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Original Scientific Paper

Improving cardiovascular risk management: a randomized, controlled trial on the effect of a decision support tool for patients and physicians

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Background **There is nonoptimal adherence of general practitioners (GPs) and patients to cardiovascular risk reducing interventions. GPs find it difficult to assimilate multiple risk factors into an accurate assessment of cardiovascular risk. In addition, communicating cardiovascular risk to patients has proved to be difficult.**

Aims **Improving primary prevention of cardiovascular disease (CVD) in primary care by enhancing patient involvement in the use of a decision support tool.**

Design **Cluster randomized trial.**

Methods **Thirty-four GPs included patients (40–75 years old) without CVD. In an interactive, small group training session lasting 4 h, the GPs in the intervention group were trained to use the guidelines on cardiovascular risk and a decision support tool. The control group received educational materials about the guidelines on paper. GPs' clinical performance and patients' risk perception and self-reported lifestyles were measured at baseline and after 6 months.**

Results **Thirty-four GPs recorded 490 consultations, 276 in the intervention and 214 in the control group. After 6 months, no significant effect of the intervention on the GPs' performance or the patients' risk perception was found. There was only an effect on self-reported lifestyle, in that more men in the intervention group than in the control group increased their physical activity (odds ratio 3.8, 95% confidence interval 1.7–8.7).**

Conclusion **The 4-h interactive, small group training did not guarantee correct application of the decision support tool and as such failed to improve GPs' performance or correct patients' risk perception. The positive effect on physical activity justifies further research on patient involvement.** *Eur J Cardiovasc Prev Rehabil* **14:44–50 © 2007 The European Society of Cardiology**

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Keywords: cardiovascular diseases, consumer participation, patient education, primary health care, primary prevention, quality assurance health care

Introduction

The incidence of cardiovascular disease (CVD) remains high and the associated burden of illness is increasing. Primary prevention, an important strategy to delay the onset of CVD, is reflected in national and international guidelines for the assessment and modification of the relevant risk factors [1–4]. However, many barriers hamper the implementation of the recommended 'high-risk' approach. Many health professionals find it difficult to assimilate multiple risk factors into an accurate assessment of cardiovascular risk, and adherence to the guidelines is less than optimal [5–9].

In addition, explaining risk to patients in order to reach a common understanding on risk level is perhaps even more

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difficult for both physicians and patients. GPs have mentioned this as an important barrier to implementation of the high-risk approach [9–12]. Since it is unlikely that guidelines could incorporate the wide range of people's preferences, true dialogue between clinicians and patients before embarking on lifelong preventive treatment is very important [13]. The guidelines recommend optimizing patients' health status by normalizing cholesterol levels and by counselling patients on smoking, physical exercise and diet or alcohol consumption. However, patient compliance with lifestyle advice in general practice is not optimal. If GPs fail to acknowledge patients' conceptions, misconceptions and preferences, this may lead to noncompliance with medical or lifestyle advice on the part of the patients [14]. Risk perception and self-efficacy seem to be key factors in patients' motivation to change their behaviour.

So far, intensive implementation strategies that focused on changing professional behaviour and adjusting practice organization have resulted in limited improvement in clinical performance [6,15]. Since the importance of patient-related barriers in addition to those relating to professional and organizational aspects [16,17] is now well recognized, more active patient involvement in decision-making seems a valid option to improve the quality of care [18–20]. We hypothesized that a decision support tool aiming to help both physicians and patients to understand the risk and options for risk management might have favourable effects in two directions: improving the physicians' performance in terms of the key recommendations of the CVD guidelines and improving patients' risk perceptions, which in turn might lead to a healthier lifestyle.

Methods

General design

A cluster-randomized trial with two arms (Fig. 1) was used to evaluate the effect of the decision support tool on GPs (as regards clinical performance) and patients (as regards risk perception and self-reported lifestyle).

Participating GPs and patients

Assuming an intraclass correlation coefficient (ICC) of 0.03, 16 GPs per arm and 15 patients per GP would be needed to have an 80% chance of detecting a 15% difference (0.5–0.65, $\alpha = 0.05$) in GP performance between the intervention and control groups [21]. To compensate for possible dropout of patients and physicians, 45 GPs (39 general practices) in the southern and central parts of The Netherlands were recruited.

The GPs were instructed to include the first 30 consecutive patients (men aged 40–70, women aged 40–75) without established CVD (i.e. acute myocardial infarction, stroke or peripheral arterial disease) whenever cardiovascular risk factors were discussed during the consultations, either at the initiative of the patient or that of the physician. Written informed consent was obtained from the participating patients after the consultation. The ethics committee of the University Hospital of Maastricht approved the study.

Randomization

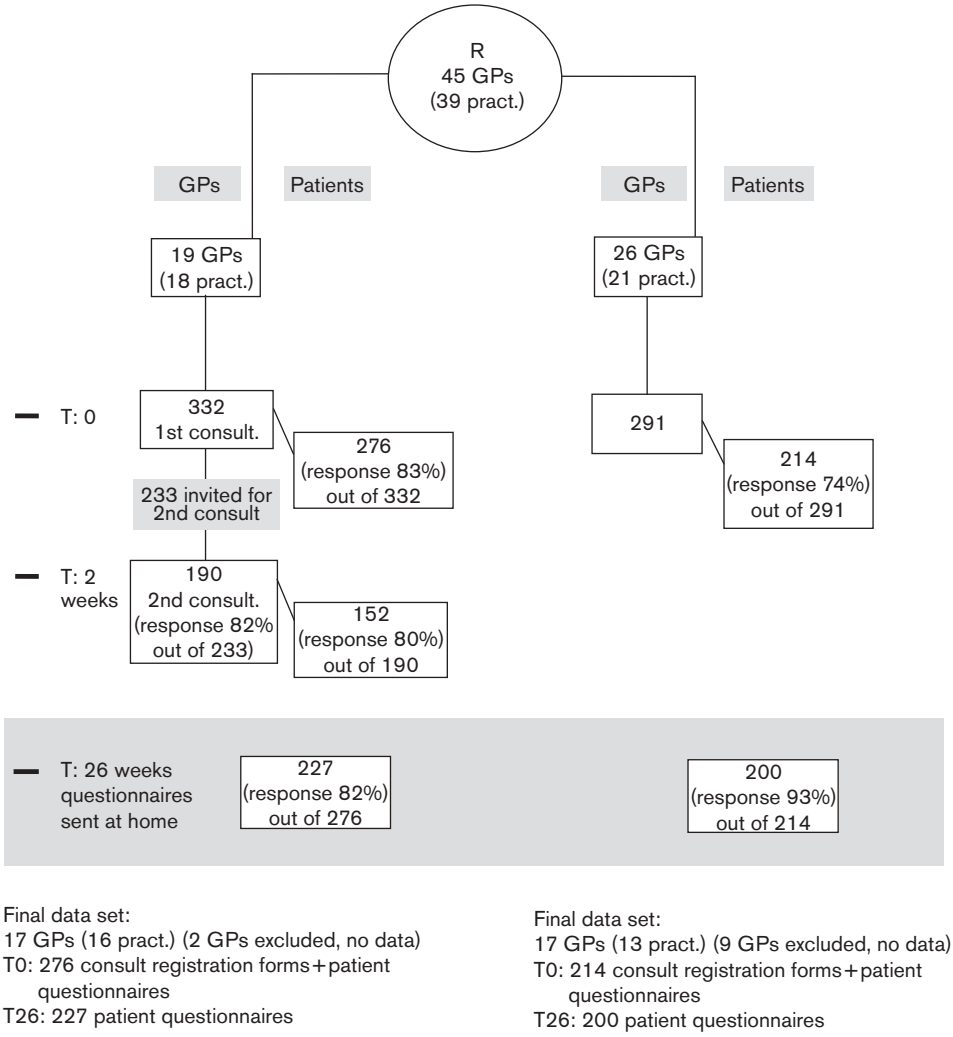
A computer was used for the stratified randomization, which was at practice level to prevent contamination of the intervention within group practices. We stratified on GPs the number of patients for which the GP was responsible (full-time equivalents (fte.)/practice size) and the availability of desktop cholesterol analysers at the practice. The latter is known to be associated with a higher level of cholesterol screening [6].

Interventions

The intervention, aimed at both physicians and patients, consisted of three elements.

(1) A 4-h interactive small group training session to instruct the physicians about the risk table and the key recommendations for management of patients at high cardiovascular risk. Role-play was used to allow the physicians to practise how the decision support tool could be used to support the consultation and to facilitate patient involvement in a time-efficient way.
(2) The actual use of a decision support tool, consisting of a small booklet in two versions: one for diabetic patients, using a persuasive tone on the importance of lifestyle changes, and one for nondiabetic patients, with a more reassuring tone. Both versions included a simplified version of the Dutch risk charts for CVD prevention. The 16-page booklets informed the patients about their absolute 10-year CVD risk, expressed in words, using natural frequencies [22], as well as percentages, including comparative data on other patient groups from the risk chart. The booklets explained the patients' absolute risk of CVD in accessible language, discussed the options for risk factor management, and invited the patients to fill out their preferences on a worksheet.
(3) The intervention included two consultations, to provide enough time for sharing information, discussion and answering questions. The GPs were instructed to present the booklet at the first consultation and to invite patients to do the 'homework' and return within 1–2 weeks to discuss their cardiovascular risk. The aim was to stimulate patient involvement during the second consultation, giving the patients time to consider their risk and preferences for risk-reducing strategies.

Fig. 1



Flow chart of trial participation. pract., general practices; consult., recorded consultations.

The core element, the decision support tool, was systematically pilot-tested. The intervention period lasted 8 months.

The GPs in the control group received only written educational materials on the content of the Dutch guidelines on cholesterol.

Variables and instruments

Outcome at physician level

Five performance indicators The GPs' clinical performance was evaluated by constructing five performance indicators. Some indicators reflect the underuse and overuse of tests in the screening and classification of patients, others the management of hypercholesterolaemia (Table 2). The numerator of the performance indicator was calculated by estimating the patients' actual risk, or potential risk in the case of an incomplete risk profile, from the available data on age, sex, diabetes, smoking, hypertension and familial predisposition to CVD. The performance indicator on lifestyle advice applied to all smoking or obese patients (irrespective of their actual risk), since these risk factors are also important in terms of the prevention of other diseases. Hence, the numerator of the performance indicator of lifestyle advice comprised all relevant patients, not only those at high cardiovascular risk.

Outcome at patient level

Risk perception Risk perception is a construct with two components: absolute probability and comparative probability, each of them assessed by one question [23].

Table 1 Characteristics of the general practitioners (GPs), their practices and the patients (valid percentages)

	Intervention	Controls
Physicians		
Number	17	17
Mean age	49 ± 5	47 ± 7
Sex (male)	13 (38)	12 (35)
Mean working experience (years)	19 ± 7	16 ± 8
Full-time employment (fte)	13 (38)	7 (21)*
Practices		
Number	16	13
Single-doctor	7 (21)	7 (21)
Location: urban (1000 addresses/km^2)	12 (35)	9 (26)
Desk-top cholesterol analysers	3 (9)	2 (6)
With specialized CVD clinics	8 (24)	4 (12)
Patients		
Number	276	214
Age	54 ± 10	54 ± 10
Sex (male)	124 (45)	96 (45)
Estimation of high CVD risk[a]	51 (19)	31 (15)
Potentially at high CVD risk[b]	166 (60)	121 (57)
Diabetes	49 (18)	29 (21)
Smoking	92 (33)	49 (23)*
Hypertension	123 (45)	106 (50)
Family history of CVD[c]	126 (46)	83 (39)
Hypercholesterolaemia	27 (27)	8 (11)*
Socio-economic status (SES)		
High	32 (12)	20 (10)
Intermediate	118 (44)	96 (46)
Low	116 (44)	95 (45)

[a]High cardiovascular (CVD) risk according to the Dutch guidelines, with all diabetic patients labelled as high-risk. [b]Possibility of high cardiovascular risk according to the Dutch guidelines; risk assessment is recommended. [c]First-degree relative with coronary heart disease (CHD) before the age of 60. *$P < 0.05$.

Table 2 Performance of the GPs in terms of the key recommendations of the cholesterol guidelines. Multi-level logistic regression analysis, adjusted for clustering of the data at GP level (95% CI)

	Probability, adjusted for clustering (95% CI)	
	Intervention ($n = 17$ GPs, 276 patients)	Control ($n = 17$ GPs, 214 patients)
Classification		
Appropriate risk classification I[a]	0.86 (0.75–0.92)	0.76 (0.62–0.86)
Appropriate risk classification II[b]	0.64 (0.50–0.76)	0.63 (0.55–0.72)
Assessment		
Appropriate assessment	0.85 (0.71–0.93)	0.82 (0.64–0.92)
Management		
Appropriate smoking advice	0.82 (0.66–0.91)	0.91 (0.68–0.98)
Appropriate dietary advice	0.69 (0.55–0.81)	0.79 (0.58–0.91)

CI, confidence interval. [a]I, indicates underuse: all patients at high risk having a cholesterol test/all patients at high risk. [b]II, indicates overuse: all patients at high risk having a cholesterol test/all patients having a cholesterol test.

Absolute probability: 'How do you estimate your risk of developing a cardiovascular disease within the next 10 years?' (7-point scale, 1 = very low, 7 = very high).Comparative probability: 'How do you estimate your risk compared to that of your peers?' (5-point scale, 1 = much lower, 5 = much higher).

A patient was labelled as having high absolute or comparative probability perception if he/she scored higher than the midpoint of the scale.

Anxiety Anxiety was assessed by these two questions.

'Do you ever think that you might develop a cardiovascular disease, such as an acute myocardial infarction or a stroke?' (6-point scale).

'Are you worried about developing a cardiovascular disease? Can you indicate on a scale of 1 to 10 how worried you are?'

A patient was labelled as anxious if their scores on both questions were higher than the midpoint of the scale.

Appropriateness of perceived risk and anxiety In order to judge whether the perceived risk and anxiety were appropriate (i.e. in line with actual risk), the patients' actual risk (high/low) was estimated by means of the Dutch risk table (absolute 10-year risk of a CVD, cut-off point 20% at 40 years, 40% at 60 years). Unlike recommendations by the Dutch guidelines at the time of the study, but in line with what was observed in daily practice and what is recommended in recent guidelines, all patients with diabetes were labelled as at high risk [1,9]. If data were missing, serum cholesterol values and blood pressure were derived from recent population cohort data, taking patients' age and sex into account [24]. Since we did not want to interfere with the methods used by the GPs, biological parameters such as cholesterol and blood pressure were not measured in a standardized way.

Self-reported lifestyle Self-reported lifestyle involved smoking (during the past 7 days), physical activity (more than 2 h a week), alcohol use (more than 2 units a day) and obesity [body mass index (BMI) > 30].

Other variables Self-efficacy regarding favourable lifestyle changes was measured on a 5-point scale and socio-economic status (SES) was measured as a standardized combination of highest level of education and job level achieved.

Measurement procedures

After each consultation, the physicians recorded patient outcomes on specially designed recording forms [25], indicating the risk factors, results of laboratory tests, management plan and whether the patient had been invited for a follow-up visit. At the end of each consultation, GPs handed the patients a questionnaire and asked them to return it to Maastricht University by prepaid post. A final questionnaire was sent to each patient's home 6 months after the first or second consultation (see below).

Statistical analysis

Of the patients in the intervention group, some had one and some two consecutive consultations that were

recorded. Although the instruction was to delay decisions on management to the second consultation, some GPs already decided on risk management in the first consultation and used only one consultation. Therefore, physicians' performance was assessed on the data of the first consultation or the combined data for the first and second consultations. Differences in physicians' and patients' individual characteristics at baseline were tested for significance with a chi-squared test. Differences in patients' risk perception (and its appropriateness), lifestyle and self-efficacy were tested with a *t*-test for the differences between the groups, while a paired *t*-test or a McNemar test was used for the differences within the group. The effect of the intervention on the GPs' performance and on the patients' risk perception and lifestyle was evaluated using multilevel regression analysis with a random intercept for practice to account for possible clustering of the patient data (Stata version 8; StataCorp, College Station, Texas, USA). Patients' SES and self-efficacy were included in the model as independent variables, to reduce error.

Results

Participant flow

After randomization, the intervention group included 19 GPs (18 practices), while the control group consisted of 26 GPs (21 practices) (Fig. 1). Eleven GPs were excluded from data analysis because they failed to include any patients, resulting in 17 GPs per group. The GPs in the intervention group recorded 332 first consultations (276 patient questionnaires were returned, response 83%) and invited 233 (70%) patients for a second consultation, of whom 190 (57%) actually returned to discuss their risk. The GPs in the control group recorded 291 consultations, and 214 patients returned their questionnaires (response 74%). Analysis of characteristics of the nonresponders revealed no significant differences between the groups. The response to the questionnaires sent to patients' homes after 26 weeks was 82% ($n = 227$) in the intervention group and 93% ($n = 200$) in the control group.

Characteristics of participating physicians and patients

Most of the GPs were male, their mean age was nearly 50 years and they had on average more than 16 years of working experience (Table 1). Their practices were mostly located in urban areas, and fewer than half of them were single-doctor practices. The intervention group included more practices with specialized CVD clinics and significantly more full-time GPs.

The mean age of the patients was 54 years, and 55% were female (Table 1). There were some differences between the two groups in cardiovascular risk factors such as smoking and hypercholesterolaemia, resulting in slightly more patients at high risk in the intervention group (19%) than in the control group (15%).

Effects of the intervention

Physician level

The performance indicators of the GPs revealed good performances (Table 2). The results for the first indicator show a tendency towards an intervention effect: 86% of the patients at high risk in the intervention group were actually tested, compared to 76% in the control group. But this difference was only 10% and thus not significant.

Patient level

For each component of patients' perceived risk, only small nonsignificant changes between and within the groups were observed (Table 3). In the intervention group, 18% of the patients estimated their absolute probability of developing CVD as high and 15% estimated their risk as higher than that of their peers; the corresponding figures for the control group were 21 and 14%.

In the intervention group, 17% of the patients were anxious, compared to 13% in the control group. Although the reduction in anxiety over time was larger in the intervention group, it was too small to be significant.

Evaluation of the appropriateness of the perceived risk revealed only small inconsistent changes over time on both components. There was no significant change in appropriateness of anxiety. After 26 weeks, the proportion

Table 3 Description of risk perception and self-reported lifestyle; total, $n = 490$; intervention, $n = 276$; controls, $n = 214$; valid percentage (%)

	T=0		T=26 weeks	
	Intervention	Controls	Intervention	Controls
Risk perception				
Absolute probability perception				
high	49 (18)	44 (21)	37 (16)	36 (18)
appropriate[a] (A)	194 (72)	145 (70)	154 (70)	140 (71)
Comparative probability perception				
higher than peers	40 (15)	30 (14)	27 (12)	34 (17)
appropriate (B)	193 (72)	156 (74)	163 (74)	143 (73)
Anxiety				
anxious	45 (17)	28 (13)	35 (16)	32 (16)
appropriate[b] (C)	181 (69)	155 (74)	152 (69)	141 (73)
Appropriate on all				
A+B+C	146 (53)	128 (60)	126 (46)	114 (53)
Lifestyle				
Smoking	92 (33)*	49 (23)*	66 (29)	45 (23)
Insufficient physical activity*	84 (31)*	47 (22)*	53 (24)**	51 (26)
BMI>30	52 (19)	39 (18)	35 (16)	30 (15)
Alcohol>2 units per day	75 (27)	59 (28)	52 (24)	47 (25)

Missing data are not reported. Number of missing data varied per outcome from 0 to 59 at T0 and from 0 to 56 at T26weeks. BMI, body mass index. [a]High probability perception + high actual risk or low perceived risk + low actual risk. [b]Anxious + high actual risk or not anxious + low actual risk. *$P<0.05$ between groups; **$P<0.05$ within groups.

of patients with appropriate scores on risk perception and anxiety had decreased from 53 to 46% in the intervention group and from 60 to 53% in the control group. Subgroup analysis of the patients at high risk revealed the same findings; no effects were seen.

After 6 months, more patients in the intervention group had stopped smoking than in the control group but the difference was not significant. There was a significant intervention effect on physical activity (McNemar test, $P < 0.05$). More patients in the intervention group (+ 31) had sufficiently increased their physical activity than in the control group (−4). The effect differed between men [odds ratio (OR) 3.8] and women (OR 0.9). Self-efficacy and SES contributed to physical activity as well, as men of high SES were doing less well in terms of physical activity than those of low SES (Table 4).

Discussion

The present cluster-randomized study evaluated whether provision of, and training in the use of, a decision support tool in primary care would improve the quality of the cardiovascular preventive care offered by GPs, and would result in a more realistic risk perception by patients, which might in turn lead to a healthier lifestyle.

Contrary to our expectations of this innovative intervention, we found no substantial changes in GP performance in the intervention group compared to the control group, even though the GPs in the intervention group had more contact with their included patients. Nor did we find any effect of the intervention on the appropriateness of patients' risk perception, and inducement of fear was not observed either. Regarding patients' lifestyle, we observed a significant improvement only in self-reported physical activity among men in the intervention group compared to the men in the control group. Self-efficacy and, surprisingly, low SES contributed to this effect as well, showing that appropriate risk perception might not be the only condition that attributes to a change of lifestyle.

Table 4 Multi-level regression analysis, clustered at GP level, of patients' physical activity, odds ratio, (95% CI)

	Physical activity[a] at T26 weeks
Physical activity at T0 (yes versus no)	12.5 (7.0–22.4)*
Sex (men versus women)	0.4 (0.14–0.88)*
Intervention (training versus control)	
For men	3.8 (1.7–8.7)*
For women	0.9 (0.4–2.0)
Self-efficacy (yes versus no)	1.5 (1.1–2.0)*
SES	
Medium versus low	0.8 (0.40–1.63)
High versus low	0.4 (0.16–0.78)*

SES, socio-economic status. [a]Physical activity: 0 = less than 2 h walking, cycling or sports per week. *$P < 0.05$.

In this effectiveness trial, the selection of patients to be included was implicitly generated by the GPs' routines and habits, thus reflecting real practice conditions. Most of the GPs had a special interest in cardiovascular prevention, which ensured a minimum attitude and performance level. The intervention was not entirely applied as intended, and we lost some GPs between randomization and follow-up, diminishing the power to detect small but relevant differences [26]. The GPs included fewer patients than intended, and only 70% of the patients in the intervention group were actually invited for a second consultation. Since the decision support tool was well accepted by the patients, this study may have underestimated the potential effect of the intervention on the outcome.

In developing the intervention, we tried to address the most important barriers and to use proven strategies. During training, the GPs welcomed the decision support tool as something they had lacked so far. Nevertheless, it seems that we may have made life more complicated for the GPs. What we tried to do is to introduce two new features at the same time. The first was the application of the high-risk approach by using the risk tables, and the second was the use of a decision support tool that, in our view, demanded a different approach to patient care by spreading it over two consultations instead of one. Apparently, this is quite a complex innovation and our implementation strategy, consisting of a 4-h training session, may not have been powerful enough to meet this implementation challenge.

Time pressure was an important barrier to the use of the decision support tool, as has also been recognized by others [27]. More intensive training in patient involvement and the use of decision support tools seems advisable but is no guarantee for success [13,28–30]. Using practice nurses instead of the GPs seems a more promising approach to cardiovascular prevention in primary care [31,32].

The patients seemed eager to learn or become involved, since more than 80% of the invited patients returned to discuss their risk. Nevertheless, this did not result in a more realistic risk perception, as has also been found by others [19,33,34]. Extending the decision support to include better preparation of patients for involvement in decision-making, and a greater focus on implementation of the decision tool, might have yielded more favourable effects [35].

In conclusion, introduction of the high-risk approach, namely using a risk table and a decision support tool to enhance patient involvement, demands an intensive implementation strategy. The decision support tool used in our study did not affect patients' risk perception.

However, there seemed to be a beneficial effect of the decision support tool on the patients' self-reported lifestyle. We feel that this type of intervention deserves more research.

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