.5 mmol/L, we estimated that to achieve a power of 0.90 with alpha being 0.05, we would require 85 subjects in each group. Allowing for a dropout rate of up to 30%, the target recruitment number was 122 patients in each group.

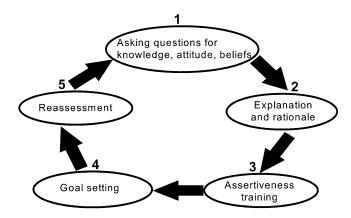


Fig. 1. The coaching cycle; a five-stage process (see Methods/The Coach Model). Stage 1: asking the patient questions to establish knowledge, attitude, and beliefs about achieving the target levels for their particular risk factors. Stage 2: explanation and rationale of recommended therapy. Stage 3: assertiveness training so that the patient can negotiate treatment needs with the doctor. Stage 4: Goal setting—negotiating a plan of action to be achieved by the next coaching session. Stage 5: reassessment at next coaching session—evaluating progress toward goal. This cyclical process continues until the target cholesterol is achieved.

Secondary outcome measures were fasting serum triglyceride (TG), high-density lipoprotein cholesterol (HDL-C), and the calculated low-density lipoprotein cholesterol (LDL-C) level, measured at 6 months postrandomization.

2.6. Laboratory methods

Serum TC and TG were measured by enzymatic colorimetric methods. HDL-C was measured directly using a homogeneous method. LDL-C was calculated by the Friedewald equation, except when TG exceeded 4.5 mmol/L [26]. The central laboratory used for the analyses is accredited by the National Association of Testing Authorities (NATA) Australia, and by the International Standards Organisation (ISO-9002).

2.7. Assignment

Patients were allocated to coaching intervention and usual care groups on the basis of random numbers in blocks of 10 and stratified by cardiac procedure (CABG or PCI). The allocation schedule was computer generated by an assistant not involved in the study. Patients were randomized the day after they were discharged from hospital. The assistant communicated with the coach by telephone.

2.8. Masking

The coach was aware of patient assignment and administered regular coaching sessions (total of four) to the patients assigned to the intervention group. The coach contacted the patients assigned to the usual care group twice—once to assess their well being, and once to ask them for a blood sample (6-month measure of serum lipid profile). It was not possible to blind recipients to the fact that personal coaching was provided. All patients underwent usual medical care throughout the follow-up period. The laboratory personnel performing the serum lipid profile at 6 months were not aware of treatment assignment.

2.9. Statistical analysis

Statistical analyses were performed with Stata (Release 6.0, Stata Corporation, College Station, TX). Results are expressed as mean (95% confidence intervals) or median (range) where appropriate. Student's *t*-test and chi-squared analysis were used to compare continuous and categorical variables, respectively. Factors affecting final serum TC level were evaluated with analysis of variance (ANOVA) and analysis of covariance (ANCOVA).

3. Results

3.1. Participant flow and follow-up

From July 1996 to March 1997, 245 patients (183 men, 62 women) were randomly assigned to receive either regular personal coaching by telephone (n = 121) or usual care (n = 124).

As shown in Figure 2, of the 245 patients recruited into the study, 219 patients (107 coaching intervention; 112 usual care) completed the trial. The outcome was based on

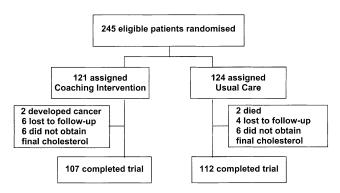


Fig. 2. Flow of patients through trial.

the final TC level measured 6-months postrandomization. Therefore, the 26 patients who did not complete the trial were excluded from the main analysis. The only significant difference in the characteristics of the patients who completed the study from those who did not complete the study was an excess of patients with diabetes in the group who failed to complete the study (P < .02).

Demographic and medical characteristics of completed study participants were similar for the two groups (Table 1). The education level of the study participants was not recorded. The patients had the usual range of medical knowledge found in Victoria. All were able to converse with the coach in English.

3.2. Length of coaching sessions

For the patients who were coached, the time spent over the phone was longest for the first coaching session, with a median time of 20 min (Table 2). Thereafter, the average call times were shorter at a median of 10–11 min.

3.3. Lipid outcome levels at 6 months postrandomization

As shown in Table 3, the mean TC level measured at 6 months for the group who received regular personal coaching was significantly lower than for the group that was not coached. However, only 33 (31%) of the coached and 11 (10%) of the usual care patients (Fig. 3) achieved the target TC level of <4.5 mmol/L (P<.001).

3.4. Lipid-lowering drug therapy at 6 months postrandomization

The number of patients taking lipid-lowering drug therapy in the coaching intervention and usual care groups was

Table 2
Length of phone coaching sessions (time in minutes) for the coaching intervention group

Coach sessions	Min	0.25	Median	0.75	Max
Session 1	5	15	20	25	45
Session 2	3	9	11	16	40
Session 3	4	8	11	19	66
Session 4	3	9	10	15	61

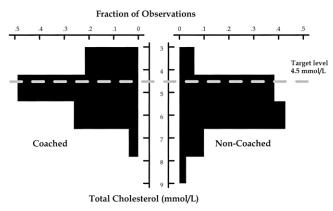
Table 3 Lipid levels 6 months postrandomization for coaching intervention and usual care groups

Lipid level (mmol/L)	Coaching intervention	Usual care	P
TC; mean (95%CI)	5.00 (4.82-5.17) ($n = 107$)	5.54 (5.36-5.72) ($n = 112$)	0.0001
TG; median (range)	1.60 (0.5-6.6) $(n = 107)$	1.65 (0.3-6.0) $(n = 112)$	0.8086
HDL-C; mean			
(95%CI)	1.12 (0.52-1.72) $(n = 98)$	1.16 (0.52-1.80) $(n = 106)$	0.4035
LDL-C; mean			
(95%CI)	3.11 (2.94-3.29) ($n = 96$)	3.57 (3.39-3.75) $(n = 105)$	0.0004

67 (63%) and 67 (60%), respectively. Of the patients taking a lipid-lowering drug in the coached group, 65 (97%) were taking an HMGCoA reductase inhibitor (statin) compared with 62 (93%) in the usual care group. Of the patients prescribed a statin in the coached group, 52 (80%) were on simvastatin, 8 (12%) on pravastatin, 3 (5%) on fluvastatin, and 2 (3%) were on atorvastatin. Of the patients prescribed a statin in the usual care group, 46 (74%) were on simvastatin, 10 (16%) on fluvastatin, 6 (10%) on pravastatin, and none were on atorvastatin. The median (range) dose of simvastatin used for patients in the coached and usual care groups was 20 (10-40) mg in both groups. At 6 months, there was no significant difference in the prescription of lipid-lowering drug therapy either in the patient numbers treated or the dose prescribed between the coaching intervention and usual care groups.

3.5. Attendance at an outpatient cardiac rehabilitation program

There was no significant difference between the two groups in the attendance at a cardiac rehabilitation program. Of the patients who were coached, 57 (53%) attended a car-



Distribution of total cholesterol levels in the two groups of patients.

Fig. 3. Histogram of total cholesterol levels in coached and usual care groups in relation to target total cholesterol level of <4.5 mmol/L.

diac rehabilitation program. Of the patients who were not coached, 56 (50%) attended cardiac rehabilitation.

3.6. Factors influencing final serum cholesterol level

Variables that determined the final serum TC level were assignment to coaching (P < .001), prescription of lipid-lowering drug therapy (P < .001) and patient gender (women had a higher cholesterol than men, P < .05).

Variables that did not impact on the final measured TC level were age, body mass index, past history of hospitalization for ischaemic heart disease, location of residence, country of origin, marital status, living arrangements, employment status, and occupation classification. In particular, the diagnostic category of the patient (CABG or PCI) did not influence the final serum TC level, nor did attendance at an outpatient cardiac rehabilitation program.

The combined influences of coaching and lipid-lowering drug therapy are shown in Figure 4. A one-way analysis of variance indicated a significant difference between these four groups (P < .001).

Multivariate analysis was performed using variables found significant on univariate analysis in the 219 patients who completed the study. This analysis showed that each of the factors influencing cholesterol remained statistically significant in the final model. Coaching and being prescribed statins were both highly significant predictors of the final TC level (P < .0001 and P < .0003, respectively). Women had a significantly higher TC level than men (P < .007). This analysis showed that coaching alone reduced the TC level by 0.53 mmol/L and that lipid-lowering drug therapy alone by 0.46 mmol/L. If the patient was a man not a woman, the TC level was lower by 0.32 mmol/L. Thus multivariate analysis confirms the bivariate analysis (Fig. 4) in showing that coaching and the taking of drug therapy were equal, independent, and additive in their effects on TC level.

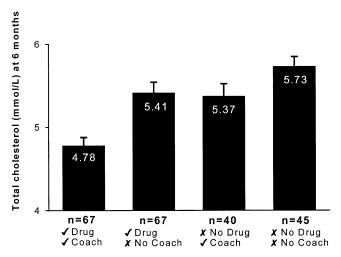


Fig. 4. Impact of coaching intervention on total cholesterol level in patients taking lipid-lowering drug therapy versus patients not taking lipid-lowering drug therapy.

In this study, coaching appeared to be comparable in magnitude to the prescription of a lipid-lowering drug.

There was a small, insignificant difference in baseline cholesterol level between the coached and usual care groups (Table 1). Analysis of covariance (ANCOVA) was used to investigate the additional influence of baseline TC level on the final TC level. Data for baseline cholesterol level was only available in 146 patients. This analysis showed that the effects of gender were explained by women having higher baseline TC level than men. In this sample of 146 patients, the three independent predictors of final TC were prescription of a lipid-lowering drug (P < .0001), assignment to coaching (P < .0005) and the baseline TC level (P < .052).

There were 145 patients who had a baseline TC level and 73 patients who did not. These patients were similar in all respects except that 86% of PCI patients had a baseline TC level compared with 51% of CABG patients (P < .0001); similarly, 57% of patients who underwent a cardiac rehabilitation program had a baseline TC level measured compared with 77% of those who did not undergo a cardiac rehabilitation program (P = .008).

The mean cholesterol of 75 coached patients fell by $0.328 \,$ mmol/L from baseline to 6 months postrandomization whereas the mean cholesterol of 71 usual care patients rose from baseline to 6 months by $0.163 \,$ mmol/L (P < .02). Forty-two of 75 (56%) of coached patients had a fall in TC from baseline to 6 months compared with 32 of 71 (45%) of usual care patients, but this difference was not statistically significant.

4. Discussion

The results of this study indicate that coaching patients with CHD can improve TC and LDL-C levels in these patients 6 months posthospitalization. The group of patients who were coached achieved a TC level of 5.00 mmol/L compared with a target level of 4.50 mmol/L. In so doing, the average serum TC level for the coached patients was 9% lower than the 5.54 mmol/L measured in the noncoached patients. The LIPID study [5], which investigated the effects of cholesterol lowering with pravastatin (40 mg daily) versus placebo on CHD death in patients with past history of CHD, achieved an 18% reduction in TC level in the intervention group and a relative reduction in risk of CHD death of 24%. The coaching intervention in the present study achieved half the cholesterol reduction achieved in the LIPID study. By inference from the LIPID study, the effect of coaching might produce a reduction of coronary death and morbidity rates of around 12%.

The mechanism of the positive effect of coaching was not directly identified in this study. A potential explanation would be that more patients in the intervention group were prescribed lipid-lowering drug therapy or that coached patients were receiving a higher dose of drug. However, the patient self-reported data of lipid-lowering medication prescribed showed that there was no difference in the prescrip-

tion of lipid-lowering drug therapy either in the patient numbers treated or the dose prescribed between the coaching intervention and usual care groups. The effect of coaching in patients not on drug therapy is likely to be due to improved lifestyle factors. The greater effect of coaching in patients on drug therapy suggests a possible additional effect of coaching on adherence to prescribed medication.

Despite our intentions to achieve the target TC level of <4.5 mmol/L, only 31% of coached patients achieved this goal compared with 10% of noncoached patients. This technique of coaching involved empowering patients by giving them the knowledge and the skill to enable them to work in partnership with their treating doctor to achieve the target TC level. The coach attempted to influence the lipid management by coaching the patient to make demands on the treating doctor. The coach did not manage the patient, so that ultimately the responsibility and the decision to treat the patient remained with the doctor. The treatment gap, even in the coached patients, may reflect: deficiencies in coaching; problems with patient adherence to treatment prescribed; failure to up-titrate drug therapy if appropriate to reach the target TC; inability of drug and dietary modification to lower the cholesterol to target levels; or even a reluctance by the treating doctors to achieve the targets recommended.

The treatment gap has been described in many countries [6–11]. In the UK, there is evidence to show that there has been improvement in the management of cholesterol over the past decade, but less than half of patients are still not achieving their target TC level of ≤5.2 mmol/L [7,8]. The recent Lipid Treatment Assessment Project (L-TAP) [10] in the United States has revealed that only 18% of the patients with CHD are achieving the NCEP-specified LDL-C target level of <2.6 mmol/L. There have been many attempts to close the treatment gap, including extensive pharmaceutical marketing and intensive education of medical practitioners. The community surveys confirm that these measures have only been partially successful.

A review of the literature to find studies with similar objectives to the present study has revealed six nurse-based programs delivering specific interventions on risk factor status. Of these six randomized controlled trials [14–19], only two studies [14,15] demonstrated a significant difference in lipid concentrations between the intervention group and the control group. The MULTIFIT study [14] showed that case-management by nurses achieved substantially lower serum TC levels in patients than did usual medical care. Similarly, Campbell et al. [15] evaluated nurse-led clinics and reported that lipid management improved in the intervention group compared with the control group. The other studies [16-19] failed to show an improvement in TC level. In two studies [16,17] there was improvement in selfreported adherence to regimens that might reduce coronary risk, but this was not reflected in the objective measures of risk factors.

The four studies [16–19] that did not demonstrate an improvement in outcome for lipid levels focussed on behavior

patterns rather than target end points for risk factor reduction. The objective in these studies was to influence the process towards risk reduction. Achievement of goals related to this process did not result in improved risk factor levels. Thus, although these studies were directed toward risk factor reduction, they failed to achieve their intended results.

The MULTIFIT study [14] and the study by Campbell et al. [15] selected a therapeutic lipid goal and set out to achieve this goal. The objective of these studies was to achieve a clearly defined end point, and was similar to our study in that respect. Our study set the target for TC level and coached patients to achieve it. The MULTIFIT study [14] was a risk factor management study delivered by telephone and mailouts. The intervention involved nurses prescribing lipid-lowering drugs to patients as appropriate. The effectiveness of the intervention in MULTIFIT was attributable to increased use of lipid-lowering drug therapy. So, the MULTIFIT group, supported by a Health Maintenance Organisation Kaiser Permanente, was competitive with, and outperformed, usual medical care. The Scottish study by Campbell et al. [15] was of nurse-managed clinics, but the nurses were not allowed to prescribe medications. For this, the nurses arranged referral to a general practitioner. The nurses worked with usual medical care to achieve therapeutic targets. However, although their study was more cooperative with usual care than the MULTIFIT study, it was still a management program, and was conducted in an outpatient clinic setting. Although drugs were not prescribed by the nurses in their study, the clinic approach was more interventionist than the telephone counselling used in MULTIFIT. The effectiveness of the Scottish intervention was also due to more uptake of lipid-lowering drug therapy, compared with the control group. By contrast, the effectiveness of the coaching intervention in the present study is best explained by both adherence to drug therapy and adherence to lifestyle advice.

Our approach of applying coaching to the risk factor management of patients with CHD supports usual medical care rather than competes with it. The coaching intervention by telephone is less intrusive and less competitive with usual care than outpatient clinics. Coaching does not involve prescription of medication, and hence, coaching does not seek to take over the medical management of patients. Rather, it is a method that enhances current care and thereby integrates fully into existing systems of health care delivery. The other distinguishing feature of this method is that coaching is outcome focussed. This means setting a target level for a particular risk factor and coaching patients to achieve it.

Effective coaching teaches the patient to get the most value from a consultation with their usual doctor in achieving the goals of secondary prevention. The coach model enables patients to take more responsibility for their own medical management. Coaching may be an appropriate method of bridging the gap between evidence-based medicine and community effectiveness in the "real world."

4.1. Study limitations

This has been a randomized controlled trial studying the lipid levels achieved at 6 months in coached patients versus usual-care patients. This necessarily introduces an obligatory bias, namely the treatment received, not intention to treat. There were more patients with diabetes among those who failed to complete the study, but otherwise, there were no differences from the patients who completed the study.

For this study the control group was usual medical care. By even contacting the patients 2 weeks after discharge to inform them of their inclusion in the study we risked "contaminating" the usual care lipid results. It could be argued that simply repeated calling of the patient rather than coaching of the patient was sufficient to produce a positive result in this study. However, this is not usual medical care, and indeed, would be a reasonable hypothesis to test in the future.

This study was performed by a single coach, from a single center, and within a time period (1996–1998) when there may have been some uncertainty among medical carers regarding lipid goals for patients with established CHD. It is important to show that the coaching intervention used in this study is transferable to other coaches, to other patient groups, and remains effective in a different time period to the present study. If coaching is an effective mechanism and coaching methods are transferable, then the results from this study should be reproducible.

4.2. Study applications

The obvious implication of this study is that there should be a hospital-based coach, perhaps dietitian, in all hospitals with a cardiac unit. Ideally, this coaching service would be provided by the hospital to all patients. For coaching to become implemented into clinical practice we need to know whether the results of this study can be replicated by other hospital-based coaches in other environments-that is, generalizablity. Secondly, we believe it very important that the coach gives evidence-based advice independent from a particular hospital physician or group who could be seen to be in competition with usual medical care. And finally, someone will have to pay the coach. Conceptually coaching could be self-funded, because a reduction of TC similar to that achieved in this study-if sustained-could result in substantially fewer readmissions with suspected or definite acute coronary syndromes with direct savings to the health care system. Such factors need further research.

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