Original Investigation

An Education Program for Risk Factor Management After an Acute Coronary Syndrome
A Randomized Clinical Trial

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IMPORTANCE Lifestyle improvements after an acute coronary syndrome reduce cardiovascular risk but are difficult to achieve.

OBJECTIVE To determine whether a nurse-led or dietician-led cardiovascular risk factor education program would improve risk factor reduction over the long term after an acute coronary syndrome.

DESIGN, SETTING, AND PARTICIPANTS The Réseau Insuffisance Cardiaque (RESICARD) PREVENTION study was a 2-arm, parallel-group, multicenter, randomized clinical trial at 6 tertiary care hospitals in France. Patients hospitalized in a cardiac intensive care unit for an acute coronary syndrome with at least 1 lifestyle risk factor (current smoking, sedentary lifestyle, or overweight or obesity) were randomized according to a computer-generated list with sequentially numbered, sealed envelopes.

INTERVENTION Patients underwent an education program in a unique non–hospital setting (a House of Education) or were treated according to physicians’ usual standard of care.

MAIN OUTCOMES AND MEASURES The primary outcome was a composite that included at least 1 of the following: smoking cessation, at least 3 hours per week of physical activity, at least 5% reduction in weight, and at least 4% reduction in waist circumference. Patients were followed up for 1 year. An intent-to-treat analysis was performed.

RESULTS From June 21, 2006, to July 30, 2008, a total of 251 patients were randomized to the House of Education and 251 to conventional care. The 2 groups did not differ significantly at 12 months in the primary composite outcome (51.8% vs 49.8% success rate; adjusted relative risk [aRR], 1.11; 95% CI, 0.90-1.37) or with correction of all risk factors (aRR, 1.22; 95% CI, 0.89-1.66). Similarly, the 2 groups did not differ by physical activity (aRR, 1.05; 95% CI, 0.92-1.21), smoking cessation (aRR, 0.99; 95% CI, 0.87-1.13), and weight or waist reduction (aRR, 1.07; 95% CI, 0.84-1.36).

CONCLUSIONS AND RELEVANCE Compared with conventional care, the House of Education did not result in superior improvement in lifestyle-related cardiovascular risk factors after an acute coronary syndrome.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT00337480
Acute coronary syndrome (ACS) has been estimated to affect 1.4 million people each year in Europe. Risk factors include poor diet, tobacco smoking, physical inactivity, high body mass index, large waist circumference, and regular alcohol consumption, as well as hypertension, dyslipidemia, diabetes mellitus, and a family history of cardiovascular disease. Most of these factors are modifiable, and lifestyle changes such as improved diet, smoking cessation, and increased physical activity can greatly reduce cardiovascular risk.

Effective management of coronary heart disease is multimodal and includes appropriate drug therapy, revascularization, and cardiac rehabilitation. European and North American guidelines recommend pharmacologic treatments and lifestyle interventions to reduce the risk of recurrent events in patients following an ACS. Secondary prevention can be achieved by patient education, exercise programs, and counseling and support. However, this approach assumes adequate continuity of patient care, with rapid and accurate communication between the cardiac intensive care unit and primary care physicians, particularly during the patient’s transition from the hospital to community care. Indeed, evidence suggests that collaborative models that enhance communication among care providers can improve the quality of care and outcomes for patients with chronic conditions.

We developed an individualized education program provided in a unique non-hospital setting (a House of Education) to optimize support for patients after an ACS to help them reduce their cardiovascular risk factors. Furthermore, communication between the House of Education providers and the primary and secondary care providers was optimized by a specific Internet system that allowed quick and efficient communication of patient assessment. The primary objective of this randomized study was to determine the effect of the House of Education at 12 months on cardiovascular risk factors in patients discharged from the hospital after an ACS.

Methods

The study protocol was approved by the ethics committee Comité de Protection des Personnes Île-de-France V, Hôpital Saint-Antoine. All participants gave their written informed consent in accord with the Declaration of Helsinki. The Réseau Insuffisance Cardiaque (RESICARD) PREVENTION study was planned, conducted, and reported following the Consolidated Standards of Reporting Trials guidelines for nonpharmacologic treatments. We planned a 2-arm, parallel-group, multicenter, randomized clinical trial performed in cardiac intensive care units of 6 tertiary care hospitals in France.

Setting and Participants

The study was performed in 5 state university hospitals (Hôpital Saint-Antoine, Hôpital Lariboisière, Hôpital Pitié-Salpêtrière, Hôpital Bichat, and Hôpital Ténon) and in 1 private hospital (Hôpital La Roseraie). All were located in Paris, France, or its suburbs.

We screened all patients hospitalized in a cardiac intensive care unit for an ACS. Patients were eligible if they were at least 18 years of age, were hospitalized in a cardiac intensive care unit for an ACS (unstable angina, ST-segment elevation myocardial infarction, or non-ST-segment elevation myocardial infarction), and had at least 1 of the following education-modifiable risk factors: current smoking (for ≥12 months), sedentary lifestyle (<3 hours of physical activity per week), or overweight or obesity (body mass index ≥25 for overweight or ≥30 for obesity, calculated as weight in kilograms divided by height in meters squared). Patients also had to be willing and able to attend regular visits at an outpatient program.

Randomization and Interventions

Patients were randomized at a 1:1 ratio during their hospitalization according to a computer-generated list with blocks of varying size stratified on centers. The list was prepared and maintained by an independent statistician (MD) at the clinical trial unit. Allocation was concealed in sequentially numbered, sealed opaque envelopes. After verifying a patient’s eligibility criteria and obtaining informed consent, the investigator included the patient in the trial and informed the clinical trial unit of the inclusion and randomization of the patient.

Baseline characteristics were measured during the hospitalization. Data were sent via the secure Internet system to the House of Education before a patient’s first appointment, which took place within 1 month after discharge.

Blinding was not feasible in this study. However, independent research staff rather than the treating physician performed outcome assessments.

Theoretical Framework

Lifestyle modifications following an ACS are difficult to achieve. Their success depends on the availability of an adequate support system for patients not usually provided by primary and secondary care physicians because of time constraints. They also require effective communication and information sharing between physicians in primary and secondary care settings.

We studied a multidisciplinary individualized education program provided by staff outside of the hospital in a unique House of Education. We hypothesized that such a setting may be beneficial in adequately coordinating the management of cardiovascular risk factors.

House of Education

The House of Education was a non–hospital-based office dedicated to patient education, with no physician involved, and was easily accessible by public transportation. It comprised a nurse who was specialized in smoking cessation counseling, a dietician who had received training in physical activity counseling, and an administrative coordinator who offered individual consultations 5 days per week, with a telephone hotline available from 9 AM to 6 PM if patients needed information about cardiovascular risk factors and therapeutic education. A schematic representation of the program is shown in Figure 1.

Patients attended the House of Education at least 6 times: these included a visit within the first month after discharge and then at months 2, 3, 6, 9, and 12. Patients could attend additional consultations at any time up to 12 months after the in-
Patient information was shared among care providers via a secure Internet system with a digital pen, which allowed quick and efficient sharing of data among primary care physicians, primary care cardiologists, physicians in the cardiac intensive care unit, and nurses and dieticians from the House of Education. The patient discharge form and the synthesis of the results are shown in eFigure 1 in the Supplement.

At hospital discharge, information related to the hospitalization period, the patient’s risk factors, and objectives for risk factor management was recorded via the Internet system. An e-mail was automatically sent to the staff at the House of Education and to the primary care physicians (general practice and cardiologists). The staff and the primary care physicians could log into the system using a secure access to see all patient information.

After each consultation at the House of Education, the team completed a document indicating the patient’s treatments and risk factors, with the clinical variables (blood pressure, physical activity, tobacco use, and weight and waist circumference) and biological variables (glycated hemoglobin level and low-density lipoprotein cholesterol level). These data were displayed graphically, clearly showing any changes in risk factor level over time, and were accessible to the patient’s care providers at all times via the secure Internet system. Information on levels of physical activity was collected in a self-reported questionnaire (available on request from the author).

Adherence to the patient’s diet was evaluated by the dietician in a declarative manner and was recorded in the patient’s file; after the consultation, the dietician provided the patient with a personalized document detailing dietary recommendations.

Comparative Intervention
Patients in the control group attended appointments with their primary care physician and primary care cardiologist within 1 month of discharge. These physicians then followed up with the patients according to their usual practices. The sharing of patient data between physicians in the primary and secondary care settings was not standardized and was done at the physician’s discretion.

Cointerventions
Information was recorded on the prescription of cointerventions (eg, nicotine supplements, hospitalization in a rehabilitation center, and others). The administration was left to the discretion of the care provider.

Outcomes and Follow-up Period
The primary endpoint was a composite that involved correction of at least 1 of the following 3 cardiovascular risk factors between baseline and month 12: (1) smoking cessation (complete cessation for smokers, with nonsmokers at baseline and month 12 considered successes and nonsmokers at study inclusion who started smoking [or relapsed] during the 12 months considered failures); (2) overweight or obesity (≥4% reduction in waist circumference or ≥5% reduction in weight, with patients having a body mass index of less than 25 at baseline and at 12 months considered successes and patients who be-
came overweight during the study considered failures); and (3) physical activity (≥3 hours per week).

Secondary end points, from baseline to month 12, included the following 6 outcomes: (1) Correction of all 3 cardiovascular risk factors mentioned above. (2) Correction of each individual cardiovascular risk factor mentioned above. (3) Correction of other risk factors, including hypertension (blood pressure to <140/90 mm Hg), diabetes mellitus (glycated hemoglobin level to <6.5%), and dyslipidemia (low-density lipoprotein cholesterol level to <100 mg/dL) (to convert glycated hemoglobin level to proportion of total hemoglobin, multiply by 0.01; to convert cholesterol level to millimoles per liter, multiply by 0.0259). (4) Physical and mental summary scores of the 12-Item Short Form Health Survey for quality of life (continuous variables on a scale of 0 to 100, with higher scores indicating higher quality of life). (5) The number of correct answers on a patient knowledge questionnaire comprising 19 questions. (6) Patient satisfaction on a numeric scale rated 0 to 10, with higher scores indicating higher levels of satisfaction.

We had planned to evaluate the levels of satisfaction recorded by the primary care physicians and primary care cardiologists. However, this outcome was not collected for logistical reasons.

Outcome Assessments
Data from all patients were evaluated by an independent data collector at Hôpital Saint-Antoine at 6 and 12 months after enrollment. At these visits, biological variables were recorded, clinical measurements were obtained (blood pressure and weight and waist circumference), and questionnaires were administered (physical activity, 12-Item Short Form Health Survey for quality of life, and patient satisfaction and patient knowledge questionnaire), with treatment modifications and events during the past 6 months documented. All patients had specific case report forms completed at their 6-month and 12-month visits. If a patient could not attend an evaluation visit, an assessment via telephone was performed. Follow-up assessments were obtained at 6 and 12 months after enrollment for all patients.

Statistical Analysis
Sample Size Calculation
Using data from the literature, we estimated that 45% of patients receiving conventional care and 60% of patients attending the House of Education would have corrected at least 1 cardiovascular risk factor by 12 months. Therefore, 231 participants per group were required for 90% power to demonstrate a clinically relevant difference between the groups. Assuming a dropout rate of 10%, we aimed to recruit 510 patients (255 per group).

Quantitative Data
Quantitative data are expressed as means (SDs); ranges and qualitative data are expressed as counts and percentages. End points were estimated as part of a linear model using generalized estimating equations. A Poisson distribution and log-link function were chosen for the binary criteria to assess relative risks in the context of frequent outcomes, and a normal distribution and identity link function were chosen for continuous criteria. The variance-covariance matrix was postulated by a symmetrical composition so it could consider a constant correlation between 2 patients in the same hospital. For the Poisson distribution, the parameter covariance matrix and the likelihood function were adjusted by the scale parameter (deviance divided by df) to take into account a potential over-dispersion. When relevant, an adjustment factor was used to include a prognostic criterion. In addition to generalized estimating equation models, generalized mixed-effects models were performed to assess the robustness of our results. For each of the end points, the significance level was set at 5%.

The primary end point was analyzed according to the intent-to-treat principle. Missing data were imputed by a Markov chain Monte Carlo method of multiple imputations. The primary analysis involved all patients with complete or imputed data. Sensitivity analyses were performed to assess the stability of the results of the primary analysis, one using only patients with complete data and one with replacement of missing data. All statistical analyses were performed using commercially available software (SAS, version 9.2; SAS Institute).
Results

The flow of patients in the trial is shown in Figure 2. From June 21, 2006, to July 30, 2008, a total of 251 patients were randomized to the House of Education and 251 to conventional care; overall, 193 and 207 patients, respectively, attended the 6-month visit, and 203 and 215 patients, respectively, attended the 12-month visit. A total of 21 patients (8 House of Education and 13 conventional care) were assessed during a telephone interview instead of a study visit at 6 months and 63 patients (27 House of Education and 36 conventional care) at 12 months.

Baseline characteristics for patients in the 2 treatment groups were well balanced (Table 1). Overall, 84.3% of patients were male, and the mean (SD) age was 56.9 (10.9) years.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>House of Education (n = 251)</th>
<th>Conventional Care (n = 251)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, No. (%)</td>
<td>203 (80.9)</td>
<td>220 (87.6)</td>
</tr>
<tr>
<td>Age, mean (SD) [range], y</td>
<td>58.0 (10.9) [35-87]</td>
<td>55.7 (10.9) [30-81]</td>
</tr>
<tr>
<td>Type of acute coronary syndrome, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST elevation myocardial infarction</td>
<td>122 (48.8)</td>
<td>117 (47.0)</td>
</tr>
<tr>
<td>Non-ST-elevation myocardial infarction</td>
<td>88 (35.2)</td>
<td>82 (32.9)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>40 (16.0)</td>
<td>50 (20.1)</td>
</tr>
<tr>
<td>Main cardiovascular risk factor, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoking</td>
<td>127 (50.6)</td>
<td>146 (58.4)</td>
</tr>
<tr>
<td>Physical inactivity</td>
<td>68 (27.1)</td>
<td>70 (28.0)</td>
</tr>
<tr>
<td>Overweight or obesity</td>
<td>198 (78.9)</td>
<td>191 (76.4)</td>
</tr>
<tr>
<td>No. of main cardiovascular risk factors, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>129 (51.4)</td>
<td>127 (50.8)</td>
</tr>
<tr>
<td>2</td>
<td>102 (40.6)</td>
<td>89 (35.6)</td>
</tr>
<tr>
<td>3</td>
<td>20 (8.0)</td>
<td>34 (13.6)</td>
</tr>
<tr>
<td>Diabetes mellitus, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>66 (26.3)</td>
<td>63 (25.2)</td>
<td></td>
</tr>
<tr>
<td>History of hypertension, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>125 (49.8)</td>
<td>120 (48.0)</td>
<td></td>
</tr>
<tr>
<td>Blood pressure, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic &gt;140 mm Hg at admission</td>
<td>89 (35.9)</td>
<td>104 (41.9)</td>
</tr>
<tr>
<td>Diastolic &gt;90 mm Hg at admission</td>
<td>51 (20.6)</td>
<td>50 (20.2)</td>
</tr>
<tr>
<td>Systolic &gt;140 mm Hg at discharge</td>
<td>35 (14.5)</td>
<td>35 (14.8)</td>
</tr>
<tr>
<td>Diastolic &gt;90 mm Hg at discharge</td>
<td>11 (4.6)</td>
<td>14 (5.9)</td>
</tr>
<tr>
<td>Low-density lipoprotein cholesterol level &lt;100 mg/dL, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>107 (48.4)</td>
<td>89 (41.0)</td>
<td></td>
</tr>
<tr>
<td>Glycated hemoglobin level &lt;7% among patients with diabetes mellitus only, %a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 (40.0)</td>
<td>27 (49.1)</td>
<td></td>
</tr>
<tr>
<td>Most common drug at discharge, No. (%)</td>
<td></td>
<td></td>
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<tr>
<td>Aspirin</td>
<td>239 (95.6)</td>
<td>243 (97.6)</td>
</tr>
<tr>
<td>Statins</td>
<td>232 (92.8)</td>
<td>240 (96.4)</td>
</tr>
<tr>
<td>β-Blockers</td>
<td>219 (87.6)</td>
<td>227 (91.5)</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>209 (83.6)</td>
<td>223 (89.9)</td>
</tr>
<tr>
<td>Angiotensin-converting enzyme inhibitors</td>
<td>166 (66.7)</td>
<td>159 (64.4)</td>
</tr>
<tr>
<td>Nitrate derivatives</td>
<td>91 (36.7)</td>
<td>99 (39.9)</td>
</tr>
<tr>
<td>Patient knowledge questionnaire, score range 0-19, mean (SD) [range]b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.7 (1.6) [2-12]</td>
<td>7.5 (1.5) [3-12]</td>
<td></td>
</tr>
<tr>
<td>12-Item Short Form Health Survey for quality of life, score range, 0-100, mean (SD) [range]b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>45.8 (9.8) [16-63]</td>
<td>45.7 (10.0) [16-61]</td>
</tr>
<tr>
<td>Mental</td>
<td>44.9 (11.1) [13-64]</td>
<td>44.1 (11.2) [16-63]</td>
</tr>
</tbody>
</table>

SI conversion factors: To convert cholesterol level to millimoles per liter, multiply by 0.0259; to convert glycated hemoglobin level to proportion of total hemoglobin, multiply by 0.01.

a In total, 66 patients in the House of Education group and 63 patients in the conventional care group had diabetes mellitus.

b Higher scores indicate better results.
The most common types of ACS were ST-elevation myocardial infarction (47.9%) and non-ST-elevation myocardial infarction (34.1%). Regarding cardiovascular risk factors, 54.5% of patients were current smokers, 27.5% had a sedentary lifestyle, 51.8% were overweight, and 26.0% were obese. Each hospital recruited 7.4% to 23.1% of the total number of patients (Figure 2). At discharge from the hospital, 96.6% of patients were taking aspirin, 94.6% took statins, 89.6% took β-blockers, 51.8% were overweight, and 26.0% were obese.

### Table 2. Results of the Primary and Secondary End Points for the House of Education vs Conventional Care (Primary Analyses and Adjusted Models)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>House of Education (n = 251)</th>
<th>Conventional Care (n = 251)</th>
<th>Adjusted Relative Risk (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction of ≥1 cardiovascular risk factor</td>
<td>502 130 (51.8)</td>
<td>125 (49.8)</td>
<td>1.11 (0.90-1.37)</td>
<td>.34</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction of all cardiovascular risk factors</td>
<td>502 68 (27.1)</td>
<td>55 (21.9)</td>
<td>1.22 (0.89-1.66)</td>
<td>.21</td>
</tr>
<tr>
<td>Nonsmokers or smoking cessation</td>
<td>502 184 (73.3)</td>
<td>176 (70.1)</td>
<td>0.99 (0.87-1.13)</td>
<td>.89</td>
</tr>
<tr>
<td>≥4% Reduction in waist circumference or ≥5% reduction in weight</td>
<td>502 119 (47.4)</td>
<td>111 (44.2)</td>
<td>1.07 (0.84-1.36)</td>
<td>.59</td>
</tr>
<tr>
<td>Physical activity ≥3 h per week</td>
<td>502 193 (76.9)</td>
<td>183 (72.9)</td>
<td>1.05 (0.92-1.21)</td>
<td>.47</td>
</tr>
<tr>
<td>Blood pressure &lt;140/90 mm Hg</td>
<td>502 186 (74.1)</td>
<td>180 (71.7)</td>
<td>1.03 (0.89-1.19)</td>
<td>.71</td>
</tr>
<tr>
<td>Low-density lipoprotein cholesterol level &lt;100 mg/dL</td>
<td>502 181 (72.1)</td>
<td>160 (63.7)</td>
<td>1.10 (0.94-1.29)</td>
<td>.24</td>
</tr>
<tr>
<td>Glycated hemoglobin level &lt;7% among patients with diabetes mellitus only</td>
<td>129 40 (60.6) (n = 66)</td>
<td>24 (38.1) (n = 63)</td>
<td>1.73 (0.94-3.21)</td>
<td>.10</td>
</tr>
</tbody>
</table>

### Figure 3. Adherence to Individual Consultations With the Nurse (A) and the Dietician (B)

The percentages are based on the number of patients who were expected to have a consultation with the nurse (n = 126) and with the dietician (n = 207).

### Table 3

The mixed-effects approach produced similar estimated relative risks (95% CIs). These results are summarized in eTable 1 and eTable 2 in the Supplement.

### Medical Changes

At 12 months, the following proportions of patients had maintained and decreased their drug dosages, respectively: 84.6% and 0.2% for aspirin, 82.6% and 1.8% for β-blockers, 83.6% and 2.1% for clopidogrel, 80.0%, and 3.1% for angiotensin-converting enzyme inhibitors, and 72.6% and 13.7% for nitrate derivatives. No major differences were observed among the groups. These results are summarized in eTable 3 in the Supplement.

### Adverse Events

The most common serious adverse events during the study in the House of Education and conventional care groups, respectively, were the following: death (2.9% and 2.8%); arrhythmia (1.6% and 2.8%); coronary angiography (7.3% and 8.9%); sched-
Labeled angioplasty (4.9% and 3.2%); ACS, stent thrombosis, or chest pain (13.5% and 12.6%); and dyspnea, lung edema, or congestive heart failure (3.7% and 2.4%). Seven deaths occurred in each group: 3 in the House of Education and 5 in the conventional care group were cardiovascular, 1 in the House of Education and 1 in the conventional care group were noncardiovascular, and 3 in the House of Education and 1 in the conventional care group were from an unknown cause.

Discussion

This multicenter randomized trial evaluated the effect of a specific individualized education program on lifestyle risk factors to optimize support for patients after an ACS and to improve control of their cardiovascular risk factors. This novel approach used a secure Internet system with a digital pen and paper provided in a House of Education, a unique setting outside of the hospital and without direct physician involvement. We had speculated that a nonmedical approach (with no direct prescription of medication) at a House of Education involving a dietician, a nurse trained in smoking cessation, and efficient communication with primary care physicians via the Internet would facilitate patient adherence to our program of risk factor reduction; however, we found no additional benefit with this method over usual care in achieving target cardiovascular risk levels.

Various patient education programs to improve cardiovascular risk factors have been assessed. The Coaching Patients on Achieving Cardiovascular Health (COACH) trial used an approach that was somewhat similar to ours. It compared the addition of regular personal coaching (The COACH Program) via telephone and mailings to achieve target levels for specific risk factors vs usual care alone. After 6 months, patients who received coaching had achieved greater reductions in their mean total cholesterol and low-density lipoprotein cholesterol levels and in their weight, dietary improvements, and regular walking regimens compared with control subjects, but coaching had no effect on triglycerides or high-density lipoprotein cholesterol levels or on smoking cessation.

In a recently published study of 703 patients with symptomatic ischemic heart disease, Fihn et al showed that a collaborative care intervention had no effect on symptoms of angina or self-perceived health. However, collaborative care increased physician adherence to practice guidelines by 4.5% but largely with respect to the use of diagnostic testing and not greater use of evidence-based treatments.

A recent Cochrane systematic review showed that an intervention using counseling and education aimed at behavioral changes did not reduce total or coronary heart disease mortality or clinical events in the general population but demonstrated that it may be effective in reducing mortality among high-risk populations. This systematic review and other studies in the field have also highlighted the high heterogeneity of the educational programs proposed to patients (eg, direct counseling, telephone monitoring, or schemes that included patient-level, provider-level, or system-level interventions). These programs are usually complex interventions involving several components and are difficult to describe, standardize, and administer consistently to patients or to evaluate. Complex interventions also tend to work in a complicated manner, and any effect may vary by patient characteristics, skills of care providers, and the setting and circumstances of their delivery.

In this study, we aimed to perform a pragmatic trial. Consequently, we used broad eligibility criteria, which included patients with at least 1 cardiovascular risk factor who were selected just after an ACS in the cardiac intensive care unit. We cannot exclude that the intervention might be useful in a more selected population, such as patients with more cardiovascular risk factors or a population that would be formally selected according to their motivation for the program.

Furthermore, we did not implement any intervention to improve patient adherence to the program that would not subsequently be used in clinical practice. Our results highlight that attendance at the House of Education greatly decreased over time, and many patients failed to receive the care available. To overcome this issue, the consultation could be provided by telephone. Nevertheless, treatment adherence was low, especially for smoking cessation support.

The American College of Cardiology and the American Heart Association recommend pharmacologic treatments and lifestyle interventions to reduce the risk of recurrent events in patients following an ACS. Our results demonstrated that most patients receive pharmacologic therapies. At hospital discharge, more than 80% of the patients in our study received pharmacologic therapies (aspirin, statins, β-blockers, or clopi...
dogrel), and most patients maintained or increased their treat-
ment dosage during 1 year. In contrast, our findings showed
that modification of patient behavior is difficult and that,
despite a specific education program, only about one-quarter
of patients could correct all their cardiovascular risk factors.

Our study has some limitations. First, patients, care pro-
viders, and data collectors were not blinded to the interven-
tion, which may have influenced the care and behavior of
patients in the control group. Second, 11.9% of patients were
unable to be reached for follow-up analysis or refused a
follow-up visit at 12 months. To assess potential bias, we
performed a sensitivity analysis that excluded these pa-
ients, and the results were consistent with the main intent-
to-treat analysis (data not shown). Third, at the 12-month
assessment, follow-up data could be collected by
telephone instead of during a visit, and levels of physical
activity were self-reported for 10.7% and 14.3% of the
experimental and control patients, respectively. However,
an ancillary study that evaluated the reproducibility of an
assessment by telephone or during a follow-up visit indi-
cated that the risk of bias was negligible (eTable 4 and eFig-
ure 2 in the Supplement). Fourth, the results achieved
herein may differ from those that might be achieved in
other health care systems, where routine clinical care may
not yield similar outcomes.

In conclusion, treatment following an ACS was assessed
by a health care network that included management in a House
of Education. The program resulted in no additional reduc-
tions in cardiovascular risk factors compared with conven-
tional care.

ARTICLE INFORMATION

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REFERENCES


Bending the Curve on Cardiovascular Risk

Stephan D. Fihn, MD, MPH

Cardiovascular risk reduction has been a cornerstone of cardiologic and primary care practice for almost half a century and by any measure has been an overwhelming success. Cardiovascular mortality in the United States has fallen dramatically during the past 4 decades, including a 33% decline in the last decade, largely attributable to improved management of hypertension, diabetes mellitus, and hypercholesterolemia, along with a reduction in smoking. Despite these dramatic achievements, cardiovascular disease still accounts for nearly one-quarter of all deaths in the country, higher than for cancer, the next leading cause. Moreover, there are serious concerns that much of the progress to date may be eroded by increasing rates of obesity and diabetes, raising mortality even higher.

It is in this context that a new emphasis on prevention is emerging, driven in part by recent changes in health care legislation. Propelled by consensus about the unsustainability of the rate of rise in the costs of health care, more effective coordination of care and preventive services have been situated at the core of solutions being promoted to reverse this trend. Expenditures to treat cardiovascular disease substantially outstrip those for any other condition, amounting to a staggering $360 billion annually in the United States. Therefore, it is logical that health care delivery systems are reformulated to shift the focus of care to prevention.

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