

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

BACKGROUND:

- Lifestyle improvements after an acute coronary syndrome (ACS) reduce cardiovascular risk but are difficult to achieve
- Cardiovascular risk factors such as poor diet, smoking, physical inactivity, high body mass index (BMI), large waist circumference, and regular alcohol consumption are modifiable
- Collaborative models that enhance communication among care providers can improve the quality of care and outcomes for patients

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 ACS

METHODS:

- **Design:** 2-arm, parallel-group, multicenter, randomized clinical trial; Duration: 12 months
- **Inclusion criteria:** ≥ 18 years of age, hospitalized in a cardiac intensive care unit (ICU) for an ACS (unstable angina, ST-segment elevation MI, or non-segment elevation MI), 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 (BMI ≥ 25 for overweight and ≥ 30 for obesity). Patients also had to be willing and able to attend regular visits at an outpatient program
- **Exclusion criteria:** Not discussed.
- **Primary outcome measure:** Composite that involved correction of at least 1 of the following 3 cardiovascular risk factors between baseline and month 12:
 - 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)
 - Overweight or obesity ($\geq 4\%$ reduction in waist circumference or $\geq 5\%$ reduction in weight, with patients having a BMI of < 25 at baseline and at 12 months considered successes and patients who became overweight during the study considered failures)
 - Physical activity (≥ 3 hours/week)
- **Secondary outcome measures:**
 - Correction of all 3 CV risk factors
 - Correction of each individual CV risk factor
 - Correction of other risk factors, including HTN (BP $< 140/90$ mm Hg), diabetes mellitus (HbA1c $< 6.5\%$), and dyslipidemia (LDL < 100 mg/dL)
 - 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)
 - Number of correct answers on a patient knowledge questionnaire comprising 19 questions
 - Patient satisfaction on a numeric scale rate 0 to 10, with higher scores indicating higher levels of satisfaction

RESULTS:

- A total of 502 patients were enrolled in the study. There were 22 patients lost to follow-up and 36 patients who were lost due to follow-up refusal. The data was handled using an intent-to-treat method.
- **Primary outcome measure***: The 2 treatment groups did not differ in the primary composite endpoint (correction of at least smoking, physical inactivity, overweight, or obesity) with an adjusted relative risk of 1.11 (95% CI, 0.90-1.37).
- **Secondary outcome measures:**

Outcome	No	Study (n=251)	Control (n=251)	Adjusted Relative Risk (95% CI)	P value
Correction of ≥ 1 CV risk factor*	502	130 (51.8%)	125 (49.8%)	1.11 (0.90-1.37)	0.34
Correction of all CV risk factors	502	68 (27.1%)	55 (21.9%)	1.22 (0.89-1.66)	0.21
Nonsmokers or smoking cessation	502	184 (73.3%)	176 (70.1%)	0.99 (0.87-1.13)	0.89
$\geq 4\%$ reduction in waist circumference or $\geq 5\%$ reduction in weight	502	119 (47.44%)	111 (44.2%)	1.07 (0.84-1.36)	0.59
Physical activity ≥ 3 hrs per week	502	193 (76.9%)	183 (72.9%)	1.05 (0.92-1.21)	0.47
Blood pressure $< 140/90$ mm Hg	502	186 (74.1%)	180 (71.7%)	1.03 (0.89-1.19)	0.71
LDL < 100 mg/dL	502	181 (72.1%)	160 (63.7%)	1.10 (0.94-1.29)	0.24
HbA1c $< 7\%$ among patients with DM only	129	40 (60.6%) n=66	24 (38.1%) n = 63	1.73 (0.94-3.21)	0.10
12-item Short Form Health Survey (Physical)	502	47.5 (9.3)	47.3 (9.4)	0.39 (-1.38 to 2.15)	0.44
12-item Short Form Health Survey (Mental)	502	47.5 (11.2)	47.6 (11.2)	-0.92 (-3.27 to 1.43)	0.43
Patient knowledge questionnaire, score range 0-19	502	14.8 (2.4)	15.2 (2.3)	-0.20 (-0.63 to 0.24)	0.37

- **Author's conclusion:** A nurse- and dietician-led education program aimed at reducing cardiovascular risk factors in patients post-ACS resulted in no additional reduction in risk factors compared with conventional care.

STRENGTHS:

- Long study duration (12 months)
- Similar characteristics at baseline
- Low potential for conflict(s) of interest resulting in bias
- Broad inclusion criteria

LIMITATIONS:

- Unblinded
- Decreasing compliance over 12-month study period
- Lack of consistency in the control group
- Diet and physical activity were self-reported

- Nurse providing smoking cessation consultation could not prescribe nicotine replacement therapies, and it is unclear what patients used
- No description of specific dietary recommendations
- Unclear how biological and clinical variables were measured if the patient had a follow-up via telephone

CONCLUSION:

- Although the study showed that cardiovascular risk factors were not significantly reduced in the study group, there is still value in the use of a multidisciplinary team to educate patients with chronic conditions.
 - Because there were so many patients who completed a follow-up visit via telephone, the study investigators may not have been able to accurately measure their clinical and biological variables. There may have been a difference between the two groups, but it is difficult to show results if the patients did not attend the follow-up visits.
- Future research:
 - Education and lifestyle interventions have the potential to reduce cardiovascular risk factors, but it may be more beneficial to involve all members of the healthcare team to produce a more significant change. A trial should be done involving more disciplines to determine the effect this would have on risk factor reduction.

Reference: Cohen A, Assyag P, Boyer-Chantenet L, Cohen-Solal A, Perdrix C, et al. An Education Program for Risk Factor Management After an Acute Coronary Syndrome: A Randomized Clinical Trial. *JAMA Intern Med.* 2014; 175(1):40-48.

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