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Effects of a brief cardiovascular prevention program by a health advisor in primary care; the '*Hartslag Limburg*' project, a cluster randomized trial

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ABSTRACT

Objective. To determine in primary care patients at high risk for a cardiovascular event, the effects on biomedical risk factors for and incidence of cardiovascular events, of a brief cardiovascular prevention program executed by a health advisor.

Method. Design: cluster randomized controlled trial with 1275 patients (24 general practices) in and around Maastricht, the Netherlands (1999–2004).
Intervention: health advisors were to complete computerized cardiovascular risk profiles, provide multi-factorial tailored health education and advice, and communicate with GP's to optimize treatment.
Outcome: differences in changes in risk factors between baseline and follow up at 6, 18, and 36 months and incidence of cardiovascular events at 36 months.

Results. Process: Because of logistic reasons risk profiles were put on paper instead of in the computerized patient files. On average patients attended 2.3 counseling sessions. Interaction with GPs was less productive than expected. Outcome: Effect after six months on BMI (-0.20 kg/m^2 (95% CI -0.38 to -0.01, $p=0.039$), Cohen's d: -0.18), and after 18 months on HDL-cholesterol ($+0.05$ mmol/l (95% CI $+0.01$ to $+0.09$, $p=0.014$), Cohen's d: 0.14). No other (subgroup) effects were found.

Conclusion. Given the lack of clinically meaningful effects, implementation of this intervention in its present form is not justified.

Introduction

It is recommended to direct cardiovascular prevention efforts at high risk populations and high risk individuals (Manuel et al., 2006; NCEP expert Panel, 2002; Paulweber et al., 2010; Wiersma and Goudswaard, 2007). However, identification of high risk patients in primary care is hampered by inadequate risk factor recording (de Koning et al., 2005; Sheerin et al., 2007; van Wyk et al., 2005) and pharmacological treatment of cardiovascular risk factors is far from optimal (Kotseva et al., 2008). Finally, doctors often are not good in performing health educational tasks, like health counseling (Hulscher et al., 1999; Hulscher et al., 2006; Kedward and Dakin, 2003).

Some trials (Fullard et al., 1987; Hulscher et al., 1997a) and a review (Hulscher et al., 1999) showed that supporting the doctor by a trained nurse might have a positive effect on the implementation of cardiovascular guidelines, e.g. by improving logistics of completion of risk profiles, by task delegation to other practice professionals and by organizing a regular follow up of patients. However, data on the effectiveness of cardiovascular prevention interventions, including health counseling, on individual cardiovascular risk level of patients are contradictory, as reviews have shown (Ebrahim et al., 2006; Hobbs, 2004).

The southern part of the Dutch province of Limburg faces a high prevalence of cardiovascular disease, mortality and behavioral cardiovascular risk factors in comparison with the rest of the country (Plat et al., 2005; Regional Public Health Institute, 1999). In this context the '*Hartslag Limburg*' project was developed. The project combined a strategy directed at the community, and one directed at individual high risk patients visiting their general practitioner (GP) or cardiologist (Ronda et al., 2004; Ruland et al., 1999).

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At the start of the project (1999) there was no guideline on integrated cardiovascular risk management yet. Most general practices did not have structured cardiovascular consultation hours. Paramedical staff that could support the GP with this task was lacking. Traditional practice assistants were not qualified to perform such a task. Therefore, we developed the function of 'health advisor', who could bridge the gap between practice assistant and GP. This specifically trained professional would support the GP with his cardiovascular prevention tasks. This function could later be taken up by the practice team itself, e.g. by trained (experienced) practice assistants or practice nurses.

In a cluster randomized trial we evaluated *Hartslag Limburg's* strategy that was directed at individual high risk patients in primary care. The project consisted of a behavioral study (with modest effects on fat consumption and physical activity level), which has been reported elsewhere (Harting et al., 2006) and a biomedical study, which is reported here. We tested the hypothesis that introduction of a health advisor for cardiovascular high risk patients (i.e. with or without established cardiovascular disease) in primary care would result in lower levels of biomedical risk factors as compared to usual care after a follow up of 6, 18 and 36 months, respectively. The health advisor should complete computerized risk profiles, should give tailored health education and advices and should confer with the GP to optimize treatment. In addition, we were interested in a possible difference in incidence of cardiovascular events after 36 months of follow-up.

Methods

Design

A cluster randomized controlled trial was designed to compare outcomes in cardiovascular high risk patients (i.e. with established cardiovascular disease, or without established cardiovascular disease but with a high risk for first cardiovascular events) in practices that were randomly assigned to support from a health advisor versus usual care. Neither the GPs nor the participating patients were blinded to the intervention. The intervention period was intended to be brief (not more than six sessions in 3–6 months). The study had a total follow up time of three years. The Medical Ethics Committee of Maastricht University approved the study (MEC 97-043.1).

Randomization of practices ('clusters')

All (ninety) GPs in the region of Maastricht received a letter in which they were invited to join the study. Randomization took place at practice level to avoid contamination between intervention and control subjects. GPs agreed to join the study without knowing whether their practice would be an intervention or a control practice.

Before randomization practices were stratified with regard to (a)socioeconomic status of the practice area (based on income and education level of the practice area that were obtained from the municipality),(b)preventive attitude and activities of participating GPs (assessed by a questionnaire used in a study about cardiovascular prevention in general practice (Hulscher et al., 1997b)), and (c) practice size. Accounting for the number of participants that was needed, it was calculated that smaller practices (i.e. list size<2350 patients) were to include 54 participants and bigger practices (list size>2350 patients) 108 participants.

Using the three stratification variables, practices that were similar were matched in pairs. Within each pair, practices were randomly assigned to the intervention or control group by two members of the study team (PMvL, JWvR). One member coded each comparable practices as A or B. The other member randomly allocated A or B to the intervention group, without knowing what practice was coded A or B.

Participants

Patients with established cardiovascular disease or diabetes, or with only a high cardiovascular risk based on a combination of risk factors (≥20% risk for a cardiovascular event in the next 10 years, according to the Framingham risk score), were eligible for the study, as advocated in the then current guideline on hypercholesterolemia (Thomas et al., 1999).

An initial selection of patients was made from the GPs' medical files using the cardiovascular International Classification of Primary Care (ICPC) codes and from medication files of practice-related pharmacies (Gebel and Lamberts, 2000) (Table 1). From this selection the GP invited patients by letter in alphabetical order until the required number of participants per practice ('cluster') was reached. The actual inclusion took place during a consultation at the GP's office: patients were given information about the study and were asked to sign an informed consent form by the GP.

Intervention

In the intervention practices two health advisors (an experienced practice assistant and a dietician with a fairly high level of education) were introduced. They were extensively trained by the project team and external experts in educational and health behavior change techniques both theoretically and by observed patient contacts. This is described in detail in a previous publication of our study group (Harting et al., 2004).

Their work consisted of three elements:

1. *Completion of cardiovascular risk profile.* A computerized cardiovascular risk profile had to be drawn up using data from the baseline measurements of the project (smoking, BMI, blood pressure, family history, physical exercise, lipids), intended to be integrated in the patients' computerized medical files.
2. *Tailored health education and advice.* Each health advisor kept office in various intervention practices. Their health behavior change protocol was based on general (health) counseling models and various theories of behavior change. The protocol instructed the health advisors to explore specific factors hampering behavioral change and consequently to apply appropriate intervention strategies. General concepts were patient-centeredness and shared decision-making (Harting et al., 2004).
   Before their first visit, patients completed a questionnaire about their lifestyle and personal priorities. Participant and health advisor discussed the patient's cardiovascular risk profile and the results of the questionnaire. Together they decided on the topics for their sessions. Targets for change were made, together with follow up appointments.
   The following 'rules for life' were communicated: participants should not smoke; their fat consumption should consist of unsaturated fat and not exceed 35% of the total energy intake; and they should be physically active for at least 30 min a day, during at least five days a week. Health advisors could refer patients to activities organized by the '*Hartslag Limburg*' community project, like guided supermarket tours to identify healthy food products, sports clubs, etc. Furthermore, free trial packages of nicotine replacement agents and bupropion were available to support smoking cessation efforts.
   The length of a full health behavior change course was flexible, but was intended not to exceed six sessions. It was expected that a relatively brief intervention would be more easily accepted and implemented in primary care. The first session was to last 45 min and the follow up meetings 30 min at maximum. Telephonic booster sessions could also be used.

Table 1
Hartslag Limburg, Maastricht and surrounding area, 1999–2004, in- and exclusion criteria.

Patient inclusion criteria	Patient exclusion criteria
▪Pre-existing cardiovascular disease (ICPC-codes K74 Angina pectoris, K75 Acute myocardial infarction, K76 Other chronic ischemic heart diseases, K77 Congestive heart failure, K89 Transient ischemic attack (TIA), K90 Stroke, K91 Atherosclerosis, K92 Peripheral arterial vascular disease)	▪>75 years of age ▪Severe cardiac co-morbidity ▪Other potentially terminal diseases ▪Cognitive disability to participate in study (e.g. dementia etc.) ▪Inability to make practice visits on a regular basis ▪Participation in another cardiovascular intervention study ▪Living outside the Maastricht area
▪Diabetes mellitus (ICPC-code T90)	
▪Severe hypertension (diastolic ≥ 105 mm Hg) or severe hypercholesterolemia (≥8 mmol/l)	
▪Men with two or more of following risk factors: age ≥ 60 years, hypertension (ICPC-codes K86 and K87), hypercholesterolemia (ICPC-code T93), smoking (ICPC-code P17), cardiovascular disease in parent of sibling below 60 years of age	

Cholesterol: mg/dl = 38.7 × mmol/l.
ICPC: International Classification of Primary Care.