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IMPROVING THE QUALITY OF CARDIOVASCULAR PREVENTIVE CARE
IN GENERAL PRACTICE

Optimaliseren van de kwaliteit van cardiovasculaire preventieve zorg
in de huisartspraktijk

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de Rector Magnificus

Prof.dr.ir. J.H. van Bemmel

en volgens besluit van het College voor Promoties.
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door

Claudia Monique Lobo

geboren te Paramaribo (Suriname).

CONTENTS

CHAPTER 1

General Introduction

Adapted from Hart Bulletin 1996;27:106-9

Background

One of the main priorities of Dutch healthcare policy is the reinforcement of disease prevention, as is the case in many other Western countries. The prevalence of chronic diseases is increasing, mainly due to ageing of the population, better prevention, and improved medical interventions. One chronic condition that has increased substantially is cardiovascular disease,[1] which represents about 40% of total mortality in the Netherlands.[2] However, adequate delivery of preventive services can reduce cardiovascular morbidity and mortality.[3,4]

Despite a high level of support for the importance of prevention, physician delivery of preventive services remains below recommended levels.[5-9] A substantial proportion of high-risk patients remain unrecognized and those being treated receive suboptimal care.[10] The risk these patients face can be substantially reduced by appropriate management.
In the Netherlands, the general practitioner (GP) has a central role as the 'gatekeeper' in the healthcare system. He/she is the first health care professional a patient consults with health problems.[11] Most GPs have a continuing personal relationship with their patients, and are aware of both their medical and social background. This makes Dutch general practice uniquely placed to effectively target preventive interventions. Delivering effective care could result in many more patients receiving better quality care and enjoying better health.

Specific guidelines for the management of cardiovascular diseases and risk factors have been developed and published by the Dutch College of GPs in their 'standards'.[12] These standards provide specific recommendations and criteria for diagnostic procedures, treatment, health promotion and surveillance of cardiovascular problems in general practice. Together, this package of guidelines forms a suitable point of reference for improving patient care.

In this thesis we target cardiovascular preventive care from a continuous quality improvement point of view in a project called CARPE (CArdiovascular Risk reduction in Primary carE). We created a multifaceted intervention based on a 'quality cycle' and used outreach visitors for its implementation, since this approach has

proven successful in modifying professional behavior.[13] In addressing prevention we considered Donebedian's model [14] to assess quality of care: i.e. we distinguish structure, process and outcome. Donabedian designed this well known and very influential model in order to be able to judge quality of care. We considered practice organization and clinical performance as parts of structure and process and we also addressed the outcome of preventive care on quality of life.

Structure, process and outcome

Practice organization

The organization of general practice encompasses structural elements and to a large degree defines the process of care. Structural elements comprise the possibilities and prerequisites for good running processes of care.

Shortcomings in the organizational setting within the practice are considered important barriers to prevention in primary care.[11,15,16] Numerous studies have shown that systematic prevention and disease management requires an adequate practice organization[17-20] and that organizational interventions can increase the delivery of preventive services.[21-23] An audit in 95 practices in the Netherlands showed that only very few practices were sufficiently well organized to provide effective preventive services.[24] More studies report that primary care clinics fail to use an organized approach to providing preventive services.[25,26] Thus, efforts to implement prevention should be directed both at individual GPs and the organization of healthcare services.

Background characteristics of practices and practice staff can be seen as structural aspects of care and are therefore important items to be considered. Quality improvement initiatives will be more efficient when we know which GPs or practices are most, or least, likely to comply with clinical prevention. Background characteristics of GPs and practices associated with cardiovascular prevention contribute substantially to variations in healthcare delivery [27] and are associated with adherence to preventive guidelines.[28]

In this thesis, we identified organizational aspects as structural elements related to cardiovascular preventive care. We assume that appropriate performance of each aspect of organizing preventive care will improve the total quality of care provided.

Organizational approaches do not focus on individual performance, but on creating the necessary conditions to allow change. Lack of good quality of care is basically seen as a system failure. The organizational setting requires more extensive research, in order to show how it can contribute to more effective preventive services.

Clinical decision-making

The clinical decision-making of individual GPs entails the application of medical knowledge in the interaction between GP and patient. In Donabedian's model, clinical decision-making is part of the process of care.

Assessment of actual clinical decision-making may give insight into quality of care and into feasibility and attainment of evidence-based recommendations. Previous studies have reported on successful strategies to improve prescribing and diagnostic test ordering.[13,29] In this thesis we have considered appropriate performance of all stages and aspects of consultations with high-risk patients: diagnosis, assessment and evaluation of additional risk factors, counseling and education, pharmacological treatment, clinical follow-up, and patient referral.

In this work we have used the national guidelines of the Dutch College of General Practitioners [30-33] to identify evidence-based indicators for the actual management of patients with hypertension, hypercholesterolemia, angina pectoris, or heart failure. These guidelines are based on scientific evidence, broad consensus, and clinical experience.[34] We selected key recommendations from the national guidelines, which are detailed descriptions of specific clinical actions along with the clinical situations calling for those actions. The selected key recommendations coincide with the recommendations from international guidelines.[35-38]

Patient outcome

The ultimate aim of any intervention program is to improve clinical outcome, which can be assessed by parameters such as mortality, morbidity and quality of life aspects.[39] It takes a long period of time to identify changes in morbidity and mortality. In addressing patient outcome in the time span of the project, we chose to explore the health-related quality of life, since this an important consideration in healthcare decisions and it is accepted as a clinical outcome measure of health care.[40]

Health-related quality of life is a widely used term to describe various aspects of the patients' situation. One goal of health-related quality of life studies, with its focus on

the patients' point of view, is to achieve that the increase in span of live years coincides with maintaining an optimal health-related quality of life. Moreover, low health-related quality of life could be a risk factor for subsequent cardiovascular events or complications.[41]

In patients with cardiovascular conditions the health-related quality of life is often impaired. Any cardiovascular patient is faced with problems in several domains of daily life, and investigations in this field should cover physical, mental and social health.

Choice of patient groups

The intervention was aimed at patients with high cardiovascular risk, since these patients should benefit most directly from an individualized approach to preventive care by the general practice team.[42,43] Patients with hypertension, diabetes, hypercholesterolemia or cardiovascular disease were considered patients at high-risk of a cardiovascular disease event. There are doubts about the effectiveness of interventions for reducing mortality and morbidity in unselected groups of middle-aged adults, but focusing on known high-risk cases, however, proved to have beneficial effects, while the effects on patients with established cardiovascular disease have shown to be substantial.[3,44,45] Cost-effectiveness analyses indicate similar priorities.[46]

Multifaceted interventions

Intervention programs are needed to change structure and process in order to affect outcome. General practice faces a formidable task in implementing interventions in everyday clinical practice. The literature on implementing evidence-based change tells us that multifaceted interventions, targeted at specific obstacles to change, are most effective in inducing change.[47,48]

For this study we utilized the 'outreach visitor model' to improve prevention in general practice. The principles of educational outreach [49,50] combine different strategies. These strategies include a personal audit of practice routines, feedback to

the practice, and instruction, education, guidance and support over a prolonged period of time. Educational outreach visits (providing individual instruction at the physician's surgery) have shown to be a promising approach to modify professional behavior [13] and to improve professional practices.[8,23,51] The trained outreach visitors in our study made use of a theoretical model of change to implement the multifaceted intervention.[49]

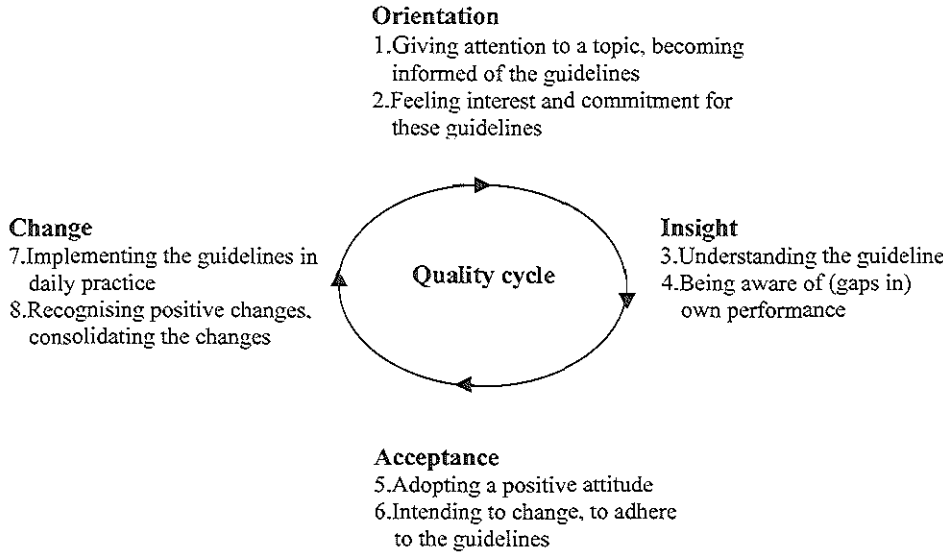
We believe there may be an important role for outreach visitors in implementing a comprehensive package of disease management for high-risk cardiovascular patients.[52]

In the Netherlands, experience with the model of implementing interventions by outreach visitors has been gained in the HAPP project [24,53] and the 'Preventie: maatwerk' project. Findings of the first project form the basis of our study. Hulscher and Van Drenth performed a non-randomized controlled trial and concluded that their multifaceted outreach visit intervention was more effective in improving cardiovascular preventive services in general practice than the more common feedback method, regarding both the organization of prevention and the recording of cardiovascular risk factors. These findings were used to improve and update the facilitator intervention method used in our study.

The 'Preventie: maatwerk' project used outreach visitors to improve detection and registration of cardiovascular risk factors. They also showed an effective implementation strategy by outreach visitors.

The multifaceted intervention created for the present work was based on a theoretical model of change, known as the "Quality cycle" (Figure 1), which is based on theoretical approaches for translating evidence-based guidelines into clinical practice and on empirical evidence about the effectiveness of different implementation strategies. Implementing changes involves a well-planned stepwise process, including a combination of interventions, linked to specific obstacles to change.[49] The subsequent steps taken to achieve improvement are orientation, insight, acceptance and change.

Figure 1. Quality cycle



The intervention used in this study addressed a comprehensive program on cardiovascular and diabetic care in general practice. Each topic was addressed using the stepwise, cyclic improvement process of the quality cycle. The help of the outreach visitor was practical and tailored to the individual practice, guided by the wishes and capabilities of the practice team.

Aim of the study

A randomized controlled study was conducted to assess to what degree improvement of the quality of preventive care for patients at high cardiovascular risk in general practice can be achieved through a multifaceted intervention by outreach visitors.
We looked at the quality of preventive care and, more specifically, at the organization of prevention, at clinical performance and at quality of life as a clinical outcome. In addition, we present the process evaluation, the costs of the intervention and the experiences of the practice members involved.

Structure of this thesis

Chapter 2 describes the testing of a model that was designed to assess which organizational determinants are related to performance of preventive activities.
Chapter 3 describes the multifaceted intervention and its process evaluation, addressing the feasibility by evaluating whether the intervention was used as planned, whether the practice team accepted the intervention and what the costs involved were.
Chapter 4 describes the effects of the intervention on the quality of organizing preventive care; in addition, we aimed to identify which practice characteristics are related to a successful change process. *Chapter 5* presents an assessment of which key characteristics of the intervention were important for attaining success of the program.
Chapter 6 describes the effects of the comprehensive intervention on clinical performance and *Chapter 7* deals with the effect of the implementation on the quality of life in patients at high cardiovascular risk.
Chapter 8 concludes the thesis with a general discussion, which is followed by summaries in English and Dutch.

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CHAPTER 2

Organizational Determinants of Cardiovascular Prevention in General Practice

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Submitted

ABSTRACT

Objective
To assess organizational determinants of prevention of cardiovascular disease.
Design
A cross-sectional study.
Setting and Subjects
130 general practices in the Netherlands. Data were collected by questionnaires.
A causal model was designed and analyzed by path analysis.
Results
Important differences between adequacy of equipment and organization in practice were found. The greatest direct effect on the preventive activity record keeping was found for the number of general practitioners in the practice. The greatest effect on appropriate follow-up of patients was found for general practitioners working part-time versus full-time. Of the practice management features, particularly teamwork proved to be important. The greatest indirect effect on both follow-up and record keeping was the number of general practitioners in the practice.
Conclusion
In exploring the organizational setting as a barrier to prevention and disease management, the designed model showed no large effects. No causal interpretations could be drawn. Despite the wide variety of practice organizational items investigated, a strong influence of non-measured variables is evident. Teamwork in the practices proved to be the most important feature of practice management. Teamwork also showed significant relations with two major preventive activities: i.e. follow-up and record keeping.

INTRODUCTION

As for many Western countries, one of the main priorities of Dutch health policy is the reinforcement of disease prevention. Cardiovascular disease represents 39% of total mortality in the Netherlands.[1] Delivery of preventive services can reduce cardiovascular morbidity and mortality.[2,3] Despite a high level of support for the importance of prevention, physician delivery of preventive services falls far below recommended levels.[4,5] The barriers to prevention can be divided into three broad categories: barriers related to the physician, to the patient and to the organizational setting within the practice.[6,7] The organizational setting requires more extensive research, in order to show how it can contribute to more effective preventive services. Although the organization of clinical practice settings is an important factor in the delivery of preventive services, few primary care clinics have any type of organized approach to providing preventive services.[8,9,10]

Systematic prevention and disease management requires adequate practice management [7,11,12] and adequate organization of medical practice [13,14]; for example, by systematic delegation of health promotion activities to the ancillary staff.[15-17] Written protocols on prevention, and the degree to which the general practitioners (GPs) and ancillary staff work as a team are also important.[12,18,19] Written protocols foster teamwork and provide a sense of direction, which should lead to better patient care and professional satisfaction.

Background characteristics of GPs and practices associated with cardiovascular prevention, may contribute substantially to variations in health care delivery [20] and are associated with adherence to preventive guidelines.[21] Quality improvement initiatives will be more efficient when we know which GPs or practices are most, or least, likely to comply with clinical prevention.

In order to improve preventive activities, we need to identify the relations between practice characteristics, practice management and preventive services. For this purpose we designed a model in which practice management features are intermediate conditions towards preventive activities. The basic hypothesis is that practice characteristics, though more easily observable in general, are causally more remote from preventive activities than practice management features and operate through them.

In the present study we divided the organizational activities related to cardiovascular preventive care into four practice management features: tasks performed by the practice assistant, presence of separate clinics, availability of instruments and materials, and teamwork within the practice.[15-17] We selected three preventive activities as indicators for quality of care: case finding, follow-up and record keeping.[15] The underlying assumption is that adequate performance of these activities will improve the quality of care provided. As an important feature of practice management, a teamwork approach can promote strong commitment toward prevention and disease management.[16, 18] Our focus on teamwork is justified by studies showing the value of unity of effort for the promotion of clinical prevention.[22-25]
The aim of the present study was to describe and test a model designed to assess which organizational determinants are related to performance of preventive activities.

MATERIAL AND METHODS

Study design

A total of 130 general practices participated in this cross-sectional study. This study served as a baseline for an intervention trial to optimize the quality of cardiovascular care. Practices were recruited via bulletins and personal mailings until a convenient number for the trial was sampled. Practices had to meet the inclusion criteria of presence of a computer system and of ancillary staff. Questionnaires were mailed to the practices to obtain information on practice characteristics and on adherence to selected practice management features. One general practitioner and one practice assistant per practice were asked to complete these questionnaires for their practice. Two weeks after the mailing, research assistants (who also performed observations during this visit) collected the questionnaires. Data were collected from November 1996 until March 1997. The practices were located in the southern half of the Netherlands. Two university departments of general practice (Rotterdam and Nijmegen) acted as research centers.

Model

We designed a model in which practice management features are intermediate conditions towards preventive activities (Figure 1).

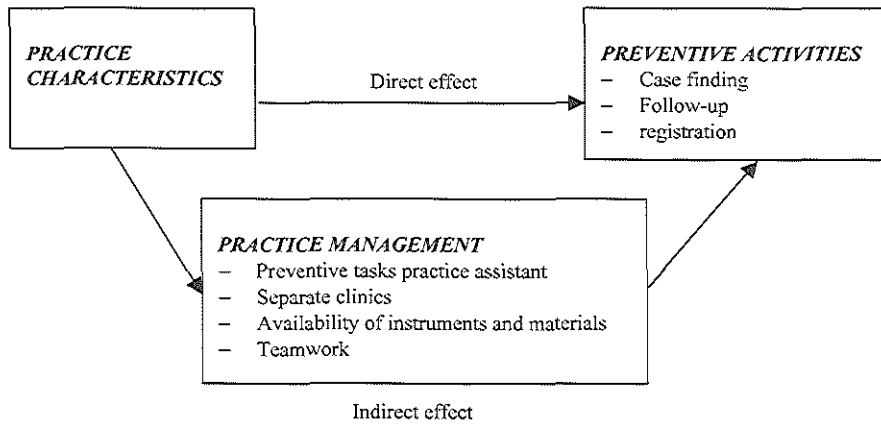

Figure 1.
Model in which practice management features are intermediate conditions towards preventive activities.

To explore which determinants lead to better performance of these preventive activities we assessed *practice characteristics* including GP and practice assistant characteristics, as well as four *practice management* items:

a. Preventive tasks performed by the practice assistant;
b. The presence of separate preventive clinics;
c. Availability of instruments and materials in the practice needed to perform preventive tasks;
d. Teamwork done in the practice.

The following *preventive activities* were distinguished:

a. Performing case finding in order to detect patients with hypertension and hypercholesterolemia in the practice;
b. Having an adequate follow-up policy for cardiovascular risk patients;
c. Having adequate record keeping for cardiovascular care.

The items for preventive and practice management activities were derived from guidelines developed by the Dutch College of General Practitioners and by consensus procedures.[26-28]

Variables

Practice characteristics

To explore which background conditions characterize a well-organized practice for cardiovascular prevention, we assessed a comprehensive set of practice characteristics (Table 1).

Practice management

The items concerning practice management are presented in Table 2 (A-D). The variables concerning the 'preventive tasks performed by the practice assistant' (Table 2A) were converted into sumscores in order to enable further analysis.

The variables concerning 'presence of separate clinics in the practice' also included the usage in the practice of a smoking cessation package (Table 2B).[29] The Minimal Intervention Strategy, aimed at cessation of smoking, has shown to be effective in changing smoking habits.[30] To systematically perform consultations with cardiovascular (risk) patients a separate clinic is recommended. We checked for separate clinics for hypertensive and diabetic patients.

The variables concerning 'availability of instruments and materials' are presented in Table 2C. Before the analysis, we also converted the variables 'instruments' and 'leaflets' to sumscores. A place to work for the practice assistant was defined as availability of a consultation room for consulting patients without being disturbed.

The variables of 'teamwork in the practice' are presented in Table 2D. The combined variable 'written protocols' was considered as a protocol on diabetes mellitus, hypertension, or detection of patients at risk.

Table 1. Practice characteristics of the participating practices (n=130).

Practice characteristic		*% practices*
1. Setting	Single-handed	61
	Duo or group/health center	39
2. List size (number of patients per full-time GP)	< 2500	30
	≥ 2500	70
3. Location (addresses per km^2)	Urban = ≥ 1000	64
	Rural = < 1000	36
4. Number of GPs	1	55
	2	34
	≥ 3	11
5. Number of practice assistants	1	29
	≥ 2	71
6. Mean age of the GPs (years)	≤ 45	59
	> 45	41
7. Mean age of the practice assistants (years)	≤ 35	60
	> 35	40
8. Mean working experience of the GPs (years)	≤ 15	55
	> 15	45
9. Mean working experience of the practice assistants (years)	≤ 10	51
	> 10	49
10. Employment of the GPs	Part-time	50
11. Employment of the practice assistants	Part-time	87
12. Gender of the GPs in the practice	Male	65
	Male and female	29
	Female	6
13. Pharmacy attached	Yes	4
14. Involved in vocational training	Yes	29
15. Certified practice assistants	Yes	85
16. Member of the Dutch College of General Practitioners	Yes	86
17. NHS patients	≤ 60 %	41

Preventive activities

The items concerning preventive activities are presented in Table 3.

For the combined variable 'appointment cards' the total number of cardiovascular risk factors and diseases for which appointment cards were given was used for analysis. We considered systematic entries (flags or ICPC-code) of hypertension, diabetes mellitus, cardiovascular history and cardiovascular family history as adequate. The diagnoses that had to be recorded were hypertension, cholesterol and diabetes mellitus. A risk profile should at least include blood pressure, smoking and the cardiovascular history and these should be recorded separately from the regular consultation notes.

Table 2. Adherence to organizational requirements for a systematic approach to cardiovascular risk reduction: practice management.

Practice management		*Percentage present (n=130)*
A. Preventive tasks performed by the practice assistant		
1. Measurements taken	- blood pressure	83
	- glucose	92
	- cholesterol	38
	- height	19
	- weight	47
	- body mass index	12
2. History questions asked	- cardiovascular history	22
	- cardiovascular family history	20
	- smoking habits	30
	- alcohol intake	11
3. Advice given on	- diet	57
	- smoking	30
	- losing weight	37
	- exercise	27
	- alcohol	13
B. Presence of separate clinics		
1. Separate clinics for	- hypertensive patients	13
	- diabetic patients	22
2. Use of smoking cessation package (MIS) *		20
C. Availability of instruments and materials		
1. Instruments:	Doppler device	40
	Cholesterolmeter	40
	Body mass table	73
	Nomogram	25
2. Leaflet**	Hypertension	89
	Cholesterol	87
	Angina Pectoris	37
	Peripheral Arterial Disease	19
	Transient Ischemic Attack	14
	Diabetes Mellitus	82
	Heart failure	33
	Smoking	83
	Diet	85
	Exercise	38
3. Adequate ancillary staff present†		65
4. Separate room for the practice assistant††		95
D. Teamwork in the practice		
1. Written protocols‡ on	- diabetes mellitus	26
	- hypertension	19
	- detecting patients at risk	4
2. Hold regular, scheduled meetings§		39

*) *The Minimal Intervention Strategy is a smoking cessation package shown to be feasible and effective*

**) *Checked by observation whether the leaflets were within reach during the consultation*

†) *Adequate ancillary staff present = 0.8 fte practice assistance per 2500 patients (norm)*

††) *A place to work for the practice assistant = a well equipped consultation room for consulting patients without being disturbed.*

‡) *Written protocols are a support for the practice assistant with her tasks and enables the GP to survey the activities done by the practice assistant.*

§) *Scheduled meetings are those scheduled in advance and in which the tasks performed by the practice assistant are evaluated.*

Table 3.
Adherence to organizational requirements for a systematic approach to cardiovascular risk reduction: preventive activities.

Preventive activities		*Percentage present (n=130)*
A. Case finding		
1. Case finding for	- hypertensive patients	47
	- hypercholesterolemic patients	86
B. Follow-up of cardiovascular risk patients		
1. Make an appointment immediately after the visit		85
2. Make an identifiable note		25
3. Provide an appointment card for patients with:	- diabetes mellitus	34
	- hypertension	31
	- cholesterol	16
	- angina pectoris	19
	- peripheral arterial disease	19
	- heart failure	19
4. Contact patients who fail to attend an appointment		57
C. Record keeping		
1. Computerized patient records*		81
2. Systematic entries concerning four risk factors**		7
3. Record risk factors separately from the regular consultation notes†		14
4. Record diagnoses separately from the regular consultation notes††		60
5. Risk profile for cardiovascular patients‡		6
6. Register preventive activities separately		40

*) *100% computerized = practices which do not use any written medical records: all patient data were entered into the computer*

**) *Systematic entries were at least necessary for hypertension, diabetes mellitus, individual and family cardiovascular history*

†) *The risk factors that had to be recorded separately were hypertension, smoking and individual cardiovascular history*

††) *The diagnoses concerned are hypertension, cholesterol and diabetes mellitus*

‡) *The risk factors at least present in a risk profile for cardiovascular patients are: blood pressure, smoking, individual history*

Analysis

Statistical analysis of the data was performed using the SPSS statistical software. The unit of analysis was the practice (n=130). If necessary, data gathered on an individual level (practice staff members) were aggregated to practice characteristics by taking the average of the individuals per practice. Adherence to the practice management items and preventive activities were assessed for each practice. The data were dichotomized: a practice either did or did not adhere.

With the variables concerning practice management factor analysis was performed to obtain four comprehensive variables, representing the four practice management items. This was also done with the variables concerning preventive activities to obtain three variables. Only 'adequate ancillary staff present' showed an opposite sign in the component matrix and had to be left out of further analysis. All calculated factor scores were used for further analysis.

In trying to disentangle the potentially complex set of relationships, we performed three path analyses with each of the three preventive activities as dependent variables. Practice management items that showed univariately a significant relation ($p<0.05$) with a dependent variable were entered into the model. The same was applied to practice characteristics that had a significant relation either with the preventive activities or with the practice management variables in the model.

Path analysis models are represented visually using one-way arrows leading from each explanatory variable to each variable, which it influences directly (Figure 1). The magnitude of the effect is reflected by the path coefficient (correlation coefficient or standardized regression coefficient). Using regression analysis both the direct effect of the practice characteristics on the preventive activities and the indirect effect via the practice management items were determined. The indirect effect was calculated by multiplying the subsequent path coefficients.

For each regression analysis the influence of non-measured variables (residual path coefficient) was calculated.[31]

RESULTS

The participating general practices were comparable to the average Dutch general practice with regard to setting, number of general practitioners and gender of the GPs in the practice; however, the general practitioners in the present study tended to be younger, with less working experience and more of the practices were located in urban areas.

Adherence to organizational aspects for cardiovascular prevention

Table 2 and 3 show the extent to which the general practices adhered to the aspects of a systematic approach to cardiovascular prevention.

Of all 130 practices, 13% had separate clinics for hypertensive patients and 22% for patients with diabetes mellitus. The Minimal Intervention Strategy was performed in 20% of the practices. Since more than 96% of the practices had a blood pressure meter, a glucose meter, weighing scales and a height measuring staff, these items are not mentioned in the table.

Written protocols were available for diabetes mellitus in 26% of the practices. A follow-up appointment immediately after the visit (Table 3B) was made in 85% of the practices; 19% of the practices used written patient records as well as electronic medical records. A risk profile with at least the risk factors blood pressure, smoking and cardiovascular history was made in 6% of the practices (Table 3C).

Relations between practice characteristics, practice management and preventive services

In univariate analyses, none of the considered practice characteristics had a significant relation with the preventive activity 'case finding', leaving only the preventive activities record keeping and follow-up as dependent variables to be used in path analysis. The practice characteristics 'setting, employment of the GPs, working experience of the GPs, mean age of the GPs, number of practice assistants, number of GPs, only female GPs in the practice, mixed sexes in the practice and certified practice assistants' showed a significant relation in univariate analyses with either 'teamwork' or the dependent variable 'follow-up'. Therefore these practice characteristics were entered into the model. For the preventive activity 'record

keeping' the practice characteristics 'pharmacy attached' and 'amount of NHS patients registered in the practice' could be added (Table 4).

Table 4.
Results of path analysis showing direct and indirect effects of practice characteristics and practice management items on record keeping and follow-up – path coefficients (correlation coefficient) mentioned.

	RECORD KEEPING		*FOLLOW- UP*	
Practice characteristics	**Indirect effect (through teamwork)**	**Direct effect**	**Indirect effect (through teamwork)**	**Direct effect**
Setting 1=solo, 2=non solo	0.03	-0.26	0.02	0.02
Employment of GPs 1=full-time, 2=part-time	-0.004	-0.11	-0.01	0.20
Working experience of the GPs 1≤15 yr, 2>15yr	0.01	0.29*	0.01	-0.05
Age of the GPs 1≤45yr, 2>45yr	-0.04	-0.21	-0.04	0.19
Number of practice assistants 1=one, 2=more	0.02	0.02	0.02	0.06
Number of GPs 1=one, 2=two, 3=three or more	0.06	0.30	0.08	-0.12
Female GPs in the practice 1=mixed sexes/only male, 2=female	0.03	0.22*	0.03	0.12
Mixed sexes in the practice 1=mixed sexes/only female, 2=male	-0.03	-0.02	-0.03	-0.02
Certified practice assistant 0=no, 1=yes	0.02	-0.03	0.03	0.07
Pharmacy attached 0=no, 1=yes	0.02	0.16		
Amount of NHS patients 1<60%, 2≥60%	0.02	0.15		
Practice management				
Teamwork	x	0.20*	x	0.21*

* significant ($p<0.05$)

In multivariate analysis, practices where only women GPs worked and practices where GPs worked with a working experience less than 15 years showed a significant relation with the preventive activity 'record keeping'. None of the practice characteristics showed a significant relation in multivariate analysis with the preventive activity 'follow-up'.

The magnitude of the direct effect is shown in Table 4. The higher the path coefficient, the better record keeping or follow-up is performed. It is seen that the practice characteristic 'number of general practitioners in the practice' has the greatest direct effect on the preventive activity 'record keeping'. The greatest effect on 'follow-up' is found for part-time working GPs.

Practice management and preventive activities

Of the practice management features, only teamwork showed a significant relation with both record keeping and follow-up in univariate analysis, hence we performed path analysis with teamwork as intermediate variable. Table 4 also presents the indirect effects (via teamwork). The greater this effect, the more the practice characteristic is explanatory to the performance of record keeping or follow-up. Number of general practitioners in the practice has the greatest indirect effect on both follow-up and record keeping through teamwork. Teamwork showed no relation with the preventive activity 'case finding'.

For record keeping the largest difference between indirect effect and direct effect is shown by the variable 'working experience by the general practitioner'. For follow-up this was the variable 'number of GPs working in the practice'.

The influence of non-measured variables (residual path coefficient) was 0.9 or more in every step of the path analysis.

DISCUSSION

In order to explore the practice organizational setting as a barrier to prevention and disease management, we tried to conceptualize a causal model with observational variables; only small effects were found. Although we selected a wide variety of practice characteristics and practice management items, there remains a strong

influence of variables that were not measured. We conclude that with the chosen model the found relations are too small for causal interpretations.

Although several practice characteristics showed strong crude associations with preventive activities, the number of important predictors was reduced after simultaneous adjustment in multivariate analysis, because of associations between practice characteristics. The remaining preventive activities were 'record keeping' and 'follow-up'. GPs with a working experience less than 15 years and practices where only female GPs worked, registered risk factors or diseases significantly better. It was earlier reported that female GPs are more likely to include preventive activities in their clinical practice.[21] Other studies have shown that younger physicians are more likely to comply with recommendations on preventive care.[32] In the present study we found no direct relation with age of the GP, although the GPs that participated were younger than the average Dutch GP. It is reported that practices with a pharmacy attached will guard the surveillance of patients through the medication used [33] that single-handed practices are less likely to be running health promotion clinics.[34] Our study did not confirm these two latter findings.

We found that 'teamwork in the practice' is a very important feature of practice management. Teamwork showed significant relations with two of the preventive activities: follow-up and record keeping. This may be explained by the fact that preventive activities can only be performed effectively when the practice staff members communicate about their activities and have written protocols on their actions.[18] A well-equipped practice is apparently not sufficient to perform preventive activities; practice staff need to work together in order to implement preventive care efficiently. Although many others have stressed the importance of teamwork,[22-25] it has not been conceptualized before as an intermediate step in a causal model. We found that the presence of three or more GPs in a practice is related to good teamwork, which is associated with better performance of record keeping and follow-up. However, the direct effect of the practice characteristics on the preventive activities was stronger than the indirect effect through teamwork.

Our results on adherence to selected aspects of the organization of preventive care show considerable variation in the degree to which practices have integrated preventive care into daily routine. Considering that data were collected from practices willing to participate in a future study to implement prevention of cardiovascular disease in general practice, we may have selected relatively well-motivated practices.

This implies that, overall, an even higher proportion of practices may not have an adequate practice organization to carry out prevention.

Cardiovascular disease prevention and disease management will remain a heavy burden for the general practitioner, but if teamwork is performed in the practice, this is a favorable condition for two major preventive activities: follow-up and record keeping. The emphasis in education is often aimed at changing knowledge and skills in order to change behaviour[12]; the question is, whether this is an effective approach. Influence on collaboration between practice staff could contribute more to changing cardiovascular preventive behavior in general practice.

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CHAPTER 3

Process Evaluation of a Multifaceted Intervention to Improve Cardiovascular Disease Prevention in General Practice

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Submitted

ABSTRACT

Objectives
Process evaluation of a multifaceted intervention to improve cardiovascular and diabetes care in general practice.
Study design
Intervention study: process evaluation.
Population
Outreach visitors supported the 62 intervention practices.
Outcomes measured
The feasibility of the intervention was addressed by evaluating whether the intervention program was performed as planned and the extent to which it was accepted by the practice team. In addition, the costs of the intervention program were determined.
Results
The intervention was largely carried out as planned, although the intervention period had to be extended by three months. Of the 18 topics that could be addressed during the intervention period 12 (mean) were addressed. The number of outreach visits per practice was 15.2 (mean) and each visits lasted about one hour. Most practice members (i.e. GPs and practice assistants) endorsed both the key recommendations for clinical decision-making and cardiovascular risk profiling.
Of all GPs, the majority (range 63%-98%) agreed with the guidelines for clinical decision-making, and 29%-97% had a positive opinion about the guidelines for practice organization. GPs and practice assistants considered that the outreach visitor had sufficient knowledge and skills to support them in changing the practice organization. GPs were less positive about the outreach visitor's knowledge and skills in optimizing clinical decision-making; however 78% believed that the outreach visitor contributed to effecting change in their clinical decision-making. Finally, the total costs of the intervention per practice were 4317 Euro.
Conclusions
This process evaluation has demonstrated that the intervention was mainly carried out as planned and achieved a high satisfaction rating from the participating practice members.

INTRODUCTION

It is generally accepted that the general practitioner (GP) plays a pivotal role in prevention, early detection, treatment and surveillance of patients with (a high risk of) cardiovascular problems; however, there is still substantial room for improvement.[1-5] Because multifaceted interventions are more effective than single interventions,[6-9] we previously conducted a trial to assess to what extent improvement of the management of preventive care for patients at high cardiovascular risk in general practice can be achieved through a multifaceted intervention by outreach visitors (OVs).[10] The intervention concerned a comprehensive program on cardiovascular and diabetes care in general practice. For that program, the support of the OV was practical and tailored to the needs and preferences of the individual practice.

Although the effectiveness of the OV approach has been proven earlier,[11-16] detailed evaluation of the change process itself is scarce. For a better understanding of the determinants of successful change, it is important to look inside the 'black box' of the intervention.[17] To this end, a process evaluation allows to determine whether the intervention was actually carried out as planned.

Implementing change in professional performance is a complex process which is influenced by (amongst others) acceptance of the intervention by its participants. Assessment of these personal experiences can serve as a measure of the success of the intervention; e.g. potential barriers to change may emerge, which then can later be removed and thus improve the acceptance of future implementation programs.

Another element of process evaluation is the determination of the costs of the intervention, which can provide an indication of the relative efficiency of the intervention.[18]

Our earlier outcome evaluation of program revealed significant changes in many aspects of organizing preventive care.[10] The current study complements that outcome evaluation by giving an accurate representation of the multifaceted intervention. We focus on its process evaluation, the feasibility of delivering the intervention, its acceptability to the care providers and, finally, the costs of the intervention.

METHODS

Setting

This observational study was carried out in 62 intervention practices, whereas our earlier mentioned randomized controlled trial also included 62 control practices.[10] All participating general practices were situated in the southern part of the Netherlands. Outreach visitors (OVs) supported all 62 intervention practices; baseline and post-intervention measurements were performed.

Outreach visitors

The intervention was carried out by five OVs with a background as practice nurse who received specific training (including pilot practices) for their OV task. During the intervention period the researchers (BF, CL) gave continuous guidance and evaluated the practice progress every three months. Problems and solutions were discussed and the OV's satisfaction with the progress of the practice was monitored.

The OVs were not involved in patient care but were guests in the practices providing support to the practice team (i.e. GPs and practice assistants; PA). In the Netherlands PAs can be involved in administrative tasks as well as specific parts of patient care.

Aim of the project

The project (CARPE: CARdiovascular risk reduction in Primary carE) aimed to implement a comprehensive program on cardiovascular and diabetes care for high-risk patients in general practice. Patients with hypertension, diabetes, hypercholesterolemia or cardiovascular disease were considered patients at high-risk of a cardiovascular disease event.

The program's starting point was a detailed description of practice organization and clinical decision-making in an 'ideal' practice. This included:

- Availability of optimal computer facilities, instruments and materials;
- Performing adequate risk profiling of high-risk patients;
- Organizing separate preventive clinics for patients with diabetes or hypertension;
- Availability of a system for monitoring follow-up;
- Intense involvement of staff in preventive tasks;
- Insurance of quality by means of protocols and regular staff meetings;
- Performing clinical decision-making according to current evidence-based guidelines;

- Knowledge and skills of GPs for appropriate performance of all stages and aspects of consultations with high-risk patients: diagnosis, assessment and evaluation of additional risk factors, patient counseling and education, pharmacological treatment, follow-up, and referral;
- Well trained ancillary staff members to perform their part of patient care.

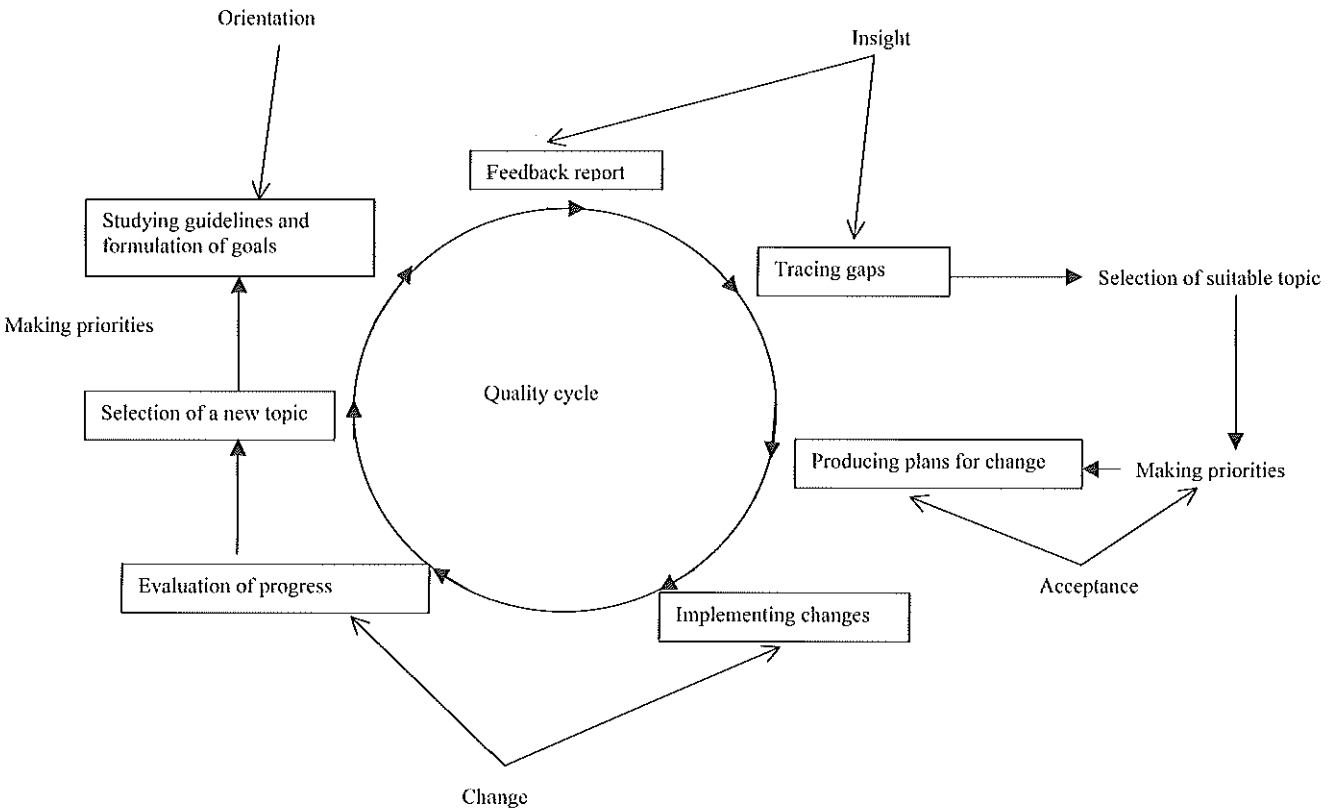
The description of such an 'ideal practice' was derived from combining the national evidence-based guidelines issued by the Dutch College of General Practitioners and consensus procedures.[2,13,19]

Implementation strategy

A multifaceted intervention was developed and tested in pilot practices. The multifaceted intervention included the provision of information, feedback, educational materials, and practical tools by trained OVs during practice visits. The OVs focused on implementing guidelines for organizing and performing cardiovascular preventive activities. Per full-time OV, 20 practices could be supported. The practices were to be visited 15 times during a period of 18 months; the first 8 visits were aimed at optimizing the organization of prevention in the practice whereas the last 7 visits focused on clinical decision-making.

The intervention strategy was standardized with regard to the period of exposure, the structure and the content of the support. Checklists were used to guide the course of the visits. Table 1 lists the 18 topics that should be addressed during the intervention. Apart from the general topics, the OV followed the subsequent steps of a theoretical model of change, starting at orientation (Figure 1). Through a cyclic process, OV and practice team analyzed the performance, selected topics that required attention, introduced plans for change, and evaluated progress. Within each step of the process, specific problems and barriers were identified and addressed.[6]

Figure 1. Quality cycle



Practice organization

At baseline, data were gathered on the performance of the prevention of cardiovascular disease by comparing the actual practice organization with the 'ideal' practice. These data, collected in a feedback report, were sent to the general practice by mail. The OV discussed this feedback report with the practice team, in order to give them more insight in their situation and to create awareness of gaps/shortcomings in actual performance. Subsequently, the practice team (supported by the OV) drew up a list of gaps and planned changes. Then the practice team prioritized the aspects of care needing attention; this list of priorities was used as guidance during the intervention. The OV wrote a specific implementation plan for each gap selected; this plan outlined the changes considered necessary to achieve an optimal level of the chosen topic, as well as the expected time needed to achieve this.

Each practice was offered a manual with standardized instructions, protocols and materials. If necessary, information and education was given to improve knowledge, skills or attitudes. The OV supported the practice during the implementation of the planned changes and discussed progress and barriers, so that changes could be consolidated. It was the intention that during the intervention all gaps should be discussed. Every practice member involved in the topics to be discussed was supposed to be present at these visits, which were planned to last one hour.

Clinical decision-making

Besides the practice organization issues, the OV addressed clinical decision-making of the GP for patients at high cardiovascular risk. During baseline measurements, data were gathered on actual clinical decision-making related to cardiovascular diseases and risks. From the eighth visit onward, before each visit, all GPs in the practice received a feedback report on the specific medical condition to be addressed during the visit. The feedback reports were based on the baseline performance data and informed the GPs about their current clinical decision-making in relation to the key recommendations from Dutch guidelines. During the visit, the OV and the GPs discussed the content of the feedback reports, prioritized specific aspects of decision-making for improvement and made plans for change. The feedback was divided in individual performance (on hypertension, hypercholesterolemia and diabetes mellitus) and group performance of all practices (on heart failure, angina pectoris, transient ischemic attack and peripheral arterial disease). The OV provided guidance, support, and educational materials to

achieve improvement. As part of a follow-up visit, the OV and the GPs discussed the extent to which the plans were carried out and which aspects of decision making needed further attention.

It was the intention that on the tenth visit the OV evaluated the progress of the practice; for this a form was used which included questions about the practice members' satisfaction with the project in general, the progress and barriers, etc. During the final visit the OV evaluated the entire intervention period with the practice members.

Measurements and variables

During the intervention the OV reported details of each visit on contact forms. At each visit the OV asked the participating practice members about the amount of time devoted to the project; the GPs and PAs registered the time spent on preparing for the visit and the visit itself.

After post-intervention measurements, questionnaires were sent to the participating GPs and PAs to assess their experiences with the project. The first part of the questionnaire addressed attributes of guidelines, knowledge, skills and attitudes, as well as factors in the social, organizational, legal-economic setting. The second part concerned their experiences with the program itself. Answers could be given on a five-point Likert scale (strongly disagree, disagree, neutral, agree and strongly agree); when the latter two were scored, the answer was considered positive.

Analysis

Descriptive statistical analysis of the data was performed using the SPSS statistical software. The unit of analysis was the practice (n=62). If necessary, data gathered on an individual level (practice members) were aggregated by taking the average of all individuals in a practice.

In the analysis of the questionnaires addressing the experiences of participants with the implementation program, the individual care provider was the unit of analysis. For each of the participating practices, the cost of performing the intervention was calculated by calculating the time spent by the OV and each practice member involved.

RESULTS

Withdrawals

Four general practices discontinued collaboration during the intervention (after 4, 5, 6 and 8 visits, respectively): one because of illness of the GP, one considered the intervention to be too burdensome, and two practices due to changes in personnel.

Course of the intervention

Table 1 shows the percentage of practices that addressed the itemized topics during the intervention. Apart from the general topics and feedback, the topics 'key recommendations for clinical decision-making' received the most attention (57 practices; 92%), whereas 'regular, scheduled meetings' were least worked upon (9 practices; 15%).

It took 21 months to carry out the intervention. Table 2 shows, per practice, that the number of outreach visits was (mean) 15.2 lasting (mean) 57.5 minutes each. Apart from attending the outreach visits, the PAs invested far less time in the project than the GPs.

Of the 18 topics that could be addressed during the intervention period (Table 1), 12 were actually addressed. Of all practices, 69% had their first evaluation during the tenth visit.

Acceptance of the intervention by practice members

In total, 222 questionnaires were sent to the practices. Of these, 199 questionnaires were returned (90%), of which 182 (82%) were useful for analyses (85 from GPs and 97 from PAs).

Of all GPs, the level of agreement with the guidelines for clinical decision-making ranged from 63%-98% (Table 3), whereas their positive opinion about the guidelines for practice organization ranged from 29%-97%. The offered information and the feedback report on practice organization were read by more than 90% of the GPs and PAs. The feedback reports on clinical decision-making subjects were also read by more than 90% of the GPs, but by fewer PAs (71%-73%). The group performance feedback on heart failure, angina pectoris, transient ischemic attack and peripheral arterial disease was considered by the GPs to be less helpful in implementing change

in their performance than the individual feedback on hypertension, hypercholesterolemia and diabetes mellitus (53% vs. 76%, respectively).

The opinion of GPs and PAs about the OVs knowledge, skills and performance was positive. More PAs than GPs complained about the amount of time the intervention took for both practice organization (51% vs. 29%, respectively) and clinical decision-making (59% vs. 27%, respectively).

Table 1. Topics addressed in the intervention (n=62 practices).

Topic of the intervention		***Percentage of practices that addressed the topic***
General	1. Explanation of the project	100
	2. Selection of priorities	100
	3. Implementation plan	100
	4. Evaluation	94
Practice organization	5. Feedback on practice organization	100
	6. Delegation of tasks to the practice assistant	44
	7. Separate clinics	67
	8. Instruments and materials	89
	9. Stop smoking program	60
	10. Cholesterol flow chart	18
	11. Written protocols	21
	12. Regular, scheduled meetings	15
	13. Recording of risk factors	29
	14. Cardiovascular risk profile	90
	15. Follow-up	68
	16. Case-finding	24
Clinical decision-making	17. Feedback on clinical decision making	95
	-1 hypertension	
	-2 diabetes mellitus	
	-3 hypercholesterolemia	
	-4 heart failure	
	-5 angina pectoris	
	-6 transient ischemic attack	
	-7 peripheral arterial disease	
	18. Key recommendations of the guidelines	92

Table 2.
Overview of quantitative aspects of the intervention per practice (n=62 practices).

Aspect of the intervention	*Mean*	*Min.*	*Max.*	*Standard deviation*
- Number of visits	15.2	4.0	17.0	2.6
- Duration of visits (min)	57.5	10.9	86.8	14.3
- Preparation time for the visits (min)	81.2	18.4	134.2	22.7
- Time to work out the visits (min)	25.0	6.3	48.7	8.7
- Waiting time in the practices (min)	6.4	1.0	18.9	4.1
- Time invested by GPs (hours)	18.2	1.0	85.0	12.9
- Time invested by PAs (hours)	9.9	0.0	84.0	11.7
- Number of addressed topics	12.1	4.0	17.0	2.6
- Number of visits until addressing the first topic	3.2	3.0	5.0	0.5
- Number of visits to discuss feedback reports	4.6	1.0	9.0	2.0

Costs of practice visits

The OV visited 62 intervention practices (mean) 15.2 times including practices that withdrew. The number of visits per practice ranged from (minimum) 4 to (maximum) 17 visits. The number of GPs participating in these visits ranged from 1 to 4 (mean 1.52), and the number of PAs ranged from 0 to 5 (mean 1.94).

Table 4 itemizes the costs of the intervention. The mean total cost of the intervention per practice was 4317 Euro.

Tables 3 A-D .
Experiences of the general practitioners (GPs) and practice assistants (PA) with the intervention.

A. Attributes of guidelines	*%*	*Positive opinion*
Content of guidelines for clinical decision-making		
1. To diagnose hypertension, it is necessary to measure the blood pressure in *3 to 5 follow-up* visits.	GP	95
2. In patients with peripheral arterial disease it is necessary to check risk factors for cardiovascular disease *annually*.	GP	87
3. At check-ups of patients with diabetes mellitus it is necessary to ask *explicitly* about *increase or loss* of bodyweight and *problems with the diet*.	GP	98
4. When an elevated cholesterol level is found, it is necessary to give *detailed* information about the *meaning* of elevated cholesterol levels and about its *treatment*.	GP	87
When pharmacological treatment of hypertension is suboptimal *(>160mmHg and/or >90mmHG)* the medication should be adjusted.	GP	73
5. In patients with heart failure the *electrolytes and the creatinine level* should be checked once every 6 months.	GP	63
6. In patients with a high risk for cardiovascular disease, the blood pressure has to be measured *annually*.	GP	84
7. Patients with angina pectoris have to be referred to the specialist in case of:	GP	77
- complaints at rest or complaints that do not decrease within 15 minutes at rest or after treatment with nitrates.		
- unstable angina pectoris.		
- complaints that give huge impairments in daily life in spite of treatment with combination therapy.		
The general practitioner has to treat *all other* patients with angina pectoris himself or herself.		
Content of the guidelines for practice organization		
1. Patient' leaflets about risk factors for cardiovascular disease have to be available in the room where the consultation takes place.	GP	57
2. Separate clinics are necessary for adequate preventive care in patients with a high risk of cardiovascular disease.	GP	29
3. For adequate preventive care in patients with a high risk of cardiovascular disease, it is necessary to delegate tasks to the practice nurse.	GP	71
4. Agreements about delegated medical tasks from the general practitioner to the practice nurse should be written down.	GP	85
5. Patients that do not comply with their follow-up appointment should be contacted.	GP	47
6. In patients with a high risk of cardiovascular disease, a total risk profile should be filled out.	GP	97
7. The cardiovascular risk profile of each patient with a high risk of cardiovascular disease should be updated annually.	GP	87

B. General judgments about other attributes of the project guidelines in general		
1. As far as I can judge now, these guidelines are scientifically well-grounded.	GP	91
2. These guidelines help me in taking a closer look at my patient care.	GP	98
Characteristics of the individual clinician		
1. I lack certain knowledge to apply these guidelines well.	GP	6
2. I lack certain skills to apply these guidelines well.	GP	2
3. I have difficulty to change my old routines.	GP	52
Characteristics of the environment of the individual clinician		
1. Working according to these guidelines demands a additional financial allowance.	GP	40
2. Working according to these guidelines takes too much time.	GP	71

C. Appraisal of the different feedback reports		
1. Did you read the offered chapters of the written material?	GP	93
	PA	90
2. Did you read the feedback report on the practice organization?	GP	92
	PA	90
3. Did you read the feedback report on your hypertension, hypercholesterolemia and diabetes consultations?	GP	94 (all)
	PA	71- 73
4. Did you read the feedback report on your heart failure, angina pectoris, TIA and peripheral arterial disease consultations?	GP	92
		91
		89
		91
5. The feedback report on the practice organization helped me gain insight in our practice organization.	GP	71
	PA	90
6. The feedback report on our practice organization contributed to a change in our practic organization.	GP	75
	PA	64
7. The feedback reports on my consultations with patients with hypertension, hypercholesterolemia and diabetes helped me gain insight in my professional performance.	GP	81
	PA	76
8. The feedback reports on my consultations with patients with heart failure, angina pectoris, TIA and PAV, helped me gain insight in my professional performance.	GP	53
9. The feedback reports on my consultations with patients with hypertension, hypercholesterolemia and diabetes helped me to change my professional performance.	GP	76
	PA	70
10. The feedback reports on my consultations with patients with heart failure, angina pectoris, TIA and PAV, helped me to change my professional performance	GP	53

D. Appraisal of the outreach visitor		
1. The OV had *enough knowledge* to support me to change our practice organization.	GP	89
	PA	96
2. The OV had *enough skills* to support me changing our practice organization.	GP	83
	PA	92
3. The visits of the OV to support the change in our practice organization took too much time.	GP	29
	PA	51
4. The visits of the OV contributed to a change in our practice organization.	GP	88
	PA	79
5. The OV had *enough knowledge* to support me to change my professional performance	GP	65
	PA	87
6. The OV had *enough skills to* support me to change my professional performance.	GP	66
	PA	83
7. The visits of the OV to support the change in my professional performance took too much time.	GP	27
	PA	59
8. The visits of the OV contributed to a change in my professional performance.	GP	78
	PA	73

Table 4. Costs of the intervention (n=62 practices).

Costs of the intervention		*Mean costs per practice (Euros)*
- Outreach visitor	- Costs for presence at a practice visit	276
	- Costs for preparation time, traveling time and time to work out the visit	935
	Subtotal time costs outreach visitor	1211
- Practice assistant	- Costs for presence at a practice visit	296
	- Costs for extra time (reading of reports, etc.)	271
	Subtotal time costs PA	567
- General practitioner	- Costs for presence at a practice visit	955
	- Costs for extra time (reading of reports etc.)	1245
	Subtotal time costs GP	2200
	Subtotal all time costs	3978
Traveling expenses outreach visitor	Public transport, costs of fuel, etc.	339
	Total	4317

DISCUSSION

The principles of educational visiting have been well formulated,[16] but little has been published about the actual process. The present study on the process evaluation of a project aimed to implement a comprehensive program on cardiovascular and diabetes care for high-risk patients in general practice has shown that the intervention was carried out as planned and with high satisfaction ratings reported by the participating practice members.

The multifaceted intervention was standardized in order to limit variation in the delivery of the intervention. This standardization was achieved for number and duration of visits, going from general topics to practice organization to clinical decision making, evaluation on the tenth visit, discussion of feedback reports and use of educational materials. The period of exposure (18 months) had to be extended to 21

months for practical reasons (e.g. summer vacations, etc.). Of the 18 topics that could be addressed during the intervention, the mean number of addressed topics was 12. We considered the intervention to be feasible and, with some minor adjustments, it was carried out as planned.

A number of recommendations and lessons can, however, be learned from this process evaluation. Outreach visitors were accepted to facilitate change in both practice organization and clinical decision-making. Most staff members were positive about the knowledge and capabilities of the OV with regard to practice organization and (to slightly less extent) their role in addressing clinical decision-making. As shown earlier,[20] the GPs did not regard the visits as an intrusion but as a service; they were prepared to read the material and talk about their performance.

The regular visits by the OV were evaluated as pleasant and indispensable for progress toward changing practice habits. Most practice members were pleased with the face-to-face visits; the OV was considered the 'big stick' that encouraged the practice employees to carry out the intervention.

Regular evaluations were considered positive; the practice team had the opportunity to express their feelings and ideas about different aspects of the project. The OV could use the midterm evaluations to adapt the remainder of the intervention. The a priori timing of the evaluations turned out to be realizable.

Overall, participation in the implementation program was good. Interventions that require the active participation of health professionals in change generally require a high degree of motivation from the practice team if they are to have an impact.[21] Regarding the feedback reports, the practice members indicated that they were useful, acceptable and effective in changing their practice organization and clinical decision-making. Individual feedback was considered more effective than group feedback.

The major obstacles experienced were time constraints and the discrepancy between the predicted amount of work and the actual amount. PAs indicated more often than GPs that the visits of the OV took too much time. This might be because the tasks of some PAs were extended due to the intervention (e.g. making protocols, organizing separate clinics and other preventive activities). In addition, it may be more difficult for a PA to be aware of the benefits of prevention over a longer period of time.

It is difficult to generalize about the costs of the intervention. For an individual practice the costs may seem unacceptably high; although any effort toward quality improvement will generate some costs. For instance, by participating in the project the GPs received 6

hours of accreditation (CME approval), whereas in other circumstances they would have to pay to obtain such accreditation. From a societal point of view, however, costs may well be counterbalanced by long-term revenues, in terms of years and quality of life gained. Limited duration of the project does not allow measuring health outcomes; therefore cost-effectiveness ratios should be subject of future evaluations of the project.
Some limitations to the process evaluation methods should be mentioned. First, all practices volunteered to participate and therefore may have been more motived to adopt the intervention. This type of limitation tends to be inevitable in studies addressing change in professional behavior, as willingness to change is a prerequisite to participate. Second, a bias toward social desirability may have influenced the answers concerning satisfaction with the intervention. Withdrawal from the intervention was a minor problem only.
Based on the results of this study, future support programs can be developed. We found that a one-hour visit could easily be integrated in practice routine. Earlier studies reported that a higher frequency and intensity of the visits.[13,14,22] To determine the minimum number of visits to achieve a positive outcome requires studies with a different design.
In conclusion, our earlier outcome evaluation showed a successful intervention in changing the management of preventive care. This current process evaluation addressed the feasibility of the multifaceted intervention. It was found that the intervention could be carried out as planned and, moreover, achieved high satisfaction ratings from the participating practice members. Whether the costs of the intervention are in fact worth the effort should be the subject of future evaluations of the project.

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CHAPTER 4

Improving Quality of Organizing Cardiovascular Preventive Care in General Practice by Outreach Visitors: A Randomized Controlled Trial

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ABSTRACT

Background

Adequate care for patients with cardiovascular risks requires an adequate practice organization. Educational outreach visits are a promising approach to modify professional behavior.

We aimed to assess whether the quality of cardiovascular preventive care in general practice can be improved through a comprehensive intervention implemented by an educational outreach visitor.

Methods

After baseline measurements general practices (n=124) in the southern half of the Netherlands were randomly allocated to either intervention or control group. The intervention, based on the educational outreach model, comprised of 15 practice visits over a period of 21 months and addressed a large number of issues around task delegation, availability of instruments and patient leaflets, record keeping and follow-up routines. Twenty-one months after the start of the intervention, post-intervention measurements were performed.

The difference between ideal and actual practice in each aspect of organizing preventive care was defined as a deficiency score. Primary outcome measure was the difference in deficiency scores before and after the intervention.

Results

All practices completed both baseline and post-intervention measurements. The difference in change between intervention and control group adjusted for baseline, was statistically significant ($p<0.001$) for each aspect of organizing preventive care. The largest absolute improvement was found for the number of preventive tasks performed by the practice assistant.

Conclusions

This study showed that a comprehensive intervention implemented by outreach visitors was effective in improving organization of cardiovascular preventive care in general practice.

INTRODUCTION

Cardiovascular diseases are among the most prevalent health problems in general practice; a major part of all chronic problems are of cardiovascular origin.[1] Priority should be given to implementing preventive measures in patients with established coronary heart disease.[2] It is generally accepted that the general practitioner (GP) plays a pivotal role in prevention, early detection, treatment and surveillance of patients with (a high-risk of) cardiovascular problems; however general practice is not yet performing these tasks satisfactorily.[3-5] A substantial proportion of high-risk patients remain unrecognized and those being treated receive sub-optimal care.[6] High quality of care for patients with cardiovascular risks or problems requires an adequate practice organization[7-9] and practice support mechanisms may produce sustained improvements in physician behavior.[10-12]

Well-planned strategies, composed of a variety of interventions and methods, have been effective in achieving lasting improvements in medical practice.[13-16] Educational outreach visits (providing individual instruction at the physician's surgery) are a promising approach to modify professional behavior[17] and to improve professional practices. Outreach visits are effective in improving record keeping and cardiovascular preventive activities,[18,19] optimizing the organization of services,[20] prescribing behavior [21,22] and in cancer early detection and preventive services.[23] None of these latter studies, however, included simultaneous interventions targeting different aspects of organizing preventive care.

The present study investigated an educational outreach strategy designed to improve major aspects of organizing prevention of cardiovascular disease in general practice. The strategy was based on a theoretical model of change distinguishing the subsequent steps of orientation, insight, acceptance and change.[13]

We believe there may be an important role for outreach visitors (facilitators) in implementing such a comprehensive package of disease management for high-risk cardiovascular patients [25], but the effectiveness of such an intervention has not yet been evaluated in a randomized controlled trial. We aimed to assess to what extent improvement of the quality of organizing preventive care for patients with cardiovascular risks or problems in general practice can be achieved through a comprehensive intervention by trained outreach visitors. In addition, we aimed to identify practice characteristics related to a successful intervention.

METHODS

General practice in the Netherlands has many similarities to the United Kingdom. Important difference are that the number of GPs per practice is much lower than in the UK, with many practices run by a single GP, and the size of ancillary staff is much smaller (on average less than one full time ancillary staff member per full time GP). This staff, called practice assistants, usually combines the tasks of a receptionist with some tasks of the British practice nurse. Most Dutch practice assistants do not have a nursing background.

Design and practices

A randomized controlled trial was performed in the southern half of the Netherlands. Practices were invited by letter and via regional GP bulletins to participate in the study. Inclusion criteria were: presence of a computer system (considered necessary for adequate record keeping and follow-up), ancillary staff present and no major changes planned during the course of the project. After baseline measurements 124 general practices were randomly allocated to either intervention group or control group. The study was powered to detect a difference of 5% between baseline and post-intervention measurements in the experimental practices as well as a difference of 5% between experimental and control practices (alpha = 0.05, beta = 0.10). Practices were numbered and the person responsible for the randomization process was blinded for the practices' identity, to ensure allocation concealment. We stratified (block size: four) with regard to practice type (single-handed versus partnership). After 21 months of intervention, post-intervention measurements were performed. Data were collected from November 1996 until February 1999.

Intervention

Box 1 provides a general description of the entire intervention, which comprised both organization of prevention and clinical decision-making. The latter is subject of a separate paper; here we focus on aspects of practice organization. We considered six aspects relevant for the organization of preventive care in general practice. Some of these can be seen as *conditions* needed to perform adequate disease management: availability of instruments and materials, involvement of the practice assistant in preventive tasks,[11,18] presence of separate preventive clinics and teamwork within the

practice.[8,25,26] Two other groups of items can be seen as process indicators of actual preventive care, addressing record keeping and follow-up routines.

From the total 15 visits, the first eight visits of the intervention were dedicated to the organization of preventive care. Although the emphasis changed towards clinical decision making from the ninth visit onward, aspects of organization of preventive care were evaluated until the end of the intervention.

For each aspect the outreach visitors followed the subsequent steps of a theoretical model of change (orientation, insight, acceptance and change).[13] The intervention design allowed practice members to draw up and prioritize their own list of gaps and planned changes, as recommended for continuous quality improvement. This list was used as guidance throughout the intervention period.

Measurements and variables

Data ware collected by questionnaire and through study observers, at baseline and after 21 months. Information on practice characteristics was collected by questionnaire at baseline. One GP and one practice assistant per practice completed these questionnaires. Answers to questions about the availability of instruments and materials were checked in the practice by a study observer.

The control practices received baseline and post-intervention measurements simultaneously with the intervention group, but did not receive any stimuli between randomization and post-intervention measurements.

Box 1
General description of the intervention

Aim
The project (CARPE: CARdiovascular risk reduction in Primary carE) aimed to implement a comprehensive program on cardiovascular and diabetes care in general practice. The program content was based on national guidelines (Dutch College of General Practitioners) and consensus procedures,[13] it comprised a detailed description of practice organization and clinical decision-making in an 'ideal' practice.

The 'ideal' practice is well equipped with optimal computer facilities, materials and leaflets. Risk profiling of high-risk patients and separate preventive clinics for patients with diabetes or hypertension are all well organized. There is a system for monitoring follow-up. Staff is intensively involved in preventive tasks and quality is insured by means of protocols and regular staff meetings. Clinical decision-making is according to latest evidence-based guidelines. The GPs have the knowledge and skills for appropriate performance of all stages and aspects of consultations with high-risk patients: diagnosis, assessment and evaluation of additional risk factors, counseling and education, pharmacological treatment, follow-up, and referral. Ancillary staff members are well trained to perform their part of patient care.

Implementation strategy
Outreach visitors supported GPs and their staff to implement a comprehensive program on cardiovascular and diabetes care in a schedule of 15 outreach visits per practice in a period of 21 months. Most visitors were former practice assistants and experienced in performing outreach visits. For this study, they were specially trained in national guidelines on cardiovascular and diabetes care for general practice, the concept of the 'ideal' practice, and the methods and materials of the intervention. The visitors facilitated implementation of the program; they were not involved in patient care.
The protocol of the visits was highly structured to limit variation. In the first eight visits the intervention focused on practice organization and the last seven visits on clinical decision-making. Subsequent steps in a theoretical model of change were used to achieve improvement. These steps are: orientation, insight, acceptance and change.
Individualized feedback reports, including the key recommendations of the national guidelines and the consensus procedures, were produced to provide orientation and insight. The feedback, based on baseline data, informed the GPs and their staff about their actual practice organization and daily clinical decision-making in relation to the key recommendations. The feedback report was also intended to create awareness of (gaps in) actual performance in comparison to the 'ideal' practice. Acceptance was aimed at by supporting the practice members to draw up and prioritize a list with gaps and planned changes targeted to their personal circumstances.
Throughout the visits the outreach visitors provided guidance, advice, training and educational materials for each gap to reach the goals and achieve changes. Progress was evaluated regularly. During the intervention all gaps in both practice organization and clinical decision-making were intended to be discussed.

Analysis

The unit of analysis was the practice. In organizing prevention of cardiovascular disease, the proportion of practices that adhered to each aspect was assessed. Data on outcomes were dichotomized. For each item a score indicating non-adherence (0) or adherence (1) was given and changes from baseline were tested with Mann-Whitney U tests, because percentage data are usually not distributed normally. Sumscores were made, composed of the scores of all individual items for each of the six aspects of preventive care, both at baseline and after the intervention. These changes were tested using T-tests. In order to satisfy the assumptions of the linear model, and because practices with high baseline values have less room for improvement, we computed for each of the six aspects of preventive care a 'deficiency score', i.e. logarithm of the difference between the maximum possible score minus the actual score, both at baseline and after the intervention period. The main outcome measure was the difference between the deficiency scores in each aspect of organizing preventive care before and after the intervention, this enabled us also to consider the *ratio* of baseline score and post-intervention score.

Comparisons between intervention and control practices were made on an intention-to-treat basis. In order to compare the intervention and control group for the main outcome measures, regression analyses with adjustment for baseline deficiency score were performed. To assess the influence of practice characteristics, multiple linear regression analyses were performed with each main outcome measure (four practice management elements and two preventive activities) as dependent variable. Practice characteristics with $p<0.25$ in univariate analyses and interactions with the intervention, together with baseline deficiency scores, entered the model.

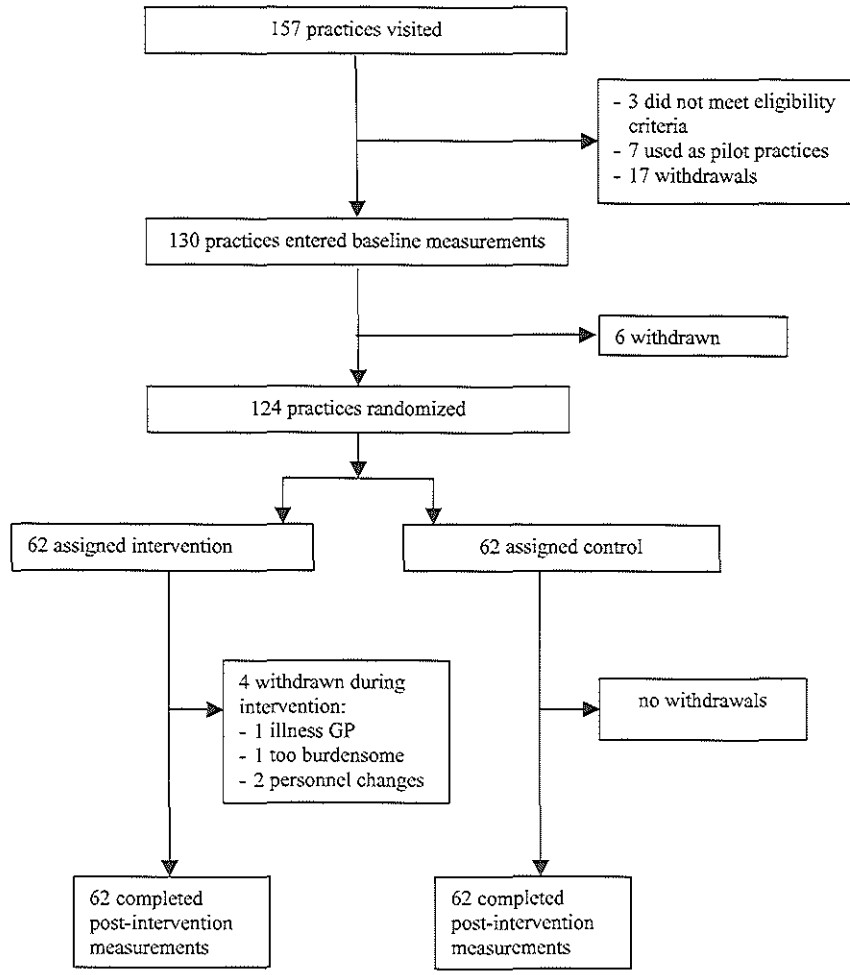
RESULTS

Trial profile

Invitations were sent to 715 practices together with a reply form. We received 414 replies (response rate: 65%) and all practices in which at least one GP replied positively were visited (Figure 1). Of these, 130 practices met our inclusion criteria. Six practices withdrew during baseline measurements, hence were not randomized. All

124 randomized practices completed both baseline and post-intervention measurement questionnaires and were included in the analysis.

Figure 1. Trial profile



Characteristics of study groups

The characteristics of the practices are presented in Table 1. There were only small differences in baseline characteristics between intervention and control practices.

Table 1. Practice characteristics

Practice characteristic		*% Intervention practices (n=62)*	*% Control practices (n=62)*
1. Setting	Single-handed	61	61
2. List size: number of patients per full-time GP	< 2500	36	31
3. Location of the practice: addresses per m^2	Urban = ≥ 1000	66	63
4. Number of GPs	1	57	55
	2	29	37
	≥ 3	14	8
5. Number of practice assistants	1	27	32
	≥ 2	73	68
6. Mean age of the GPs (years)	≤ 45	58	61
7. Mean age of the practice assistants (years)	≤ 35	57	66
8. Mean working experience of the GPs (years)	≤ 15	57	54
9. Mean working experience of the practice assistants (years)	≤ 10	58	55
10. Employment of all GPs in the practice	Part-time	47	52
11. Employment of all practice assistants in the practice	Part-time	82	84
12. Gender of the GPs	Male only	63	68
	Male and female	29	27
	Female only	8	5
13. Pharmacy attached to the practice		3	3
14. Involved in vocational training		29	27
15. Certified practice assistants		82	87
16. Member of the Dutch College of General Practitioners		84	89
17. NHS patients	≤ 60 %	39	42

Adherence to the practice management elements and preventive activities

Final data on adherence to the practice management elements and preventive activities were gathered 21 months after randomization. Table 2 shows that there was much variation in changes in adherence for all items. Most items necessary for the care of patients with established cardiovascular disease showed improvement. For record keeping, risk factors (hypertension, smoking and individual cardiovascular history) were recorded more adequately and there was a significant increase in the proportion of practices making risk profiles. For follow-up, more practices made appointments immediately after the visit and the reason for encounter was better identified. Not all cardiovascular patients received appointment cards.

Combining all 58 items of organization of preventive care (Tables 2a and 2b combined), we found that 50% of the intervention practices adhered to at least 40 of the items after the intervention. No single practice adhered to all items; 8% adhered to less than half of the items.

The means of the sumscores for each group of items are presented in Table 3, which shows that there was much room for improvement on every aspect of organization of preventive care at baseline. All aspects improved after intervention. In the intervention practices, the largest absolute improvement was found for the number of preventive tasks performed by the practice assistant. The control practices improved on some items, but far less than the intervention practices. The difference between intervention and control group as to deficiency score after intervention, adjusted for baseline, was significant ($p<0.001$) for all aspects of organizing preventive care. The table shows there is still room for improvement after the intervention period on every aspect.

We repeated the analyses without adjustment for the intervention to gain insight in the contribution the intervention made to the variation of our outcome measures. For all items, addition of the intervention doubled the percentage of variance explained.

Multiple linear regression analyses showed that practices with fewer GPs and smaller list size improved most on record keeping. The percentage explained variance for change in record keeping activities was 37%. No relation was found between the practice characteristics and other aspects of organizing prevention.

Table 2. Percentage of practices adhering to separate issues of preventive care

		Intervention (n=62)		*Control (n=62)*		*Change Interv.*	*Change Control*	*Sign P*
		Before	After	Before	After			
A. Availability of instruments and materials								
1. Instruments	Blood pressure meter	100	100	98	100	0	2	
	Doppler device	44	44	31	34	0	3	
	Weighing scale	100	100	100	100	0	0	
	Measuring staff	97	100	97	100	3	3	
	Glucose meter	98	98	100	98	0	-2	
	Cholesterol meter	39	42	44	47	3	3	
	Body mass index table	71	95	76	86	24	10	
	Nomogram	23	55	28	21	32	7	*
	Urine sticks	100	100	100	100	0	0	
2. Leaflets	Hypertension	82	98	95	92	16	-3	*
	Cholesterol	89	98	86	98	9	12	
	Angina pectoris	36	82	37	47	46	10	*
	Peripheral arterial disease	19	76	18	27	57	9	*
	Trans. ischaemic attack	15	74	13	32	59	19	*
	Diabetes mellitus	82	98	82	94	16	12	
	Heart failure	36	81	30	41	45	11	*
	Smoking	79	100	90	95	21	5	**
	Diet	84	97	87	95	13	8	
	Exercise	44	84	31	42	40	11	*
3. Adequate ancillary staff present[b]		55	68	70	68	13	-2	*
4. Separate room for the practice assistant[c]		95	100	95	92	5	-3	
B. Presence of separate preventive clinics								
1. Separate clinics for	Hypertensive patients	15	55	13	29	40	16	*
	Diabetic patients	19	53	26	45	34	19	
2. Use of smoking cessation package (MIS)[a]		16	53	24	16	37	-8	*
C. Preventive tasks performed by the practice assistant								
1. Measurements taken:	Blood pressure	77	94	89	87	17	-2	*
	Glucose	87	95	95	92	8	-3	**
	Cholesterol	34	42	42	45	8	3	
	Height	15	60	26	27	45	1	*
	Weight	40	77	57	63	37	6	*
	Body mass index	7	69	19	23	62	4	*
2. History questions asked:	Cardiovascular history	16	61	31	24	45	-7	*
	Cardiovascular family history	15	61	27	24	46	-3	*
	Smoking habits	27	77	32	39	50	7	*
	Alcohol intake	15	65	8	24	50	16	*
3. Advice given on:	Diet	52	76	63	66	24	3	**
	Smoking	29	60	29	39	31	10	**
	Losing weight	32	61	40	45	29	5	**
	Exercise	24	58	27	37	34	10	**
	Alcohol	11	37	11	16	26	5	**
D. Teamwork in the practice								
1. Written protocols[d]	Diabetes mellitus	27	71	27	39	44	12	*
	Hypertension	16	68	26	34	52	8	*
	Detecting patients at risk	3	31	5	18	28	13	
2. Hold regular, scheduled meetings[e]		42	66	52	61	23	9	

Table 2. continued

	Intervention (n=62)		*Control (n=62)*		*Change Interv.*	*Change Control*	*Sign P*
	Before	**After**	**Before**	**After**			
E. Record keeping							
1. Computerised patient records[f]	84	94	79	81	10	2	
2. Systematic entries concerning four risk factors[g]	8	27	3	7	19	4	**
3. Record risk factors separate from the consultation notes[h]	10	57	10	13	47	3	*
4. Record diagnoses separate from the consultation notes[i]	50	73	68	77	23	9	
5. Risk profile for cardiovascular patients[j]	3	40	10	8	37	-2	*
6. Register preventive activities separately	35	53	39	34	18	-5	
F. Follow-up							
1. Make an appointment immediately after the visit	82	95	87	81	13	-6	**
2. Make an identifiable note	20	68	28	31	48	3	*
3. Provide an appointment card for patients with							
Diabetes mellitus	39	75	33	49	36	16	*
Hypertension	37	80	28	44	43	16	*
Cholesterol	22	42	11	24	20	13	
Angina pectoris	22	37	17	18	15	1	**
Peripheral arterial disease	22	37	17	16	15	-1	*
Heart failure	22	34	17	18	12	1	
4. Contact patients who fail to attend an appointment	65	75	63	68	10	5	

Legends to Table 2.

*) *Significant difference between change intervention and control group p<0.01*
**) *Significant difference between change intervention and control group p<0.05*

a) *The Minimal Intervention Strategy is a smoking cessation package shown to be feasible and effective*
b) *Adequate ancillary staff present = 0.8 fte practice assistance per 2500 patients (norm)*
c) *A place to work for the practice assistant = a well equipped consultation room for consulting patients without being disturbed.*
d) *Written protocols are a support for the practice assistant with her tasks and enables the GP to survey the activities done by the practice assistant.*
e) *Scheduled meetings are those scheduled in advance and in which the tasks performed by the practice assistant are evaluated.*
f) *100% computerised = practices do not use any written medical records: all patient data were entered into the computer*
g) *Systematic entries were considered necessary for hypertension, diabetes mellitus, individual and family cardiovascular history*
h) *Risk factors that had to be recorded in a recommended location were hypertension, smoking and individual cardiovascular history*
i) *The diagnoses concerned are hypertension, cholesterol and diabetes mellitus*
j) *Risk factors at least present in a risk profile for cardiovascular patients: blood pressure, smoking, individual history*

Table 3. Adherence to aspects of practice organization: number of items adhered to, crude change between baseline and post-intervention and change in deficiency score

Aspect of practice organization	*# items*	*Intervention practices (n=62)*						*Control practices (n=62)*						*p**
		number of items			deficiency score			number of items			deficiency score			
		before	after	Δ	before	after	Δ	before	after	Δ	before	after	Δ	
- Availability of instruments and materials	21	13.9	17.9	4.0	1.9	0.9	-1.0	14.2	15.1	1.0	1.8	1.7	-0.2	<0.001
- Presence of separate clinics	3	0.5	1.6	1.1	0.9	0.3	-0.6	0.7	0.9	0.2	0.8	0.6	-0.2	<0.001
- Preventive tasks by the practice assistant	15	4.8	9.9	5.1	2.2	1.2	-1.0	6.0	6.5	0.5	2.1	1.9	-0.2	<0.001
- Teamwork in the practice	4	0.9	2.3	1.4	1.1	0.6	-0.4	1.1	1.4	0.3	1.0	0.9	-0.1	<0.001
- Record keeping	6	1.9	3.4	1.5	1.4	0.8	-0.6	2.1	2.2	0.1	1.3	1.3	-0.0	<0.001
- Follow-up	9	2.8	5.2	2.4	1.7	1.2	-0.5	2.7	3.0	0.3	1.7	1.7	-0.0	<0.001

* *Significance of the difference in change in deficiency score from baseline between intervention and control practices*

DISCUSSION

The comprehensive intervention program using outreach visits was carried out successfully and proved to be effective in improving organization of preventive care. We performed both baseline and post-intervention measurements in all participating practices and the intervention program could be implemented completely in almost all intervention practices. The intervention proved to be effective on all aspects of the organization of preventive care, which supports the validity of the theoretical model.

A number of limitations should be mentioned. Inviting practices to participate in a study may introduce selection bias: motivated practices may be more successful and implementing changes in less motivated practices may be more difficult. This is inevitable in studies addressing change in professional behavior, as willingness to change is a prerequisite to participate.

The assessment of adherence to separate elements of preventive care was carried out by means of questionnaires. Not all items could be verified by the observers visiting the practices, hence leaving some room for social desirability bias. As this would affect practices in the intervention group as well as the control group, we do not believe this to be a major obstacle in interpreting our findings.

The intervention practices showed significantly more improvement in adherence to organization of preventive care. Control practices also improved, but this change was not significant. The change in the control practices could be the result of a Hawthorne effect [31] or due to societal changes. During the study period there was much attention nationwide for prevention and cardiovascular risks and diseases; however, the marginal change in the control practices illustrates that media attention is not sufficient to change behavior.[32]

It is unclear which specific parts of the intervention contributed most to the final effects. We assume that it is the combination of elements of the intervention that is crucial (i.e. offering practice-tailored support, repeating messages during subsequent visits, involving the practice team and feeding-back behavior), since different factors determining actual preventive care are addressed.[27]

In the intervention group each aspect of organizing preventive care was successfully implemented. Concentrating care on high-risk patient groups can influence patient outcome measures.[28] We found that the proportion of practices that offered separate

preventive clinics for hypertensive patients almost quadrupled in the intervention group. Stop smoking packages, known to be difficult to implement,[29] were also used by more practices. Many of the instruments were already present before the intervention and therefore showed no change. Record keeping, a very important element in preventive practice organization, showed a large increase. As found in other studies,[19,30] the item of record keeping that showed the largest change was the recording of cardiovascular risk factors (hypertension, smoking and individual cardiovascular history) in a recommended location of the file. Probably more importantly, the proportion of practices making risk profiles (including at least blood pressure, smoking and individual cardiovascular history) improved from 3 to 40%. Completion of risk profiles is a prerequisite for adequate care, as it allows comprehensive management of cardiovascular patients. Furthermore, the availability of a risk profile avoids unnecessary actions and questions at future consultations.

Even after 21 months of intervention there is still room for improvement. Low adherence at baseline did not necessarily imply large changes (e.g. Doppler device and cholesterol meter). Availability of instruments and materials showed relatively little improvement, but most practices were already well equipped. Most practices did not have separate preventive clinics before the intervention, afterwards there was still much room for improvement. This element requires trained personnel and organization skills, which are capacities that may evolve in time.

A longer intervention period may produce further improvement, although most aspects of organization of preventive care were implemented in the first nine months of the intervention and evaluated during the period thereafter. The costs of the intervention program were estimated to be about 4300 EUR per practice.

Thinking about the implications of our findings for practice, we can state that the outreach visitor model is a feasible an effective option for changing preventive practice in primary care. To assess continuation of effects and cost-effectiveness a long-term evaluation is needed, which should include patient outcomes.

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CHAPTER 5

Organizing Cardiovascular Preventive Care in General Practice: Determinants of a Successful Intervention

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ABSTRACT

Background
Although outreach visitor interventions have proven to be effective, more detailed studies are needed to understand what elements of interventions work and why.
In this study we investigate the determinants of success of an intervention for optimizing cardiovascular preventive care in general practice.
Methods
After baseline measurements and randomization 62 general practices received a comprehensive intervention program, by means of outreach visitors, lasting 21 months. Data on practice management and preventive activities were gathered at baseline and at post-intervention measurements. Key characteristics of the intervention considered as possible determinants of success were gathered by questionnaire. The difference between ideal and actual practice in each aspect of organizing cardiovascular preventive care was calculated as a deficiency score. The difference between deficiency scores before and after the intervention were the main outcome measures.
Results
The key characteristic *duration of exposure to an aspect* (in months) was positively related to the change in availability of separate clinics and in the amount of teamwork. The improvement in instruments and materials was positively related to the GPs opinion about the given feedback. No relations were found between the key characteristics and changes in record keeping or follow-up routines.
Conclusion
Although implementation of a comprehensive prevention program is effective, we could not fully disentangle the 'black box' of the intervention. The duration of exposure to an aspect of organizing cardiovascular care was the key determinant to success.

INTRODUCTION

Cardiovascular diseases are among the most prevalent health problems in general practice; a major part of all chronic problems are of cardiovascular origin.[1] It is generally accepted that the general practitioner (GP) plays a crucial part in prevention, early detection, treatment and surveillance of cardiovascular problems in patients with a high-risk of cardiovascular disease. In general practice these tasks are not yet performed satisfactorily. [2-6] One of the factors influencing physician behavior is the way prevention in practice is organized. Systematic prevention and disease management requires adequate practice management and adequate organization of medical practice.[7-10] Furthermore, practice support mechanisms are required for sustained improvements.[11, 12]

Medical practice can be improved effectively by well-planned strategies, composed of a variety of interventions and methods.[13-16] Such combined strategies preferably include a personal audit of practice routines, feedback to the practice, and instruction, education, guidance and support over a prolonged period of time. The 'outreach visitor model' is based on these principles of educational outreach.[13, 17] Educational outreach visits can be effective in improving some areas of professional practice,[18-21] but even these interventions do not always enhance performance.[22]

In a systematic review of outreach visits, Thomson O'Brien et al. also showed effect of outreach visits, but reported that the interventions used varied enormously.[23]

We previously reported on the implementation of a comprehensive intervention program by outreach visitors aimed to optimize cardiovascular preventive care in general practice. The primary analysis of this randomized controlled trial showed significant changes for each aspect of organizing preventive care.[24] Although our intervention was successful in optimizing practice organization, it is unclear which specific parts of the intervention contributed to the effects we found.

Numerous studies have addressed different kind of interventions in general practice,[23] however to our knowledge there are no studies in which an attempt was made to discover which determinants contribute to the found effects of the intervention. To establish which elements of an intervention work and the reasons why, we have to look inside the 'black box' of the intervention.[25]

In the present study we assessed which key characteristics of the intervention were important for attaining success of the program.

METHODS

Design and practices

A randomized controlled trial was performed in the southern half of The Netherlands from November 1996 until February 1999. Practices were invited by letter and via regional GP bulletins to participate in the study. After baseline measurements, 124 general practices were randomly allocated to either the intervention or the control group. The 62 intervention practices received 21 months of intervention; after this period post-intervention measurements were performed. Control practices did not receive any stimuli between randomization and post-intervention measurements.

Intervention

The intervention, which has been described more extensively in a previous paper,[24] comprised both practice organization and clinical decision-making. We focus here on aspects of the organization of preventive care, which we divided into six separate domains. Some of these cam be seen as conditions needed to perform adequate disease management, while others actual performance. Items were derived from guidelines developed by the Dutch College of General Practitioners and by consensus procedures.[20, 26, 27]

The first eight visits were dedicated to improving practice organization. Although the emphasis changed towards clinical decision-making from the ninth visit onward, practice organizational aspects continued to be addressed until the end of the intervention period.

For each aspect the outreach visitors followed the subsequent steps of a theoretical model of change (orientation, insight, acceptance and change).[13,17] The intervention design allowed practice members to draw up and prioritize their own list of gaps and planned changes (goal setting, as recommended for continuous quality improvement).[28] This list was used as guidance throughout the intervention period.

Measurements and variables

Data on aspects of practice organization (Table 1) were gathered by questionnaire and observation, at baseline and after 21 months of intervention.

The eight key characteristics of the intervention were derived by discussion among the project team while creating the intervention. They included the number of visits spend

on each aspect, total number of visits, duration of exposure to an aspect, time invested, priority given, change of facilitator, opinions of the GP and practices assistant about the intervention and opinion of the GP about guidelines.

The outreach visitors reported each visit in detail on a contact form: e.g. traveling time, aspects discussed, number of visits used to change a particular aspect of practice organization. We used this form to obtain the number of visits during which each aspect was discussed, the total number of visits per practice, and the duration of exposure to an aspect (in number of months). During each visit the outreach visitors asked the practice employees the amount of time spent (excluding the visits) on meetings, reading and education, with this information the mean time invested per GP and per practice assistant was calculated. During the intervention period the outreach visitors and the authors (BF and CL) had regular meetings to discuss the progress made by the practice employees. The variable 'priority given' was considered positive when the practices chose an aspect of practice organization as a priority and started the intervention period with that aspect. We also noted which practices changed outreach visitor during the course of the intervention. At the end of the intervention all practice employees completed a questionnaire concerning their experiences on the feedback they had received, the educational materials and their opinion about the knowledge and capabilities of the outreach visitor. In addition we asked the GPs about their agreement with practice organizational guidelines. Their answers could be given on a five-point scale (strongly disagree, disagree, neutral, agree and strongly agree); when the latter two were scored, the answer was considered positive. These questions were asked at the individual level and later aggregated to practice level. When at least 50% of the GPs or practice assistants per practice had a positive opinion, that variable was considered positive.

Analysis

The practice was the unit of analysis. Frequencies and descriptive analyses were used to describe the actual exposure of the practices to the key characteristics of the intervention. All analyses were made on an intention-to-treat basis.

We computed for each of the six aspects of preventive care a 'deficiency score', i.e. logarithm of the difference between the maximum possible score minus the actual score, both at baseline and after the intervention period. The main outcome measure

was the difference between the deficiency scores in each aspect of organizing preventive care before and after the intervention.

To assess the influence of the key characteristics of our intervention, multiple linear regression analyses were performed with each of the main outcome measures as dependent variable. The outcome measures addressed the preventive tasks performed by the practice assistant, the presence of separate preventive clinics, the availability of instruments and materials, the amount of teamwork in the practice, follow-up routines and record keeping. The key characteristics with $p<0.25$ in univariate analyses entered the model.

RESULTS

All 124 practices received baseline and post-intervention measurements. Four intervention practices did not complete the intervention period: one because of illness of the GP; one found the intervention too burdensome and two due to personnel changes. There were no dropouts in the control group.

Outcome

For all six domains, the difference in change between intervention and control practices was statistically significant, ($p<0.001$), and in favor of the intervention practices. (Table 3 of chapter 4).[24]

Key characteristics of the intervention

There was considerable variation in the number of visits spent on the different aspects of practice organization (Table 2). The subject of separate clinics was discussed most, while the mean number of visits spent on an issue was lowest for teamwork. The table shows that no single aspect was addressed in all practices. Over 21 months the total number of visits per practice was 15 (SD 2.6). On average, the practices worked on each practice organization aspect for a period of 4 months. Apart from visits, the time spent by GPs on meetings, reading and education averaged 18 hours, ranging from 1 to 85 hours; for practice assistants the mean time spent was close to 10 hours.

Table 1. Aspects of organizing cardiovascular preventive care

Domains	*Items*
A. Availability of instruments and materials	1. Instruments: blood pressure meter, Doppler device, weighing scale, measuring staff, glucose meter, cholesterol meter, body mass index table, nomogram and urine sticks 2. Leaflets on: hypertension, cholesterol, angina pectoris, peripheral arterial disease, transient ischemic attack, diabetes mellitus, heart failure, smoking, diet and exercise. 3. Adequate ancillary staff present 4. Separate room for the practice assistant
B. Presence of separate preventive clinics	1. Separate clinics for hypertensive and diabetic patients 2. Use of smoking cessation package (MIS)
C. Preventive tasks performed by the practice assistant	1. Measurements taken: blood pressure, glucose, cholesterol, height, weight and body mass index. 2. History questions asked: cardiovascular history, cardiovascular family history, smoking habits and alcohol intake 3. Advice given on: diet, smoking, losing weight, exercise and alcohol
D. Teamwork in the practice	1. Written protocols on diabetes mellitus, hypertension and detecting patients at risk 2. Hold regular, scheduled meetings
E. Record keeping	1. Computerised patient records 2. Systematic entries concerning four risk factors 3. Record risk factors separately from the consultation notes 4. Record diagnoses separately from the consultation notes 5. Risk profile for cardiovascular patients 6. Register preventive activities separately
F. Follow-up	1. Make an appointment immediately after the visit 2. Make an identifiable note 3. Provide an appointment card for patients with: diabetes mellitus, hypertension, cholesterol, angina pectoris, peripheral arterial disease and heart failure 4. Contact patients who fail to attend an appointment

Although most visits were spent on the organization of separate clinics, the subject of record keeping was worked on for the largest period of time.

Additionally, we found that 16% of the practices worked on teamwork during the intervention and 95% of the practices addressed record keeping.

Most practices gave priority to and started the intervention period with improving record keeping (44%). The questionnaire about experiences revealed that in more than 69% of the participating practices the GPs and in 58% the practice assistants were positive about the feedback they received. In 67% of the practices the GPs and in 74% the practice assistants were positive about the used materials. In 79% of the practices the GPs and in 84% the practice assistants had a positive opinion about the outreach visitor. In 92% of the practices the GPs were positive about the guidelines we provided concerning record keeping.

Determinants of success

Multivariate linear regression analysis revealed no relationship between the key characteristics of the intervention and the increase of preventive tasks performed by the practice assistant. The duration of exposure to an aspect (in months) was positively related to the change in availability of separate clinics and of teamwork. The GPs' opinion about the given feedback was a positively related to improvements in available instruments and materials.

No relationship was found between the key characteristics and the changes in record keeping or follow-up routines.

Table 2. Key characteristics of the intervention (n=62 practices)

Key characteristic		***Mean (range)***	***Standard deviation***
Number of visits spent on	- Preventive tasks	3.3 (0–10)	2.5
	- Separate clinics	3.6 (0 – 9)	2.4
	- Instruments and materials	2.9 (0–10)	2.2
	- Teamwork	0.9 (0 – 7)	1.9
	- Follow-up	1.8 (0 – 7)	1.8
	- Registration	3.2 (0 – 8)	1.9
Total number of visits		15.1 (4 – 17)	2.6
Duration of exposure (in number of months) to the aspect			
	- Preventive tasks	3.1 (0 – 17)	3.5
	- Separate clinics	4.5 (0 – 16)	3.9
	- Instruments and materials	5.2 (0 – 15)	3.4
	- Teamwork	4.5 (0 – 12)	3.2
	- Follow-up	3.8 (0 – 16)	3.2
	- Registration	5.6 (0 – 15)	3.6
Time invested (hours) per	- GP	18.2 (1 – 85)	12.9
	- Practice assistant	9.9 (0 – 84)	11.7
		Number of practices	**Percentage**
Priority given to	- Preventive tasks	9	14.5
	- Separate clinics	7	11.3
	- Instruments and materials	10	16.1
	- Teamwork	3	4.8
	- Follow–up	6	9.7
	- Registration	27	43.5
Change of facilitator		12	19.4
≥ 50 % of the practice employees positive opinion about:			
Feedback	GP	43	69.4
	Practice assistant	36	58.1
Used materials	GP	42	67.7
	Practice assistant	46	74.2
The facilitator	GP	49	79.0
	Practice assistant	52	83.9
Positive opinion of the GP about guidelines concerning:			
	- Preventive tasks	42	67.7
	- Separate clinics	18	29.0
	- Instruments and materials	36	58.1
	- Teamwork	51	82.3
	- Follow–up	31	50.0
	- Registration	57	91.9

DISCUSSION

The comprehensive intervention program was carried out successfully. To gain insight into which of the program elements contributed to the observed effects, we a priori identified key characteristics of the intervention program. While designing the intervention, these key characteristics were derived by discussion among the project team. They all seemed likely to be important when considering the models of change used to create the multifaceted intervention. Duration of exposure to program aspects turned out to be the most important determinant of success.

Several factors may have biased our results. The practices volunteered to participate and may have been especially interested to adopt the intervention. Withdrawal from the intervention (four practices) was a minor problem as these practices agreed to perform post-intervention measurements. To assess sustainability of the effects a longitudinal evaluation is needed. Finally, in this paper we did not explore the cost-effectiveness, nor the effect of improvement of cardiovascular preventive care on patient outcome.

Promoting teamwork in primary care has become an important issue over the last decade, both in the United Kingdom and in the United States of America.[9, 12, 29-31] Good teamworking is a key part of providing high quality care.[32] However, we found that only 16% of the practices addressed teamwork during the intervention and the mean number of visits spent on this element was less than one. In some practices the teamwork elements were already present in the practice and the outreach visitor needed only one visit to review the written protocols with the practice employees, but a substantial number of practices did not address teamwork.

There was little variation in the mean number of months each practice worked on a particular aspect; ranging from an average of 3.1 months for preventive tasks performed by the practice assistant to 5.6 months for record keeping. However, there was a difference in time invested on the project per GP (mean 18.2 hours) and per practice assistant (mean 9.9 hours). Although general practices are working as multidisciplinary groups more and more, in The Netherlands the GP is still the first person in charge of quality improvement in the practice and is the first person to obtain information and initiate meetings before the other employees can follow.

The number of visits used to change an aspect was agreed between the outreach visitor and practice employees. When the outreach visitor thought that more visits were needed, the employees were encouraged to devote more visits to this aspect. On the other hand, extra time was allowed when the employees needed more time to get the aspect incorporated into their practice. The largest number of visits was spent on starting separate preventive clinics, probably because this required the most effort from the practice employees. To enable the practice assistant to have a major role in these clinics, considerable education and training is required.

The absence of a relationship between any of the key elements of the intervention and the changes in three domains of preventive care (tasks of the assistant, record keeping and follow-up routines) was surprising. One explanation could be that other unmeasured characteristics were related to the change in these domains, but more probable is the explanation that not a specific aspect of the program but the program as a whole was effective.

It has been reported previously that goal setting is essential for behavior change.[27] Our results do not confirm that giving priority to a certain aspect has an influence on the change for any aspect of organizing preventive care. Although it would seem obvious a priori that more visits by an outreach visitor imply more change, this study did not confirm this. An explanation may be, that it is more beneficial to direct attention towards topics that are ranked lower in terms of interest than topics that are ranked higher, as shown in a study on continuous medical education.[33]

The GP's opinion on the guidelines concerning the aspects that were addressed during the intervention was mostly positive, but showed no relationship to the performance of the practices. It has been reported previously that a positive opinion alone is not enough to change behavior.[34]

In practices where at least half of the GPs were positive about the given feedback, the greatest change was found for the availability of instruments and materials. Although we supplied feedback on all elements of practice management, the feedback report started with a large section addressing this topic. Perhaps this part was most strongly remembered by GPs. We expected to find that opinions on the knowledge and capabilities of the outreach visitor would be an important determinant for a successful intervention, however, this was not the case for any aspect of organizing preventive care.

The duration of exposure to an aspect showed the strongest relationship with changes in the presence of separate clinics and of teamwork. An important implication for practice is that if practices aim to incorporate separate clinics and teamwork in their daily routine, they should take their time to prepare for these changes.
Introducing organizational change in a multidisciplinary context is a complex task and still largely unexplored.[30, 35, 36] Multifaceted interventions targeting different barriers tend to be more effective than single interventions.[14] Particularly educational outreach visits combined with social marketing have been shown to be a promising approach to modify professional behaviour.[23] In the effective multifaceted intervention we used, we combined audit of practice routines, feedback to the practice, and instruction, education, guidance and support over a prolonged period of time.

In conclusion, although implementation of a comprehensive prevention program is effective, we could not fully disentangle the 'black box' of the intervention. Duration of exposure to program aspects was the most important determinant of success. Perhaps key characteristics of the intervention other than those we selected are also of importance, or perhaps the structure is just too complicated to unravel and we should accept that well-defined multifaceted interventions by outreach visitors can bring about major changes in the organization of preventive care, but it is not possible to identify precisely why.

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CHAPTER 6

Intensive Support to Improve Clinical Decision-Making in Cardiovascular Care: A Randomized Controlled Trial in General Practice

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Submitted

ABSTRACT

Problem
The management of patients at high cardiovascular risk in general practice is not optimal. It remains unclear whether intensive support improves general practitioners' (GPs') clinical decision making in cardiovascular care and which practices benefit most.

Design
Cluster randomized controlled trial with two arms: intensive support versus no special attention.

Background and setting
124 practices with a total of 185 GPs in The Netherlands.

Key measures for improvement
Compliance rates for twelve evidence-based indicators for the actual management of patients with hypertension, hypercholesterolemia, angina pectoris, or heart failure. Compliance was assessed via the prospective recording of patient encounters at the start and end of the study.

Strategies for change
Feedback reports and support from trained non-physicians during four outreach visits.

Results
The GPs reported 30 101 clinical decisions at baseline and 22 454 decisions at post-intervention. The intervention resulted in statistically significant improvements for five of the twelve indicators: assessment of risk factors for patients with hypercholesterolemia (odds ratio 2.04; 95% confidence interval 1.44 to 2.88) and patients with angina pectoris (3.07; 1.08 to 8.79), provision of information and advice to patients with hypercholesterolemia (1.58, 1.17 to 2.13) and patients with hypertension (1.55, 1.35 to 1.77), and checking clinical signs of deterioration for patients with heart failure (4.11, 2.17 to 7.77). In particular, single-handed practices, non-training practices, and practices with older GPs gained benefits from intervention.

Lessons learnt
Intensive support from facilitators is an effective strategy to alter certain aspects of GPs' clinical decision making in cardiovascular care. The strategy deserves further development and wider application.

INTRODUCTION

This report contributes to the development of effective interventions to improve physicians' clinical decision making. Previous studies have shown successful strategies to improve prescribing and diagnostic test ordering.[1,2] The present trial evaluates the effectiveness of a multifaceted intervention targeted at various aspects of the clinical management of patients at high cardiovascular risk in general practice. The evaluation relied on the prospective recording of patient encounters by the participating practitioners. The trial also therefore provided practical experience with applying such a measurement tool.

General practitioners (GPs) are challenged to improve their clinical decision making for patients at high cardiovascular risk. High-risk patients, such as patients with hypertension or cardiovascular disease, should be given highest priority in preventive cardiology as they stand to gain the greatest benefits from medical treatment.[3] The management of these patients in general practice is, however, not optimal.[4-6] The clinical decision making of GPs may be optimized by implementing evidence-based guidelines.

Specific strategies are needed to enhance implementation of clinical guidelines.[7] Multifaceted interventions targeting different barriers to change tend to be more effective than single interventions.[8] Educational outreach visits combined with social marketing appear to be a particularly promising approach to modify health professional behaviour.[1] In primary and secondary prevention of cardiovascular disease, multifaceted interventions delivered in outreach visits have been found to optimize practice organization and the recording of risk factors.[9-11] It remains, however, unclear whether intensive and multifaceted support is effective when targeted at GPs' decision making in daily cardiovascular care. It is possible that the complexity and multiplicity of clinical decision-making provide barriers to successful implementation. Furthermore, there is little insight into which practice characteristics are related to successful implementation. Such insight can help tailor future interventions.

METHODS

Study design

We conducted a cluster randomized controlled trial in general practice from 1996 to 1999. Practices in the southern part of The Netherlands were recruited via bulletins and by letter until a total of 124 practices were randomized. Inclusion criteria were the presence of a clinical computer system, employment of practice assistant(s) and no major changes in personnel or premises planned during the course of the trial. We considered these criteria crucial for the conduct of the improvement project.

After baseline measurement, the practices were randomly allocated to receive intensive support (intervention group) or no special attention (control group). The practices were numbered and the person responsible for the randomization process was blind to the practice identities. A random-number generator was used to select permuted blocks with a block size of four. We stratified with regard to practice type (single-handed versus partnership) as this characteristic has been found to predict change in practice organisation.[9]

Key measures for improvement

The key measures were compliance rates for evidence-based indicators for the actual management of patients with hypertension, hypercholesterolemia, angina pectoris, or heart failure. We used the national guidelines issued by the Dutch College of General Practitioners (DCGP) to identify the indicators.[12-15] These guidelines are based on scientific evidence, broad consensus, and clinical experience.[16] We asked a group of five GPs involved in research and guideline development but not participating in the trial to select the key recommendations from the national guidelines. The recommendations are detailed descriptions of specific clinical actions along with the clinical situations calling for those actions. The selected key recommendations coincidence with the recommendations from international guidelines.[3,17-19] We categorized the key recommendations into performance indicators. After the trial, we selected all of the indicators, which allowed detection of an absolute difference of 15% in compliance rates between intervention and control groups with more than 90% power at a 5% significance level. Changes in care provision are usually no more than 10%.[20] The twelve selected indicators are presented in Table 2. The smallest difference we would have been able to detect across the indicators was 7% ($\alpha = 0.05$, $\beta = 0.10$).

The post-hoc power estimations take into account the design effect of cluster randomisation.[21]

Process of gathering information

Using the key recommendations, we developed forms for the prospective recording of patient encounters for each of the medical conditions considered in this study. Due to the high incidence of hypertension, separate forms were created for newly diagnosed versus already treated (with or without medication) hypertension. The encounter forms included items pertaining to the age, sex, and clinical characteristics of the patient and also the decisions regarding the performance (yes/no) of specific clinical actions. While the forms were based on the key recommendations, they did not contain any clues to the recommendations. GPs have been shown to complete similar forms reliably (kappa of 0.79; Spies TH, personal communication).

Immediately prior to and upon completion of the 21-month implementation period, the GPs completed encounter forms during routine consultation hours for a period of two months. The GPs were asked to complete the forms immediately after eligible encounters. The data from the encounter forms were then entered into a computer by personnel blind to group allocation.

The characteristics of the participating practices were derived from a questionnaire completed by one GP per practice at baseline. Data were collected on type of practice (single-handed versus partnership), practice location, number of GPs and practice assistants, working hours of each professional, age of GPs, patient list size, and involvement in GP vocational training.

Analysis

We used the data from the encounter forms to assess the clinical decision-making. The assessment pertained mainly to clinical actions performed during the present patient encounter. Particular actions were however also taken to be performed, when the GP reported performance in a previous contact (such as advice on smoking cessation) or within the recommended period (such as blood pressure measurement within the last 12 months). Actions with missing data were considered not performed.

The practice was the unit of analysis to describe changes in clinical decision making. We calculated the mean compliance rate for each performance indicator at baseline and the mean change from baseline. The compliance rate for an indicator was the

number of decisions in accordance with the recommendations divided by the total number of decisions made with respect to that indicator.

Multilevel logistic regression analysis (GLMMIX procedure in SAS) was used to assess the influence of the intervention on clinical decision making and to identify practice characteristics which were related to success of the intervention.[21] Multilevel analysis takes into account the relatedness of the clinical decisions made within a particular practice. P-values less than 0.05 were considered statistically significant.

Strategy for change

The GPs in the intervention practices received feedback reports and support from facilitators to improve clinical decision making for hypertension, hypercholesterolemia, angina pectoris, and heart failure. The intervention comprised four outreach visits per practice. Each practice received support from one facilitator; in partnerships, the facilitator could see more than one GP at the same time. Before each visit, all GPs in the practice received a feedback report on the medical condition to be addressed during the visit. The feedback reports were based on the baseline performance data and informed the GPs about their current clinical decision-making in relation to the key recommendations from the DCGP guidelines. During the visit, the facilitator and the GPs discussed the content of the feedback reports, prioritized specific aspects of decision making for improvement and made change plans. The facilitator provided guidance, support, and educational materials to achieve improvement. As part of a next visit, the facilitator and the GPs discussed the extent to which the plans were carried out and which aspects of decision making needed further attention.

The intervention was part of a larger implementation project concerned with practice organization and clinical decision-making with regard to patients at high cardiovascular risk. The focus of the project was on the implementation of a comprehensive program of recommendations derived from the DCGP guidelines and consensus procedures. The facilitators conducted 15 outreach visits per practice, lasting an average of one hour per visit, equally distributed across a period of 21 months. The first eight visits concerned practice organization; the other seven visits concerned clinical decision making. The protocol for the visits was highly standardized to limit variation and based on a model of change.[9] The facilitators were specially

trained to support the GPs and to carry out the project protocol. Most of the facilitators had worked as a practice assistant in the past but none of them were trained physician.

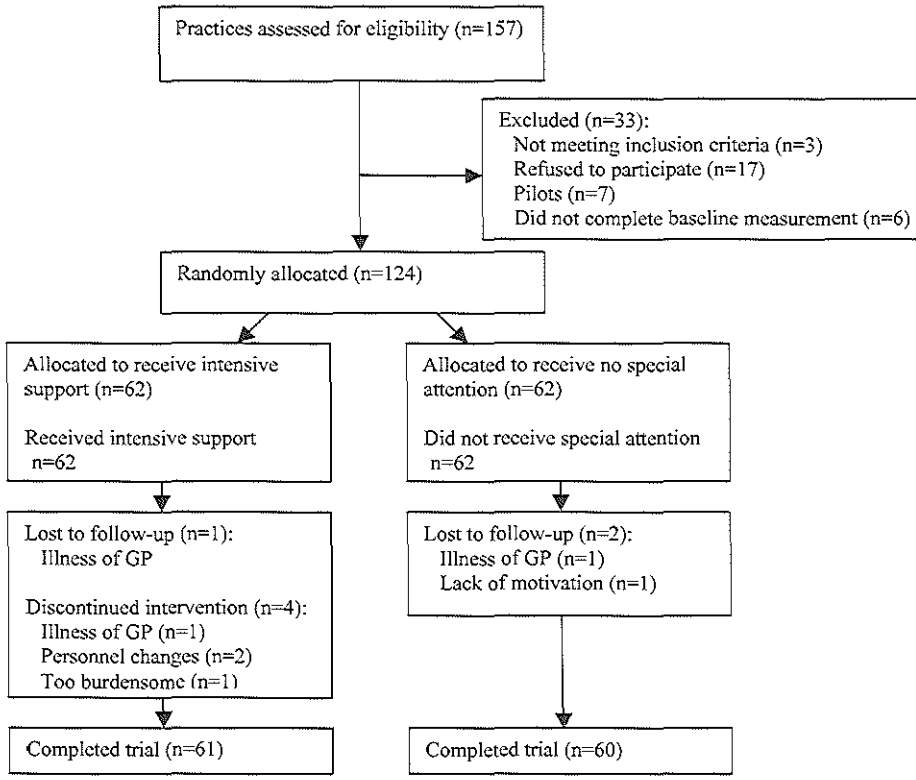

Figure 1. Trial profile

RESULTS

Table 1 shows the baseline characteristics of the 124 participating practices (185 GPs) and the number of patient encounters. Four intervention practices (4/62 = 6%) did not receive a per protocol intervention. These practices received feedback but no support from a facilitator with regard to clinical decision-making. Three other practices (3/124 = 2%) were lost to follow-up (Figure 1). In general, the ages and gender of the patients were found to be evenly distributed across the intervention and control groups for the encounters at baseline and post-intervention measurement. The proportion males with treated hypertension at post-intervention, however, was lower for the intervention group than the control group (39.2% versus 46.0%, p=0.003, multilevel analysis). The GPs reported 30.101 clinical decisions at baseline and 22.454 decisions at post-intervention (Table 2).

Table 1. Practice characteristics at baseline and numbers of patient encounters

	Intervention group n (%)	*Control group n (%)*
Practices at baseline		
Total	62	62
Single-handed	38 (61)	38 (61)
Mean age of GPs >45 years	26 (42)	24 (39)
<2500 patients per full-time equivalent GP	20 (35)	19 (31)
Urban location*	26 (42)	25 (40)
Training practice	18 (29)	17 (27)
≥0.8 full-time equivalent practice assistant employed per 2500 patients	40 (65)	44 (71)
Patient encounters		
Newly diagnosed hypertension		
Baseline	122	153
Post-intervention	93	107
Treated hypertension		
Baseline	1994	1854
Post-intervention	1605	1725
Hypercholesterolemia		
Baseline	247	288
Post-intervention	174	172
Angina pectoris		
Baseline	169	166
Post-intervention	148	97
Heart failure		
Baseline	121	115
Post-intervention	75	76

* ≥ 1500 addresses per km^2.

Table 2. Baseline mean compliance rates and mean changes in compliance rates across practices, by trial group

Medical condition; performance indicator (number of key recommendations included in the indicator)	*Number of practices*		*Number of decisions*		*Compliance rate %*	
	Baseline	*Post-intervention*	*Baseline*	*Post-intervention*	*Baseline mean (95% CI)*	*Mean change (95% CI)*
Newly diagnosed hypertension; assessment of risk factors (9)						
Intervention	46	40	1098	837	79 (75 to 83)	-2 (-9 to 5)
Control	48	44	1377	963	75 (71 to 79)	0 (-6 to 6)
Newly diagnosed hypertension; provision of information and advice (10)						
Intervention	46	40	860	688	57 (50 to 65)	5 (-6 to 16)
Control	48	44	1102	742	54 (48 to 60)	-1 (-10 to 8)
Treated hypertension; provision of information and advice (5)						
Intervention	62	61	4822	3585	64 (59 to 70)	5 (-1 to 10)
Control	62	60	4567	3991	57 (52 to 63)	-3 (-8 to 2)
Treated hypertension; increasing the antihypertensive medication[*] (1)						
Intervention	62	57	700	446	31 (26 to 37)	8 (-1 to 16)
Control	61	60	681	567	32 (28 to 37)	4 (-3 to 11)
Treated hypertension; scheduling a follow-up appointment (3)						
Intervention	62	61	1756	1382	76 (72 to 80)	1 (-4 to 6)
Control	62	60	1615	1551	72 (66 to 77)	0 (-5 to 5)
Hypercholesterolaemia; assessment of risk factors (9)						
Intervention	53	51	2223	1566	90 (87 to 93)	5 (2 to 8)
Control	57	53	2592	1548	89 (86 to 92)	2 (-2 to 5)
Hypercholesterolaemia; provision of information and advice (7)						
Intervention	53	51	1449	1036	77 (72 to 82)	7 (1 to 13)
Control	57	53	1699	1019	77 (73 to 80)	0 (-6 to 6)
Angina pectoris; assessment of risk factors (2)						
Intervention	48	39	292	246	89 (85 to 93)	8 (2 to 15)
Control	46	24	280	170	92 (89 to 96)	0 (-7 to 6)
Angina pectoris; provision of information and advice (4)						
Intervention	48	39	341	348	69 (63 to 76)	-7 (-18 to 4)
Control	46	24	325	222	67 (60 to 75)	-9 (-23 to 4)
Angina pectoris; prescribing aspirin and sublingual nitrate (2)						
Intervention	49	41	338	296	55 (48 to 62)	10 (-1 to 21)
Control	49	26	332	194	54 (48 to 60)	1 (-14 to 17)
Heart Failure; checking clinical signs of deterioration (4)						
Intervention	41	25	460	300	78 (71 to 85)	12 (0 to 25)
Control	36	22	484	304	83 (77 to 89)	-7 (-17 to 2)
Heart failure; provision of information and advice (3)						
Intervention	41	25	345	225	80 (73 to 86)	0 (-8 to 8)
Control	36	22	363	228	79 (73 to 85)	6 (-2 to 15)

[*]Increasing the dosage or starting a drug from a different class in case of a diastolic blood pressure above 90 mm Hg.

The intervention resulted in statistically significant improvements for five of the twelve indicators (intention to treat analyses, Table 3): assessment of risk factors for patients with hypercholesterolemia and patients with angina pectoris, provision of information and advice to patients with hypercholesterolemia and patients with treated hypertension, and checking clinical signs of deterioration for patients with heart failure. Exclusion of those practices that did not provide data for a particular indicator either before or after intervention had marginal effects on the findings for that indicator. Single-handed practices, non-training practices, and practices with older GPs benefited most from intensive support on the provision of information and advice to patients with hypercholesterolemia and patients with treated hypertension. Other practice characteristics were found to be associated with effects for only one or no indicators (Table 4).

*Table 3. Effect size of the intervention on clinical decision making**

Medical condition; performance indicator	*Odds ratio*	*95% CI*	*p Value*	*Intracluster correlation coefficient*
Newly diagnosed hypertension; assessment of risk factors	1.07	0.77 to 1.47	0.696	0.09
Newly diagnosed hypertension; provision of information and advice	1.32	0.94 to 1.86	0.109	0.19
Treated hypertension; provision of information and advice	1.55	1.35 to 1.77	<0.001	0.18
Treated hypertension; increasing the antihypertensive medication†	0.87	0.61 to 1.24	0.432	0.06
Treated hypertension; scheduling a follow-up appointment	0.96	0.75 to 1.22	0.727	0.11
Hypercholesterolemia; assessment of risk factors	2.04	1.44 to 2.88	<0.001	0.15
Hypercholesterolemia; provision of information and advice	1.58	1.17 to 2.13	0.003	0.09
Angina pectoris; assessment of risk factors	3.07	1.08 to 8.79	0.037	0.12
Angina pectoris; provision of information and advice	1.02	0.61 to 1.71	0.929	0.05
Angina pectoris; prescribing aspirin and sublingual nitrate	1.44	0.86 to 2.41	0.168	0.05
Heart Failure; checking clinical signs of deterioration	4.11	2.17 to 7.77	<0.001	0.21
Heart failure; provision of information and advice	0.85	0.43 to 1.67	0.636	0.15

* Multilevel analysis with adjustments for baseline compliance, practice characteristics, and patients' age and gender.

† Increasing the dosage or starting a drug from a different class in case of a diastolic blood pressure above 90 mm Hg.

*Table 4. Practice characteristics predicting success ($p<0.05$) of the intervention**

Medical condition: performance indicator *Practice characteristic*	*Odds ratio†*	*95% CI*	*p Value*
Treated hypertension: provision of information and advice			
Non-training practice	1.70	1.19 to 2.43	0.004
<2500 patients per full-time equivalent GP	1.52	1.11 to 2.08	0.008
<0.8 full-time equivalent practice assistant employed per 2500 patients	1.42	1.04 to 1.93	0.024
Single-handed	1.42	1.03 to 1.95	0.031
Mean age of GPs >45 years	1.35	1.01 to 1.82	0.046
Hypercholesterolemia: assessment of risk factors			
≥0.8 full-time equivalent practice assistant employed per 2500 patients	3.11	1.38 to 6.98	0.006
Hypercholesterolemia: provision of information and advice			
Mean age of GPs >45 years	4.21	2.19 to 8.09	<0.001
Non-training practice	2.87	1.28 to 6.44	0.011
Single-handed	2.66	1.29 to 5.49	0.008

* Multilevel analysis.
† Practice characteristic present versus not present.

DISCUSSION

Intensive support from facilitators improved GPs' clinical decision making with regard to the assessment of risk factors and the provision of information and advice for certain types of patients at high cardiovascular risk, and also the checking of clinical signs of deterioration for patients with heart failure. The intervention may also ultimately improve patient outcomes; identification of the presence of risk factors provides opportunities to reduce risk. The provision of information by doctors has been found to improve compliance with therapy, satisfaction with the care delivered, and health outcomes, whereas lifestyle interventions aimed at patients at high cardiovascular risk were shown to reduce morbidity and mortality.[22-25] Early detection of deterioration in patients with heart failure may promote adjustment of the therapy and thereby prevent hospitalisation.[26]

Just why the intensive support was effective for five of the twelve indicators remains unclear. Comparison across the indicators is hindered by differences in the baseline compliance rates and power across the indicators. Moreover, we do not have insight into the motives of the GPs for apparently ignoring certain recommendations. All kinds of professional, patient and environmental barriers may undermine clinical decision making.[27] Remarkably, the trial did not show an increase in the prescription

of recommended medication. This lack of an effect is in contrast to the findings of a review showing outreach visits to reduce inappropriate prescribing.[1]

Our finding that in particular single-handed practices gained benefits from the intensive support also contrasts with a previous study. Hulscher et al. found a positive relation between partnership and improving the organization of cardiovascular disease prevention.[9] One possible explanation for this discrepancy is that partnerships have more people available to optimize practice organization while GPs in single-handed practices do not have to share the support for clinical decision making with other GPs. Partnerships, training practices, and practices with younger GPs seem to need extra support with respect to the provision of information and advice.

At post-intervention, the GPs in the intervention group may have selectively recorded patient encounters in comparison with the control group, because the GPs were not blind to the allocation of their practice. Selective recording is nevertheless unlikely, because the groups did not substantially differ with regard to the number of patient encounters, the mean age of the patients, or the proportion males. Moreover, the intervention did not improve compliance for all indicators.

Our study has several other limitations. The practices volunteered to participate and may have been more interested and motivated than other practices. Furthermore, we did not explore the effects on patient outcome. The outcome measures were nevertheless based on well-accepted recommendations and detailed assessment of the GPs' clinical actions in actual clinical situations.

Lessons learnt and next steps

Prospective recording of patient encounters proved feasible but had nevertheless some drawbacks. For some indicators, such as the prescription of angiotensin-converting enzyme inhibitors and other medication to patients with heart failure, a sufficient number of decisions to adequately evaluate the effectiveness of the intervention were not available. The schedule of the trial did not allow us to lengthen the recording period. In addition, the GPs generally included 25% fewer encounters at post-intervention than at baseline, possibly due to a lack of motivation. Finally, prospective recording appears to be less suitable for the assessment of compliance with recommendations for the diagnosis of diseases and risk factors, because practitioners will obviously fail to include encounters in which they overlook the diagnosis.

In conclusion, intensive support from non-physicians improved clinical decision making for some but not all aspects of cardiovascular care. The strategy therefore needs further development. The facilitators asked the GPs about barriers to change but may need more intensive training to be able to identify and tackle these barriers. The effectiveness of support from non-physicians is important in terms of the costs when compared to support from physicians. Finally, some effects of the intervention were more pronounced for certain practice characteristics. These findings need confirmation but suggest differences in the intensity of support required across practices. In our opinion, intensive support from facilitators evolves from a promising approach to an evidence-based strategy for the implementation of guidelines.

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CHAPTER 7

Effect of a Comprehensive Intervention Program on Quality of Life in Patients at High Cardiovascular Risk: A Randomized Controlled Trial

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Submitted

ABSTRACT

Background
We implemented a comprehensive intervention program that proved successful in optimizing practice organization and clinical decision-making. In this paper, health-related quality of life is investigated as a clinical outcome.

Objective
To evaluate the effect of the implementation of an intervention program on the quality of life in patients at high cardiovascular risk.

Research design
Randomized controlled trial. Intervention practices (n=62) received a comprehensive intervention program (by means of outreach visitors) lasting 21 months. Quality of life was assessed by the MOS 36-Item Short-Form Health Survey (SF-36). Three patient categories were distinguished: diabetes mellitus, cardiovascular disease and hypertension.

Results
Health-related quality of life deteriorated in all respondents, but more pronounced in the control group. In diabetes patients the differences between intervention and control group were significant for the subscales vitality and mental health. Patients with cardiovascular disease had changes in vitality and physical functioning. In patients with hypertension, there were no differences between the intervention and control group for any of the subscales.

Conclusion
Our comprehensive intervention program resulted in changes in health-related quality of life on several domains, particularly in patients with diabetes or with cardiovascular disease.

INTRODUCTION

The prevalence of chronic diseases is increasing, mainly due to ageing of the population, better prevention, and improved medical interventions. One condition that has increased substantially is cardiovascular disease.[1]

To prevent mortality and morbidity and to improve quality of life, numerous cardiovascular prevention programs have been implemented and studied, but with varying success rates.[2-4] The ultimate aim of any intervention program is to improve clinical outcome, which can be assessed by parameters such as mortality, morbidity and quality of life aspects.[5]

We previously reported on the implementation of a comprehensive intervention program (by outreach visitors) in general practice [6], which was designed to establish and optimize prerequisites for the management of cardiovascular care; the program proved successful in optimizing practice organization and clinical decision-making [6], being structural and process elements. The intervention was aimed at patients with high cardiovascular risk (e.g. hypertension and cardiovascular disease) because this group stands to gain the greatest benefit from medical treatment.[7] These patients should benefit most directly from an individualized approach to preventive care by the general practice team.[8,9]

The present study investigates health-related quality of life (HRQL).[10] Quality of life is a widely used term to describe various aspects of the patients' situation. HRQL is an important consideration in health care decisions and can provide a clinical outcome measure of health care.[11] One goal of HRQL studies, with its focus on the patients' point of view, is to achieve that the increase in span of live years coincides with maintaining an optimal HRQL. Moreover, low HRQL could be a risk factor for subsequent cardiovascular events or complications.[12]

In patients with cardiovascular conditions and risks the HRQL is often impaired. Any cardiovascular patient is faced with problems in several domains of daily life, and investigations in this field should cover physical, mental and social health. The aim of this study was to evaluate the effect of the implementation of a comprehensive intervention program on the quality of life in patients at high cardiovascular risk.

METHODS

Study design and subjects

A randomized controlled trial was performed in the southern half of the Netherlands from November 1996 until February 1999. Practices were recruited by letter and via regional GP bulletins until a sufficient number of practices were sampled. After baseline measurements, 124 general practices were randomly allocated to either intervention group or control group. Practices were numbered and the person responsible for the randomization process was blinded for the identities of the practices, to ensure allocation concealment.

The control practices received baseline and post-intervention measurements simultaneously with the intervention group. Control practices did not receive any stimuli between randomization and post-intervention measurements. After the intervention, which lasted 21 months, post-intervention measurements were performed in all practices.

During baseline measurements, over a period of two months the general practitioners (GPs) and their staff handed out a questionnaire to patients at high cardiovascular risk. A pre-set maximum number of participating patients per practice was determined for different patient categories, reflecting their relative prevalence in general practice.[13] The participating GPs identified patients known to the practice with diabetes mellitus, cardiovascular disease or hypertension,. Each practice was allowed to enroll 70 patients in the trial: there were questionnaires for patients who were known to the GP with hypertension (n=20), diabetes (n=15), angina pectoris (n=8), heart failure (n=8), hypercholesterolaemia (n=5), myocardial infarction (n=5), transient ischaemic attack (n=3), stroke (n=3), and peripheral arterial disease (n=3). All patients were treated by their GP for their condition. The respondents could return their questionnaire, which included a consent form, in a stamped addressed envelope to the research team. The researchers stimulated practices by telephone to invite patients, until at least 20 patients from the practice had returned their questionnaire. After 21 months, at the start of post-intervention measurements, a second questionnaire was sent by mail to the respondents of the first questionnaire. Before this second mailing, GPs were allowed to exclude patients that had died, had established life-threatening morbidity, left the practice, or were considered unsuitable for participation due to psychosocial

reasons. One postal reminder was sent. The ethical board of the Erasmus University Rotterdam approved the project.

Intervention

Box 1 gives a general description of the intervention, which comprised two aspects of practice organization for prevention (practice management elements and preventive activities) and clinical decision-making. The outreach visitors stimulated adequate practice organization, registration and task delegation to achieve optimal case finding and addressed appropriate diagnosis of cardiovascular risk factors and diseases. The GPs and their staff were encouraged to apply pharmacological and non-pharmacological treatments (e.g. information on lifestyle changes and advice on smoking cessation) according to evidence-based guidelines issued by the Dutch College of General Practitioners and consensus procedures.[14]

Measurements and variables

The MOS 36-Item Short-Form Health Survey (SF-36) is an instrument suitable to examine the influence of interventions on HRQL.[15] It is a generic health status instrument designed for use across a wide range of chronic disease populations, which has been shown to have excellent reliability and validity.[16-19]

During baseline and post-intervention measurements data were gathered on patient items. The questionnaires addressing patient items comprised the SF-36 and additional questions on gender, age, education level, employment and insurance status. The SF-36 is a self-administered questionnaire, which contains 36 questions measuring both positive and negative health states. For the purpose of this study we used the Dutch translation.

Three dimensions of health are central in the SF-36: physical, mental and social health, included in eight scales: physical functioning, role limitations (physical problem), bodily pain, general health perception, vitality, role limitations (emotional problem), social functioning and mental health. In computing scale scores, item scores were coded and summed into scale scores. The scores were transformed into a scale from 0 (worst health) to 100 (best health).

As recommended, the scales were aggregated into two summary measures: a physical component scale (PCS) and a mental component scale (MCS). The PCS and MCS

were constructed and scored to reduce the SF-36 from an eight-scale profile to two summary measures without substantial loss of information.

Taking into account the distribution of patients' self-reported risk factors, we divided all patients into three mutually exclusive categories of sufficient size: patients with diabetes mellitus; patients with cardiovascular disease (hypercholesterolemia, transient ischemic attack, stroke, heart failure, angina, myocardial infarction and peripheral arterial disease) without diabetes; and patients with hypertension without cardiovascular disease and without diabetes. We assumed that GPs make these distinctions in their normal management of high-risk patients.

Analysis

Statistical analysis of the data was performed using SAS, release 6.12. Outcome variables were the differences between baseline scores and the scores of the SF-36 subscales at post-intervention measurements. In order to take within practice correlations into account, multilevel linear regression analysis was performed (PROC MIXED; patients nested within practices), adjusting for gender, age, education, employment and insurance.

Box 1. Description of the intervention program.

General description of the CARPE project (CARdiovascular risk reduction in Primary carE)

Aim: To implement a comprehensive program on cardiovascular and diabetes care for patients at high-risk for cardiovascular disease, in general practice. The content of the program comprised a detailed description of practice organization and clinical decision-making in the 'ideal' practice.

In the 'ideal' practice the following items are performed:
- Optimal computer facilities, instruments and materials are available;
- Adequate risk profiling of high-risk patients is performed;
- Separate preventive clinics for patients with diabetes or hypertension are all well organized;
- There is a system for monitoring follow-up;
- Staff is intensively involved in preventive tasks and quality is insured by protocols and regular staff meetings;
- Clinical decision-making is according to latest evidence-based guidelines;
- The GPs have the knowledge and skills for appropriate performance of all stages and aspects of consultations with high-risk patients: diagnosis, assessment and evaluation of additional risk factors, counseling and education, pharmacological treatment, follow-up, and referral;
- Ancillary staff members are well trained to perform their part of patient care.

Procedure: Outreach visitors supported GPs and their staff with the implementation of the intervention in 15 outreach visits per practice in a period of 21 months. Most visitors were former practice assistants, experienced in performing outreach visits and specially trained for this study. The visitors provided suggestions and guidance; the practice team implemented the changes. Each visit, the person involved in the discussed aspect was present, most of the visits were with all staff members. The protocol of the visits was highly structured to limit variation. In the first eight visits the intervention focused on practice organisation and in the last seven visits on clinical decision-making. A visit lasted on average one hour.

Implementation strategy: Subsequent steps in a theoretical model of change were used to achieve improvement. These steps are: orientation, insight, acceptance and change. Feedback reports, based on baseline data, were produced to provide orientation and insight. The feedback report was also intended to create awareness of (gaps in) actual performance in comparison to the 'ideal' practice. The outreach visitors stimulated acceptance by supporting the practice members to draw up and prioritise a list with gaps and planned changes targeted to their personal circumstances. The practice members and outreach visitors identified and discussed barriers to change. Throughout the visits the facilitators provided guidance, advice, training and educational materials for each gap to reach the goals and achieve changes. Progress was evaluated regularly.

RESULTS

At baseline, 3964 respondents returned their questionnaires. At the time of post-intervention measurements GPs had excluded 279 (7%) patients, mostly because these patients left the practice, or had died. Of the remaining 3685 patients the response in the post-intervention measurements was 3176 (86%) patients. For 2412 respondents both baseline and post-intervention SF-36 questions were analyzable and, of these, 2268 could be allocated to the three patients categories. Table 1 gives the baseline characteristics of the patient categories by control and intervention group. There were no large differences between scores, but the SF-36 scores in the diabetes mellitus patients were slightly higher in the intervention group than in the control group. For all patient categories, the control group had slightly more men and more were employed.

Quality of life

Table 2 gives the changes in all subscales of the SF-36 scores that occurred between baseline and post-intervention measurements, by patient category. Before multilevel analysis we analyzed variables that were thought to be potential confounders (gender, age, education, employment and insurance) for their effect on outcome scores and then adjusted for these. The overall picture is that the quality of life decreased for all respondents, but decreased more in the control practices than in the intervention practices. In all three patient categories the lowest baseline score was for general health.

The differences between intervention and control group were significant in two subscales for two categories: for those with diabetes mellitus the 'vitality' and 'mental health' subscale, and for the cardiovascular disease group the 'vitality' and 'physical functioning' subscale. For patients with hypertension there was no significant difference between the intervention and control group on any of the subscales or the summary scales.

Considering the overall of changes, patients with cardiovascular disease in the intervention practices have a better physical score than those in the control group. It is noteworthy that the changes in the overall physical score (PCS) are negative in all

groups whereas the changes in the overall mental score (MCS) are mostly positive (differences not significant).

Table 1. Baseline characteristics of cardiovascular disease categories in intervention and control practices.

	Diabetes Mellitus		*Cardiovascular disease*		*Hypertension*	
	Intervention	*Control*	*Intervention*	*Control*	*Intervention*	*Control*
Number of subjects	278	259	300	317	539	575
Number (%) of men	141 (51.0)	143 (55.2)	192 (64.2)	217 (68.5)	227 (42.2)	260 (45.2)
Mean (SD) age in years	66.2 (9.9)	65.0 (9.8)	67.8 (9.2)	66.8 (10.0)	60.7 (11.1)	60.4 (11.2)
(%) Education:						
- Primary	37.9	34.3	33.5	31.4	21.6	19.3
- Lower secondary	39.1	36.8	37.1	40.1	46.3	47.2
- Higher secondary	14.8	20.9	19.4	20.1	20.0	22.5
- University	8.2	7.9	10.1	8.4	12.2	11.0
(%) Employed	20.8	22.8	15.8	21.7	38.7	41.9
(%) Insurance:						
- NHS	73.6	69.8	68.9	70.7	59.8	58.2
- Private	26.4	30.5	31.1	29.3	40.2	41.8
Mean (SD) SF-36 scores:						
- PF- Physical functioning	74.2 (23.6)	77.4 (21.9)	70.5 (22.3)	70.6 (22.6)	84.5 (17.5)	84.6 (17.7)
- RP- Physical role functioning	71.6 (40.2)	76.2 (37.2)	64.6 (41.5)	61.4 (42.6)	84.5 (31.5)	83.4 (32.5)
- BP- Bodily pain	76.0 (25.5)	79.1 (24.0)	73.7 (24.0)	73.7 (24.3)	83.0 (22.4)	83.7 (21.6)
- GH- General health	59.9 (19.4)	62.8 (19.1)	58.9 (18.8)	58.1 (18.7)	69.5 (11.0)	69.2 (17.3)
- VT- Vitality	62.0 (21.7)	65.8 (18.7)	60.8 (20.6)	60.9 (19.5)	67.8 (18.4)	66.4 (18.7)
- RE- Role emotional	78.8 (36.2)	82.1 (33.7)	76.0 (38.1)	71.5 (40.6)	85.6 (31.1)	85.0 (31.9)
- SF- Social functioning	81.9 (22.2)	83.4 (20.2)	80.0 (22.2)	78.6 (23.7)	87.8 (19.4)	86.3 (20.7)
- MH- Mental health	73.0 (18.9)	74.3 (17.1)	71.1 (19.4)	71.6 (17.9)	75.7 (16.9)	74.1 (16.9)
Summary scores:						
- PCS- overall physical	46.0 (10.5)	47.6 (9.4)	44.6 (9.6)	44.4 (9.9)	50.7 (8.3)	50.9 (8.0)
- MCS- overall mental	50.5 (10.4)	51.3 (9.4)	50.0 (10.9)	49.5 (10.9)	51.7 (9.8)	50.8 (9.7)

Table 2.
Changes in SF-36 scores between baseline and post-intervention measurements by patient category for subscales of the SF-36, adjusted for gender, age, education, employment and insurance.

A. For patients with *diabetes mellitus*.

SF-36 scale	*Intervention*	*Control*	*Adjusted difference (95% CI)*	*P-value*
PF	-3.6	-4.4	0.83 (-2.44 to 4.10)	0.620
RP	-3.6	-4.9	0.59 (-6.56 to 7.74)	0.872
BP	-0.1	-3.9	3.75 (-0.44 to 7.94)	0.083
GH	-1.3	-3.2	1.87 (-0.80 to 4.54)	0.173
VT	0.8	-4.1	5.20 (2.24 to 8.16)	<0.001
RE	-0.1	-3.0	0.19 (-7.16 to 7.54)	0.959
SF	-0.7	-3.1	1.88 (-2.10 to 5.86)	0.359
MH	1.7	-2.8	4.06 (0.85 to 7.27)	0.015
PCS	-1.4	-1.8	0.42 (-1.05 to 1.89)	0.573
MCS	1.0	-1.2	1.65 (-0.29 to 3.59)	0.108

B. For patients with *cardiovascular disease*.

SF-36 scale	*Intervention*	*Control*	*Adjusted difference (95% CI)*	*P-value*
PF	-1.9	-5.3	3.54 (0.48 to 3.60)	0.025
RP	-0.4	-0.6	1.68 (-5.36 to 8.72)	0.641
BP	2.3	-0.3	3.84 (-0.08 to 7.76)	0.058
GH	0.5	-1.6	1.80 (-0.70 to 4.35)	0.169
VT	-0.9	-2.4	3.15 (0.70 to 5.60)	0.013
RE	-1.2	5.4	-6.22 (-13 to 0.56)	0.075
SF	-0.2	-3.1	3.33 (-0.49 to 7.15)	0.090
MH	0.9	-0.6	1.95 (-0.66 to 4.56)	0.144
PCS	-0.1	-1.5	1.70 (0.29 to 3.11)	0.020
MCS	0.3	0.5	-0.17 (-1.68 to 1.34)	0.826

C. For patients with *hypertension*.

SF-36 scale	*Intervention*	*Control*	*Adjusted difference (95% CI)*	*P-value*
PF	-2.6	-2.9	0.28 (-1.60 to 2.16)	0.768
RP	-1.3	-1.4	-0.21 (-4.29 to 3.87)	0.920
BP	-0.2	-2.3	2.10 (-0.57 to 4.77)	0.123
GH	-1.9	-0.6	-0.65 (-2.71 to 1.41)	0.538
VT	-0.6	-0.6	0.61 (-1.43 to 2.65)	0.557
RE	3.7	1.8	1.67 (-2.92 to 6.26)	0.477
SF	-0.5	-0.4	0.53 (-2.06 to 3.12)	0.692
MH	1.0	0.8	0.57 (-1.17 to 2.31)	0.524
PCS	-1.3	-1.3	0.07 (-0.79 to 0.93)	0.875
MCS	1.0	0.8	0.42 (-0.74 to 1.58)	0.481

See table 1 for abbreviations for abbreviations of the SF-36 subscales.

DISCUSSION

In the present study, the effect of the implementation of a comprehensive preventive program on the perception of quality of life in patients with three types of cardiovascular conditions was assessed. After finding that our intervention was successful in optimizing both practice organization and clinical decision-making, the next step was to assess effect at patient level. The results show that the intervention program had a positive impact (less impairment) on several domains, particularly in patients with diabetes and with cardiovascular disease.

The SF-36, being a generic instrument is highly suited for surveying patients with cardiovascular diseases or cardiovascular risks.[15-19] The patients in the present study were enrolled during consultations and were probably seen regularly by their GP for their chronic condition. Although our intervention was not aimed specifically at individual patients, but rather at practice employees, we were able to detect changes in patients' HRQL.

There was an interval of at least 21 months between baseline and post-intervention measurements, which might explain the overall deterioration in HRQL in all respondents.[20]

For diabetic patients there was a trend towards improvement after intervention in all scales, and in most scales for patients with cardiovascular disease. In all three patient categories the vitality scale scored poorly at baseline. The intervention led to a significant improvement in the vitality and mental health scale in diabetes mellitus patients. The effect size in the vitality scale is considered to be both clinically and socially relevant.[21]

In the cardiovascular disease group the intervention had a positive effect on vitality, with the largest improvement seen in physical functioning. Trends toward improvement were apparent in seven of the eight scales. The cardiovascular disease group was the only one in which an overall summary score was significant, namely that of the overall physical score. It has previously been reported that patients with coronary heart disease have the most benefit in physical aspects.[2,22]

For patients with hypertension (a condition that is often asymptomatic) none of the changes in subscales or overall scales proved to be significant. In similar patients Bardage et al. found changes in most of the eight SF-36 domains,[12] however their study was aimed at the general population whereas ours was based on patients visiting

their GP. In the Medical Outcome Study, Stewart et al. reported lower general health perception in hypertensive patients compared with patients without chronic conditions, but they used the SF-20, a shorter and earlier version of the SF-36.[23]

A number of issues may limit the representativeness of the study data. First, our results are based only on self-completed questionnaires to measure quality of life; however this instrument has been validated and used extensively. Representativeness may be somewhat compromised, since the participating practices were invited to join the study and may have been more motivated towards change than the average Dutch practice. Bias may have occurred, since the participating GPs identified patients known to have diabetes mellitus, cardiovascular disease or hypertension. It is therefore conceivable that the group of patients receiving the questionnaires from the GP experienced more complaints than the patients with these conditions that did not receive a questionnaire. On the other hand, it is also possible that the GP did not give the questionnaire to severely ill patients, thus leading to an underrepresentation with respect to levels of severity.
For this study, we believe that randomization at practice level was relevant, because the individual professional's behavior influences patient management to the extent that patients seen by the same professional cannot be assumed to be independent.
Despite these limitations, the data probably do provide a representative overview of patients a GP frequently sees.

In conclusion, implementation of a comprehensive intervention program in general practice had a positive effect on several domains of quality of life in patients at high cardiovascular risk.

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CHAPTER 8

General Discussion

INTRODUCTION

The main aim of this thesis was to assess to what degree improvement of the quality of preventive care for patients at high cardiovascular risk in general practice could be achieved through a multifaceted intervention by outreach visitors.

To achieve this aim we conducted a randomized controlled trial. After baseline measurements, 124 general practices were randomly allocated to either intervention group or control group. The intervention, which lasted 21 months, was followed by post-intervention measurements in all practices.

In this thesis the initial focus is on practice organization, which is a crucial subject because it can help to improve patient care and to improve efficiency in ordinary practice. First we established the organizational determinants, followed by an accurate representation of the multifaceted intervention, including the costs to carry out the intervention. Then we performed a process evaluation and assessed the effect of the intervention on the quality of preventive care in practice organization settings and on clinical decision-making. Subsequently, we assessed which determinants of the intervention contributed to its success and, finally, we determined quality of life as patient outcome.

In this chapter conclusions are drawn and the main findings are discussed.

Major findings and Conclusions

Organizational determinants

In order to explore factors in the practice organizational setting as barriers to prevention and disease management, we conceptualized a causal model. Our results on adherence to selected aspects of the organization of preventive care showed considerable variation in the degree to which practices have integrated preventive care into daily routine.

General practitioners (GPs) with a working experience of less than 15 years and practices with only female GPs were found to register risk factors or diseases significantly better. The presence of three or more GPs in a practice was found to be related to good teamwork, which is associated with better performance of registration and follow-up. Teamwork in the practice turned out to be a crucial feature of practice

management, showing significant relations with two main preventive activities: follow-up arrangements and registration policy.

Description of the intervention and process evaluation

After establishing a detailed protocol for the multifaceted intervention, we performed a process evaluation and demonstrated that the intervention was mainly carried out as planned and achieved a high satisfaction rating from the participating practice members.

A number of recommendations and lessons can be learned from this process evaluation for implementing such a comprehensive program on cardiovascular and diabetes care. Outreach visitors were accepted to facilitate change in both the practice organization and clinical decision-making. Regular visits by the outreach visitor were evaluated as pleasant and especially indispensable for progress toward changing practice habits. Written educational materials were accepted by practice members. Regular evaluations were considered positive and seen as an opportunity to express feelings and ideas about different aspects of the project. Participation in the implementation program was overall good. A visit of one hour could be easily integrated in practice routine.

In addition, we also determined the costs of the intervention. The mean total cost of the intervention was more than 4300 Euro per practice; this is more than 20 million Euro for a national implementation.

Effect evaluation considering practice organization

The comprehensive intervention program using outreach visits was carried out successfully and proved to be effective in improving organization of cardiovascular preventive care in general practice. The intervention was effective for all aspects of the organization of preventive care, which supports the validity of the theoretical model.

We found that the proportion of practices offering separate preventive clinics for hypertensive patients almost quadrupled in the intervention group. Stop smoking packages were also used by more practices. Record keeping, a crucial element in preventive care, showed a large increase. The item of record keeping that showed the largest change was the recording of cardiovascular risk factors (hypertension, smoking and individual cardiovascular history) in a recommended location of the file. Probably more importantly, the proportion of practices making risk profiles (including

at least blood pressure, smoking and individual cardiovascular history) increased from 3% to 40%. The intervention practices showed significantly more improvement in adherence to organization of preventive care compared to the control practices.

Determinants of a successful intervention

To gain insight into which of the program elements contributed most to the observed effects in organization of prevention, a priori we identified key characteristics of the intervention program, characteristics that seemed to be important when considering the models of change used to create the multifaceted intervention. Duration of exposure to program aspects proved to be the most important determinant of success. There was little variation in the mean number of months each practice worked on a particular aspect, ranging from an average of 3.1 months for preventive tasks performed by the practice assistant to 5.6 months for record keeping. However, there was a considerable difference in time invested on the project by GPs (mean 18.2 hours) and by practice assistants (mean 9.9 hours).

The number of visits used to change a specific aspect was agreed between the outreach visitor and the practice employees. The largest number of visits was spent on setting up specific separate preventive clinics. We found that 16% of the practices addressed teamwork during the intervention and the mean number of visits spent on this element was less than one. In practices where at least half of the GPs were positive about the given feedback, the greatest change was found for the availability of instruments and materials. The duration of exposure to an aspect showed the strongest relationship with changes in the presence of separate clinics and of teamwork.

Effect evaluation concerning clinical decision-making

Intensive support from outreach visitors improved GPs' clinical decision-making with regard to the assessment of risk factors and the provision of information and advice for certain types of patients at high cardiovascular risk, and also the checking of clinical signs of deterioration for patients with heart failure.

The intervention resulted in significant improvements for 5 of the 12 indicators: assessment of risk factors for patients with hypercholesterolemia and patients with angina pectoris, provision of information and advice to patients with hypercholesterolemia and patients with treated hypertension, and checking clinical

signs of deterioration for patients with heart failure. Single-handed practices, non-training practices, and practices with older GPs benefited most from intensive support on the provision of information and advice to patients with hypercholesterolemia and patients with treated hypertension.

Patient outcome

After finding that our intervention was successful in optimizing both practice organization and clinical decision-making, the next step was to assess effect at patient level. The results at patient level show that the intervention program had a positive impact (less impairment) on several domains, particularly in patients with diabetes and with cardiovascular disease.

Health-related quality of life deteriorated in all respondents, but was more pronounced in the control group. The intervention led to a significant improvement in the vitality and mental health scale in diabetes mellitus patients. In the cardiovascular disease group the intervention had a positive effect on vitality, with the largest improvement seen in physical functioning. Trends toward improvement were apparent in 7 of the 8 scales. In patients with hypertension, there were no differences between the intervention and control group for any of the subscales.

DISCUSSION

Actual performance of cardiovascular preventive care in general practice is still below recommended levels. In our project we implemented a multifaceted intervention on cardiovascular preventive care in general practice. We followed a structure of outreach visitors implementing an intervention based on quality assurance. The implementation of the multifaceted intervention was carried out as planned and proved successful in structure, process and patient outcomes.

Structure and process

High quality of care for patients with cardiovascular risks or problems requires an adequate practice organization.[1-4] It is acknowledged that general practice is 'ideally placed' to provide coordinated cardiovascular preventive care, but most practices cannot do this without initial, if not continuing, external support. Practice process

change requires significant effort and is difficult to initiate without consensus and group support.[5-7]

We found that a well-equipped practice is not sufficient to perform adequate preventive care. Teamwork in the practice turned out to be the most crucial feature of practice management (chapter 2). Promoting teamwork in primary care has become an important issue over the last decade, both in the UK and in the USA.[5,7-9] Good teamwork is a key element of providing high quality care.[10] The most successful systems use the skills of the entire healthcare team and the practice infrastructure to provide prevention services.[11]

The effect of the multifaceted intervention on practice organization was impressive (chapter 4). Every aspect of practice organization showed significant improvement. An important finding was the large improvement of making risk profiles for high-risk patients. Completion of risk profiles is a prerequisite for adequate care, as it allows comprehensive management of cardiovascular patients. Furthermore, the availability of a risk profile avoids unnecessary actions and questions at future consultations. Improvement in the recording of cardiovascular risk factors has been reported before.[12,13]

The effect on clinical decision-making was less impressive, but nevertheless satisfying (chapter 6). The intervention improved clinical decision making for several aspects of cardiovascular care. An important finding was the improvement in GPs' clinical decision making with regard to the assessment of risk factors for certain types of patients at high cardiovascular risk. Risk factor profiles are closely linked to subsequent morbidity and mortality in patients with cardiovascular heart disease.[14]

One may wonder why the change in clinical decision-making was not significant on every aspect. All kinds of professional, patient-related and environmental barriers may undermine clinical decision-making.[15] There may have been barriers that have been addressed inadequately in our intervention. We should not forget that the outreach visitors in our study were non-physicians. Although the outreach visitors did ask the GPs about barriers to change, they may have needed more intensive training to be able to identify and tackle these barriers.

Patient outcome

Health-related quality of life is an important consideration in healthcare decisions and can provide a clinically relevant outcome measure of health care.[16]

Systematic approaches to implementing clinical prevention services have been shown to result in improved health outcomes.[17-19] When data on patient outcomes are not available, or in case of conflicting evidence, physicians may be justified in not wanting to change their practices. However, we found the effect size in the vitality scale in diabetes mellitus patients to be clinically and socially relevant. This finding may stimulate GPs in maintaining a structured practice organization.

Workload

Societal changes affect the degree to which individual GPs are likely to consider improvement of their cardiovascular preventive care. Nowadays, the use of the word 'prevention' in an invitation flyer can deter possible participants, because it is associated with a lot of additional work. In our process evaluation (chapter 3) more than 70% of the GPs indicated that working according to the project guidelines took too much time. It would be interesting to ask the same question in about five years, when consolidated changes in disease management should have resulted in a decrease in the GPs' workload. For instance, it is conceivable that routine tasks performed by ancillary staff will allow a GP to dedicate his/her attention to other priorities.

In the Netherlands there is currently a shortage of GPs. An advantage of this situation is that more GPs may consider the possibility to delegate more patient care to their practice assistants. Practice assistants have strong professional interests and growing self-awareness, and the majority would welcome job changes that would allow them more time and responsibility in patient care.[20]

Prevention or 'normal care'?

In our project we aim at patients at high cardiovascular risks. Focusing on known high-risk cases has beneficial effects and the effects on patients with established cardiovascular disease are substantial.[21-23] Cost-effectiveness analyses indicate similar priorities.[24]

When addressing prevention in this thesis, we actually consider secondary prevention. Preventive care for patients at high risk for cardiovascular disease is seen as secondary prevention; some argue that this kind of prevention is simply adequate

treatment, and should not be seen as something in addition to the normal quality of care.

From this viewpoint it can be argued that with the aging of the population and increasing morbidity the GP alone is not capable of performing adequate care. More support in general practice is needed to perform adequate care.

Costs of the intervention

The benefits of systematic health promotion in general practice are real, but must be weighed against the costs in relation to other priorities. By performing economic evaluations we can give information about the relative efficacy of the intervention.[25]

The objective of valuing costs is to obtain an estimate of the worth of resources.

In our project the mean total cost of the intervention was more than 4300 Euro per practice. It is difficult to generalize the interpretation of the costs of the intervention. For an individual practice it is perhaps an unacceptably large amount, although any effort toward quality improvement will generate costs. For instance, by participating in the project the GPs received 6 hours of accreditation, in other circumstances they would have to pay to obtain these accreditation hours. From a societal point of view, however, costs may well be counterbalanced by long-term revenues, in terms of years and quality of life gained.

The costs made initially for the maintenance of changes will diminish gradually and an important advantage is that improved systems of care for one disease can have spillover benefits for other conditions. At first, quality initiatives in one area tend to draw time, resources, and motivation away from others. But, eventually, it provides GPs with an excellent foundation on which to build an integrated system that will allow the parallel implementation of different preventive services to diverse patient groups within the same setting.

Limitations

A number of issues may limit the representativeness of our study. First, the practices volunteered to participate and may have been especially interested to adopt the intervention. This limitation is generally inevitable in studies addressing change in professional behavior, as willingness to change is a prerequisite to participate. In the results on adherence to aspects of the organization of preventive care this limitation

could imply that overall, an even higher proportion of practices may not have an adequate practice organization to carry out prevention.

In the process evaluation there is a possibility of social desirability bias when we asked for acceptance of the intervention.
In the effect evaluation regarding clinical decision-making, more GPs in the intervention group may have selectively recorded patient encounters at post-intervention (compared with the control group), because the GPs were not blind to the allocation of their practice. Selective recording is, however, unlikely because the groups did not differ substantially with regard to the number of patient encounters, the mean age of the patients, or the proportion of males. Moreover, the intervention did not improve compliance for all indicators.

Four practices did not finish the intervention. We considered these withdrawals to be a minor problem as these practices agreed to perform post-intervention measurements. A possible limitation in the health-related quality of life outcomes is that our results are based on self-completed questionnaires to measure quality of life; however, the SF-36 has been validated and used extensively. Bias may have occurred, since the participating GPs identified patients known to have diabetes mellitus, cardiovascular disease or hypertension. It is therefore conceivable that the group of patients receiving the questionnaires from the GP experienced more complaints than patients with these conditions that did not receive a questionnaire. On the other hand, it is also possible that the GP did not give the questionnaire to severely ill patients, thus leading to an underrepresentation with respect to levels of severity.

Recommendations

Future research

The effect of multifaceted interventions has already been demonstrated; prior to trying new strategies, the effect should be evaluated after, for example, 2 and 5 years to know whether the changes found for practice organization and clinical decision-making have been sustained and to include patient outcomes on morbidity, mortality and cost-effectiveness.
Intensive support from non-physicians improved clinical decision-making for some but not all aspects of cardiovascular care. The strategy therefore needs further

development. The effectiveness of support from non-physicians versus physicians is important in terms of the costs; therefore it would be interesting to compare physician and non-physician support.

After effective organization of general practice, more attention needs to be paid to the interface between general practice and hospital care so that these high-risk patients do not get 'lost' between the two services.

In the future, automated data systems for managing clinical care should be easier to use in daily practice. For example, risk factor information should be easily accessible and patient information should be exchangeable between the different care providers of general practice and hospital staff.

Practice and policy making

An appropriate question to ask is whether practices are able to institute the magnitude of changes made during this project without the support and intense follow-up that was provided by the outreach visitors. Ideally, when wanting to address secondary prevention, a GP should be able to receive funding from health insurance companies to engage an outreach visitor to give support over a fixed period of time. An example where financial incentives have been successful in the Netherlands is the uptake of influenza vaccinations. This should also be considered for cardiovascular disease prevention; for example, a preventive consultation.

To deliver adequate quality of preventive care more ancillary staff is needed in general practice. A new phenomenon in general practice in the Netherlands is the 'practice nurse'; this is a qualified person that takes over preventive tasks for diabetes mellitus and COPD in at least three general practices. This support is funded by the government, together with health insurance companies and the Dutch National Association of General Practitioners. Future evaluations should establish whether this less intensive strategy also induces sustained changes.

Government policies should stimulate the total management of high-risk patients, from practice organization to clinical decision-making at different stages of the consultation. General practice needs help to be able to improve cardiovascular preventive care with regard to structure and process. We have demonstrated that outreach visitors could provide this help.

Conclusion

Adapting a multifaceted intervention such as the CARPE project allows support to both practice assistant and general practitioner in improving practice organization and clinical decision-making.

When initiating this project, we expected that this study would offer a feasible model for large-scale implementation of standards and improvements in the care for patients with cardiovascular risk indicators or diseases in general practice. We believe that our results indicate that the multifaceted intervention with support by outreach visitors is such a model. This trial demonstrates that general practices will work to improve the quality of their prevention service systems. The intervention used was well received and to a significant degree internalized by the practices involved.

Our project has again proved the effectiveness of a multifaceted intervention to implement evidence-based medicine in daily practice. This kind of evidence-based implementation is needed to further narrow the gap between research and practice.

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CHAPTER 9

Summary

This thesis describes the results of the CARPE-project. The aim of this project was to assess to what degree the quality of preventive care for patients at high cardiovascular risk in general practice could be improved through a multifaceted intervention by outreach visitors.

Patients with hypertension, diabetes mellitus, hypercholesterolemia or cardiovascular disease are considered patients at high-risk of a cardiovascular disease event. It is generally accepted that the general practitioner (GP) plays a pivotal role in prevention of complications in these patients; however general practice is not yet performing these tasks satisfactorily. High quality of care for patients with cardiovascular risks or problems requires an adequate practice organization and adequate clinical decision-making. Educational outreach visits have shown to be a promising approach to modify professional behavior.

In a randomized controlled trial we investigated whether the support by outreach visitors is effective. After baseline measurements 124 general practices were randomly allocated to either intervention group or control group. After 21 months of intervention, post-intervention measurements were performed. During 15 practice visits trained outreach visitors supported the practices by means of providing information, feedback, education and materials. The goal of the intervention was to implement guidelines concerning practice organization and evidence-based decision-making.

Chapter 1 presents the introduction and the aims of the present work.

With baseline data we tested in *Chapter 2* a model to assess which organizational determinants are related to performance of preventive activities. We looked at the direct effects of practice characteristics on preventive activities and indirect effects of practice characteristics through practice management items on preventive activities.

Important differences were found in adequacy of the organization in the different practices. The number of general practitioners (GPs) in the practice had the greatest effect on the quality of record keeping. The greatest effect on appropriate follow-up of patients was found for GPs working part-time versus full-time. Of the practice management features, particularly teamwork proved to be important. We found that the presence of three or more GPs in a practice is related to good teamwork, which is in turn associated with better performance of record keeping and follow-up.

Despite the wide variety of practice organizational items investigated, a strong influence of non-measured variables is evident. Teamwork in the practices proved to be the most important feature of practice management. Teamwork also showed significant relations with two major preventive activities: i.e. follow-up and record keeping.

Chapter 3 describes the multifaceted intervention and its process evaluation, addressing the feasibility by evaluating whether the intervention developed as planned and whether the practice team accepted the intervention; in addition, the costs of the intervention are determined.

The intervention was largely carried out as planned, although the intervention period had to be extended by three months. Of the 18 topics that could be addressed during the intervention period, 12 were addressed. The number of outreach visits per practice was 15 and each visit lasted about one hour. Most practice members (i.e. GPs and practice assistants) endorsed both the key recommendations for clinical decision-making and cardiovascular risk profiling.

Of all GPs, the majority agreed with the guidelines for clinical decision-making and for practice organization. GPs and practice assistants considered that the outreach visitor had sufficient knowledge and skills to support them in changing the practice organization. GPs were less positive about the outreach visitor's knowledge and skills in optimizing clinical decision-making; however, more than seventy percent believed that the outreach visitor contributed to effecting change in their clinical decision-making. Finally, the total costs of the intervention per practice were just over 4300 Euro.

This process evaluation has demonstrated that the intervention was mainly carried out as planned and achieved a high satisfaction rating from the participating practice members

Chapter 4 describes the effect of the intervention on the quality of organizing preventive care. In addition, we aimed to identify practice characteristics related to a successful intervention.

The aspects of practice organization we considered were task delegation, availability of instruments and materials, separate clinics, teamwork, record keeping and follow-up routines. The difference in change between intervention and control group was

- Intensive support from facilitators was an effective strategy to alter certain aspects of GPs' clinical decision-making in cardiovascular care.
- The intervention resulted in improvement of health-related quality of life on several domains in patients with diabetes mellitus and with cardiovascular disease.

Samenvatting

In dit proefschrift worden de resultaten beschreven van het CARPE-project (CArdiovascular Risk reduction in Primary carE). Dit project had als doel in de huisartspraktijk het effect te onderzoeken van een zorgvuldig ontwikkeld interventieprogramma op de zorgverlening aan patiënten met hart- en vaatziekten en patiënten die daar een verhoogd risico op hebben.

Preventie van complicaties bij hoog-risicopatiënten behoort tot het dagelijks werk van de huisarts en vertegenwoordigt een zeer groot volksgezondheidsbelang. Hoog-risicopatiënten zijn patiënten met suikerziekte (diabetes mellitus), een hoog cholesterol (hypercholesterolaemie), een hoge bloeddruk (hypertensie) of patiënten met een reeds bestaande ziekte van hart- of bloedvaten (TIA, angina pectoris, hartfalen, decompensatio cordis en perifeer arterieel vaatlijden). Ondanks het belang van preventie blijkt de kwaliteit van de zorgverlening op dit gebied niet optimaal te zijn. Voorwaarden om deze preventieve taken adequaat uit te voeren zijn een goede praktijkorganisatie en evidence-based medisch handelen. Uit eerder onderzoek is gebleken dat ondersteuning van buitenaf door middel van praktijkbezoeken door consulenten een succesvolle aanpak is om professioneel gedrag te veranderen.

Volgens het design van een gerandomiseerde, gecontroleerde trial hebben we onderzocht of ondersteuning door consulenten werkelijk effectief is. Na een voormeting werden 124 huisartspraktijken verdeeld in een groep die gedurende 21 maanden de interventie ontving en een controlegroep. De interventieperiode werd gevolgd door een nameting in zowel de interventie- als de controlepraktijken.

De interventie bestond uit een combinatie van het verschaffen van informatie, feedback, educatie en praktische hulpmiddelen en het begeleiden van veranderprocessen door getrainde consulenten tijdens 15 bezoeken per praktijk. Doel van de interventie was het implementeren van richtlijnen voor een optimale praktijkorganisatie en voor wetenschappelijk onderbouwd medisch handelen.

In *Hoofdstuk 1* wordt de inleiding beschreven met de doelstellingen van het project.

Met de gegevens uit de voormeting hebben we in *Hoofdstuk 2* een model getest om te bepalen welke factoren van de praktijkorganisatie gerelateerd zijn aan de uitvoering van preventieve activiteiten. Hierbij onderscheiden we niet alleen de directe effecten van praktijkkenmerken op preventieve activiteiten, maar ook de indirecte effecten via praktijkmanagement.

We vonden aanzienlijke verschillen in praktijkorganisatie tussen de verschillende praktijken. Indien er meerdere huisartsen in de praktijk aanwezig waren, bleek de kwaliteit van de registratie in de praktijk beter te zijn (o.a. alle patiëntgegevens in de computer, risicofactoren en diagnoses noteren, maken van een risicoprofiel). Parttime werkende huisartsen bleken hun patiënten beter te volgen door goede vervolgafspraken te maken, een afspraakkaartje mee te geven en eventueel te laten bellen als de patiënt zijn afspraken niet nakomt (follow-up). Van de items van praktijkmanagement, bleek vooral het werken als team belangrijk. De aanwezigheid van drie of meer huisartsen in een praktijk was gerelateerd aan werken als team en dit had tevens het grootste indirecte effect op de preventieve activiteiten follow-up en registratie.
Het werken als team bleek het belangrijkste onderdeel van praktijkmanagement en leidde tot een significante verbetering van twee belangrijke preventieve activiteiten: follow-up en registratie. Ondanks de grote hoeveelheid gemeten kenmerken van de praktijkorganisatie, was er toch ook een grote invloed van niet gemeten variabelen.

Hoofdstuk 3 beschrijft de interventie en de procesevaluatie. We onderzochten of de interventie volgens plan verliep en of de interventie geaccepteerd werd door de praktijkmedewerkers. Bovendien werden de kosten van de interventie in kaart gebracht. De interventie werd grotendeels volgens het vooropgestelde plan uitgevoerd, hoewel de interventieperiode met drie maanden verlengd moest worden. Van de 18 onderwerpen die de consulenten ter sprake konden brengen tijdens de praktijkbezoeken, kwamen er gemiddeld 12 aan bod. Er waren gemiddeld 15 bezoeken per praktijk en elk bezoek duurde gemiddeld een uur. De kernrichtlijnen voor medisch handelen en het maken van een cardiovasculair risicoprofiel kwamen in meer dan 90% van de praktijken aan bod.
De meerderheid van alle huisartsen was het eens met de richtlijnen voor zowel het medisch handelen als de praktijkorganisatie. Zowel huisartsen als praktijkassistentes achtten de kennis en kunde van de consulenten voldoende om hen te ondersteunen in het veranderen van de praktijkorganisatie. Huisartsen waren minder positief over de kennis en kunde van de consulenten met betrekking tot het medisch handelen, hoewel 78% wel van mening was dat de consulenten een bijdrage leverden aan verandering van het medisch handelen. De kosten voor het uitvoeren van de interventie bedroegen ongeveer 4300 Euro per praktijk.

Met deze procesevaluatie hebben we aangetoond dat de interventie grotendeels volgens plan verliep en resulteerde in een hoge mate van tevredenheid bij de deelnemende praktijkmedewerkers.

In *Hoofdstuk 4* wordt het effect van de interventie op de kwaliteit van de praktijkorganisatie beschreven. Bovendien wilden we nagaan welke praktijkkenmerken samenhangen met een succesvolle interventie.
De onderzochte aspecten van praktijkorganisatie waren: aanwezigheid van instrumenten en materialen, delegeren van taken aan de praktijkassistente, houden van aparte spreekuren, werken als team, registratie en follow-up. Voor elk onderzocht aspect was het verschil in verandering tussen interventie- en controlegroep significant. Het grootste verschil in verandering werd gezien voor registratie, wat zowel het goed noteren van risicofactoren inhoudt als het volledig in kaart brengen van alle risicofactoren bij cardiovasculaire patiënten. Concluderend toont deze studie aan dat het interventieprogramma, geïmplementeerd door consulenten, effectief was bij het verbeteren van de organisatie van cardiovasculaire preventie in de huisartspraktijk.

Hoewel interventies door consulenten hun effect reeds bewezen hebben, zijn meer gedetailleerde studies nodig om te begrijpen welke elementen van de interventie werkzaam zijn en waarom. In *Hoofdstuk 5* onderzoeken we welke hoofdkenmerken van onze interventie belangrijk zijn voor het bereikte succes van het programma.
Het opzetten van aparte spreekuren voor patiënten met diabetes mellitus en hypertensie en het werken als team waren aspecten die verbeterden naarmate er meer tijd (in maanden) aan werd besteed. In praktijken waarbij de huisartsen positief waren over de geleverde feedback, bleek een positieve relatie te bestaan met de aanwezigheid van instrumenten en materialen.
Concluderend, hoewel de implementatie van een omvangrijk preventieprogramma succesvol is gebleken, konden we het geheim achter het succes van de interventie niet volledig ontrafelen. Veel tijd besteden aan een bepaald aspect van de praktijkorganisatie was de belangrijkste determinant van succes.

Hoofdstuk 6 beschrijft het effect van de gecombineerde interventie op het medisch handelen. Het was nog onduidelijk of intensieve ondersteuning het medisch handelen van huisartsen beïnvloedt en welke praktijken hier het meeste van profiteren.

We hebben bepaald in welke mate de richtlijnen werden gevolgd voor twaalf evidence-based indicatoren met betrekking tot het feitelijk handelen bij patiënten met hypertensie, hypercholesterolaemie, angina pectoris of hartfalen. Dit werd onderzocht door de deelnemende huisartsen consulten te laten registreren van hoog-risico patiënten tijdens de voor- en de nameting.
De interventie resulteerde in significante verbeteringen voor vijf van de twaalf indicatoren, namelijk voor het bepalen van risicofactoren van patiënten met hypercholesterolaemie en angina pectoris, voorlichting geven aan patiënten met hypercholesterolaemie en patiënten met hypertensie, en nagaan van de klinische toestand van patiënten met hartfalen. Solopraktijken, praktijken zonder opleidingsplaats en praktijken met oudere huisartsen hadden het meeste profijt van de interventie.
Intensieve begeleiding door consulenten blijkt dus naast de verbetering van de praktijkorganisatie, ook een effectieve strategie te zijn om bepaalde aspecten van het medisch handelen van huisartsen met betrekking tot cardiovasculaire zorg te verbeteren.

Het uiteindelijke doel van elke interventie is een verandering op het niveau van de patiënt. Ons gecombineerde interventieprogramma bleek succesvol in het optimaliseren van de praktijkorganisatie en het medisch handelen, nu moest nog de stap naar de patiënt gemaakt worden. In *Hoofdstuk 7* wordt het effect beschreven van de interventie op de kwaliteit van leven bij patiënten met een hoog risico op hart- en vaatziekten.
De kwaliteit van leven werd gemeten met de MOS 36-Item Short-Form Health Survey (SF-36). Hierbij hebben we drie patiëntencategorieën geselecteerd: patiënten met diabetes mellitus, met cardiovasculaire ziekten en met hypertensie.
Tussen voor- en nameting bleek bij alle respondenten een algemene achteruitgang in kwaliteit van leven, maar bij de controlegroep was de achteruitgang aanzienlijk groter dan bij de interventiegroep. Bij diabetes mellitus patiënten was het verschil tussen interventie- en controlegroep significant op de domeinen vitaliteit en psychische gezondheid. Patiënten met cardiovasculaire ziekten lieten veranderingen zien voor vitaliteit en lichamelijk functioneren. Bij patiënten met hypertensie zagen we geen verschillen tussen interventie- en controlegroep.

We concluderen dat ons gecombineerde interventieprogramma gunstige gevolgen had voor de kwaliteit van leven op verschillende domeinen, met name bij patiënten met diabetes mellitus of met cardiovasculaire ziekten. De omvang van het effect bij diabetes mellitus patiënten kan worden beschouwd als zowel klinisch en maatschappelijk relevant.

Hoofstuk 8 beschrijft de belangrijkste bevindingen van deze studie in de vorm van een algemene discussie. De belangrijkste conclusies van dit proefschrift zijn:

- Werken in teamverband in een praktijk is belangrijk voor het uitvoeren van preventieve activiteiten.
- De gecombineerde interventie werd grotendeels volgens plan uitgevoerd.
- De interventie was effectief in het optimaliseren van de organisatie van cardiovasculaire preventieve zorg.
- De hoeveelheid tijd die werd besteed aan bepaalde aspecten van het interventieprogramma bleek de belangrijkste determinant van succes.
- De intensieve ondersteuning door consulenten was een effectieve strategie om bepaalde aspecten van het medisch handelen in de huisartspraktijk te veranderen.
- De interventie resulteerde in verbetering van de kwaliteit van leven op verschillende domeinen bij patiënten met diabetes mellitus en met cardiovasculaire ziekten.

Nawoord

Het onderzoek en het schrijven van dit proefschrift had ik niet kunnen afronden zonder de hulp en steun van vele mensen, waarvan ik een aantal in het bijzonder wil noemen.
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Curriculum Vitae

Claudia Lobo werd op 27 juli 1967 geboren te Paramaribo (Suriname). In 1985 behaalde zij het atheneum-B diploma aan het Groen van Prinsterer Lyceum te Vlaardingen. Aansluitend begon zij met de studie geneeskunde aan de Erasmus Universiteit te Rotterdam. Het doctoraal examen werd in 1990 behaald en het artsexamen in 1992 (*cum laude*). Tijdens haar studie heeft zij gedurende vijf maanden gewerkt op de afdeling Kindergeneeskunde van het Dr. Soetomo Hospital te Surabaya (Indonesië). Het afstudeeronderzoek werd verricht op de afdeling Perinatal Research aan de University of Colorado Health Sciences Center te Denver (Verenigde Staten). Van augustus 1992 tot september 1993 heeft zij gewerkt als arts-assistent in het Holy Ziekenhuis te Vlaardingen op de afdeling Algemene Heelkunde. Aansluitend begon zij de tweejarige opleiding tot huisarts te Rotterdam. Vanaf oktober 1995 werkte zij als huisarts te Hellevoetsluis en startte zij als onderzoeker op het CARPE-project. Na de geboorte van haar dochter Laura, in november 1997, was zij naast haar onderzoekswerkzaamheden huisarts te Capelle a/d IJssel. De combinatie arts-onderzoeker en huisarts is zij blijven vervullen tot de geboorte van haar zoon Roel, in september 1999. Na deze periode richtte zij zich volledig op het onderzoek, allereerst bij de Afdeling Huisartsgeneeskunde te Rotterdam, vervolgens in Sydney (Australië), waarna zij terugkeerde naar Rotterdam en dit proefschrift afrondde. Sinds oktober 2001 is zij werkzaam als huisarts te Prinsenland, Rotterdam. Zij is getrouwd met Hans de Wilt.