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Community-Based Lifestyle Intervention in Patients With Coronary Artery Disease

The RESPONSE-2 Trial

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ABSTRACT

BACKGROUND Among patients with coronary artery disease (CAD), improvement of lifestyle-related risk factors (LRFs) reduces cardiovascular morbidity and mortality. However, modification of LRFs is highly challenging.

OBJECTIVES This study sought to evaluate the impact of combining community-based lifestyle programs with regular hospital-based secondary prevention.

METHODS The authors performed a randomized controlled trial of nurse-coordinated referral of patients and their partners to 3 widely available community-based lifestyle programs, in 15 hospitals in the Netherlands. Patients admitted for acute coronary syndrome and/or revascularization, with ≥1 LRF (body mass index >27 kg/m^2, self-reported physical inactivity, and/or smoking) were included. All patients received guideline-based usual care. The intervention was based on 3 lifestyle programs for weight reduction, increasing physical activity, and smoking cessation. The primary outcome was the proportion of success at 12 months, defined as improvement in ≥1 qualifying LRF using weight (≥5% reduction), 6-min-walking distance (≥10% improvement), and urinary cotinine (200 ng/ml detection limit) without deterioration in the other 2.

RESULTS The authors randomized 824 patients. Complete data on the primary outcome were available in 711 patients. The proportion of successful patients in the intervention group was 37% (133 of 360) compared with 26% (91 of 351) in the control group ($p = 0.002$; risk ratio: 1.43; 95% confidence interval: 1.14 to 1.78). In the intervention group, partner participation was associated with a significantly greater success rate (46% vs. 34%; $p = 0.03$).

CONCLUSIONS Among patients with coronary artery disease, nurse-coordinated referral to a comprehensive set of community-based, widely available lifestyle interventions, with optional partner participation, leads to significant improvements in LRFs. (RESPONSE-2: Randomised Evaluation of Secondary Prevention by Outpatient Nurse SpEcialists 2; NTR3937) (J Am Coll Cardiol 2017;70:318–27) © 2017 by the American College of Cardiology Foundation.

Patients with coronary artery disease (CAD) are at high risk of recurrent events and mortality. Improvement of lifestyle-related risk factors (LRFs), including overweight, physical inactivity, and smoking, is associated with a significantly lower risk of recurrent events (1,2). Therefore, guidelines on secondary prevention of CAD recommend medical treatment plus lifestyle interventions for all patients (3–5). However, a significant gap exists between guideline recommendations and daily practice.

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In particular, attempts at improving LRFs have been disappointing (6–8).

Most studies have focused on a single LRF, including counselling, support systems, or easy access (9–11). Nurse-coordinated referral to a comprehensive set of easily accessible, existing community-based programs has not been studied. In addition, most studies have not included patients' partners, which may be essential to change a patient's daily routines (12,13).

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The RESPONSE-1 (Randomized Evaluation of Secondary Prevention by Outpatient Nurse Specialists) trial showed that nurse-led care was effective in reducing drug-treated cardiovascular risk factors and improving quality of life in patients with CAD (14,15). Guidelines now recommend the integration of nursing care into secondary prevention (16). However, the impact of nurse-led care on LRFs has been shown to be limited (11,15,17).

We hypothesized that a strategy of nurse-coordinated referral to a comprehensive set of ≤3 community-based, existing interventions to achieve weight loss, improvement of physical activity, and smoking cessation, on top of usual care, and including the patient's partner, improves LRFs in patients with CAD.

METHODS

STUDY DESIGN. The RESPONSE-2 trial was a randomized trial conducted in 15 hospitals in the Netherlands. Study methods have been published and are summarized later (18). The institutional review boards of all recruiting hospitals approved the protocol, and written informed consent was obtained from all patients. The protocol was registered at the Dutch trials register on April 8, 2013.

PATIENT POPULATION. Adult patients were eligible <8 weeks after hospitalization for acute coronary syndrome, and/or coronary revascularization, if they had ≥1 of the following LRF: 1) body mass index (BMI) ≥27 kg/m^2 (because a BMI only slightly >25 may not provide sufficient motivation, and minor improvement could be classified as success); 2) self-reported physical inactivity (<30 min of physical activity of moderate intensity 5 times per week, guideline based); or 3) self-reported smoking <6 months before hospital admission, and if motivated to attend ≥1 lifestyle program.

Exclusion criteria were planned revascularization after discharge; life expectancy ≤2 years; congestive heart failure New York Heart Association functional class III or IV; visits to outpatient clinic and/or lifestyle program not feasible; no Internet access; and anxiety or depressive symptoms (Hospital Anxiety and Depression Scale >14), because this was expected to hinder lifestyle changes (19).

RANDOMIZATION. After the baseline interview, patients were randomized by an automated online protocol to the intervention group or the control group, using randomly varying block sizes (4, 6, or 8 allocations), stratified by hospital (18).

ABBREVIATIONS AND ACRONYMS

6MWD = 6-min-walking distance

BMI = body mass index

CAD = coronary artery disease

CI = confidence interval

LRF = lifestyle-related risk factor

RR = risk ratio

USUAL CARE. All patients received usual care, including visits to the cardiologist and cardiac rehabilitation, according to national and international guidelines (4,5), and up to 4 visits to a nurse-led secondary prevention program. The nurse program addressed (counseling on) healthy lifestyles, drug-treated risk factors, and medication adherence (4,5,20). As per current guidelines, cardiac rehabilitation included ≤12 weeks of outpatient physical rehabilitation plus counselling on secondary prevention, psychological support, and work resumption.

Patients were seen by registered nurses, with experience in cardiovascular care and training in motivational interviewing.

INTERVENTION. Patients in the intervention group were referred by the nurse to ≤3 community-based lifestyle programs (18). The number and sequence of the lifestyle programs was determined by the patient's risk profile and preference. Partners were offered free participation in the programs. Three lifestyle programs were used in their existing format, uniformly in all participants:

1. Weight Watchers offers a program that emphasizes a healthy diet, changing unhealthy behavior and regular physical activity, and uses group motivation, coordinated by a Weight Watchers' coach. Access to this program was for the duration of 1 year.
2. Philips DirectLife offers an Internet-based program aimed at improving physical activity. An accelerometer measures physical activity and an online coach provides personalized feedback. Access to this program was for the duration of 1 year.
3. Luchtsignaal is a smoking cessation program in the Netherlands that uses telephone counselling based on motivational interviewing by trained professionals, for the duration of 3 months. Nicotine replacement or varenicline therapy was prescribed, as appropriate.

DATA COLLECTION AND MEASUREMENTS. Data were collected at baseline (first visit after discharge)