Prevention of Cardiovascular Diseases in Deprived Neighbourhoods

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Prevention of Cardiovascular Diseases in Deprived Neighbourhoods

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Contents

Status of the manuscript

Chapter 2
Different distribution of cardiovascular risk factors according to ethnicity: a study in a high-risk population
J Immigr Minor Health, in press

Chapter 3
Prevention of cardiovascular diseases: focus on modifiable cardiovascular risk
Heart 2006;92:741-745

Chapter 4
No evidence for marked ethnic differences in accuracy of self-reported diabetes, hypertension and hypercholesterolemia
J Clin Epidemiol 2007;60:1271-1279

Chapter 5
Intensified preventive care to reduce cardiovascular risk in deprived neighbourhoods: a randomised controlled trial in healthcare centres
in revision

Chapter 6
Process evaluation of an intensified intervention to reduce cardiovascular risk in a multi-ethnic patient population
Eur J Cardiovasc Nurs, in press

Chapter 7
Effect of periodical measurements on the cardiovascular risk in a multi-ethnic high-risk population
Submitted for publication

Chapter 1

General introduction

BACKGROUND

Worldwide, cardiovascular diseases (CVD) remain the leading cause of morbidity and mortality even though mortality rates in the industrialised countries have declined over the past decades. Recent WHO reports show that an estimated 17 million people die every year of CVD, particularly from myocardial infarction and strokes [1]. In Western countries, such as the Netherlands, discrepancies in cardiovascular morbidity and mortality according to ethnicity and socio-economic status still exist [2,3]. Although improvements have been made in reducing cardiovascular mortality and morbidity at the national level, the prevalence of cardiovascular risk factors (such as smoking behaviour and overweight) is higher among individuals with a low socio-economic status and, more specifically, among ethnic minorities than those people with a high socio-economic status and the indigenous Dutch population [4-6]. Persons with a low socio-economic status and ethnic minorities mainly live in the so-called deprived neighbourhoods [7]. In the Netherlands, neighbourhoods are identified as "deprived" according to an index based on income, the number of individuals that depend on social benefits, and the level of urbanisation [8].

The causes of inequalities in cardiovascular health between deprived and non-deprived neighbourhoods are multi-factorial [9]. In contrast to cancer and other chronic conditions, however, considerable progress has been made in understanding many of the risk factors for CVD. There is substantial evidence that the modifiable risk factors - such as smoking, elevated blood pressure and cholesterol levels - increase an individual's risk of CVD.
Because many of the cardiovascular risk factors are modifiable, there is an urgent need to develop appropriate and effective intervention strategies to tackle health inequalities due to CVD, because of the considerable health and economic burden that these diseases put on society [10,11].
In this thesis, major issues that should be considered when designing, implementing and evaluating interventions to reduce inequalities in CVD in deprived neighbourhoods will be dealt with. These include the identification of high-risk individuals that should be targeted by intervention activities, assessment of the prevalence of cardiovascular risk factors, and tailoring intervention to the specific needs of the target population, including process evaluation of the intervention to explain the success or the failure of the intervention programme.

Identification of high-risk individuals (Chapters 2 and 3)

As already mentioned, the population in Dutch deprived neighbourhoods consists of a heterogeneous group of individuals, including an indigenous population of low socio-economic status and a large proportion of people from different ethnic backgrounds.

People from non-western countries constitute 10% of the Dutch population and more than 70% is concentrated in deprived neighbourhoods.
In the Netherlands, national guidelines for the prevention of cardiovascular risk factors include recommendations as to when and which intervention strategies should be initiated depending on an individual's risk for developing CVD.
In the more recent guidelines risk is defined in terms of the absolute risk of developing a cardiovascular event in the next 10 years. Risk thresholds of the absolute cardiovascular risk have been introduced to identify individuals without prior CVD that should be targeted by therapeutic strategies. These absolute risk threshold values may differ across countries due to differences in the prevalence of cardiovascular risk factors per country, but also as a consequence of the availability of health care resources. The most widely used method for the assessment of cardiovascular risk is based on equations derived from the Framingham Heart Study and includes the following independent (modifiable or non-modifiable) risk factors: age, sex, and diabetes (which are non-modifiable), cholesterol to HDL cholesterol ratio, systolic blood pressure, and smoking (which are modifiable) [12,13]. Most guidelines use an absolute risk of a cardiovascular event in the next 10 years of 20% or higher. Risk reductions that can be achieved will be larger if the increased risk is mainly determined by the modifiable risk factors. Consequently, taking the proportion of absolute risk that is modifiable into account may be useful when deciding about (cost) effectiveness of interventions. Until now, very few studies have explored this latter approach.

Assessment of cardiovascular risk factors (Chapter 4)

Different methods and data sources may be used to assess the prevalence of cardiovascular risk factors, such as medical records, clinical examinations and self-reports. Self-reported data are still commonly used in the assessment of cardiovascular risk factors in population-based studies, due to their availability and relatively low costs. In addition clinical measurements may not always be possible, or may be inappropriate because of the expected burden for the patient. Therefore, it is necessary to determine the accuracy of self-reports compared to other more objective criteria - such as data based on medical records or clinical examination. Furthermore, information is needed about the accuracy of self-reported cardiovascular risk factors among different ethnic groups, because reporting behaviour is also culturally dependent.

Intervention to reduce cardiovascular risk (Chapter 5, 6 and 7)

The last issue addressed in this thesis is the type of intervention required to reduce the risk of developing CVD in high-risk populations in deprived neighbourhoods. Taking into account the diversity of the population in deprived neighbourhoods, their different cultural and socio-economic conditions and the prevalence of risk factors, one may

question whether a general approach to cardiovascular disease prevention should be the starting point, since in earlier studies the effectiveness of general interventions among different ethnic groups was limited or lacking [14]. One of the limitations of interventions to eliminate health disparities that have been identified in the literature is that a relatively small number of studies have been culturally tailored for the ethnic minority groups [14].

We designed a tailored intervention targeted to general practices in deprived neighbourhoods to reduce cardiovascular risk in a heterogeneous patient population at high risk of developing CVD. A randomised controlled trial design was considered the optimal approach to determine the effectiveness of the intervention.
The trial evaluated the effectiveness of intensified preventive care in patients at high risk of developing CVD by assigning a practice nurse and a peer health educator to general practices. High-risk individuals were defined as having a modifiable part of the 10-year absolute risk of CVD which was equal to or larger than 5%. This modifiable risk was defined as the proportion of the 10-year absolute risk attributed to the following modifiable risk factors: smoking, and elevated levels of blood pressure and cholesterol.
With regard to the setting where the intervention takes place, general practice was considered a logical choice for the delivery of intervention and prevention activities since almost all patients in the Netherlands are registered within a general practice and GPs act as gatekeepers in the Dutch healthcare system. Due to the high workload in these general practices, extra staff (e.g. practice nurses) is needed to organise this preventive care more efficiently. Furthermore, language and cultural barriers between the GP and ethnic minority patients may hamper the communication resulting in an even poorer quality of care. This means that involving a peer health educator in preventive interventions directed at cardiovascular risk factors may help to bridge language and cultural differences between patients and healthcare providers. Our proposed intervention strategy was innovative in that way, and combined several current and past initiatives to support GPs in deprived neighbourhoods and promote preventive care for CVD.

A further essential step in studies assessing the effect of such complex interventions is to include a process evaluation to understand the findings and put them into perspective. However, little attention is generally paid to process evaluation in clinical trials, which may be explained by various factors [15,16]. These include: the lack of measurement instruments to evaluate intervention processes, the fact that these evaluations are generally time consuming, and that most attention is given to publication of the results of a clinical trial rather than providing information on the intervention process. To explain the success or failure of our intervention, a process evaluation was embedded in our

study on the effectiveness of intensified preventive care in general practice. This process evaluation aimed to describe whether the target group was reached by the intervention activities, whether the intervention programme was performed according to protocol, and to describe the experiences of the different participants in the study.

AIM AND STRUCTURE OF THE THESIS

The general aim of this thesis is to contribute to and expand previous research on prevention of cardiovascular diseases in deprived neighbourhoods, inhabited by an ethnically heterogeneous population.

Chapter 2 compares the prevalence of cardiovascular risk factors among inhabitants of deprived neighbourhoods from different ethnic backgrounds and with increased cardiovascular risk, and discusses whether these results provide evidence for the need of tailoring intervention according to ethnicity. In **Chapter 3** we present the method of taking into account modifiable risk factors when identifying high-risk patients, instead of only considering the absolute risk thresholds recommended by current guidelines; the consequences of this general approach on patient selection and exclusion is discussed. **Chapter 4** explores whether ethnic differences exist in the accuracy of self-reported cardiovascular risk factors as compared to general practice medical records and a gold standard based on measurements and use of medication.

Chapter 5 presents the results of a randomised controlled trial conducted in primary healthcare centres to reduce cardiovascular risk by a structured collaboration of the practice nurse, a peer health educator, the GP assistant and the general practitioner.

In **Chapter 6** we present a process evaluation to put the results of the randomised controlled trial into perspective. **Chapter 7** presents the results concerning the effect of periodical measurements and follow-up of high-risk patients compared to usual care from the general practitioner. Finally, **Chapter 8** discusses whether all interventions in deprived neighbourhoods are doomed to fail; we also discuss the potential of an alternative intervention strategy (i.e. the Polypill) to reduce the gap in cardiovascular health between different subgroups in society.

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Chapter 2

Different distribution of cardiovascular risk factors according to ethnicity:

a study in a high-risk population

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J Immigr Minor Health, in press

ABSTRACT

This study compares the distribution of cardiovascular risk factors in different ethnic groups at high risk of developing cardiovascular diseases within general practices.
A total of 430 patients (179 Dutch, 126 Turks, 50 Surinamese, 23 Moroccans, 23 Antilleans and 29 from other ethnic groups) were included in the study. Data collection consisted of questionnaires and physical and clinical examinations. 54% was female. The mean age was 53.1 (SD 9.9) years. There were important ethnic differences in the distribution of cardiovascular risk factors. Compared to the Dutch, ethnic minorities had significantly greater odds of being diabetic (OR = 3.2 to19.4); but were less likely to smoke (OR = 0.10 to 0.53). Turkish individuals had a lower prevalence of hypercholesterolemia but were 2.4 times more likely to be obese than the Dutch. Hypertension was very common in all ethnic groups and no significant ethnic differences were found. These findings provide additional evidence of the need for tailored interventions for different ethnic groups in general practices.

INTRODUCTION

People living in deprived neighbourhoods continue to be at greater risk for developing cardiovascular diseases (CVD) than the general population [1, 2]. In the Netherlands, as in many European countries, people from ethnic minorities form a large group of all people living in the most deprived neighbourhoods. This group consists of Turks, Moroccans, Surinamese, Antilleans, and many others, with marked differences in cultural background, history and life style. Similar to other western countries such as the USA and UK [3-5] the overall cardiovascular mortality is generally higher among ethnic minority groups than in the general population [6].

Although several international studies have shown that both prevention through life style changes and improved treatment regimes play an important role in reducing cardiovascular diseases and related cardiovascular risk factors [7-10], the question rises whether ethnic specific interventions are more appropriate, since most studies have been conducted in white populations [11,12] and the effectiveness of general interventions is disappointing in ethnic minority groups [13,14]. An important step in investigating whether interventions tailored to various ethnic minority groups are necessary to efficiently reduce cardiovascular risk, is the assessment and comparison of the cardiovascular risk profile of high-risk people from different ethnic backgrounds.

According to a systematic review of Uitewaal et al [15] some major risk factors such as diabetes, smoking and obesity, are more prevalent among Turkish and Moroccan minorities than among the native Dutch population. Further information about the distribution of modifiable cardiovascular risk factors in individuals of different ethnic origins, is warranted.

We conducted a study in a multi-ethnic population at high risk of developing CVD to identify ethnic specific cardiovascular risk factors within general practices.

METHODS

Data were collected in 2003 from patients from three primary healthcare centres representing five general practices (18 general practitioners) situated in deprived neighbourhoods of two major Dutch cites: Rotterdam and The Hague. Area deprivation in the Netherlands is defined according to an index, based on income and number of people dependant on social benefits and level of urbanisation [16].

Study population

We selected 1131 patients aged 30-70 years living in deprived neighbourhoods, with one or more registered cardiovascular risk factors (smoking, hypertension,

hypercholesterolemia, diabetes mellitus, family history of CVD, or history of CVD) from the electronic GP medical records to participate in a randomised controlled trial to reduce cardiovascular risk. In total 536 patients signed informed consent for the trial. Reasons for exclusion were: not reached after repeated home visits (n = 193) and subject refusal to participate (n = 402). Main reasons for refusal were: not interested (n = 114), language problems (n = 72), treated by a specialist (n = 49), had no time (n = 45) and other reasons (n = 122) like planned to go abroad for longer than six months and being too ill to participate. Complete questionnaires and physical and biochemical measurements were available from 430 patients.

Physical and biochemical measurements

Participants underwent a limited physical examination including blood pressure, weight and height measurements, which took place at their home by trained research assistants. Systolic and diastolic blood pressures were measured with a validated automatic sphygmomanometer, with participants in sitting position and after they had been resting for at least five minutes. The average of two measurements, taken with a 10 minutes interval was used for the analysis. Weight was measured with subjects wearing light clothes and no shoes; height was measured without shoes to the nearest cm. The body mass index (BMI) was determined by dividing the weight in kg by the square of height in meters. Blood samples were taken at the laboratory to assess fasting glucose, HbAc1 and lipid profile (total and HDL cholesterol and triglycerides). LDL-cholesterol was calculated using the Friedewald formula.

Questionnaire

A research assistant interviewed participants in their preferred language at the participant's home. The questionnaire was translated from Dutch into Turkish and Moroccan Arabic. For other groups, we used the Dutch questionnaire and, where possible interviewers from the same ethnic background were involved.
We used a structured questionnaire that included questions on demographic and socioeconomic characteristics (educational level, income and working status), family and personal history of CVD, health behaviour (physical activity, diet, smoking and alcohol consumption) and medication use.

Definitions of ethnicity and cardiovascular risk factors

Ethnicity was defined according to the country of birth of the respondents. We considered five ethnic groups: indigenous Dutch, Turkish, Moroccan, Surinamese, and Antilleans. A sixth group comprised small numbers of individuals from different other origins.

The cardiovascular risk factors were defined as follows:

- Diabetes mellitus: was considered present if the measured fasting glucose ≥ 7.0 mmol/l [17]; and/or patients currently used diabetes medication.
- Hypertension: patients were considered as hypertensive if the systolic blood pressure was ≥ 140 mm Hg and/or diastolic blood pressure was ≥ 90 mm Hg [18] and/or currently used anti-hypertensive medications.
- Hypercholesterolemia was defined as total cholesterol ≥ 5.0 mmol/l [19]; and/or current use of lipid-lowering medication.
- Smoking behaviour: participants reported whether they smoked (current smokers) and if they had stopped whether they had smoked at least 100 cigarettes during their lifetime (ex-smokers) [20].
- Overweight and obesity: we classified participants as overweight in case of a BMI between 25 kg/m^2 and 30 kg/m^2 and as obese if their BMI was ≥ 30 kg/m^2 [21].
- 10-year absolute risk of developing CVD was determined using the Framingham risk function [22]. Two 10-year risk-thresholds were considered: ≥ 10% and ≥ 20%.

Table 1: Characteristics of non-responders (n = 595), responders (n = 536) and responders with complete cardiovascular risk profile (n = 430)

	Non-responders	Responders	Complete CV risk profile
Gender (%)			
Males	51	46	46
Females	49	54	54
Age (years) (mean (sd))	55.5 (9.7)	53.2 (9.7)	53.1 (9.9)
30-39	9	9	10
40-49	18	28	28
50-59	36	35	33
≥ 60	38	26	28
Ethnicity (%)			
Dutch	38	40	42
Turkish	22	27	29
Moroccan	4	6	5
Surinamese	12	12	12
Antillean	2	5	5
Other	22	10	8
Cardiovascular risk factors (%) (based on data from GP records)			
Diabetes	39	31	29
Hypertension	49	44	44
Hypercholesterolemia	20	22	23
Smoking	27	32	30
History of CVD	33	31	32
Family history of CVD	15	17	19

Values are proportion or mean (SD)
CVD: cardiovascular diseases

Statistical analysis

To compare the differences in cardiovascular risk factors between the six ethnic groups, we used Chi-square tests for categorical variables. Differences in continuous variables were assessed using one-way analysis of variance.
We examined the associations between ethnicity and cardiovascular risk factors and cardiovascular risk using multiple logistic regression analysis to adjust for differences in age and gender between the ethnic groups. We used SPSS software version 12.0 for data analysis.

Ethics

The study protocol was approved by the local ethics committee of the Erasmus Medical Centre of Rotterdam. All participants gave their informed consent to participate.

RESULTS

The response rate was 47%. There were no remarkable differences between responders and non-responders in background characteristics or known cardiovascular risk factors (table 1). Responders were on average two years younger than non-responders (53. 2 ± 9.7 years versus 55.5 ± 9.7 years) and there were fewer diabetics among responders than among non-responders (31% and 39%).
In table 2 we present the background characteristics of the various ethnic groups with completed risk profile. Large differences between the ethnic groups were present according to age, educational level and working status. All ethnic minority groups were on average four to eight years younger than Dutch people. A greater proportion of Moroccans than other ethnic groups had no school education. There were fewer employed individuals among the Turks and more retired people among the Dutch compared to the other ethnic groups.
The results of the clinical measurements showed that the levels of HbAc1, fasting glucose and triglycerides were significantly different across the ethnic groups (table 3). The diastolic, but not systolic blood pressure was significantly different according to ethnicity. There were significant differences in the BMI, with Turkish people having the highest BMI. The Dutch had the highest 10-year absolute risk to develop CVD.
Table 4 shows that there were important ethnic differences in the prevalence of diabetes, hypercholesterolemia, smoking behaviour and obesity. Moroccan individuals had the greatest proportion of diabetics (74%) while the Dutch had the lowest proportion (17%). The prevalence of hypercholesterolemia was highest in Dutch (86%) and of obesity in the Turkish participants (61%). There were more smokers among Dutch (41%) than other ethnic groups. Further analysis of the gender difference in smoking behaviour showed that the greatest

Table 2: Demographic characteristics of the ethnic groups participating in the study

	Dutch	Turkish	Moroccan	Surinamese	Antillean	other	total	overall Significance (p value)
	n= 179	n = 126	n = 23	n = 50	n = 23	n = 29	n = 430	
Females (n(%))	88 (49)	76 (60)	15 (65)	29 (58)	15 (65)	9 (31)	232 (54)	0.028
Age (years) (mean (sd))	57.5(8.7)	48.8 (9.3)	49.5(10.3)	51.7 (9.0)	52.2 (8.0)	53.0 (8.5)	53.1 (9.9)	0.0001
Age categories (years) (n(%))								0.0001
30-39	6 (3)	24 (19)	4 (17)	6 (12)	2 (9)	2 (7)	44 (10)	
40-49	31 (17)	50 (40)	11 (48)	17 (34)	7 (30)	5 (17)	121 (28)	
50-59	66 (40)	31 (25)	3 (13)	17 (34)	10 (44)	16 (55)	143 (33)	
≥ 60	76 (43)	21 (17)	5 (22)	10 (20)	4 (17)	6 (21)	122 (28)	
Highest Educational level [a] (n(%))								0.0001
No	16 (10)	39 (32)	17 (74)	7 (15)	3 (14)	4 (17)	86 (21)	
Low	63 (38)	62 (51)	2 (9)	13 (27)	3 (14)	8 (33)	151 (37)	
Lower secondary	63 (38)	10 (8)	2 (9)	17 (35)	12 (57)	6 (25)	110 (27)	
Higher secondary	13 (8)	8 (7)	0 (0)	8 (17)	2 (10)	5 (21)	36 (9)	
Higher	13 (9)	3 (3)	2 (9)	3 (6)	1 (5)	1 (4)	22 (5)	
Working status (n(%))								0.0001
Employed	62 (35)	21 (17)	8 (35)	22 (44)	13 (57)	10 (35)	136 (32)	
Housewife/man	43 (24)	58 (46)	12 (52)	14 (28)	5 (22)	6 (21)	138 (32)	
Retired	42 (24)	7 (6)	2 (9)	3 (6)	0 (0)	2 (7)	56 (13)	
Incapacitated for work	22 (12)	9 (7)	1 (4)	3 (6)	4 (17)	8 (28)	47 (11)	
Unemployed	10 (6)	31 (25)	0 (0)	8 (16)	1 (4)	3 (10)	53 (12)	
Public health care insurance [b] (n(%))	153 (86)	116 (95)	23 (100)	44 (88)	19 (86)	27 (93)	382 (90)	0.054

Values are number (%) or mean (SD)
Missing values: a =25;b = 5

Table 3: Biochemical and physical characteristics of the study population by ethnicity

	Dutch n= 179	Turkish n = 126	Moroccan n = 23	Surinamese n = 50	Antillean n = 23	other n = 29	total n = 430	overall significance (p value)
HbAc1 (%)	6.1 (0.9)	6.4 (1.4)	7.7 (1.8)	7.2 (1.9)	6.7 (1.5)	6.5 (1.1)	6.5 (1.4)	0.0001
Fasting glucose (mmol/l)	6.1 (2.0)	6.4 (2.2)	8.8 (3.8)	7.6 (3.2)	6.6 (2.1)	6.8 (2.2)	6.6 (2.4)	0.0001
Total cholesterol (mmol/l)	5.6 (1.0)	5.4 (1.0)	5.4 (0.8)	5.2 (0.9)	5.7 (1.2)	5.7 (1.4)	5.5 (1.0)	0.083
HDL-cholesterol (mmol/l)	1.4 (0.5)	1.3 (0.4)	1.2 (0.4)	1.3 (0.3)	1.5 (0.4)	1.3 (0.4)	1.4 (0.4)	0.060
LDL-cholesterol (mmol/l)	3.4 (0.9)	3.2 (0.9)	3.1 (0.9)	3.2 (0.8)	3.6 (1.0)	3.4 (1.4)	3.3 (1.0)	0.362
Triglycerides (mmol/l)	1.8 (1.1)	2.0 (1.2)	2.2 (1.9)	1.6 (0.7)	1.5 (0.6)	2.1 (1.5)	1.9 (1.2)	0.037
Systolic blood pressure (mm Hg)	142.5 (23.4)	139.8 (22.9)	145.3 (23.5)	149.3 (27.0)	142.8 (20.3)	136.9 (26.7)	142.3 (23.9)	0.186
Diastolic blood pressure (mm Hg)	84.3 (11.3)	87.4 (11.9)	91.3 (14.1)	90.9 (12.9)	87.2 (11.6)	83.4 (15.5)	86.4 (12.4)	0.002
BMI (kg/m^2)	29.2 (5.6)	32.0 (5.4)	30.6 (4.7)	28.7 (6.2)	31.4 (5.7)	30.8 (5.6)	30.3 (5.7)	0.0001
10-year CVD risk (%)	21.6 (13.7)	14.5 (11.5)	15.8 (12.3)	17.2 (11.2)	14.9 (7.8)	17.6 (10.2)	18.0 (12.6)	0.0001

Values are mean (SD)
CVD: cardiovascular disease
BMI: body mass index
HDL; high density lipoprotein; LDL, low density lipoprotein.

number of smokers were Turkish males and Dutch females (data not shown). Hypertension was very common in all ethnic groups and no significant ethnic differences were found.
Ethnicity was a determinant of the age and gender adjusted prevalence of all investigated cardiovascular risk factors, except for hypertension and for the absolute risk for CVD (table 5). Turks, Surinamese, Antilleans, and Moroccans had a clear increased risk of diabetes compared to the Dutch (odds ratios were 3.3, 6.7, 3.2, and 19.4 respectively). Obesity was clearly associated with a Turkish background: Turkish individuals were 2.4 times more likely to be obese than Dutch. All ethnic groups were less likely to smoke than the Dutch. Almost all non-Dutch ethnic groups had a lower prevalence of hypercholesterolemia than the Dutch, but this association was statistically significant for the Turks only. Although the Dutch had a higher 10-year CVD risk than ethnic minority groups, after adjusting for age and gender, most ethnic minority groups were more likely to have a 10-year absolute cardiovascular risk ≥ 10% and ≥ 20% than the Dutch. However, this association was not statistically significant.

DISCUSSION

Our results showed that individuals from ethnic minorities have a higher prevalence of diabetes and obesity but a lower prevalence of hypercholesterolemia and reported smoking than the native Dutch population, while the prevalence of hypertension seemed comparable between ethnic groups. Furthermore, in each ethnic group different combinations of cardiovascular risk factors were found.
The finding that diabetes was more prevalent among some ethnic groups than among the native population was also reported in other national and international epidemiological studies [15, 23-26]. In the studies by Cappucio et al [23], Bhopal et al [24], and Anand et al [25], South Asians in the UK and Canada had a higher prevalence of diabetes/glucose intolerance than people of European origin; and in the study by Winkleby et al [26] Black and Mexican American women had higher diabetes prevalence than white women. This

Table 4: Prevalence of cardiovascular risk factors by ethnicity

	Dutch	Turkish	Moroccan	Surinamese	Antillean	other	total	overall Significance (p value)
	n= 179	n = 126	n = 23	n = 50	n = 23	n = 29	n = 430	
Diabetes	30 (17)	42 (33)	17 (74)	26 (52)	8 (35)	8 (28)	131 (31)	0.0001
Hypertension	135 (75)	83 (66)	15 (65)	40 (80)	17 (74)	19 (66)	309 (72)	0.295
Hypercholesterolemia	154 (86)	90 (71)	16 (70)	40 (80)	20 (87)	19 (66)	339 (79)	0.011
Current smokers	79 (44)	43 (34)	2 (9)	9 (18)	6 (26)	9 (31)	148 (34)	0.001
Ex-smoker	66 (37)	25 (20)	3 (13)	13 (26)	6 (26)	13 (49)	126 (29)	0.004
Overweight	72 (41)	38 (31)	9 (39)	18 (38)	5 (23)	9 (33)	151 (36)	0.380
Obesity	68 (39)	74 (61)	11 (49)	16 (33)	13 (59)	16 (59)	198 (48)	0.001
10-year CVD risk ≥ 10%	140 (78)	69 (55)	14 (61)	34 (68)	17 (74)	23 (79)	297 (69)	0.001
10-year CVD risk ≥ 20%	82 (46)	30 (24)	6 (26)	17 (34)	6 (26)	11 (38)	152 (35)	0.003

Values are number (%)
CVD: cardiovascular disease

phenomenon can be explained by genetic susceptibility and/or environmental factors such as the adoption of a western diet, obesity and physical inactivity [27].
We did not find indications for a higher prevalence of hypertension in ethnic minority people than in the Dutch population, although the diastolic blood pressure was relatively higher among ethnic minorities than among the Dutch. This result is similar to other studies showing no clear differences between Turkish or Moroccan people and the native Dutch population [15]. There are some indications of a higher prevalence among Surinamese (a mixed group of African descent and people originated from South Asia) than in Dutch [28], which is in accordance with international studies that reported a higher prevalence of hypertension in South Asians [29] and people from African origin [30] compared to white populations in the UK and USA respectively.
Hypercholesterolemia, based on the level of total cholesterol, was generally higher in Dutch than in most ethnic minority people. This is in line with the limited data comparing the Turkish or Moroccan ethnic group with the Dutch [15] while no such information is available for Surinamese and Antilleans. On the other hand, the levels of other lipid components were more disadvantageous (e.g. high levels of triglycerides among Turks and Moroccans) among some ethnic groups in our study than in the Dutch. In general, ethnic comparisons of the lipid profiles remain difficult because of the limited number of studies and inconsistencies of the findings [15].
In line with previous studies [15, 23, 24] obesity was more common among minority groups, particularly Turkish people, than in the native population. The proportion of obese individuals in our study also largely exceeded national rates implying that obesity is a serious health problem among people living in deprived neighbourhoods and in particular among ethnic minority women. Native Dutch had a higher prevalence of reported smoking than non-Dutch groups, but Turkish men had a higher prevalence than Dutch men. This is in agreement with other Dutch studies showing a high smoking prevalence among Turkish men [15]. The low prevalence of smoking among ethnic minority women in our study is also consistent with previous national and international studies [15, 23-25].
The 10-year cardiovascular risk was higher in Dutch, but the age and gender adjusted 10-year risk was somewhat higher in ethnic minorities, which could be attributed to their unfavourable cardiovascular risk factors. Intervention activities are recommended according to the 10-year CVD risk [19]. This approach could result in under treatment of young ethnic minority groups with high levels of (modifiable) risk factors and over treatment of elderly Dutch people [31].

Some limitations of the present study should be mentioned. First, the nature of the study population. Because data collection took place among a population at risk of developing CVD, this means that our results can not be generalised to the general population due

Table 5: Association of cardiovascular risk factors and 10 year absolute risk with ethnicity, adjusted for age and gender

	Turkish OR (95% CI)	Moroccan OR (95% CI)	Surinamese OR (95% CI)	Antillean OR (95% CI)	Other OR (95% CI)
Diabetes	3.31 (1.83-5.98)*	19.35 (6.71-55.82)*	6.67 (3.28-13.57)*	3.24 (1.24-8.49)*	2.11 (0.84-5.31)
Hypertension	1.07 (0.61-1.87)	1.01 (0.38-2.71)	1.92 (0.86-4.31)	1.27 (0.46-3.54)	0.79 (0.33-1.89)
Hypercholesterolemia	0.42 (0.22-0.77)*	0.37 (0.14-1.02)	0.66 (0.29-1.50)	1.07 (0.29-3.91)	0.33 (0.14-0.81)*
Smoking	0.53 (0.31-0.90)*	0.10 (0.02-0.45)*	0.23 (0.10-0.52)*	0.41 (0.15-1.12)	0.42 (0.18-1.00)
Obesity	2.37 (1.41-3.97)	1.37 (0.56-3.37)	0.76 (0.38-1.52)	2.13 (0.85-5.34)	2.48 (1.07-5.74)*
10-year CVD risk ≥ 10%	1.18 (0.60-2.33)	2.13 (0.64-7.15)	1.54 (0.63-3.75)	1.92 (0.56-6.37)	1.74 (0.47-6.37)
10-year CVD risk ≥ 20%	1.17 (0.59-2.32)	1.17 (0.27-5.03)	1.68 (0.71-3.97)	1.12 (0.35-3.57)	0.91 (0.33-2.48)

*: statistically significant ($P < 0.05$)
Values are odds ratio (OR) & 95% confidence interval (CI))

the inclusion of high-risk individuals only. However, our findings point to the same direction as previous studies in the general population, and show the necessity of tailoring intervention also in this high-risk group. In addition, for the prevention of CVD, evidence has shown that targeting high-risk groups is more beneficial than targeting the general population [32]. The response rate was 47% which is satisfactory when taking into account previous studies conducted in multi-ethnic patient populations in the Netherlands [15]. We have no reason to believe that the cardiovascular risk factors are likely to be different in the individuals examined compared to those who were not because responders and non-responders in our study had a comparable cardiovascular risk profile according to GP medical records.

Since we firstly selected patients from the electronic GP medical records, our findings could be biased because of differences in access to the general practice or in the registration of risk factors between the general practitioners. Regarding access to the general practice, in the Netherlands (almost) all patients are registered in a general practice and therefore have equal access regardless of where they live. Concerning registration of risk factors, we used all available medical information from the GP medical records to identify potential high-risk patients. This yielded similar proportions of potentially high-risk individuals per general practitioner, indicating that an effect of differences in registration between the general practitioners is unlikely.

This study shows the heterogeneity of people living in deprived neighbourhoods in terms of ethnicity, demographic and socioeconomic characteristics, and particularly the distribution of cardiovascular risk factors which emphasizes the need for tailoring interventions to different ethnic groups at risk of developing CVD. Notably, attention should be given to diabetes intervention and education, since diabetes is one of the most prevalent cardiovascular risk factors among all ethnic minorities at risk of developing CVD, particularly the Moroccans. Among the Turks emphasis should be put on interventions aimed at reducing the high prevalence of obesity as well as smoking while among the Dutch hypercholesterolemia and smoking should be given higher priority than other risk factors. We found no ethnic differences in hypertension; however, taking into account previous studies we suggest that interventions with regard to Surinamese and Antilleans should take hypertension into consideration.

In conclusion, the present study shows that the different cardiovascular risk factors were not uniformly distributed among ethnic groups in deprived neighbourhoods and provides additional evidence of the need to tailor interventions for different ethnic groups in general practices.

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Chapter 3

Prevention of cardiovascular diseases: focus on modifiable cardiovascular risk

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ABSTRACT

Objective:

To determine whether the use of a 20% absolute risk threshold for cardiovascular disease as recommended in current guidelines leads to exclusion of patients with a substantial modifiable risk (≥ 5%).

Methods:

Data collected within the framework of a randomised controlled trial in three primary healthcare centres located in deprived neighbourhoods were analysed. The 10 year absolute risk and the modifiable part of risk were calculated by using the Framingham risk equation. Among patients with a modifiable risk reduction of ≥ 5% (number needed to treat ≤ 20) the characteristics and risk factors of patients with an absolute risk ≥ 20% and those with an absolute risk < 20% were compared.

Results:

293 patients aged 30–70 years at risk of developing cardiovascular disease were included, of whom 66% were women and 36% were of Dutch origin. Of all patients, 33% had an absolute risk ≥ 20% and 61% had a modifiable risk ≥ 5%. Of those at ≥ 20% absolute risk, a vast majority (98%) had a modifiable risk ≥ 5%. Among those with an absolute risk < 20%, 43% had a modifiable risk ≥ 5%; this group, who were relatively young and predominantly women, constituted 29% of the entire study population.

Conclusions:

Targeting preventive strategies at a 10 year absolute risk ≥ 20% leads to exclusion of a large group of relatively young, predominantly female patients. In total, about one quarter had an absolute risk < 20% but a modifiable risk ≥ 5% and should therefore benefit from intervention.

INTRODUCTION

Cardiovascular disease (CVD) is a major cause of disability and mortality in developed countries. Interventions targeted at modifiable risk factors, such as hypercholesterolemia, hypertension, and smoking, can delay or even prevent the occurrence of CVD [1–3]. Furthermore, multiple risk factor interventions in high risk groups are more beneficial than single risk factor interventions [4].

The most widely used method for assessment of CVD risk is based on equations derived from the Framingham heart study, which are based on multiple risk factors [5, 6]. Whether patients are identified as being at high risk and thus should be targeted for prevention activities depends on absolute risk threshold values, which vary between different guidelines [7–9].

These risk thresholds are based not only on the population prevalence of cardiovascular risk factors and CVD but also on the availability of health care resources [10]. Similar to several Western guidelines, the Dutch guidelines for hypertension and hypercholesterolemia recommend treatment in case of an absolute risk of CVD ≥ 20% [11, 12]. However, these national and international absolute risk thresholds depend largely on the non-modifiable risk factors age, sex, and diabetes mellitus. They do not take into consideration which part of the cardiovascular risk is due to modifiable risk factors to identify patients for prevention activities.

We considered whether focus on this modifiable part of the absolute risk is more appropriate for identifying those at risk of developing CVD than the currently applied absolute risk thresholds. Firstly, CVD risk reduction is larger when larger reductions of the modifiable risk factors blood pressure, cholesterol, and smoking are achieved, indicating larger absolute risk reductions and a lower number needed to treat (NNT). Different trials on cholesterol lowering and antihypertensive interventions reported NNTs of about 20—that is, 20 patients need to be treated to prevent one cardiovascular event [13–16]. This NNT corresponds to an absolute risk reduction of 5%. Secondly, the use of absolute risk thresholds in some patient groups such as women, young people, and ethnic minorities may result in under treatment because of a 10 year absolute risk < 20% compared with men, older people, and white or Western populations, respectively, despite large achievable absolute risk reductions [17, 18]. This problem is more likely to occur in deprived neighbourhoods because people living in these areas are at greater risk than the general population of developing CVD [19].

We conducted a study in a heterogeneous patient population at high risk of developing CVD, which consisted of both men and women without a history of CVD from different ethnic groups living in deprived neighbourhoods. The objective of this study was to

determine whether the use of a 20% absolute risk threshold as recommended in current guidelines leads to exclusion of patients with a substantial modifiable risk (≥ 5%).

METHODS

We used data collected within the framework of a randomised controlled trial to assess the effectiveness of a structured collaboration within the general practice to reduce cardiovascular risk. Briefly, the trial population consisted of an intervention group that received intensified preventive care and a control group that received usual general practitioner care. Both groups were invited to the general practice for assessment of their cardiovascular risk profile every three months. We performed the study in three Dutch health care centres comprising five general practices situated in the deprived neighbourhoods of Rotterdam and The Hague. Area deprivation in the Netherlands is defined according to an index based on income, number of people dependant on social benefits, and level of urbanisation [20]. In this study the baseline data of the trial were analysed.

Patient selection and data collection

To identify all potential high risk patients, two steps were followed. Firstly, the electronic general practice medical records, containing all available medical data (including consultations, laboratory results, letters from specialists, and prescriptions) were searched. All patients aged 30–70 years with one or more registered risk factors (hypertension, diabetes mellitus, hypercholesterolemia, history of CVD, family history of CVD, smoking, and measurements of blood pressure ≥ 160/90 mm Hg or total cholesterol ≥ 6.2 mmol/l within the preceding two years) were selected. Secondly, patients thus selected were invited to participate. They were informed about the study during a home visit and asked to give their informed consent. A structured questionnaire was used to measure background characteristics, cardiovascular risk factors, family history of CVD, and history of CVD. In addition, patients underwent a limited physical examination consisting of blood pressure, weight, and height measurements by a trained research assistant. Blood pressure was measured during the home visit in a sitting position with a validated electronic sphygmomanometer. Two measurements were taken separated by at least a 10 minute interval. The mean of these readings was used for the analyses. Blood samples were taken at the laboratory to measure fasting glucose, haemoglobin A1c, and the lipid profile.

Of 536 patients who signed informed consent for the trial, 430 had a completed cardiovascular risk profile. Of these, the Framingham risk formula could not be applied to

137 patients because of a CVD history and were thus excluded from analysis. Finally, data on 293 participants were available for analysis.

Determination of cardiovascular risk and modifiable risk

By using the Framingham equation, we calculated for each patient the 10 year risk of developing a CVD event [5, 17]. The formula considers the following independent variables: age (in years), sex (male/female), systolic blood pressure (in mm Hg), total cholesterol to high density lipoprotein (HDL) cholesterol ratio, smoking (yes/no), and diabetes mellitus (yes/no). Diabetes mellitus was considered to be present if it was registered in the patient's general practice records or if the patient was taking diabetes medication or had a fasting glucose concentration ≥ 7 mmol/l. We considered 10 year cardiovascular risk thresholds of 20% and 40% as recommended in several international guidelines [8, 9, 11].

The modifiable part of the absolute risk was determined in two ways (see appendix):

- A "potential" modifiable risk, which is the maximum reduction in the absolute risk by eliminating modifiable risk factors and is composed of the separate absolute risk reductions for systolic blood pressure (reduction from > 120 to 120 mm Hg), total to HDL cholesterol ratio (reduction from > 4 to 4), and smoking cessation (if patients smoke). The non-modifiable risk consists of the absolute risk for CVD based on age, sex, diabetes, and fixed values on modifiable risk factors (total to HDL cholesterol ratio is equal to 4, systolic blood pressure is equal to 120 mm Hg, and non-smoking).
- A "realistic" modifiable risk, which is the expected reduction in absolute risk according to trials on hypercholesterolemia, hypertension, and smoking [21, 22]. The non-modifiable risk is based on age, sex, diabetes, a 20% decrease in total cholesterol and 5% increase in HDL cholesterol, a 12 mm Hg decrease in systolic blood pressure, and smoking cessation [21, 22]. The modifiable risk is composed of the separate risk reductions for systolic blood pressure (if > 120 mm Hg), total to HDL cholesterol ratio (if > 4), and smoking (if patients smoke).

Data analyses

We used cross tabulations to determine the numbers and proportions of patients identified according to the absolute risk thresholds, the modifiable part of absolute risk, or both identification criteria. To assess differences in patient characteristics, we distinguished two groups: those with an absolute risk ≥ 20% and a modifiable part of risk ≥ 5%; and those with an absolute risk < 20% but with a modifiable part of risk ≥ 5%. Proportion of women, non-Dutch ethnic group, current smokers, obese patients, and patients with total cholesterol to HDL cholesterol ratio > 4, systolic blood pressure ≥ 140 mm Hg, the presence of diabetes mellitus, and a family history of CVD were compared between the groups by $\chi 2$ tests and mean age by independent t test.

Data were analysed by SPSS software, version 12.0 (SPSS Inc, Chicago, Illinois, USA).

RESULTS

Table 1 gives the general characteristics and cardiovascular risk factors of the 293 participants.

Two thirds of the patients were women (66%) and a majority had a non-Dutch background (36% were Dutch, 33% Turkish, 12% Surinamese, 6% Moroccan, and 12% others, mainly from the Antilles, Pakistan or India, and the former Yugoslavia). The study population was young (51.8 (9.3) years) but had multiple risk factors, 32% of patients were current smokers, and 36% reported having a family history of CVD.

A large group of all patients (75%) had two or more cardiovascular risk factors and about half of the patients (48%) had three or more risk factors.

Table 1: General characteristics and cardiovascular risk profile of the study population (n=293)

Ethnicity (n (%))	
Dutch	106 (36)
Turkish	97 (33)
Surinamese	36 (12)
Moroccan	18 (6)
Other	36 (12)
Diabetes * (n (%))	106 (36)
Current smoker † (n (%))	95 (32)
Ex-smoker † (n (%))	76 (26)
Family history of CVD † (n(%))	106 (36)
With ≥ 2 CVD risk factors (n (%))	220 (75)
With ≥ 3 CVD risk factors (n (%))	140 (48)
Age (years)	51.8 (9.3)
Systolic BP (mmHg)	143.0 (23.8)
Diastolic BP (mmHg)	87.9 (12.5)
HbAc1 (%)	6.5 (1.4)
Fasting glucose (mmol/l)	6.6 (2.4)
Serum total cholesterol (mmol/l)	5.6 (1.0)
Serum HDL-cholesterol (mmol/l)	1.4 (0.4)
Total cholesterol:HDL-cholesterol	4.4 (1.4)
Serum LDL-cholesterol (mmol/l)	3.4 (1.0)
Triglycerides (mmol/l)	1.9 (1.3)
BMI (kg/m^2)	30.9 (5.6)
10 year CVD absolute risk (%)	17.2 (12.6)

Values are mean (SD), unless stated otherwise

*: Based on diabetes medication use, general practice medical record or fasting glucose ≥ 7 mmol/l

†: Based on patients self reports

BP, blood pressure; CVD, cardiovascular disease; HDL, high density lipoprotein; LDL, low density lipoprotein; BMI, Body Mass Index

Table 2: Numbers and proportions of patients according to different absolute risk threshold and modifiable part of the absolute risk

	Modifiable part of absolute risk Potential reduction†		Modifiable part of absolute risk Realistic reduction‡		
10 year absolute risk*	< 5%	≥ 5%`	< 5%	≥ 5%	Total
< 20%	111 (38%)	84 (29%)	148 (51%)	47 (16%)	195(67%)
≥ 20%	2 (1%)	96 (33%)	12 (4%)	86 (29%)	98 (33%)
< 40%	113 (39%)	162 (55%)	159 (54%)	116 (40%)	275 (94%)
≥ 40%	0 (0%)	18 (6%)	1 (0%)	17 (6%)	18 (6%))
Total	113 (39%)	180 (61%)	160 (55%)	133 (45%)	293 (100%)

*: Based on the Framingham risk equation (based on age, sex, diabetes mellitus, systolic blood pressure, total cholesterol to HDL cholesterol ratio and smoking)

†: Maximum reduction in 10 year absolute risk by eliminating modifiable risk factors (systolic blood pressure reduction from >120 to 120 mm Hg, total cholesterol to HDL cholesterol ratio reduction from > 4 to 4, and smoking cessation if patient smokes)

‡: Expected reduction in 10 year absolute risk by lowering the modifiable risk factors according to results from trials (systolic blood pressure reduction by 12 mm Hg, total cholesterol reduction by 20%, HDL increase by 5% and smoking cessation).

Table 2 shows that use of a 10 year absolute risk threshold ≥ 20% identified 33% of patients. On the basis of the 5% modifiable risk threshold, 61% of patients were identified with a potential reduction ≥ 5% and 45% with a realistic reduction ≥ 5%.

A large majority of the patients at 20% or greater absolute risk had a modifiable part of risk ≥ 5%—that is, 98% had a potential modifiable risk ≥ 5% and 88% had a realistic modifiable risk ≥ 5%. These proportions correspond, respectively, to 33% and 29% of all patients. Only 1–4% had an absolute risk ≥ 20% and a modifiable risk < 5% (table 2).

Among those patients at < 20% absolute risk, a considerable group had a modifiable part of risk ≥ 5%, which could justify prevention activities: 43% with a potential modifiable part ≥ 5% and 24% with a realistic modifiable part ≥ 5%. As a proportion of all patients, these proportions were 29% and 16%, respectively (table 2). In table 3 we compare the characteristics of patients with an absolute risk < 20% and a modifiable part of risk ≥ 5% (group 1) with the characteristics of patients with an absolute risk ≥ 20% and a modifiable part ≥ 5% (group 2). The patients in group 1 were predominantly women and young. A slightly higher proportion in this group had a non-Dutch origin but this difference was not significant. Although the proportions of patients with modifiable risk factors were smaller in group 1 than in group 2, more than half of them had hypertension and hypercholesterolemia and more than one quarter had diabetes mellitus. No differences in obesity were noted between the groups.

Examples illustrating the differences between using the absolute risk threshold and the potential or realistic modifiable part of risk:

Absolute risk <20% and potential and realistic modifiable risk ≥ 5%

A middle-aged (49.5 years) female patient without diabetes has a systolic blood pressure of 191.00 mm Hg and total cholesterol to HDL ratio of 4.42. The calculated absolute risk is lower than the 20% absolute risk threshold (16.54%). However the potential modifiable risk is 11.29% and the realistic modifiable risk is 5.00%

A young male diabetic patient (age 39 years), smokes cigarettes and has a systolic blood pressure of 120 mm Hg and total cholesterol to HDL cholesterol ratio of 7.17. The absolute risk is 13.85% and the potential modifiable risk is 7.80%; the realistic reduction is 5.98%

Absolute risk ≥ 20% and potential and realistic modifiable risk < 5%

A male patient aged 67 years has a systolic blood pressure of 130 mm Hg, total cholesterol to HDL cholesterol ratio of 4.00, does not smoke and does not have diabetes. The absolute risk is 21.5%, the potential modifiable risk is 3.15% and the realistic modifiable risk is 3.31%.

Use of a higher absolute risk threshold, for example, ≥ 40% as recommended by some guidelines [9] identified a very small proportion of patients (6%). Among those patients not identified, a large group had a modifiable part of risk ≥ 5% (55% of all patients had a potential modifiable part ≥ 5% and 40% had a realistic modifiable part ≥ 5%).

DISCUSSION

Our results show that using an absolute risk threshold of ≥ 20% leads to the exclusion of patients with a large potential reduction in absolute risk mainly in women and young patients, among whom preventive activities are more cost effective in the long term. A more appropriate criterion for identifying high risk patients is the use of the proportion of absolute risk contributed by the major modifiable risk factors, namely systolic blood pressure, the total cholesterol to HDL cholesterol ratio, and smoking. We considered a modifiable part of ≥ 5% of the absolute risk to be appropriate because it discriminates between patients with and without the possibility of lowering the modifiable risk factors to target levels. This risk reduction corresponds also to the NNT to prevent one cardiovascular event by means of intervention activities.

The application of the proposed modifiable part of the absolute risk, instead of using a CVD risk threshold ≥ 20%, in general practices is advantageous for several reasons.

Firstly, it is more likely to identify those young patients who should be considered for treatment because of high levels of risk factors to prevent CVD in the long term. Similarly focusing on the modifiable risk will reduce over treatment of older people at low modifiable risk [18].

Secondly, the absolute risk of CVD is lower in women than in men. Applying the same absolute risk thresholds to men and to women excluded a large number of female

Table 3: Characteristics of patients with a 10 year absolute risk* < 20% and a modifiable risk ≥ 5% (group 1), and of patients with a 10 year absolute risk ≥ 20% and a modifiable part ≥ 5% (group 2)

	Potential reduction ≥ 5% †			Realistic reduction ≥ 5% ‡		
Characteristic	Group 1 (n = 84)	Group 2 (n = 96)	p Value	Group 1 (n = 47)	Group 2 (n = 86)	p Value
Age (mean (SD) (years)	49.9 (6.3)	59.1 (6.7)	< 0.0001	49.9 (7.0)	58.4 (6.7)	<0.0001
Age categories (mean (SD) (years)			< 0.0001			<0.0001
< 50	44 (52)	9 (9)		25 (53)	9 (11)	
≥ 50	40 (48)	87 (91)		22 (47)	77 (90)	
Women	52 (62)	33 (34)	< 0.0001	25 (53)	29 (34)	0.023
Non-Dutch	54 (64)	57 (59)	0.301	25 (53)	49 (57)	0.405
Smoking §	37 (44)	45 (47)	0.409	29 (62)	45 (52)	0.196
Hypercholesterolemia¶ʃ	53 (63)	75 (78)	0.020	39 (83)	76 (88)	0.269
Hypertension¶ʃ	50 (60)	81 (84)	< 0.0001	22 (47)	70 (81)	< 0.0001
Diabetes mellitus¶ʃ	25 (30)	41 (43)	0.050	13 (28)	35 (41)	0.095
Obesity ¶ʃ	41 (51)	50 (53)	0.459	22 (50)	46 (55)	0.372
Family history of CVD §	31 (37)	27 (28)	0.136	15 (32)	25 (29)	0.440

Values number (%) unless stated otherwise

*: Based on the Framingham risk equation (based on age, sex, diabetes mellitus, systolic blood pressure, total cholesterol to HDL cholesterol ratio and smoking)

†: Maximum reduction in 10 year absolute risk by eliminating modifiable risk factors (systolic blood pressure reduction from >120 to 120 mm Hg, total cholesterol to HDL cholesterol ratio reduction from > 4 to 4, and smoking cessation if patient smokes)

‡: Expected reduction in 10 year absolute risk by lowering the modifiable risk factors according to results from trials (systolic blood pressure reduction by 12 mm Hg, total cholesterol reduction by 20%, HDL increase by 5% and smoking cessation).

§: Based on patients' self reports

¶ʃ: Hypercholesterolaemia defined as total cholesterol to HDLcholesterol ratio > 4; hypertension defined as systolic blood pressure ≥ 140 mm Hg, diabetes mellitus defined as fasting glucose ≥ 7 mmol/l, diabetes medication use or registration in general practice medical record; obesity defined as body mass index ≥ 30 kg/m

patients from prevention activities, despite their unfavourable modifiable risk factors. Focusing on the modifiable part of the risk, rather than the absolute risk, would allow more women to be involved in prevention and treatment of CVD. Although not all risk factor intervention trials have included women, it is clear that the relative benefits on cardiovascular morbidity and mortality are similar for both sexes. The major risk factors have a substantial impact on the absolute risk in women—for example, in the US population as a whole, as many women as men die of coronary heart diseases [23]. Therefore, prevention based on cardiovascular risk factors in women should not be delayed.

Thirdly, people living in deprived neighbourhoods have a greater risk of developing CVD than the general population due to their unfavourable (modifiable) risk factors [19]. Therefore, focusing on modifiable risk is a reasonable approach, mainly because of the heterogeneity within such a population in terms of ethnicity (that is, a large proportion of non-Dutch people) and age distribution (mainly young people from ethnic minorities and elderly Dutch). The ethnic origins of the population must be taken into consideration because the Framingham risk score is derived from a population consisting of a large

majority of white patients of European origin and both underestimates and overestimates of the absolute risk in other ethnic groups have been reported [17, 24–26]. About two thirds of our study population had a non-European origin, mainly Turkish, Surinamese, or Moroccan. We found no significant ethnic differences in the proportions of identified patients according to the applied risk thresholds, but this may be because of small numbers of the different ethnic minority groups. Compared with other international guidelines, the current Dutch guidelines provide no information about the underestimation of the CVD risk in ethnic minority groups [8, 9, 27]. So the focus on the modifiable part of risk instead of the absolute risk in a heterogeneous population living in deprived neighbourhoods is a possible alternative.

Several limitations of the present study should be mentioned. The proposed modifiable part of the CVD risk is based on blood pressure measurements taken on one occasion, whereas national guidelines recommend that blood pressure should be considered after repeated measurements. Our measuring procedure may have overestimated the modifiable part of the risk and consequently of the CVD risk. On the other hand, we believe that misclassification is limited because the CVD risk assessment depends on many risk factors and because the risk formula initially was based on single measurements.

For determination of the modifiable risk, we considered that smokers can quit smoking and we included patients whose blood pressure was higher than 120 mm Hg and had a cholesterol to HDL ratio > 4. Although a limited number of patients may successfully quit smoking, according to a large Danish study smoking reduction has no impact on CVD risk whereas smoking cessation clearly reduces the risk [28]. The above mentioned blood pressure levels are relatively low to justify intervention according to the guidelines. However, evidence has shown that each 10 mm Hg drop in systolic blood pressure decreases the risk of stroke in one third of patients and that this association is continuous down to levels of at least 115/75 mm Hg [29].

We considered in this study a modifiable risk ≥ 5%. Of course, pharmacological treatment can further reduce blood pressure (systolic blood pressure < 120 mm Hg) or lipids (total cholesterol to HDL ratio < 4) resulting in higher levels of the realistic or potential modifiable risk. Consequently fewer patients would be identified for intervention activities (lower NNT). Nevertheless, we think that further reduction of modifiable risk factors is not realistic and that drug related adverse effects are more likely to exceed the benefits [30].

A major strength of this study is stating the importance of reducing modifiable risk factors for all patients, despite a lower threshold of absolute cardiovascular risk. Whether the potential or realistic modifiable risk should be taken into account in daily practice depends on the levels of the modifiable risk factors and the patient's likelihood of complying with prevention strategies. In daily practice, clinicians should discuss with patients the modifiable risk for CVD because it is a more comprehensive approach for the

prevention of CVD than just individual risk factors and it is easier to communicate with patients. Additionally clinicians should be aware that using risk charts based on absolute risk thresholds as recommended by the guidelines is inadequate for the identification of high risk patients to initiate intervention. Therefore, current guidelines regarding prevention of CVD should be adapted.

We conclude that targeting preventive strategies at patients with an absolute 10 year risk ≥ 20% would exclude a large group of relative young, predominantly female patients. This group constitutes as much as one quarter of all patients and they may benefit from preventive strategies to prevent CVD in the long term because their potential reduction in absolute risk of CVD exceeds 5%. Moreover, using the modifiable part of risk will reduce over treatment of older patients with a raised absolute risk but low modifiable risk.

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APPENDIX

CALCULATIONS OF ABSOLUTE, MODIFIABLE, AND NON-MODIFIABLE RISKS

Absolute risk (AR)

μ = 18.8144 - (1.2146 * sex)- (1.8443 * (LN(age))) + (0.3668 * LN(age) * sex) - (1.4032 * LN(SBP)) - (0.3899 * smoking) – (0.5390 * LN(TC:HDL)) - 0.3036 * diabetes –(0.1697 * sex * diabetes)

σ = 0.6536 + (μ* (-0.2402))

ϵ = exp (σ)

Γ = (LN(10) - μ) / ϵ

AR = 100 * (1 - EXP(- EXP(Γ))) .

Potential reduction: non-modifiable risk (NMR_p)

AR (if systolic blood pressure = 120 mm Hg and smoking = 0 and TC:HDL = 4)

1. Separate risk for SBP: AR with SBP and (TC:HDL = 4 and smoking = 0) – NMR_p
2. Separate risk for cholesterol: AR with TC:HDL and SBP = 120 mm Hg and smoking = 0) –NMR_p
3. Separate risk for smoking: AR with smoking=1 and (SBP = 120 mm Hg and TC:HDL = 4) - NMR_p

Potential reduction: modifiable risk (MR_p)

1 (if SBP > 120 mm Hg) + 2 (if TC:HDL> 4) + 3 (if smoking =1)

Realistic reduction: non-modifiable risk (NMR_r)

AR (if SBP – 12 mm Hg) and (smoking = 0) and (TC – TC* 20%/ HDL + HDL* 5%))

1. Separate risk for SBP: AR with SBP and ((TC – TC* 20%/ HDL + HDL* 5%) and smoking = 0) – NMR_r
2. Separate risk for cholesterol: AR with TC:HDL and ((SBP – 12 mm Hg) and smoking = 0) – NMR_r
3. Separate risk for smoking: AR with smoking=1 and ((SBP – 12 mm Hg) and (TC – TC* 20%/ HDL + HDL* 5%)) NMR_r

Realistic reduction: modifiable risk (MR_r)

1 (if SBP > 120 mm Hg) + 2 (if TC:HDL > 4) + 3 (if smoking =1)

Abbreviations: HDL, high density lipoprotein cholesterol;
SBP, systolic blood pressure; TC, total cholesterol

Chapter 4

No evidence for marked ethnic differences in accuracy of self-reported diabetes, hypertension and hypercholesterolemia

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ABSTRACT

Objective:

To assess whether the accuracy of self-reported diabetes, hypertension and hypercholesterolemia in high-risk groups differs according to ethnicity.

Study design and Setting:

We analysed data of 430 patients at high risk of cardiovascular disease from different ethnic origin, including Turkish, Moroccan, Surinamese and Dutch. Risk factors based on self-reports were compared with data from medical records and with a gold standard based on clinical measurements. Proportions of concordance between self-reports and other methods and kappa statistics were determined by ethnicity.

Results:

Concordance between self-reports and other data sources was highest in diabetes and lowest for hypercholesterolemia. Agreement of self-reports was substantial to almost perfect for diabetes (kappa: 0.84-0.76), substantial to moderate for hypertension (kappa: 0.63-0.51) and moderate for hypercholesterolemia (kappa 0.55-0.48). There was no statistically significant association between ethnicity and concordance, except for self-reporting of diabetes among Surinamese vs. Dutch indigenous patients (OR=0.37; 95% confidence interval: 0.14-0.97).

Conclusion:

There are no marked ethnic differences in the accuracy of self-reports of diabetes, hypertension and hypercholesterolemia in high-risk populations. Larger studies including multiple ethnic groups are needed to confirm these findings.

INTRODUCTION

Many studies on the prevalence of cardiovascular risk factors in ethnic minorities rely on self-reports [1-4]. Because the validity of self-reports may be subject to many problems (e.g., recall bias, unawareness of the diagnosis, or social desirability) self-reported data are often inadequate for assessing the true prevalence of cardiovascular risk factors. Furthermore, the validity of self-reported data varies among the different cardiovascular risk factors. Studies have reported substantial to almost perfect agreement between self-reported diabetes and diabetes diagnoses according to both medical records [5-9] and measurements [10-12]. However, findings on the validity of self-reported hypertension and hypercholesterolemia are inconsistent. Compared to either medical records or measurements, different studies generally reported moderate agreement for hypertension [5,7,9,13-16] whereas for hypercholesterolemia the agreement between self-reports and other data sources was moderate to low [5,7,11,12,16,17].

Specific problems can also exist concerning the accuracy of self-reported cardiovascular risk factors among ethnic minorities. For example, problems may be caused by the low level of proficiency in the language of the host country or, in case of translating questions to the mother languages of ethnic minorities, by the lack of equivalent translations [18]. In addition, the way people experience and label diseases and symptoms differ across cultures and ethnic backgrounds [19].

As far as we know, no study has compared self-reported diabetes, hypertension and hypercholesterolemia with both the medical record of the general practitioner (GP) and with clinical measurements. Moreover, only a few studies have explored the effect of ethnicity on the quality of self-reported cardiovascular risk factors, and those studies indicated that self-reported data were less accurate among some ethnic (minority) groups than among the indigenous population [14,15,17].

The aim of the present study is twofold. First, to compare the accuracy of self-reported diabetes, hypertension and hypercholesterolemia with two other data sources (i.e., medical records and a gold standard based on measurements and medication use) in a multi-ethnic population at risk of developing cardiovascular diseases. Second, to investigate whether ethnicity is associated with the accuracy of self-reports of these cardiovascular risk factors, as compared to the other data sources.

METHODS

This study used data collected in the framework of a randomised controlled trial to assess the effectiveness of a structured collaboration within general practice to reduce cardiovascular risk. Briefly, the trial consisted of an intervention group that received

intensified preventive care and a control group that received usual GP care. Both groups were invited to the general practice for assessment of the cardiovascular risk profile every three months. The study was conducted between mid-2002 until the end of 2004 in general practices located in deprived neighbourhoods of two Dutch cities (Rotterdam and The Hague) and involved individuals aged 30 to 70 years from different ethnic groups at risk of developing cardiovascular diseases. Details on the design of the trial are reported elsewhere [20].

Study population

The medical records of three primary healthcare centres representing five general practices (18 GPs) were searched to select all men and women with one or more registered cardiovascular risk factors, considered as potentially high-risk individuals to develop cardiovascular diseases. After excluding patients not eligible to participate

Table 1: Characteristics of nonparticipants (n = 595), participants (n = 536) and participants with complete cardiovascular risk profile (n = 430).

	Nonparticipants	Participants	p value nonparticipants vs participants	Complete cardiovascular risk profile
Gender			0.213	
Males	51	46		46
Females	49	54		54
Age (mean (SD)) (years)	55.5 (9.7)	53.2 (9.7)	0.001	53.1 (9.9)
Age categories (years)			0.001	
30-39	9	9		10
40-49	18	28		28
50-59	36	35		33
≥ 60	38	26		28
Ethnicity			0.026*	
Dutch	38	40		42
Turkish	22	27		29
Surinamese	12	12		12
Others	29*	21		18
Cardiovascular risk factors (based on data from GP records)				
Diabetes	39	31	0.002	29
Hypertension	49	44	0.126	44
Hypercholesterolemia	20	22	0.169	23
Smoking	27	32	0.041	30
History of CVD	33	31	0.137	32
Family history of CVD	15	17	0.350	19

* the ethnicity of a considerable number in the category "others" was not known or not traceable from the GP medical records. When this category was excluded from analyses, statistical significance was not reached.
CVD = cardiovascular disease.
All values are proportion, unless stated otherwise

because of complex co morbidity or psychological problems according to the GP, 1,131 patients were asked to give informed consent. Of these, 536 were willing to participate. The remaining patients were not reached after repeated home visits (n = 193) or refused to participate (n = 402). Main reasons for refusal were not interested (n = 114), language problems (n = 72), treated by a specialist (n = 49), time constraints (n = 45), and other reasons (n = 122) such as planning to go abroad for longer than six months and being too ill to participate.

Comparison of the medical record data of participants and non–participants revealed that nonparticipants were somewhat older (55.5 (SD 9.7) vs. 53.2 (SD 9.7) years) and had a higher prevalence of diabetes (39% vs. 31%) than participants (Table 1).

In 430 patients the questionnaire was completed, measurements of blood pressure, lipid profiles and fasting glucose were obtained and risk factor information from the GP's medical records was available. In total 179 Dutch, 126 Turkish, 50 Surinamese, and 75 patients belonging to other ethnic origins were included. Ethnicity was defined according to the country of birth because all ethnic minorities were first-generation immigrants.

Data sources

The following data sources were used to acquire information on cardiovascular risk factors.

1. Questionnaires

Trained research assistants administered the questionnaires during a face-to-face interview at the patient's home. Dutch and Surinamese participants were interviewed in the Dutch language. For the Turkish participants the interviews were conducted by bilingual interviewers in the Turkish language, using translated questionnaires. For the other ethnic groups whose knowledge of the Dutch language was considered not adequate, the interviews were conducted in their mother tongue.

We used a structured questionnaire that included questions on demographic and socio-economic characteristics, health behaviour, cardiovascular risk factors (hypertension, diabetes and hypercholesterolemia), cardiovascular diseases, and medication use.

Regarding the cardiovascular risk factors, participants were asked the following questions: "Do you have diabetes?", "Do you have a high blood pressure?", "Do you have an elevated cholesterol level?".

With respect to current use of medication, the interviewers asked the patients whether they used medication and, if so, to show all the medications used in order to accurately register the names and doses of the drugs. Subsequently, we recorded this information to distinguish between patients using antihypertensive drugs, diabetes medications and/or lipid-lowering medications.

2. GP medical records

To identify patients at high risk of developing cardiovascular disease from the medical records, we used all available medical information from the GP information system including relevant search terms of cardiovascular risk factors/diseases, the codes of the International Classification of Primary Care (ICPC) and codes specifically used in the different primary healthcare centres, prescribed medication (according to the Anatomical Therapeutic Chemical [ATC] classification), summaries of letters from specialists, laboratory results, and blood pressure measurements. This step resulted in lists of patients with one or more of the above-mentioned risk factors. The medical records of these latter patients were then reviewed by medical students who had been trained to extract the necessary information using a structured form.

Patients were classified as diabetics on the basis of ICPC code T90, prescribed diabetes medication, and/or on search terms or registration codes specific for the primary healthcare centre.

Hypertensive patients were identified according to the ICPC code K86/K87, prescribed antihypertensive medication, and/or search terms or registration codes specific for the primary healthcare centre.

Hypercholesterolemia was considered present according to ICPC code T93, prescribed lipid-lowering medication, and/or search terms or registration codes specific for the primary healthcare centre.

3. Measurements

Participants underwent a limited physical examination including blood pressure measurement, which took place at the participant's home by trained research assistants. Systolic/diastolic blood pressure was measured with a validated automatic sphygmomanometer, with participants in sitting position and after they had been resting for at least 5 minutes. The average of two measurements (taken with a 10-minute interval) was used for the analysis. Blood samples were taken at the laboratory to assess fasting glucose, HbAc1 and lipid profile (total and HDL cholesterol and triglycerides).

Based on measurements and current medication use (see point 1 "Questionnaires" above), we constructed a definition of the different cardiovascular risk factors that we considered as the gold standard. In the present study this so-called gold standard is the most objective measure of the different risk factors.

Diabetes mellitus was defined as glucose ≥ 7.0 mmol/l [21] and/or currently using diabetes medication.

Hypertension was defined as a systolic blood pressure ≥ 160 mmHg and/or diastolic blood pressure ≥ 95 [22] and/or current use of antihypertensive medication.

Hypercholesterolemia was defined as total cholesterol ≥ 6.5 mmol/l [23] and/or current use of lipid-lowering medication.

Data analysis

The proportions of cardiovascular risk factors obtained by self-report, medical records, and the gold standard per ethnic group were determined.
We computed the proportions of concordance and discordance between self-report and GP records on the one hand, and between self-report and gold standard on the other. A concordant risk factor pair is a risk factor present (or absent) according to both compared data sources. A risk factor pair is discordant if the risk factor is present according to one data source but absent according to the other. Overall concordance is calculated by adding the concordant risk factor pairs, that is risk factors were both present and absent according to the data sources.
We calculated the kappa (κ), which is defined as the level of agreement between two data sources, of which one is presumed to be more valid than the other, adjusted for agreement by chance. Agreement was compared between information available from self-reports and medical records, and agreement between self-reports and the gold standard. To evaluate the level of accuracy measured with the kappa statistic (κ) , the classification system suggested by Landis and Koch was used [24]: κ <0.40 indicates poor to fair accuracy, 0.40-0.60 moderate accuracy, 060-0.80 substantial accuracy, and 0.80-1.00 almost perfect accuracy.
To determine whether ethnicity is associated with the concordance between self-reports and GP records or gold standard, we performed logistic regression analysis with overall concordance between self-reports and other data sources as the dependent variable, and ethnicity as the independent variable adjusted for age and gender.

RESULTS

Table 2 summarises the characteristics and the prevalence of risk factors of the study population according to ethnicity: 54% of the population was female. Members of the ethnic minority groups were on average 6-8 years younger than the Dutch participants.
The proportions of diabetics were comparable between the data from self-reports (29%), medical records (29%), and clinical measurements (the gold standard) (31%). In general, more individuals were identified with hypertension and hypercholesterolemia according to self-reports than according to medical records, whereas fewer individuals were identified according to self-reports than according to the gold standard. These proportions were, respectively, 52%, 44% and 59% for hypertension and 34%, 23% and 36% for hypercholesterolemia.
Table 3 shows that the overall concordance between self-reports and medical records was highest for diabetes (93.3%) and lowest for hypercholesterolemia (78.4%). The κ values varied considerably per risk factor and were 0.84 for diabetes, 0.63 for hypertension

Table 2: Background characteristics and prevalence of cardiovascular risk factors by different data sources and ethnic groups

	Dutch n = 179	Turkish n = 126	Surinamese n = 50	Others n = 75	Total n = 430
Patient characteristics					
Females	88 (49)	76 (60)	29 (58)	39 (52)	232 (54)
Age in years (mean (SD))	57.5 (8.7)	48.8 (9.3)	51.7 (9.0)	51.7 (9.0)	53.3 (9.7)
Highest educational level					
None	16 (9)	39 (33)	7 (14)	24 (32)	86 (21)
Low	63 (37)	62 (52)	13 (27)	13 (18)	151 (36)
Lower secondary	69 (40)	10 (8)	17 (35)	24 (32)	120 (29)
Higher	24 (14)	9 (8)	12 (24)	13 (18)	58 (14)
Duration of stay in the Netherlands in years (mean (SD))	N.A.	25.0 (6.9)	23.2 (8.7)	22.0 (10.2)	23.8 (8.4)
Proficiency in Dutch language (mean (SD)) (Score: 4 (lowest) to 16 (highest))	N.A.	8.0 (6.9)	15.3 (1.5)	11.5 (4.4)	10.5 (4.5)
Prevalence of cardiovascular risk factors					
Diabetes mellitus by					
Self-reports	29 (16)	40 (32)	28 (56)	27 (36)	124 (29)
GP records	27 (15)	42 (33)	25 (50)	29 (39)	123 (29)
Gold standard	30 (17)	42 (33)	26 (52)	33 (44)	131 (31)
Hypertension by					
Self-reports	92 (52)	70 (56)	32 (64)	31 (41)	225 (52)
GP records	80 (45)	57 (45)	26 (52)	28 (37)	191 (44)
Gold standard	111 (62)	70 (56)	34 (68)	38 (51)	253 (59)
Hypercholesterolemia by					
Self-reports	77 (43)	36 (29)	17 (34)	17 (23)	147 (34)
GP records	55 (31)	22 (18)	11 (22)	12 (16)	100 (23)
Gold standard	88 (49)	31 (25)	15 (30)	20 (27)	154 (36)

Values are numbers (%), unless stated otherwise
N.A: not applicable

and 0.48 for hypercholesterolemia, indicating an almost perfect accuracy for diabetes, a substantial to moderate accuracy for hypertension, and moderate accuracy for hypercholesterolemia. With regard to ethnic differences in accuracy, κ differed slightly across the ethnic groups in diabetes (κ values ranged from 0.79 to 0.86), whereas in hypertension and hypercholesterolemia the differences in κ were larger. The accuracy in hypertension was moderate among the Dutch (κ=0.53) while among the Turks the accuracy was substantial (κ=0.70). In hypercholesterolemia, κ was moderate among the Dutch (κ=0.58) but poor among the Turks (κ=0.30).

Compared to concordance between self-reports and medical records, the overall concordance between self-reports and the gold standard for diabetes and hypertension was somewhat lower (Table 4), but the proportion was still the highest in diabetes (90%).

Table 3: Concordant and discordant risk factor pairs, overall concordance between self-reports and GP records (n (%)) and the results of the κ and 95% CI for κ by ethnicity

	Concordant risk factor pairs		Discordant risk factor pairs		Overall concordance	κ	κ 95% CI
	SR +/GP+	SR -/GP-	SR+/GP -	SR -/GP +			
Diabetes							
Dutch	23 (12.8)	146 (81.6)	6 (3.4)	4 (2.2)	169 (94.4)	0.79	0.66-0.91
Turkish	37 (29.4)	81 (64.3)	3 (2.4)	5 (4.0)	118 (93.7)	0.86	0.76-0.95
Surinamese	24 (48.0)	21 (42.0)	4 (8.0)	1 (2.0)	45 (90.0)	0.80	0.64-0.96
Others	25 (33.3)	44 (58.7)	2 (2.7)	4 (5.3)	69 (92.0)	0.83	0.70-0.96
Total	109 (25.3)	292 (67.9)	15 (3.5)	14 (3.3)	401 (93.3)	0.84	0.78-0.89
Hypertension							
Dutch	65 (36.3)	72 (40.2)	27 (15.1)	15 (8.4)	137 (76.5)	0.53	0.40-0.66
Turkish	54 (42.9)	53 (42.1)	16 (12.7)	3 (2.4)	107 (84.9)	0.70	0.58-0.82
Surinamese	25 (50.0)	17 (34.0)	7 (14.0)	1 (2.0)	42 (84.0)	0.68	0.48-0.88
Others	24 (32.0)	40 (53.3)	7 (9.3)	4 (5.3)	64 (85.3)	0.69	0.53-0.86
Total	168 (39.1)	182 (42.3)	57 (13.3)	23 (5.3)	350 (81.4)	0.63	0.55-0.70
Hypercholesterolemia							
Dutch	48 (26.8)	95 (53.1)	29 (16.2)	7 (3.9)	143 (79.9)	0.58	0.46-0.70
Turkish	13 (10.3)	81 (64.3)	23 (18.3)	9 (7.1)	94 (74.6)	0.30	0.12-0.48
Surinamese	9 (18.0)	31 (62.0)	8 (16.0)	2 (4.0)	40 (80.0)	0.51	0.26-0.76
Others	7 (9.3)	53 (70.7)	10 (13.3)	5 (6.7)	60 (80.0)	0.36	0.11-0.61
Total	77 (17.9)	260 (60.5)	70 (16.3)	23 (5.3)	337 (78.4)	0.48	0.39-0.57

SR+/ GP+: self-reports positive and GP records positive; SR-/GP-: self-reports negative and GP records negative
SR+/GP-: self-reports positive and GP records negative; SR-/GP+: self-reports negative and GP records positive;
Overall concordance: SR+/GP+ and SR-/GP-

The κ values were also slightly lower in diabetes (κ=0.76) and in hypertension (κ=0.51) and slightly higher in hypercholesterolemia (κ=0.55).

Table 5 shows that the associations of ethnicity with the concordance between self-reported cardiovascular risk factors and other data sources were not consistent.

Regarding concordance, there were no statistically significant differences by ethnicity between self-reports and other data sources for diabetes, except in one case: among the Surinamese there was significantly less concordance than among the Dutch (OR: 0.37; 95% confidence interval [CI]: 0.14-0.97).

In hypertension, all ethnic minority groups had higher OR than the Dutch, indicating that they had more concordant classifications of hypertension. These differences, however, were not statistically significant. Turkish individuals seemed to have a less concordant classification of hypercholesterolemia than the Dutch (OR: 0.61; 95% CI: 0.34-1.10).

Table 4: Concordant and discordant risk factor pairs, overall concordance between self-reports and gold standard (n (%)) and the results of κ and 95% CI for κ by ethnicity

	Concordant risk factor pairs		Discordant risk factor pairs		Overall concordance	κ	κ 95% CI
	SR +/GS +	SR -/GS -	SR+/GS -	SR -/GS +			
Diabetes							
Dutch	22 (12.3)	142 (79.3)	7 (3.9)	8 (4.5)	164 (91.6)	0.70	0.56-0.84
Turkish	36 (28.6)	80 (63.5)	4 (3.2)	6 (4.8)	116 (92.1)	0.82	0.71-0.93
Surinamese	23 (46.0)	19 (38.0)	5 (10.0)	3 (6.0)	42 (84.0)	0.68	0.48-0.88
Others	25 (33.3)	40 (53.3)	2 (2.7)	8 (10.7)	65 (86.7)	0.72	0.56-0.88
Total	106 (24.7)	281 (65.3)	18 (4.2)	25 (5.8)	387 (90.0)	0.76	0.69-0.83
Hypertension							
Dutch	76 (42.5)	52 (29.1)	16 (8.9)	35 (19.6)	128 (71.5)	0.43	0.30-0.56
Turkish	58 (46.0)	44 (34.9)	12 (9.5)	12 (9.5)	102 (81.0)	0.61	0.47-0.75
Surinamese	29 (58.0)	13 (26.0)	3 (6.0)	5 (10.0)	42 (84.0)	0.64	0.42-0.87
Others	24 (32.0)	30 (40.0)	7 (9.3)	14 (18.7)	54 (72.0)	0.44	0.24-0.64
Total	187 (43.5)	139 (32.3)	38 (8.8)	66 (15.3)	326 (75.8)	0.51	0.43-0.59
Hypercholesterolemia							
Dutch	61 (34.1)	75 (41.9)	16 (8.9)	27 (15.1)	136 (76.0)	0.52	0.39-0.65
Turkish	20 (15.9)	79 (62.7)	16 (12.7)	11 (8.7)	99 (78.6)	0.45	0.28-0.62
Surinamese	12 (24.0)	30 (60.0)	5 (10.0)	3 (6.0)	42 (84.0)	0.63	0.40-0.86
Others	13 (17.3)	51 (68.0)	4 (5.3)	7 (9.3)	64 (85.3)	0.61	0.40-0.82
Total	106 (24.7)	235 (54.7)	41 (9.5)	48 (11.2)	341 (79.3)	0.55	0.42-0.59

SR+/GS+: self-reports positive and gold standard positive; SR-/GS-: self-reports negative and gold standard negative
SR+/GS-: self-reports positive and gold standard negative; SR-/GS+: self-reports negative and gold standard positive
Overall concordance: SR+/GS+ and SR-/GS-

DISCUSSION

This study shows that the accuracy of self-reported diabetes, hypertension and hypercholesterolemia varies per risk factor and depends on the data sources with which these self-reports are compared. There were no marked ethnic differences in agreement between self-reported cardiovascular risk factors and medical records, or between self-reports and the gold standard (using clinical measurements). However, the accuracy of self-reports of diabetes among Surinamese patients was lower than among the Dutch.

The overall agreement of self-reported diabetes was substantial to almost perfect. For hypertension and hypercholesterolemia the overall agreement was moderate to substantial and moderate to fair, respectively. Our findings are in line with previous studies reporting highest κ values (0.92-0.72) for diabetes [5-8, 25] moderate values (0.41-0.75) for hypertension [5,7,9,13,25] and lowest values (0.40-0.43) for hypercholesterolemia [5, 7].

Table 5: Association (OR; 95% CI) of ethnicity with concordance between self-reports and GP records and between self-reports and gold standard (adjusted for age and gender) (n = 430); * p< 0.05

	Concordance Self-report/GP records		Concordance Self-report/gold standard	
	OR	95% CI	OR	95% CI
Diabetes				
Ethnicity				
Dutch	1.00		1.00	
Turkish	0.75	0.27-2.10	0.73	0.30-1.80
Surinamese	0.48	0.15-1.53	0.37	0.14-0.97*
Others	0.59	0.20-1.74	0.44	0.18-1.08
Gender				
Males	1.00		1.00	
Females	0.48	0.21-1.09	0.59	0.30-1.15
Age (years)	0.97	0.93-1.02	0.95	0.92-0.99*
Hypertension				
Ethnicity				
Dutch	1.00		1.00	
Turkish	1.74	0.91-3.31	1.61	0.89-2.91
Surinamese	1.62	0.69-3.77	2.02	0.88-4.67
Others	1.79	0.85-3.77	1.00	0.54-1.85
Gender				
Male	1.00		1.00	
Female	0.98	0.59-1.61	1.12	0.71-1.75
Age (years)	1.00	0.97-1.03	1.00	0.97-1.02
Hypercholesterolemia				
Ethnicity				
Dutch	1.00		1.00	
Turkish	0.61	0.34-1.10	0.97	0.54-1.76
Surinamese	0.89	0.40-1.97	1.48	0.63-3.44
Others	0.90	0.45-1.80	1.65	0.79-3.46
Gender				
Male	1.00		1.00	
Female	1.25	0.78-2.00	1.13	0.70-1.83
Age (years)	0.98	0.96-1.00	0.98	0.96-1.01

The κ values for the agreement between self-reports and the gold standard were generally lower compared to the κ values for self-reports and medical records. The proportion of patients with these risk factors was highest when using the gold standard. It is not surprising that new cases of hypertension and hypercholesterolemia are identified when measurements of blood pressure and cholesterol are made; this occurs because these measurements are not 'daily routine' in Dutch general practices and do not require constant monitoring such as, for example, in the case of diabetes. Consequently, including patients in such a trial leads to identification of additional cases not yet known to the GP. It is also possible that patients did not report a particular risk factor adequately because of unawareness of the condition, even though their GP may have registered the risk factor

in the medical records. This could, for example, occur in the case of hypercholesterolemia, a condition that is often less easily understood by patients [16, 17].

With respect to the association between ethnicity and the accuracy of self-reported cardiovascular risk factors, our results showed no marked differences between the ethnic groups. Only the Surinamese patients were significantly less accurate in self-reports of diabetes than the Dutch. This could be because of their unawareness of having diabetes because in daily practice blood glucose levels are less often determined among Surinamese than among the Dutch indigenous population. According to a study among native Dutch by Mooy et al. (in Middelkoop et al. [26]) the number of unknown (newly detected) diabetic patients equalled the number of known patients; in our study this was probably more often the case among the Surinamese than the Dutch.
Another hypothesis is that because diabetes is a common disease among Surinamese (of South Asian origin), the Surinamese were more likely to over-report this condition.
It was not possible to compare our findings on lack of ethnic differences with other studies because, as far as we know, no Dutch or international studies have investigated the accuracy of self-reports in diabetes by ethnic group. With respect to hypertension and hypercholesterolemia, a few studies conducted in the USA were found [14,15,17]. In the studies by Ford et al. [15] and Vargas et al. [14] lower sensitivities of self-reported hypertension were reported among Mexican-Americans compared to other ethnic groups in the USA, whereas Natarajan et al. [17] reported that non-Hispanic Blacks and Mexican-Americans were more likely to have a lower sensitivity of self-reported hypercholesterolemia than non-Hispanic Whites.
In the present study there are some possible explanations for the absence of differences between the ethnic groups. Firstly, there were no meaningful language differences between the interviewers and the patients that might have negatively influenced the accuracy of self-reported data; this is because the proficiency of the Surinamese in the Dutch language was good, and the Turks and other ethnic groups were interviewed in their own mother tongue. Second, the risk factors investigated might be less affected by socially desirable answers than, for example, behavioural risk factors such as smoking and alcohol consumption which are reported to yield less accurate self-reports than medical conditions among some ethnic groups [27,28].

This study has several limitations that need to be emphasised. The first is the composition of the study population. Because data collection took place among a population at risk of developing cardiovascular disease (participating in a trial aimed at reducing cardiovascular risk), this means that our results cannot be generalised to the general population because of the inclusion of high-risk individuals only. Participants in our study might, for example, have more knowledge of their cardiovascular risk factors than

the general population or be more aware of their risk factors during the recruitment process. On the other hand, our findings are in line with previous studies on the accuracy of self-reported cardiovascular risk factors in the general population.

The response rate was 47%. Although, this response rate is satisfactory when taking into account response rates achieved in other studies among multi-ethnic patient populations, the non-response raises questions about the generalisability of the findings. Comparison of most of the characteristics of participants and nonparticipants revealed similar ethnicity and a similar prevalence of most of the cardiovascular risk factors. Compared with the participants, the nonparticipants were, however, about 2 years older and had a higher prevalence of diabetes than the participating patients (39% vs 31%), suggesting that some relevant selection may have occurred. Whether this selection indeed biased our results remains difficult to discern. Especially, an age difference (even as small as 2 years) can modify the accuracy of self-reports; but one can only speculate as to whether this phenomenon differs according to ethnicity and thus actually lead to bias.

Another limitation concerns the small numbers in some of the ethnic groups. Although the OR for the association between ethnicity and the accuracy of self-reports and other data sources differed substantially from one, statistical significance was not reached. Perhaps with larger samples, more ethnic differences might have been detected. Given the wide range of 95% CIs, our study does not provide sufficient evidence that there are no ethnic differences in self-reported hypertension and hypercholesterolemia. In the case of diabetes, our results tend towards differences in the accuracy of self-reports by ethnicity.

The above-mentioned limitations suggest the need for additional research using larger representative samples of different ethnic groups from the general population (with high response rates) to investigate the validity of self-reports across ethnic groups. On the other hand, researchers should bear in mind that it is practically impossible to perform a uniform methodological procedure for all ethnic minorities in order to realise a satisfactory participation rate, even if recruitment and data collection procedures are more tailored to the specific characteristics of the different groups. We believe that the limited participation rate in our study is mainly due to the heterogeneity of our study population living in deprived neighbourhoods; that is predominantly ethnic minorities from different origins with generally no or low level education, and Dutch persons with a low socioeconomic status.

In the analysis we did not take into consideration any characteristics of the general practices. However, we have no reason to believe that there were large differences between them, since all general practices in our study were located in comparable deprived neighbourhoods, have patient populations with similar characteristics, and use similar GP information systems. Similarly, our results cannot be influenced by differences in access to (Dutch) primary healthcare between ethnic minority groups and the Dutch

participants, because almost all patients (regardless of ethnic background) have equal access to health care and use the general practice equally.

For the definition of a gold standard for hypertension and hypercholesterolemia, we chose not to use the stricter cut-off levels listed in the more recent Dutch guidelines (following the international guidelines); these cut-off levels are 140/90 mm Hg or 160/95 mm Hg for those aged 60 years and over for diagnosing hypertension, and a total cholesterol ≥ 5.0 mmol/l for diagnosing hypercholesterolemia. We stayed with our original definitions for the following reasons. First, the cut-off levels for these risk factors changed over time; our study started when the guidelines using the stricter levels had only just been published. Second, self-reports of risk factors depend on information provided by the GP who generally used the older cut-off levels when communicating a diagnosis to their patients.

Overall, our study adds to earlier research by providing new insight into the accuracy of self–reported cardiovascular risk factors according to ethnicity.

We conclude that there are no marked ethnic differences in the accuracy of self-reports of diabetes, hypertension and hypercholesterolemia in high-risk populations. Larger studies including multiple ethnic groups are needed to confirm these findings.

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Chapter 5

Intensified preventive care to reduce cardiovascular risk in deprived neighbourhoods: a randomised controlled trial in healthcare centres

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In revision

ABSTRACT

Background:

We examined the effectiveness of a structured collaboration in general practice between a practice nurse, a peer health educator, the general practitioner (GP) and a GP assistant in providing intensified preventive care for patients at high risk of developing cardiovascular diseases.

Design:

A randomised controlled trial in three healthcare centres (18 GPs) in deprived neighbourhoods of two major Dutch cities: the Hague and Rotterdam

Methods:

275 high-risk patients (30-70 years) from various ethnic groups were randomised to intervention (n=137) or usual care group (n=138). Both groups were invited every three months for the assessment of their cardiovascular risk profile.
We determined group differences in outcomes: 10-year absolute risk (Framingham risk equation), blood pressure, lipids and body mass index at 12-months follow-up.

Results:

The 10-year absolute risk was reduced by 1.76% (SE 0.81; p=0.032) in the intervention group and by 2.27% (SE 0.69; p=0.001) in the usual care group; the difference in mean change was 0.88% (95% CI -1.16 to 2.93). Within both groups significant reductions were also observed in the following individual risk factors: total cholesterol, total cholesterol/ HDLc, and LDLc; however, there were no relevant between- group differences.

Conclusion:

The cardiovascular risk profile of intervention and control patients improved after one-year follow-up. However, no extra effect of the structured preventive care on the risk for cardiovascular diseases was achieved.

INTRODUCTION

People living in deprived neighbourhoods have a greater risk of developing cardiovascular diseases (CVD) than the general population [1,2]. The population in deprived neighbourhoods is a heterogeneous group including an indigenous population of low socio-economic status (SES) and a large proportion of people with different ethnic backgrounds.

General practices located in deprived neighbourhoods often have to deal with a high workload and lack of supporting staff which can lead to inadequate management of cardiovascular risk factors [3,4]. Furthermore, language and cultural barriers between the general practitioner (GP) and ethnic minority patients may hamper the communication resulting in an even poorer quality of care [5]. Involving a peer health educator (PHE) in preventive interventions directed at cardiovascular risk factors, such as diabetes, may help to bridge language and cultural differences [6].

Studies have shown that interventions to reduce cardiovascular risk were beneficial for participants with a high risk of CVD [7]. Moreover, intensive interventions addressing primary or secondary prevention of CVD, delivered by a practice nurse (PN) or other supporting staff, demonstrated improvement in cardiovascular risk and other risk factors [8-10]. Although in groups with a lower SES and in ethnic heterogeneous populations the risk of cardiovascular events is higher, most randomised controlled trials (RCTs) to reduce cardiovascular risk in a general practice setting have involved predominantly white middle-class individuals [11].

To examine the effectiveness of adding a PN and a PHE to general practices located in deprived neighbourhoods with an ethnic heterogeneous population in reducing cardiovascular risk among high-risk patients, we conducted a RCT. The intervention consisted of structured collaboration in the general practice between a PN, a PHE, the GP and a GP assistant to provide intensified preventive care in patients at high risk to develop CVD.

METHODS

Study design

We performed a RCT consisting of an intervention group that received intensified preventive care and a control group that received usual GP care. Both groups were invited to the general practice for assessment of their cardiovascular risk profile every three months. Randomisation was performed at the patient level within each general practice.

Setting

We approached all general practices in Rotterdam and the Hague that are located in deprived neighbourhoods [12]. Other study criteria were: a fully computerised information system, capacity to appoint a PHE, and fulfilling national criteria to receive funding for a PN.
From a total of 33 responding general practices, 13 were not interested and 10 did not fulfil the study criteria. Among the 10 remaining eligible general practices, 5 withdrew mainly because of the expected high level of workload related to the intervention, and 5 constituting 3 primary healthcare centres (HCC) with a total of 18 GPs agreed to participate.

Patients

The study protocol was approved by the local ethics committee of the Erasmus Medical Centre Rotterdam.
A search in the GPs' databases was conducted to identify patients aged 30-70 years at risk for CVD using codes of the International Classification of Primary Care (ICPC), the ATC classification of drugs, free text or laboratory measurements. This first search included patients known with one or more of the following registered cardiovascular risk factors or diseases: hypertension, diabetes mellitus, hypercholesterolemia, history of CVD (myocardial infarction, angina pectoris, peripheral arterial disease, heart failure, CVA and/or TIA), having a first-degree relative with a history of CVD before the age of 60 years, smoking, or if blood pressure ≥160/90 mm Hg or total cholesterol ≥ 6.2 mmol/l as registered within the last two years. Patients were excluded if they were too ill to participate according to their GP; received exclusively specialist care; planned to go abroad for longer than 6 months; they were also excluded when no PHE from a corresponding ethnic origin was available in the HCC and their command of the Dutch language was too poor according to their GP.
Two randomisation of eligible patients resulted in a usual GP care group consisting of one third of the patients, which was kept blind during the trial (elsewhere we compare this usual care group with the study groups (see Chapter 7)); and the remaining two third of the patients were approached personally by the research assistants for their informed consent and to undergo baseline measurements.
Using the Framingham risk equation, we calculated for each patient the 10-year risk of developing a CVD event and the potential modifiable part of absolute risk [13,14]. Patients with a modifiable part of the absolute risk ≥ 5% (i.e. risk due to smoking, elevated levels of systolic blood pressure or total cholesterol to HDL cholesterol ratio) were randomly allocated to the intervention or to the control group. Patients were informed which study arm they were allocated to.

Selection and enrolment of patients took place between January 2002 and December 2003. Data collection for the trial ended in December 2004.

Intervention

The intervention was based on the formation of a team in each HCC consisting of a GP, a PN, a GP assistant and a PHE, in which the PN had a leading role. Intervention activities were based on a specially constructed protocol that was based on the current Dutch General Practice Guidelines for hypertension, hypercholesterolemia, diabetes and smoking, and which described the procedures for the GP (first responsible and treatment decisions), PN (risk assessment, coordination and informative task), GP assistant (logistical task) and PHE (ethnic-specific health education). The intervention protocol could be adapted to tailor the intervention to individual practice needs and organisation (El Fakiri et al., unpublished data).

All team members were invited to join a one-day course before the start of the intervention. The course gave information on how to deal with the intervention protocol, and the team members were trained in performing the structured team meetings. During the course of the intervention, 4 additional coaching sessions, led by an experienced GP involved in the project, were organised for the PNs and PHEs to discuss difficulties with the implementation of the intervention and in the patient contacts.

The main outcome measure was change in the 10-year absolute risk of developing CVD between baseline and 12-months follow-up as calculated by the Framingham risk equation [14]. Secondary outcome measures included changes in the lipids, HbAc1, fasting glucose, BMI and blood pressure.

At baseline and after 12 months the following measurements were performed: blood pressure, body weight, and height were measured by trained research assistants at the patient's home. Weight and height were determined to calculate the BMI. Systolic and diastolic blood pressures were measured with the patient in sitting position, using a validated automatic sphygmomanometer (Omron M4-1). The mean of two measurements, taken with at least a 10-minute interval between, was used for the analyses.

Fasting blood samples were taken at the laboratory using venous blood samples. Plasma glucose, total cholesterol, HDL cholesterol, and triglycerides were measured with the 950 AT ORTHO diagnostics. Glycated haemoglobin (HbAc1) was determined by the Variant-1 BioRad. LDL-cholesterol was calculated using the Friedewald formula.

Trained bi-lingual interviewers administrated a structured questionnaire during a face-to-face interview at the patient's home at baseline and at 12-months follow-up, which included questions on socio-demographic characteristics, health behaviour, cardiovascular risk factors, medication use and quality of life. We used country of birth of the participants to define the following ethnic groups: Dutch, Turkish, and "others".

Blinding

Neither the patient nor the GP assistant conducting the 3, 6 and 9 months risk re-assessment could be blinded to the patient's allocation to the intervention or control group. The GP was not informed about who was allocated to the intervention or control group.

Sample size and statistical analyses

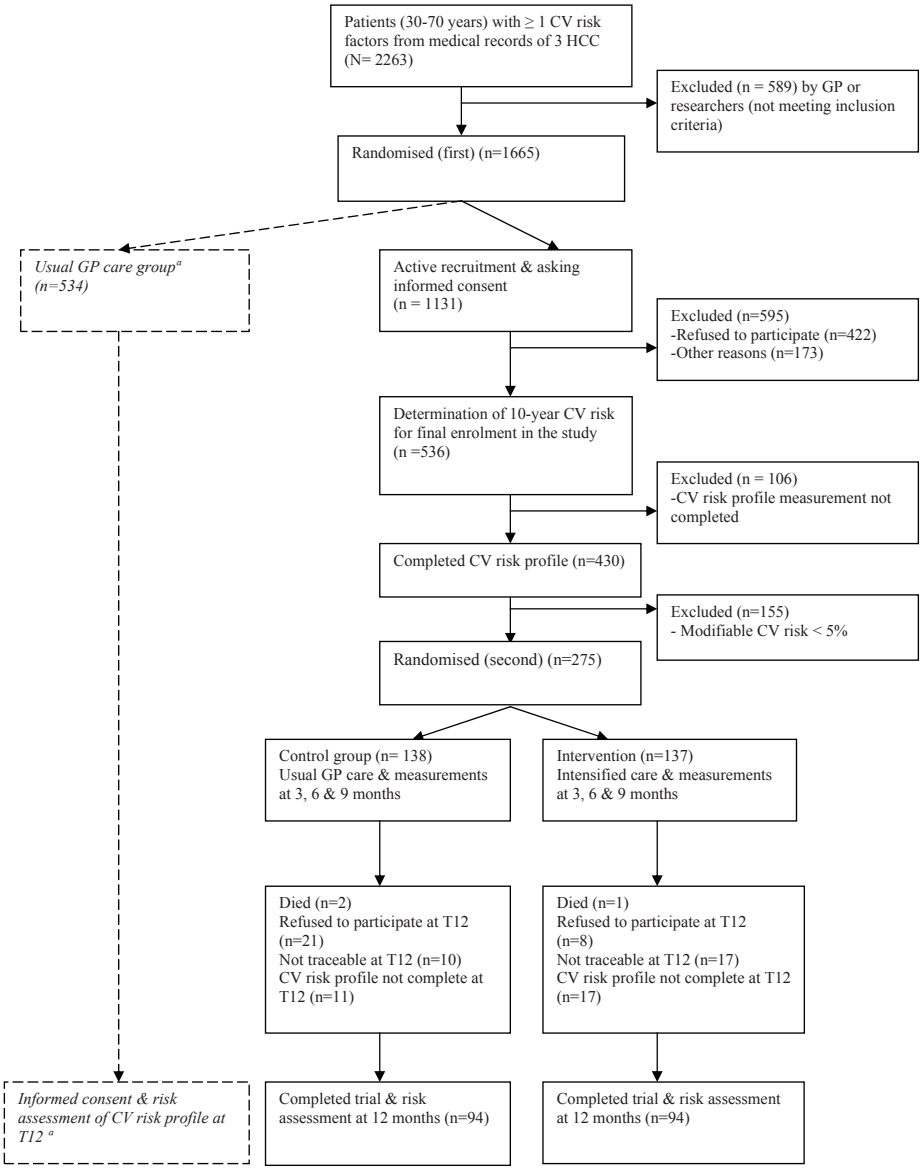
The sample size calculation was based on the assumption that a reduction in the 10-year absolute risk from 25% to 20% within a period of one year is achievable. A sample size of 51 patients was estimated to detect a difference in means of 5% in the 10-year absolute risk with alpha = 0.05 and power of 80%; this enables us to perform the whole experiment within one general practice. Conducting the experiment in different practices allows us to explore, for example, practice characteristics.
The effectiveness of the intervention was calculated as the difference after 12 months in change from baseline in absolute risk between the intervention and the control group. We hypothesized that patients receiving intensified preventive care would have a lower 10-year absolute risk at 12-months follow-up than the group receiving usual GP care.
Analyses were performed, using SPSS for windows (version 12.0), applying the mixed general linear models analysis [15]. Using this model allows subjects who are missing data on some outcomes to be included in the analysis. Analyses were carried out for all patients and sub-analyses were performed by HCC and by ethnic groups.

RESULTS

Baseline characteristics

From a total of 1,131 potentially high-risk patients that were invited to participate, 536 signed informed consent. Of this group, 430 patients completed baseline measurements. Determination of the cardiovascular risk resulted in 275 patients having a modifiable cardiovascular risk ≥ 5% that were randomly allocated to the intervention group (n=137) or the control group (n=138) (Figure 1).
Table 1 shows that there were no important differences in background characteristics between the two groups. Overall, 54% of the patients were males and 54% were from non-Dutch origin, mainly Turkish. The average age was 55.8 (SD8.5) years for the intervention and 56.1 (SD 8.6) years for the control group.
The cardiovascular risk profiles of the study groups were similar, except for smoking behaviour; there were more smokers and less ex-smokers in the intervention group than

Figure 1: Design of the trial



CV: cardiovascular

GP: general practitioner

HCC: healthcare centre

T12: 12 months follow-up

[a]: results are reported in chapter 7

Table 1: Baseline characteristics of patients (30-70 years)

	Control group (n=138)	Intervention (n=137)
Gender (n (%))		
Males	72 (52)	84 (61)
Females	66 (48)	53 (39)
Ethnicity (n (%))		
Dutch	62 (45)	65 (47)
Turkish	40 (29)	32 (23)
Other	36 (26)	40 (30)
Educational level (n=270) (n (%))		
No	24 (18)	27 (20)
Low	52 (39)	49 (36)
Lower secondary	40 (30)	32 (24)
Higher secondary	9 (7)	19 (14)
Higher	9 (7)	9 (7)
Employment (n (%))		
Employed	33 (24)	46 (34)
Housewife/man	40 (29)	36 (26)
Retired/Incapacitated for work	44 (32)	38 (27)
Unemployed	21 (15)	17 (12)
Diabetes *(n (%))	71 (51)	60 (43)
Hypertension *(n (%))	126 (91)	123 (90)
Hypercholesterolemia *(n (%))	119 (86)	113 (83)
History of CVD **(n (%))	45 (33)	49 (36)
Family history of CVD ***(n (%))	52 (38)	51 (37)
Current smokers*** (n (%))	54 (39)	72 (53)
Ex-smoker***(n (%))	42 (30)	26 (19)
Age (years)	56.1 (8.6)	55.8 (8.5)
10-year CVD risk (%)	23.9 (11.7)	25.5 (11.8)
Modifiable CVD risk (%)	12.7 (7.0)	14.0 (7.0)
HbAc1 (%)	6.4 (1.0)	6.5 (1.4)
Fasting glucose (mmol/l)	6.4 (1.9)	6.7 (2.6)
Total cholesterol (mmol/l)	5.5 (1.1)	5.6 (1.1)
HDL-cholesterol (mmol/l)	1.3 (0.4)	1.2 (0.4)
Total cholesterol:HDLcholesterol	4.6 (1.5)	4.8 (1.5)
LDL-cholesterol (mmol/l)	3.3 (1.0)	3.4 (1.1)
Triglycerides (mmol/l)	2.0 (1.2)	2.2 (1.4)
Systolic blood pressure (mm Hg)	150.9 (21.0)	150.6 (25.1)
Diastolic blood pressure (mm Hg)	89.7 (10.8)	88.5 (14.0)
BMI (kg/m^2)	30.7 (5.7)	30.2 (5.7)

Values are mean (SD) unless stated otherwise
*: according to medical records, current medication use or measurements
**: according to GP records
***: according to patients self-reports
HDL, high density lipoprotein
LDL, low density lipoprotein
CVD, cardiovascular disease
BMI, body mass index

in the control group. The 10-year absolute risk of developing CVD was 25.5% (SD 11.8) for the intervention group and 23.9% (SD11.7) for the control group.

Loss to follow-up

A total of 59 patients were lost to follow-up (died, n=3; refused to continue with the trial for various reasons, n=29; not traceable or moved away, n=27) and 28 were interviewed after 12-months follow-up but failed to complete the risk profile. There were few differences in baseline characteristics of non-responders and responders from both study arms to suggest selection bias (Table 2).

Changes in cardiovascular risk profile

Table 3 presents the mean changes in 10-year absolute risk, and risk factors from baseline to 12-months follow-up. The absolute risk reduction from baseline in the intervention group was 1.76% (SE 0.81) and in the control group 2.27% (SE 0.69). No significant decrease was seen in absolute risk in favour of the intervention group to suggest that the intervention had an effect on risk reduction compared to the control group; the difference in mean change, adjusted for baseline risk, was 0.88% (95% CI: -1.16 to 2.93).

Table 2: Baseline characteristics of subjects who responded and failed to respond to the final risk assessments by study group

	Responders (n=188)	Non-responders (n=87)	p Value*
Intervention	*(n=94)*	*(n=43)*	
Male (n(%))	52 (55)	32 (74)	0.033
Ethnicity (n (%))			0.147
Dutch	49 (52)	16 (37)	
Turkish	23 (25)	9 (21)	
Surinamese	8 (9)	5 (12)	
Other	14 (15)	13 (30)	
Age (years) (mean (SD))	56.9 (8.5)	53.4 (8.1)	0.025
Absolute risk (%)(mean (SD))	26.2 (12.5)	23.9 (10.3)	0.298
Modifiable risk (%)(mean (SD))	14.5 (7.4)	13.0 (6.1)	0.230
Control group	*(n=94)*	*(n=44)*	
Male (n (%))	52 (55)	20 (46)	0.280
Ethnicity (n (%))			0.932
Dutch	41 (44)	21 (48)	
Turkish	27 (29)	13 (30)	
Surinamese	12 (13)	5 (11)	
Other	14 (15)	5 (11)	
Age (years) (mean (SD))	57.1 (9.1)	53.9 (7.1)	0.038
Absolute risk (%)(mean (SD))	24.9 (12.2)	21.8 (10.5)	0.151
Modifiable risk (%)(mean (SD))	13.0 (7.5)	11.9 (5.8)	0.381

Values are number (%) or mean (SD)

*: χ^2 test for proportions and independent samples *t* test for mean

Table 3: Cardiovascular risk profile at baseline and after 12 months, mean change from baseline, and difference between change from baseline in the intervention and control group

	Baseline mean (SE)	12 months mean (SE)	Change from baseline mean (SE)	P Value	Difference between change from baseline in intervention and control group ¶ β (95% CI)	P Value
Absolute CVD risk (%)						
Intervention	25.5 (1.01)	23.7 (1.10)	-1.76 (0.81)	0.032	0.88 (-1.16 to 2.93)	0.393
Control group	23.9 (1.02)	21.6 (1.05)	-2.27 (0.69)	0.001		
Cardiovascular risk factors						
Systolic BP (mm Hg)						
Intervention	150.6 (2.15)	146.8 (1.78)	-3.71 (2.11)	0.081	2.36 (-2.55 to 12.48)	0.344
Control group	150.9 (1.82)	144.6 (2.02)	-6.29 (2.12)	0.004		
Diastolic BP (mm Hg)						
Intervention	88.5 (1.19)	89.3 (1.13)	0.78 (1.15)	0.499	0.21 (-2.58 to 3.01)	0.880
Control group	89.7 (0.92)	89.6 (1.08)	-0.08 (1.18)	0.949		
HbAc1 (%)						
Intervention	6.49 (0.12)	6.47 (0.11)	-0.01 (0.07)	0.835	0.03 (-0.16 to 0.23)	0.737
Control group	6.42 (0.09)	6.38 (0.09)	-0.04 (0.08)	0.450		
Fasting glucose (mmol/l)						
Intervention	6.68 (0.22)	6.42 (0.20)	-0.26 (0.13)	0.056	-0.03 (-0.39 to 0.34)	0.880
Control group	6.42 (0.17)	6.25 (0.17)	-0.18 (0.16)	0.277		

Table 3: Cardiovascular risk profile at baseline and after 12 months, mean change from baseline, and difference between change from baseline in the intervention and control group (continued)

	Baseline	12 months	Change from baseline	P Value	Difference between change from baseline in intervention and control group ¶	P Value
Total cholesterol (mmol/l)						
Intervention	5.63 (0.09)	5.27 (0.09)	-0.36 (0.09)	< 0.0001	0.03 (-0.82 to 0.22)	0.823
Control group	5.55 (0.09)	5.20 (0.10)	-0.35 (0.09)	< 0.0001		
HDL-cholesterol (mmol/l)						
Intervention	1.25 (0.03)	1.30 (0.04)	0.05 (0.02)	0.019	0.02 (-0.53 to 0.63)	0.530
Control group	1.31 (0.04)	1.34 (0.04)	0.03 (0.02)	0.172		
Total cholesterol: HDL-cholesterol						
Intervention	4.84 (0.13)	4.45 (0.14)	-0.39 (0.11)	0.001	0.05 (-0.22 to 0.32)	0.733
Control group	4.58 (0.12)	4.20 (0.12)	-0.38 (0.09)	< 0.0001		
LDL-cholesterol (mmol/l)						
Intervention	3.42 (0.09)	3.08 (0.09)	-0.33 (0.09)	< 0.0001	-0.001 (-0.22 to 0.22)	0.991
Control group	3.35 (0.09)	3.08 (0.10)	-0.27 (0.08)	0.002		
Triglycerides (mmol/l)						
Intervention	2.15 (0.12)	2.01 (0.14)	-0.14 (0.13)	0.268	0.05 (-0.23 to 0.33)	0.720
Control group	1.97 (0.10)	1.80 (0.09)	-0.17 (0.09)	0.059		
BMI (kg/m2)						
Intervention	30.2 (0.51)	29.6 (0.49)	-0.66 (0.20)	0.002	-0.22 (-0.85 to 0.41)	0.493
Control group	30.7 (0.50)	30.3 (0.50)	-0.43 (0.25)	0.085		

Values are mean (SE) or β (95% CI)

¶ adjusted for baseline measurements

CVD, cardiovascular disease; BP, blood pressure; HDL, high density lipoprotein; LDL, low density lipoprotein; BMI, body mass index

Within both study groups, significant favourable changes were achieved at 12 months in the following individual risk factors: total cholesterol, total cholesterol to HDL cholesterol ratio and LDL cholesterol. The BMI and HDL cholesterol changed favourably in the intervention group but not in the control group. However, there were no significant differences in changes between the intervention and control group.

Table 4 shows that the absolute risk dropped significantly within the intervention and control group in the second and third HCC during the study period, whereas in the first HCC no reduction in absolute risk was observed. The mean decrease in the second HCC was higher in the intervention than in the control group and was, respectively, 5.23% (SE 1.34) and 3.60% (SE 0.93); however, the difference between the study groups was not significant [-0.81 (95% CI: -3.50 to 1.89)].

With regard to ethnicity, among the Dutch a small non-significant improvement in absolute risk was achieved at the end of follow-up, but among the Turkish group there was no reduction at all in absolute risk (Table 4).

DISCUSSION

In this RCT, both the intervention and control group had significant reductions in cardiovascular risk, but there was no significant between-group treatment effect. This indicates that in this study there is no effect of structured preventive care provided by the PN and PHE on the risk for CVD in high-risk patients. Within both study groups, relevant reductions were observed in the following cardiovascular risk factors: total cholesterol, total cholesterol to HDL cholesterol ratio and LDL cholesterol; and in the intervention group the BMI and HDL cholesterol were also improved. However, no significant differences between the study groups were achieved.

Our findings are in line with several previous studies that aimed to reduce cardiovascular risk and risk factors in high-risk individuals [16-19]. Nevertheless, both the British Heart Study (BHS) [8] and the CELL study [20] showed improvements in cardiovascular risk with the use of a nurse counsellor, and the OXCHECK study [9] showed a significant reduction in cardiovascular risk factors between patients in the intervention group and the control group. Compared to the BHS and OXCHECK study (in which the control group received no measurements or only a baseline risk assessment), our control group received 3-monthly risk assessments that could be considered as a mini-intervention. Moreover, in the latter studies the health counsellor or nurse had the responsibility to provide the intervention whereas in our study the intervention was based on the structured collaboration of the general practice team in which the PN had the coordinating role. This requires additional skills of the PN, as well as the motivation and cooperation of other team members in the general practice. Furthermore, our study population included individuals with a low SES

Table 4: The 10-year absolute risk in the intervention and control group at baseline and at 12-months follow-up by healthcare centre and ethnicity

	Intervention				Control group					
	Baseline	12 months	Change from baseline	P Value	Baseline	12 months	Change from baseline	P Value	Difference between change from baseline in intervention and control group ¶	P Value
	mean (SE)	mean (SE)	mean (SE)		mean (SE)	mean (SE)	mean (SE)		β (95% CI)	
Total	25.5 (1.01)	23.7 (1.10)	-1.76 (0.81)	0.032	23.9 (1.02)	21.6 (1.05)	-2.27 (0.69)	0.001	0.88 (-1.16 to 2.93)	0.393
By healthcare centre										
Centre 1	24.3 (1.36)	26.7 (1.69)	2.37 (1.34)	0.083	23.9 (1.40)	24.0 (1.57)	0.10 (1.04)	0.927	2.14 (-1.17 to 5.46)	0.202
Centre 2	27.3 (1.95)	22.0 (1.83)	-5.23 (1.34)	< 0.0001	24.3 (1.90)	20.7 (1.58)	-3.60 (0.93)	< 0.0001	-0.81 (-3.50 to 1.89)	0.551
Centre 3	25.2 (2.20)	21.1 (2.27)	-4.05 (1.09)	0.001	23.3 (2.21)	18.3 (2.40)	-5.19 (1.29)	< 0.0001	1.99 (-1.71 to 5.69)	0.282
By ethnicity										
Dutch	28.9 (1.62)	26.6 (1.66)	-2.34 (1.05)	0.030	26.7 (1.45)	25.2 (1.45)	-1.51 (1.07)	0.164	-0.12 (-2.95 to 2.71)	0.934
Turkish	22.3 (1.88)	22.2 (1.85)	-0.04 (1.78)	0.981	21.2 (1.97)	22.1 (2.09)	0.86 (1.03)	0.411	0.31 (-3.75 to 4.36)	0.879
Other	22.5 (1.51)	19.7 (2.09)	-2.75 (1.53)	0.079	22.2 (1.78)	17.3 (1.86)	-4.91 (1.28)	0.001	1.76 (-2.42 to 5.95)	0.402

Values are mean (SE) or β (95% CI)
¶ adjusted for baseline measurements

and with different ethnic origins, which are generally hard-to-reach for participation in intervention activities.

A major explanation for the lack of an intervention effect in the present study may be the inadequate delivery of the intervention. According to process evaluation data, key components of the intervention program, such as the team meetings and the educational sessions, were often not performed as planned in some general practices (El Fakiri, submitted, 2007). We hypothesize that the intervention group and control group were (more or less) similar and, consequently, no effect could be detected in the intervention group.

Second, it is likely that the additional effect of the intervention (mainly based on health education) was negligible compared to an effect of structured measurements also provided to the control group. Uptake of the health education by the patients may have been limited by their lower educational level or other barriers such as insufficient knowledge about CVD [21,22]. At baseline, the high proportion of smokers among the intervention group compared to the control group may also be an explanation. It is known that smoking cessation by means of health education is difficult to achieve, particularly in populations with a low SES [23] whereas, for example, lowering high blood pressure and cholesterol levels are primarily targeted effectively by pharmacological intervention.

Regression to the mean may have contributed to the changes in the control and intervention group, since all patients initially had high levels of risk. This could be most manifest in systolic blood pressure that constitutes an independent variable in the risk formula. Another source of bias is the Hawthorne effect, because patients were told whether they would belong to the control group and, therefore, could have changed their behaviour. However, we found no indication for this, since analysis of patient visits to the GP did not reveal more GP consultations in the control group than in the intervention group.

A methodological limitation of the present study may be that, because the intervention was directed to general practices, some transfer of effect from the intervention to control group could take place, resulting in dilution of the effectiveness of the intervention. The GP assistants could not be blinded because of their logistical tasks, and in two out of three HCCs the involved PNs were also (part-time) GP assistants, implying that they had contacts with patients from the control group. Nevertheless, patients participating in the trial constituted a very small proportion of the general practice population so that the GP assistants were seldom confronted with these patients and, if so, were instructed before the study to perform all measurements in the routine way. Similarly, it is unlikely that patients from the control group were discussed during team meetings or were invited for individual educational sessions because of the high experienced workload in these general practices. Therefore, we believe that contamination between the intervention and control group was minimal.

The 34% dropout from the study was uniformly distributed between the intervention and control group, and no relevant differences were found between responders and non-responders in terms of baseline cardiovascular risk. Therefore, the possibility of bias due to dropout is very limited.

Although subgroup analyses gave some indications of small non-significant differences in absolute risk reductions among Dutch individuals and in one out of three HCCs, the results should be interpreted with caution because of limited statistical power. Future research should focus on these differences, particularly the differences in outcomes between the ethnic groups require special attention.

A major strength of this study is the inclusion of a heterogeneous high-risk patient population, since the participation of ethnic minorities and socio-economically disadvantaged persons in prevention trials designed to decrease cardiovascular risk is associated with particular barriers [11].

The present study shows no benefits of adding a PN and a PHE in the general practice on cardiovascular risk among high-risk patients living in deprived neighbourhoods. It is possible that the intervention program was not implemented as planned and therefore no conclusions should be drawn with regard to the effectiveness of such an intervention.

The finding that in both study groups a relevant reduction in absolute risk and some cardiovascular risk factors was found, suggests that structured measurements of the cardiovascular risk profile alone were beneficial. Therefore, in daily practice more attention should be paid to the implementation of structured measurements of risk profile focusing on active recruitment and follow-up of individuals at high risk of developing CVD. Furthermore, barriers to the implementation of preventive activities among ethnic minority groups should be taken into consideration.

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Chapter 6

Process evaluation of an intensified preventive intervention to reduce cardiovascular risk in a multiethnic patient population

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ABSTRACT

Objective:

A RCT conducted to examine the effectiveness of a structured collaboration in general practice between a practice nurse, a peer health educator, the general practitioner (GP) and GP assistant (Quattro-care) to provide intensified preventive care in patients with high risk of developing cardiovascular diseases yielded no effect in the total group, but differences across healthcare centres and ethnic groups became apparent. We conducted a process evaluation to explain these differences.

Methods:

We assessed the reach of the target group and whether the intervention was carried out as planned. Key intervention components (summarised by a score for protocol completion) included individual educational sessions with patients, structured team meetings of the Quattro care team and risk assessments (maximum score is 11).

Results:

The reach of the target group was in the first instance 91% but only a minority of patients completed intervention activities as planned. The average score of the number of intervention components was low [5.66 out of 11 (SD 2.8)] and varied between centres [4.84 (SD 2.7) to 7.40 (SD 2.8)] and ethnic groups [4.89 (SD 2.6) to 7.38 (SD 2.2)]. Team meetings were the least implemented activity according to plan.

Conclusion:

These process data indicate that intervention activities were difficult to organise in daily practice, but varied by healthcare centre and ethnic group. Adding a practice nurse and a peer health educator to the general practice did not lead to more collaboration between healthcare personnel, but rather seemed to result in unclear role divisions.

INTRODUCTION

Preventive activities aimed at reducing cardiovascular diseases (CVD) in general practice may be impeded by different factors at the organisation level, such as lack of supporting staff, low guideline compliance and bad team climate [1-3], as well as at the patient level by, for example, low educational attainment [4,5].
In the Netherlands different supporting staff have been introduced in general practices, such as practice nurses to improve quality of care and reduce workload [6], and peer health educators to bridge language and/or cultural differences in those general practices with multi-ethnic patient populations [7].
As far as we know, no information is available about structured collaboration of these supporting staff with general practitioners on preventive activities [6]. We earlier conducted an innovative intervention to reduce cardiovascular risk in three large primary healthcare centres located in deprived neighbourhoods of Rotterdam and the Hague involving a multi-ethnic patient population at high risk of developing CVD [8]. That randomised controlled trial (Quattro study) showed no effect of intensified preventive care provided by a structured collaboration of the practice nurse, peer health educator, general practitioner (GP) and GP assistant on the reduction of absolute risk on top of usual GP care. Nevertheless, we found some indications for differences in the rates of risk reduction achieved after one-year follow-up between the participating healthcare centres and between ethnic groups [8].
To explain the lack of effect of the intervention and to provide more insight in the differences between centres and ethnic groups, we conducted a process evaluation. A process evaluation is considered essential to make program effectiveness results more interpretable and to avoid type III errors, i.e. evaluating an intervention program that has not been adequately implemented and thus drawing incorrect conclusions about the effectiveness of a given intervention [9-11].
The following questions are addressed: 1) Was the target group reached by the intervention activities? 2) Was the intervention carried out as planned? 3) How did the participants experience the intervention?

METHODS

Participants

The "Quattro study" was carried out in three primary healthcare centres representing five general practices (18 general practitioners) located in the deprived neighbourhoods of Rotterdam and the Hague [12]. Inclusion criteria were: a fully computerised information

system, capacity to appoint a peer health educator and to be able to fulfil national criteria to get a practice nurse financed: a collaboration of at least three general practices with a total patient population of over 7050 patients [6].

The study population consisted of patients from different ethnic origins at high risk of developing CVD, aged 30-70 years, and living in a deprived neighbourhood. A total of 275 high-risk individuals defined as having a modifiable part of the 10 year absolute risk ≥ 5% [13] were randomly assigned to the intervention and control group. We performed selection, enrolment and randomization of patients. Details of the study design, inclusion and randomization of patients are reported elsewhere [8]. For this process evaluation we use data of the patients assigned to the intervention group (n=137).

Intervention

The intervention as planned consisted of adding a practice nurse and a peer health educator to the general practices to implement prevention activities in collaboration with the general practitioner and GP assistant. The complexity of the intervention and the diversity of patients as well as the medical problems made it necessary to form a (Quattro) team in each general practice, to be able to tailor the treatment aims to the individual patient and to divide the tasks among the Quattro team workers.

In order to reset treatment goals as required each patient is evaluated every 3 months during a team meeting. The team consisted of the general practitioner, practice nurse, GP assistant and the peer health educator, in which the practice nurse had the coordinating role. All team members (including the general practitioner and GP assistants) were invited to join a one-day course before the start of the intervention. The course gave information on how to deal with the intervention protocol, and the team members were trained in performing the structured team meetings.

The intervention protocol was based on the current Dutch College of General Practice Guidelines for hypertension, hypercholesterolemia, diabetes and smoking, and described the procedures for the general practitioner (first responsible and treatment decisions), practice nurse (risk assessment, health education, coordination and informative task), GP assistant (logistical task including measurements, patient recall and follow-up) and peer health educator (ethnic-specific health education).

Structural intervention components were individual face-to-face sessions (including an intake session) with patients performed at the general practice, team meetings (including an intake team meeting) by the Quattro team, and risk assessments every three months (consisting of physical measurements conducted at the general practice and clinical measurements at the laboratory) (see box 1). An average of three risk assessments followed by team meetings and individual educational sessions were considered sufficient during the 9-month follow-up period [14]. The team meetings also took place

in the general practice; in order to efficiently organize these meetings, different patients were discussed during one session.

In addition to the structural components of the intervention, the intervention protocol allowed adaptations in order to tailor the intervention to the individual practice needs and organisation, such as whether the GP assistant or the practice nurse should perform the logistical tasks concerning intervention patients; and whether the practice nurse, peer health educator (or both) should perform the intake and educational sessions with ethnic minority patients. Further, the intervention team could be expanded to allow other disciplines (e.g. a dietician or diabetes nurse) to participate in the structured team meetings. We assumed that this tailoring for an individual practice would allow more success when anticipating the diversity between the general practices.

After randomisation of included patients by the research team, the patients' names were mailed to the practice nurses. Similarly, for each patient a document containing relevant characteristics, cardiovascular risk and risk factors based on baseline measurements was sent to the practice nurse and served as a registration tool for the intervention activities. Subsequently, the practice nurse invited the patients to the general practice to start intervention activities.

Box 1: The intervention as planned consisted of the following components:

- Active enrolment of patients: The practice nurse or peer health educator phoned or mailed the patients to visit the general practice in order to start follow-up as soon as they received the names of the patients allocated to intervention.
- An intake session carried out by the practice nurse and/or health educator to evaluate patient health problems and specifically the cardiovascular risk profile, the likelihood to comply with health education and treatment.
- Organisation of a structured intake team meeting attended by all team members to discuss prevention strategies according to information collected during the intake session and to agree about which team members would be involved in implementing the preventive tasks. This meeting resulted in a "treatment plan" tailored to the patient risk factors and was re-evaluated every three months.
- Three risk assessments at 3, 6 and 9 months follow-up consisting of blood pressure and body weight measurements, and measurements of lipids, glucose and HbAc1.
- Three follow-up structured team meetings of the Quattro members led by the practice nurse, to discuss and evaluate the achieved results and bottlenecks encountered with regard to patient education, treatment and compliance.
- Three individual follow-up educational sessions, based on the "treatment plan" and conducted by the practice nurse and/or health educator followed each of the structured team meetings. The results of the risk assessments were discussed with the patient and feedback was given.

In two out of three healthcare centres, almost all practice nurses involved in the intervention were former GP assistants from the same general practices. In the third centre, a practice nurse (with extensive experience as a nurse) was provided by the research team. The health educators (1 to 2 per healthcare centre) were trained medical educators fluent in Turkish or Moroccan and the Dutch language, and were regarded as being representative for the majority of the target population (i.e. ethnic minorities). These migrant health educators received relevant information about cardiovascular risk and risk factors during a two-day course before the start of the intervention.

During the intervention, 4 meetings were organised by the intervention supervisor (PU) for the practice nurses and the peer health educators to discuss the implementation of the intervention.
All staff members of participating general practices received twice a year a newsletter about the progress of the study and the intervention.

Measurements

We assessed the following process evaluation components: reach, program fidelity and experiences of the different participants.

Reach of the target group

The reach is the degree to which the intervention contacted or was received by the targeted group participating in the intervention program [9].
To determine which patients were reached, we computed the proportion of participants who received an intake session and, of these, the proportion of participants discussed during the intake team meeting. We calculated the means (and standard deviations (SD)) of follow-up intake sessions, follow-up team meetings and risk assessments received. To determine any differences between patient subgroups, we subdivided various proportions and means into gender, ethnicity, age, educational level and baseline modifiable risk in relation to reach.
We also registered the dropout from the intervention program defined as the number (proportion) of patients initially allocated to the intervention but who did not complete the program (i.e. did not attend the final individual session at 9 months follow-up).

Program fidelity

We assessed the fidelity defined as the extent to which the intervention program was delivered according to key components of the intervention [9] by using the following indicators (see box 1).
1. Enrolment period of patients to the healthcare centres: this was defined as the mean time (in weeks) between patient's allocation to the intervention group by the researchers

until the date when the intake session took place. An average enrolment period of four weeks was considered as appropriate.
2. Numbers and proportions of different activities from the intervention protocol carried out: individual intake session, intake team meeting, follow-up individual sessions, follow-up team meetings, and the three-monthly risk assessments.
3. Involvement of the Quattro team members with the intervention activities. Participation of the peer health educator in the structured meetings was not "imposed" by the intervention protocol because they were part-timers and employed by different general practices. However, to bridge cultural and language differences when carrying out the individual sessions with Turkish and Moroccan participants, involvement of a peer health educator was inevitable, since a large majority of these patients were first-generation immigrants whose proficiency of the Dutch language was very limited.
To assess whether intervention was carried out according to plan we created an index of protocol completion to summarize whether participants completed the intervention activities (intake session, intake team meeting, 3 individual follow-up sessions, 3 team meetings and 3 risk assessments) as planned. For each activity, we scored a "1" if completed and a "0" if not completed. The scores for each participant were summed to determine the index of protocol completion ranging from 0 to 11. A score equal to 11 means that a patient participated in all activities and a lower score means that one or more activities were missed.
To determine the number of individual sessions and team meetings as well as team members who participated in these activities, we used data registered continuously in the patient documents by the practice nurse and/or peer health educator. The organisation of the 3-monthly risk assessments and data collection of the results were carried out by the researchers throughout the study.

Experiences of participants

Experiences of participating general practitioners, practice nurses and health educators with the intervention program were assessed after the intervention by conducting semi-structured questionnaires. Twelve out of 18 general practitioners, all participating practice nurses in the study (n=7), and 3 out of 5 health educators were interviewed. Among the non-interviewed general practitioners (n=6), 5 were represented by their colleague(s) from the same general practice, and one had stopped as a general practitioner. Two peer health educators could not be reached for interviews after repeated efforts.
The questionnaire included questions about participation in the key components of the intervention, overall judgment (whether the intervention was considered as useful or not), satisfaction with the intervention program, perceived additional workload and ideas about continuation of the use of the intervention activities in the general practice. Judgement and satisfaction were assessed by asking participants to give their opinion

using a 10-point score. Subsequently, we grouped the scores as follows: 1-4; 5-6; and 7-10 indicating, respectively, not useful/not satisfied; somewhat useful/somewhat satisfied; useful/satisfied. The scores for the experienced workload were recorded as follows: 1-4 (high workload); 5-6 (moderate workload) and 7-10 (low workload). For other topics, participants were asked to give a score on a 5-point Likert scale, or by answering "yes or no".

Experiences of patients were obtained by conducting structured interviews at the end of the 12 months follow-up of the trial [8]. In total, 111 of the 137 patients were interviewed by the research assistants. Patients were asked to give scores (on a 5-point Likert scale) regarding their satisfaction with the educational sessions, preference to continue the educational sessions and by whom these should be carried out, and perceived improvements due to intervention (i.e. a better lifestyle or health condition). The scores 4 and 5 were grouped to indicate a (very) positive opinion about the above-mentioned topics (i.e. (very) satisfied, (very) important, (very) useful, etc).

Data analysis

We computed descriptive statistics to assess the reach of the intervention, the program fidelity and the experiences of participants. To determine whether reach differs according to gender, ethnicity, age, educational level or modifiable risk, Chi-square tests were performed for nominal and categorical variables and analyses of variance for continuous variables. Differences in protocol completion between centres and ethnic groups were assessed using analyses of variance. Data for Turkish and Moroccan patients were grouped together because both obtained educational sessions from a peer health educator.

RESULTS

The majority of patient that entered the study was male (61%); 47% were Dutch, 23% Turkish; 10% Surinamese; 7% Moroccan and the remaining 13% from different ethnic backgrounds. The mean age was 55.8 (SD 11.6) years. A majority of individuals had no or low educational level (59%) and 34% was employed. Only 20% of the Turkish and Moroccan participants reported to speak and understand the Dutch language well.

Reach of the target group

Twelve patients attended no intake sessions (not reached after repeated efforts; refused follow-up due to their dissatisfaction with the organization of risk assessments and GP care) and hence did not start the program. Of 125 patients who started the program, 63 participants did not attend the final (third) individual session. The corresponding drop-

out rate is 55%. Finally, only 16 participants completed the intervention as planned: i.e. attended the intake session, all three individual sessions, and three risk assessments.
Table 1 shows some general trends in participation in the different intervention components of patient groups. Men participated less in all intervention components than women. Surinamese had the most favourable scores for most intervention components. Patients younger than 45 years less often participated in the individual intake sessions. Patients with the highest level of modifiable risk (≥ 15%) participated more often and were more frequently discussed during the intake team meeting than patients with a lower modifiable risk.

Table 1: Reach of the intervention program in relation to patient's characteristics (n=137)

	Individual Intake session (%)	intake team meeting[a] (%)	individual follow-up session[a] mean (SD) (Expected n= 3)	follow-up team meetings[a] mean (SD) (Expected n= 3)	risk assessments[a] mean (SD) (Expected n= 3)
Gender	*P=0.473*	*p=0.097*	*p=0.001*	*p=0.123*	*p=0.131*
Male	91	61	1.63 (1.2)	0.74 (1.0)	1.61 (1.0)
Female	93	74	2.32 (1.1)	1.04 (1.1)	1.88 (0.9)
Ethnicity	*p=0.002*	*p=0.047*	*p=0.073*	*p=0.001*	*p=0.387*
Dutch	99	69	2.06 (1.1)	0.63 (0.8)	1.86 (1.0)
Turks/Moroccan	78	66	1.43 (1.3)	1.03 (1.3)	1.60 (1.1)
Surinamese	100	85	2.15 (1.0)	1.85 (1.1)	1.54 (0.7)
Other	89	38	2.00 (1.2)	0.63 (0.9)	1.50 (0.8)
Age	*p=0.015*	*p=0.041*	*p=0.684*	*p=0.130*	*p=0.345*
≤ 44 years	77	40	1.80 (1.3)	1.10 (1.4)	1.40 (1.1)
45-59 years	89	61	1.98 (1.2)	0.99 (1.1)	1.81 (0.9)
≥ 60 years	100	78	1.80 (1.2)	0.60 (0.9)	1.62 (1.1)
Educational level	*p=0.159*	*p=0.645*	*p=0.113*	*p=0.272*	*p=0.073*
No	82	77	2.00 (1.2)	0.82 (1.1)	1.41 (1.1)
Low	96	62	1.68 (1.3)	0.70 (1.1)	1.74 (1.0)
Lower secondary	94	67	2.27 (0.9)	1.20 (1.1)	2.03 (1.0)
Higher	96	68	1.58 (1.2)	0.84 (1.1)	1.42 (0.8)
Modifiable absolute risk	*p=0.072*	*p=0.008*	*p=0.613*	*p=0.989*	*p=0.938*
5-9%	85	66	1.76 (1.2)	0.85 (1.1)	1.71 (1.0)
10-14%	89	46	2.00 (0.2)	0.88 (1.2)	1.67 (1.1)
≥ 15%	98	78	2.00 (1.1)	0.86 (0.1)	1.75 (0.9)

[a]: Patients who did not attend the individual intake session (n=12) were excluded from these analyses
values are mean (SD) or %

Fidelity to intervention program

Table 2 shows to what extent major features of the intervention were carried out in the healthcare centres.
The enrolment period of patients between randomization and first visit to the healthcare centre was on average 12.8 (SD 11.3) weeks, with the longest period achieved in the first centre (18.2 (SD 10.6) weeks). Analyses according to ethnicity did not show any important differences in enrolment periods between ethnic groups (data not in table).
Two third of the patients with an intake (66%) were discussed during the first structured team meeting, 46% completed 3 individual follow-up sessions, and 26% completed all 3 monthly risk assessments. Only 11% were discussed during all three follow-up team meetings, indicating that organising the team meetings was the most difficult activity to implement in the healthcare centres.

About half of the intake sessions (54%) were conducted by the practice nurse and 14% by both the practice nurse and health educator, but the proportions differed by healthcare centre: In one centre the practice nurse and the health educator carried out more than half of the intakes (53%) while this proportion was equal to or less than 5% in the other two centres. A large proportion of the intake sessions with Turkish and Moroccan individuals was conducted by the health educator alone and incidentally in the presence of the practice nurse (data not in table). Almost all intake team meetings (93%) that took place were performed by the general practitioner and practice nurse with no remarkable differences between the centres. Although the peer health educator was involved in 38% of the intake team meetings, the extent of participation differed largely per centre (14% to 82%). The GP assistant did not attend any structured team meeting.
Table 3 shows that the average scores of the number of intervention components were in general low (5.66 out of 11(SD 2.8)) but most favourable in the third healthcare centre (7.40 out of 11 (SD 2.8)). With regard to ethnicity, Turkish and Moroccan participants had the lowest (4.68 out of 11 (SD 3.4)) and Surinamese the highest score of protocol completion (7.38 out of 11 (SD 2.2)). In the first centre, Turkish and Moroccan individuals completed only 2.4 of 11 intervention components (SD 1.7).

Experiences of participants

Healthcare centre personnel

Based on the interviews with the Quattro team members, we conclude that the intervention program was implemented in different ways in the healthcare centres. While in all centres the individual sessions were generally implemented according to the intervention protocol, the team meetings were not. In one centre, structured team meetings were performed and attended by the general practitioner, practice nurse and

Table 2: Fidelity to major components of the intervention program by healthcare centre

	Total (n=137)	Centre 1 (n=62)	Centre 2 (n=45)	Centre 3 (n=30)
Males (n(%))	84 (61)	43 (70)	24 (53)	17 (56)
Non-Dutch (n(%))	72 (53)	29 (47)	18 (40)	25 (83)
Enrolment period to the healthcare centre (in weeks) (mean (SD))	12.8 (11.3)	18.2 (10.6)	10.6 (12.7)	6.4 (2.8)
Missing	(n=43)	(n=23)	(n=11)	(n=9)
Individual intake session with patient (n(%))	125 (91)	55 (89)	42 (93)	28 (93)
Conducted by:				
Practice nurse	68 (54)	27 (49)	30 (71)	11 (39)
Peer health educator	16 (13)	10 (18)	5 (12)	1 (4)
Practice nurse & peer health educator	17 (14)	0 (0)	2 (5)	15 (53)
Unknown/not registered	24 (19)	18 (33)	5 (12)	1 (4)
Intake team meeting[a] (n(%))	82 (66)	22 (40)	32 (76)	28 (100)
Attended by				
General practitioner	76 (93)	19 (86)	29 (91)	28 (100)
Practice nurse	76 (93)	20 (91)	29 (91)	27 (96)
Peer health educator	31 (38)	3 (14)	6 (19)	23 (82)
Follow-up individuals sessions (mean (SD))[a]	1.90 (1.2)	1.82 (1.2)	1.88 (1.2)	2.11 (1.0)
0	23 (18)	13 (24)	8 (19)	2 (7)
1	23 (18)	9 (16)	8 (19)	6 (21)
2	22 (18)	8 (15)	7 (17)	7 (25)
3	57 (46)	25 (46)	19 (45)	13 (46)
Follow-up team meetings (mean (SD))[a]	0.86 (1.1)	0.58 (0.8)	0.43 (0.8)	2.0 (1.1)
0	68 (54)	34 (62)	30 (71)	4 (14)
1	21 (17)	11 (20)	7 (17)	3 (11)
2	22 (17)	9 (16)	4 (10)	9 (32)
3	14 (11)	1 (2)	1 (2)	12 (43)
3 months risk assessments (mean (SD))[a]	1.71 (1.0)	1.55 (1.0)	1.88 (1.0)	1.79 (1.0)
0	15 (12)	8 (15)	4 (10)	3 (11)
1	38 (30)	19 (35)	12 (29)	7 (25)
2	40 (32)	18 (33)	11 (26)	11 (39)
3	32 (26)	10 (18)	15 (36)	7 (25)

[a]: Based on patients who attended the individual intake session (n=125)
Values are number (%) or mean (SD)

health educator, and, mostly by a dietician or diabetes nurse. In the other two centres, team meetings between the general practitioner and practice nurse, and rarely the health educator, were incidentally carried out. In one general practice, the GP's information system was frequently used by the practice nurse to communicate with and to ask the GP's advice, instead of a face-to-face team meeting. In all centres, the GP assistants were not involved at all in these (structured) team meetings.

Table 3: Index for protocol completion of key intervention components (maximum score is 11) by healthcare centre and ethnic group

	Total (n=137)	Centre 1 (n=62)	Centre 2 (n=45)	Centre 3 (n=30)
Dutch (n=65)	6.14 (2.3)	5.88 (2.4)	6.19 (2.2)	7.60 (1.7)
Turkish/Moroccan (n=41)	4.68 (3.4)	2.40 (1.7)	4.20 (2.9)	7.13 (3.5)
Surinamese (n=13)	7.38 (2.2)	8.50 (0.7)	4.67 (2.9)	8.13 (1.6)
Others (n=18)	4.89 (2.6)	4.42 (2.4)	6.00 (3.5)	5.00 (--)[a]
Total	5.66 (2.8)	4.84 (2.7)	5.62 (2.6)	7.40 (2.8)

[a]: calculation of standard deviation (SD) not possible (n=1)
Values are mean (SD)

In general the overall judgment and satisfaction of the Quattro team members about the intervention program was moderate to good (Table 4). Five of the 12 interviewed GPs considered the intervention to be useful. The mean score for overall judgment was 6.3 (SD 2.2). Seven of 12 GPs were satisfied and the overall satisfaction score was 6.5 (SD 2.0). Only one GP considered the intervention not to be useful and was not satisfied.

Almost all interviewed practice nurses and health educators (n=9) considered the intervention program to be useful (mean score was 7.1). Four practice nurses were somewhat satisfied and 5 were satisfied.

The majority of the Quattro team members (16 of 22) experienced the structured collaboration within the general practice as a good supplement to their activities, and would like continuation of one or more components of the intervention program.

Patients

A large majority of patients (85%) was satisfied with the educational sessions provided by the practice nurse and/or health educator, 72% would advise other people to participate in the educational sessions; and about half of the patients (55%) would attend these sessions again. Also, 57% reported they found the advice concerning lifestyle to be useful, and 40% reported that the educational sessions helped them to achieve a healthier lifestyle. However, for most patients (68%) it did not matter who performed the educational sessions (the GP or practice nurse/health educator) and 13% preferred the practice nurse/health educator. About 80% of the individuals considered the educational sessions to be a good supplement to the general practice activities. About one quarter of the interviewed patients (24%) reported that their health had improved because of the educational sessions.

Table 4: Experiences of general practice personnel with the intervention program (Values are number)

	General practitioner (n=12)	Practice nurse/ Peer health educator (n=10)
Overall judgement of the intervention activities		
Useful	5	9
Somewhat useful	5	1
Not useful	1	0
Missing	1	0
Overall satisfaction with intervention activities		
Satisfied	7	5
Somewhat satisfied	3	4
Not satisfied	1	0
Missing	1	1
Perceived additional workload of intervention activities		
High	2	6
Moderate	3	2
Low	5	1
Missing	2	1
Structured collaboration leads to improvement of quality of care		
Yes	8	8
Doubtful	3	2
No	1	--
Intervention activities are a good supplement to your activities		
Yes	9	8
Doubtful	2	1
No	1	1
Continuation of using intervention activities within general practice		
Yes	9	10
No	3	--

DISCUSSION AND CONCLUSION

Discussion

The present study shows that the target group was reached in the first instance (91% had an intake session) but only a minority completed the intervention program. Almost none of the patients completed all key components of the intervention protocol as planned. Despite the low program fidelity, participating healthcare professionals and patients considered the intervention program to be useful and were in general satisfied.

Although our study initially succeeded in getting a hard-to-reach group (i.e. ethnic minorities and individuals with a low SES) to participate in the intervention program, during the follow-up period the reach of different subgroups of patients was not uniform. We have no robust explanation for this low participation rate. Based on previous research this limited participation might be attributed to both organisational aspects

of the intervention as well as to patient characteristics. Nevertheless, the role of patient characteristics should be emphasised in this since the limited reach was in line with previous intervention studies performed in low-income populations and some ethnic groups. In a study by Havas et al. [15] among low-income women, participants faced many obstacles in the aim to attend educational sessions such as work, transportation, and stresses of inner-city life; and in a study by Uitewaal et al. [7] going abroad for a longer period was the main reason for non-attendance in an intervention program tailored to Turkish individuals. In our study, the characteristics of patients that affect their participation in intervention activities (i.e. male gender and younger age) are consistent with another study on a cancer prevention program involving a multi-ethnic patient population which also showed lower participation rates in younger age, men, non-whites and patients with a lower acculturation and a low income status [16].
The low participation observed in the present study is particularly worrying, because the prevalence of modifiable cardiovascular risk factors among young people living in deprived neighbourhoods is high and should be targeted by intervention strategies. Further research is needed to investigate the reasons behind this low participation rate and whether tailoring interventions specifically to this dropout group is beneficial.

Our findings showed that the fidelity to key components of the intervention was low, particularly the structured team meetings. These results are in line with other studies reporting on the complexity of putting intervention programs into practice [17]. According to Grol and Grimshaw (2003), change is rarely easy if an innovation requires complex changes in clinical practice or requires better collaboration between disciplines or changes in the organization of care. The low implementation rate of structured team meetings is not surprising because this key intervention component was by far the most complex one, requiring collaboration of different healthcare professionals, clear task division and well-defined roles [18]. In our study, practice nurses reported that they encountered many bottlenecks in the organization of these meetings, and GPs considered these meetings to be time-consuming activities. Similarly, the role of the health educator was marginal and the participation of GP assistants was (almost) completely absent, which may be indications for the lack of clear responsibilities within the intervention teams. The latter could be due to the overlap of the practice nurse's tasks and the GP assistant's tasks since most practice nurses involved in this study were former GP assistants working within the same general practices. Consequently, the GP assistants' role may have been too small and easy to brush aside, whereas the practice nurses' workload probably increased due to their attempts to take over the logistical tasks of the GP assistants. This could explain why, logistically, the intervention was not carried out in a satisfactory way given, for example, the long enrolment period of the patients. Our findings suggest that adding a practice nurse to the general practice does

not succeed in creating more collaboration, but rather seems to result in unclear division of the various roles.

The variation in program fidelity between the healthcare centres requires some thought regarding possible explanations. We hypothesize that the organizational level of the general practices, the culture with regard to teamwork, and the practice nurse's skills and expertise are mainly responsible for the large differences between the centres [18-20].

With regard to ethnic differences in the program fidelity, our results show that Turkish and Moroccan individuals had the lowest scores for protocol completion. The most logical explanation is the marginal role of the health educator in this intervention program compared to other intervention studies [21]. The limited proficiency in the Dutch language among this subgroup, the absence of language support, and the practice nurse's lack of knowledge concerning migrant's cultural background may all have negatively influenced participation in the individual educational sessions [22].

A major limitation of the present study is that the results were mainly based on data collected using a patient document, which could be biased by differences in registration between the practices nurses. Some intervention activities, such as participation in the individual sessions or team meetings, may not always have been filled in on the patient document, or were perhaps only registered in the electronic GP records. However, when we consider only the performance of the three-months risk assessments (which was continuously registered by the research team), we observe the same trends as for the individuals sessions and team meetings; this suggest that differences in the extent of implementation of intervention activities were not likely to be influenced by differences in data registration.

The dropout from the intervention program was 55%, but was not markedly different from a similar intervention performed in a Turkish patient population [7]. Although the numbers of different ethnic groups per centre were limited, the trends in all three centres (for e.g. Dutch and Turkish/Moroccan individuals) were similar. This subgroup analysis may be helpful for other investigators planning intervention studies in targeted populations.

Conclusion

The data reported in this study provide healthcare professionals, policymakers and investigators with a description of how an intervention to reduce cardiovascular risk in a multi-ethnic patient population (based on a pragmatic trial in general practices located in deprived neighbourhoods) is implemented in daily practice. The healthcare centres adapted the intervention to their own conditions by adopting some intervention activities (e.g. continuation of use of structured risk assessments and individual sessions) and leaving out other ones (e.g. team meetings). Consequently, an explanation for the differences in results across healthcare centres is difficult because centres carried out

intervention activities in different ways. This study underlines the contribution of a process evaluation to our understanding of the lack of effectiveness of the intervention program.

Practice implications

Our results imply that general practices in deprived neighbourhoods in the Netherlands are a suitable setting to, in the first instance, reach high-risk patients from different ethnic origins. Nevertheless, there is much to gain in terms of reducing dropout. We suggest that practice nurses and peer health educators should be involved in the active enrolment and close follow-up of high-risk patients to ensure early detection of adverse effects and problems in compliance.

Since different disciplines have been currently added to the general practice, more emphasis should be put on collaboration between these professionals to improve quality of care. To achieve structured collaboration of different team members to treat patients at high cardiovascular risk, adequate composition of the team, clear task divisions, and well-defined roles are a prerequisite. Appropriate training regarding teamwork for the management of cardiovascular diseases in high-risk patients should be part of the curriculum for different healthcare professionals, including general practitioners.

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Chapter 7

Effect of periodical measurements on cardiovascular risk in a multiethnic high risk population

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ABSTRACT

Objective:

To assess the effect of periodical measurements compared to usual GP care in patients at high risk of developing cardiovascular diseases (CVD).

Study design and setting:

Data collected in the framework of a randomised controlled trial (RCT) in 3 primary healthcare centres located in deprived neighbourhoods of two Dutch cities (Rotterdam & the Hague) were used to assess the effectiveness of a structured collaboration within the general practice.
Data of 107 patients allocated to usual GP care plus periodical measurements (UC&PM) and 135 patients allocated to usual GP care group (UC) were analysed. Outcome measures were reduction in the 10-year absolute risk to develop CVD, blood pressure, lipids and body mass index at 12-months follow-up.

Results:

The 10-year absolute risk decreased by 1.33% (95%CI: -2.87 to 0.21) in the UC&PM group compared to an increase of 3.43% (95% CI: 0.93 to 5.93) in the UC group. Individual CVD risk factors showed a similar trend: an unfavourable change in the risk profile of the UC group compared to improvements in the UC&PM group's risk profile.

Conclusion:

Our findings support the hypothesis that periodical measurements of the risk profile and follow-up of high-risk patients are useful to improve the cardiovascular risk profile. Due to some methodological limitations related to the chosen RCT design, it is difficult to quantify the change in the cardiovascular risk resulting from periodical measurements.

INTRODUCTION

According to current cardiovascular guidelines, high-risk patients should be seen regularly by their general practitioner to assess the patient's risk profile and initiate preventive activities when necessary [1,2]. It is known that regular health checks and follow-up favourably affect the cardiovascular risk profile in different patient groups [3-5]. Thus, also in experimental studies involving periodical measurement to assess the outcome, such measurement may itself influence the observed effect. Only few studies, however, have attempted to quantify this phenomenon.

To deal with some methodological and practical problems faced when conducting trials in daily practice (e.g. selection of an appropriate control group; difficulties to blind the intervention process, and the disruption of the delivery of care) [6,7], we designed a randomised controlled trial (RCT) in such a way that the effect of periodical measurements (by offering these to one of the two control groups) in addition to usual care could be estimated. The trial examined the effectiveness of a structured collaboration of a practice nurse, a peer health educator, the general practitioner (GP) and GP assistant in general practice to provide intensified preventive care to patients living in deprived neighbourhoods and at high cardiovascular risk. This RCT showed a similar improvement in the 10-year absolute cardiovascular risk in the intervention as well as the control group [El Fakiri et al., submitted]. The process evaluation data demonstrated a low implementation rate of the intervention activities in the intervention group [El Fakiri et al., submitted]. Based on these findings we hypothesised that the periodical measurements of the risk profile were responsible for the effects observed on the cardiovascular risk profile in both the intervention and control group.

In the present study, we aimed to quantify the effect of these periodical measurements by comparing the changes in cardiovascular risk after one year follow-up in the control group that received periodical measurements and the control group that was offered usual care only and in whom no baseline measurements of the risk profile were performed to avoid disruption of usual care.

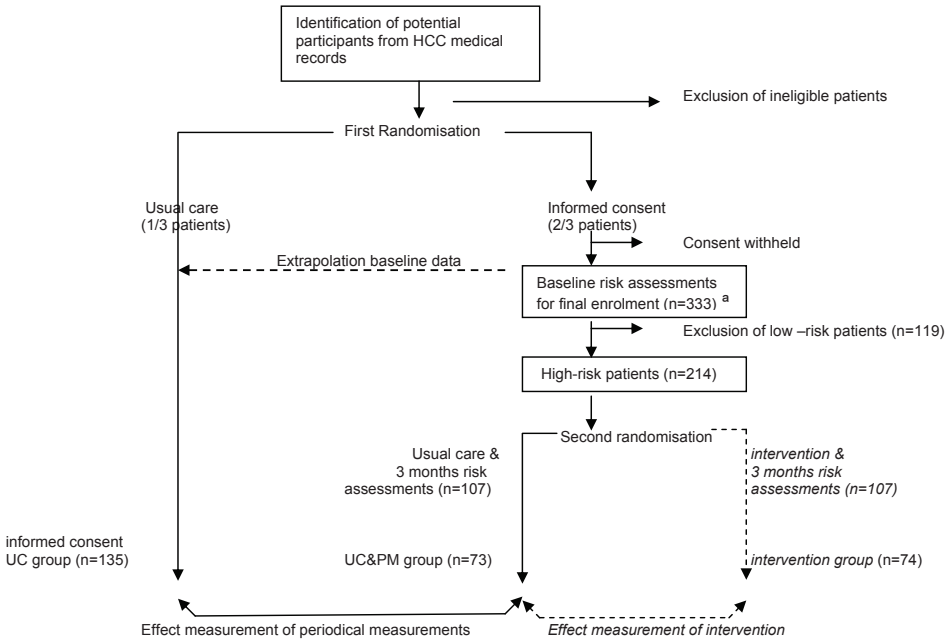
METHODS

The study design and methods of the trial have been reported in detail elsewhere [El Fakiri et al., submitted]. Briefly, a search in electronic GP records was carried out to identify patients aged 30-70 years, living in deprived neighbourhoods and at high risk of developing cardiovascular diseases (i.e. having a cardiovascular disease, one or more cardiovascular risk factors, measurement of blood pressure ≥160/95 mmHg, measurement of total cholesterol ≥ 6.2 mmol /l). Two randomisation steps at the patient level took

place within each general practice (see Figure 1). The first randomisation (1:2) resulted in a usual GP care group (referred to as the usual care group: UC group) consisting of 1/3 of the patients and this group was kept blind during the trial; and the remaining 2/3 of the patients were invited to participate in the trial. Patients that signed informed consent underwent an assessment of the baseline risk to establish final eligibility (i.e. having a modifiable part of the absolute risk ≥ 5%). Subsequently, a second randomisation (1:1) took place resulting in an intervention group receiving intensified preventive care plus periodical measurements of the risk profile and a control group (referred to as the usual care plus periodical measurements group; UC&PM group).

Patients in the UC group were invited at the end of the 12-month follow-up for an interview and assessment of the risk profile: systolic and diastolic blood pressure, weight and height to determine the body mass index (BMI), plasma glucose, total cholesterol,

Figure 1: Study design for a randomised controlled trial to assess the effectiveness of an intensified preventive care to reduce cardiovascular risk.



[a]: Numbers are different from those presented in Chapter 5 because in the present study data of patients from two participating healthcare centres only were included in the analysis.

UC&PM: usual care and periodical measurements group

UC: usual care group

HCC: healthcare centre

HDL cholesterol and triglycerides. Because no baseline risk assessments in the UC group were carried out, baseline data obtained from patients who gave informed consent after the first randomisation were used (see Figure 1).
Patients allocated to the UC&PM group were measured at baseline and again after 12 months.
The main outcome measure was the change in the 10-year absolute cardiovascular risk between baseline and 12-months follow-up as calculated by the Framingham risk equation [8].
Data were analysed by SPSS software for Windows, version 12.0. Differences in means between baseline and 12-months follow-up were determined by a paired t-test in the UC group; in the UC&PM group the analyses were performed using the general mixed model because some values of the primary outcome measures were missing due to being lost to follow-up [9]. All data are presented as mean with standard error (se); and the differences between baseline and 12-months follow-up are given as mean (se) with 95% confidence interval (CI).
The local ethics committee of the Erasmus Medical Centre of Rotterdam approved the study protocol.

RESULTS

Among the 107 patients randomised to the UC&PM group (mean age 56.4 (SD 8.5) years; 63% men), 73 completed the trial [mean age 58.6 (SD 8.5) years; 56% men]. A total of 135 patients allocated to the UC group [mean age 57.0 (SD 8.9) years; 32% men] gave informed consent and had a completed cardiovascular risk profile at the end of the trial. As noted above, for this group baseline risk assessments of the patients [n=333; 53.8 (SD 9.7) years; 47% men] obtained after the first randomisation (after selection and informed consent, before any intervention) were taken as the baseline data.
Table 1 shows that the cardiovascular risk profile of patients allocated to the UC group worsened after one year: the 10-year absolute risk increased by 3.43% (95% CI: 0.93 to 5.93) compared to a decrease of 1.33% (95% CI: -2.87 to 0.21) in the UC&PM group. Individual risk factors such as systolic and diastolic blood pressure also show a significant unfavourable change from baseline in the UC group compared to the UC&PM group.
The sub-group analyses by healthcare centre show a similar trend (table 2). In centre 1 the 10-year absolute risk to develop CVD increased in the UC group after one year (+4.18% (95% CI: 1.06 to 7.31) in contrast to no change in the UC&PM group (-0.10% (95% CI: -2.01 to 2.20)). In centre 2, there was a significant improvement in the cardiovascular risk in the UC&PM group [-3.60% (95% CI: -5.50 to -1.70)] while no improvement in the UC group was achieved [+2.18% (95% CI: -2.50 to 6.86)].

Table 1: Cardiovascular risk profile at baseline and after 12 months follow-up, and mean change from baseline in both study groups

	Baseline mean (SE)	12 months mean (SE)	Change from baseline mean (SE)	95% CI
Absolute CVD risk (%)				
UC&PM	24.07 (1.13)	22.74 (1.14)	-1.33 (0.77)	-2.87 to 0.21
UC	18.07 (1.07)¶	21.50 (1.06)	3.43 (1.27)	0.93 to 5.93
Systolic BP (mmHg)				
UC&PM	149.8 (2.1)	145.7 (2.3)	-4.07 (2.4)	-8.92 to 0.78
UC	140.8 (1.4)¶	151.6 (2.1)	10.7 (2.5)	5.83 to 15.62
Diastolic BP (mmHg)				
UC&PM	88.8 (1.1)	90.2 (1.3)	1.42 (1.4)	-1.35 to 4.20
UC	85.3 (0.7)¶	90.8 (1.0)	5.51 (1.2)	3.11 to 7.92
Total cholesterol: HDL-cholesterol				
UC&PM	4.65 (0.1)	4.27 (0.2)	-0.38 (0.1)	-0.59 to -0.16
UC	4.36 (0.1)¶	4.19 (0.1)	-0.17 (0.1)	-0.44 to 0.11
LDL-cholesterol (mmol/l)				
UC&PM	3.44 (0.1)	3.12 (0.1)	-0.32 (0.1)	-0.51 to -0.14
UC	3.33 (0.1)¶	3.44 (0.9)	0.11 (0.1)	-0.08 to 0.31
BMI (kg/m2)				
UC&PM	30.6 (0.6)	30.0 (0.6)	-0.60 (0.3)	-1.14 to -0.06
UC	30.1 (0.3)¶	31.4 (0.6)	1.34 (0.6)	0.06 to 2.61

¶:Extrapolated data of patients before second randomisation and exclusion of low risk subjects
Values are mean (SE) or 95% CI
UC&PM: usual care and periodical measurements group
UC: usual care group
CVD, cardiovascular disease; BP, blood pressure; HDL, high density lipoprotein; LDL, low density lipoprotein, BMI, body mass index

DISCUSSION

This study demonstrates that patients allocated to the group receiving usual GP care plus periodical measurements showed an improvement in the cardiovascular risk profile at the end of the study, and that the risk profile of those receiving usual GP care only worsened during the course of the study. These differences between the two study groups suggest that the achieved improvements in the cardiovascular risk profile shown in the parental RCT were predominately due to the periodical measurements and follow-up of high-risk patients.

The benefits of periodical measurements on the cardiovascular risk profile in the general population or high-risk individuals have been reported previously [3-5,10,11]. In our study, the benefits were most pronounced in blood pressure and BMI. This finding is also demonstrated by the Oxcheck study [3]. The change in blood pressure might be explained by measurement of the blood pressure and drug treatment of previously unidentified or inadequately treated hypertensive individuals.

Table 2: 10-year absolute risk (%) at baseline and 12 months follow-up and mean change from baseline by healthcare centre

	Baseline mean (SE)	12 months mean (SE)	Change from baseline mean (95% CI)
Centre 1			
UC&PM	23.9 (1.4)	23.0 (1.6)	-0.10 (-2.01 to 2.20)
UC	17.5 (0.8)¶	21.7 (1.3)	4.18 (1.06 to 7.31)
Centre 2			
UC&PM	24.3 (1.9)	20.7 (1.6)	-3.60 (-5.50 to -1.70)
UC	18.9 (1.2)¶	21.1 (1.7)	2.18 (-2.50 to 6.86)

¶: Extrapolated data of patients before second randomisation and exclusion of low risk subjects
Values are mean (SE) or mean (95% CI)
UC&PM: usual care and periodical measurements group
UC: usual care group

The present study has some methodological limitations, since the original RCT study was not primarily designed to assess the effectiveness of periodical measurements.
Notably, the two control groups are not really comparable since their "construction" was different. The UC&PM group consisted of high-risk individuals only (n=107) because of the exclusion of those having a modifiable risk lower than 5% (n=119; predominantly women (75%) and younger individuals (49.0 (SD 10.1) years); whereas the UC group is a mix of high-risk and low-risk individuals [n=135; 57.0 (SD 9.7) years; 68% women] resulting in a lower absolute risk for the total group. Nevertheless, we argue that this unequal composition most likely yields an underestimation of the effect of periodical measurements. As a consequence of the natural course, the absolute risk is expected to increase in both groups whatever the baseline risk profile, partly because of an effect of aging. In contrast, the cardiovascular risk and risk factors showed an opposite course during follow-up suggesting that a large proportion of the favourable effect shown in the UC&PM group is attributable to the periodical measurements.
There might be an overestimation of the improvements observed in the cardiovascular risk profile of the UC&PM group in comparison to the UC group, probably as a consequence of a Hawthorne effect. Patients from the UC&PM group may be more motivated to improve their lifestyle because of their participation in the periodical measurements and the feedback they may receive from the general practitioner or GP assistant as part of usual care, whereas the course of the cardiovascular risk profile in the individuals from the UC group more accurately reflects the daily routine in Dutch general practice. We are convinced that, if no periodical measurements had been carried out, the risk would not have been decreased to such an extent as now observed in the UC&PM group.
Regression to the mean might have contributed to the changes in both groups, but perhaps more so in those patients allocated to the UC&PM group (who initially had high levels of risk); this may have artificially increased the observed effect of periodical measurements. This phenomenon is expected to be the most pronounced in blood

pressure measurements that constitute an independent variable in the risk formula, and are known to be influenced by regression to the mean. However, the net differences in systolic and diastolic blood pressure between those individuals measured (UC&PM group) and those that were not measured (UC group) in our study were comparable with the results demonstrated in a meta-analysis on antihypertensive drugs effect by Collins et al. (1990) showing an average change in diastolic blood pressure of 5-6 mm Hg and in systolic blood pressure of 10-12 mm Hg [13]. This indicates that the improvements in the risk profile in the UC&PM group are due to the measurements and subsequent treatment and not just due to the regression to the mean.

Lastly, no baseline data of individual patients allocated to the UC group were available since the measurement itself was part of the intervention. It is ethically and practically unacceptable to perform baseline measurements without giving feedback to the patient or general practitioner about the results of the examination, especially in case of unfavourable results. This methodological problem was solved by extrapolating the baseline data of the other study arm obtained after the first randomisation. In our opinion this assumption is justified because randomisation is supposed to provide two study arms that are equivalent.

In conclusion, our findings support the hypothesis that periodical assessments of the risk profile and follow-up of high-risk patients are useful to improve the risk profile. However, due to some methodological problems related to the chosen RCT design, it remains difficult to precisely quantify the change in the cardiovascular risk resulting from periodical measurements.

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Chapter 8

General discussion:

Are all interventions to
prevent cardiovascular diseases
in deprived neighbourhoods doomed to fail?

INTRODUCTION

The work in this thesis has demonstrated that intensified preventive care targeted at high-risk individuals living in deprived neighbourhoods has no effect on the cardiovascular risk in addition to the usual general practitioner (GP) care after one-year follow-up (Chapter 5). Moreover, despite the ethnically tailored aspect of the intervention (i.e. by providing peer health educators from an ethnic group corresponding to that of the patient), no benefits at all were observed among the largest ethnic minority groups (i.e. Turks and Moroccans); and the implementation of intervention activities among these ethnic groups was dramatically poorer than in the Dutch participants (Chapter 6).

Given the results of these studies - and the fact that inequalities still exist in cardiovascular health between deprived and non-deprived neighbourhoods - one may wonder whether all interventions (based on health education) to prevent cardiovascular diseases (CVD) in deprived neighbourhoods are doomed to fail. To address this, we critically evaluated earlier intervention studies carried out in deprived neighbourhoods in the Netherlands with the aim to prevent CVD.

If indeed previous studies produced results similar to those yielded by our study, the question arises as to what approach should be considered in the future. Given the heterogeneous population living in deprived neighbourhoods and the multi-factorial causality of CVD in these areas, we may need to reconsider continuation or adaptation of existing intervention strategies that have shown no actual benefits and focus on alternatives that may prove to be more successful. As an alternative, the Polypill approach is discussed.

ARE CURRENT INTERVENTIONS TO PREVENT CVD TARGETED AT DEPRIVED NEIGHBOURHOODS IN THE NETHERLANDS EFFECTIVE?

Evidence for the Dutch national policy to promote healthy behaviour to reduce CVD is limited or even unknown among those with a low socio-economic status (SES) [1,2]. Preventive interventions specifically targeted to low SES groups to reduce health inequalities that have shown some benefits focused mainly on children at primary school (i.e. school-based interventions targeted at smoking and teeth-brushing behaviour) or on working conditions (exposure to physically strenuous labour); but not on the prevention of CVD and their related risk factors in adults [1,2].

The available studies related to the prevention of CVD have been diverse in their objectives, design, study population and setting. Without attempting to conduct a systematic review, we have evaluated four studies (including individual or community interventions)

Table 1: Overview of some intervention studies aimed to prevent cardiovascular diseases in different deprived neighbourhoods in the Netherlands

Study	Population (indigenous/low SES/ ethnic minorities), setting	Design	Intervention	(main) outcome measures	Conclusion
De Vries (2005)	Habitants of South-east Drenthe; deprived region in terms of mortality and unhealthy lifestyle	8-years Community-based intervention	Different activities on nutrition, exercise, smoking and stress	Kok's phase model for behavioural change through information	No effect of intervention
Uitewaal et al. (2005)	Turkish diabetic patients in Rotterdam	Non-randomised, intervention and control group	Peer health educator to diabetes patients: face-to-face individual and group session	HbAc1	No effect of intervention
Kloek et al. (2005)	18-65 years individuals: 3 experimental and 3 matched comparison "deprived" neighbourhoods in Eindhoven	Quasi-experimental; 2 year community intervention	Different activities on lifestyle (nutrition projects in primary schools, information on healthy nutrition and lifestyle for adults, gymnastic classes, quit smoking courses, annual large community events, neighbourhood walking tours). Most used channels of communication were face-to face (single and multiple sessions)	Fruit & vegetable consumption, physical activity, smoking, alcohol consumption, intermediate outcomes of behaviour	No effect of intervention
Hart slag Limburg (2006)	25-70 Dutch participants, no focus on ethnicity	5 year community, combined with high-risk strategy	Computer-tailored nutrition education, nutrition education tours in supermarkets, public-private collaboration with the retail sector, creating walking and bicycling clubs, walking and cycling campaigns, stop-smoking campaign; commercials on local television and radio, newspaper articles, pamphlet distribution.	BMI, waist circumference, blood pressure, serum glucose (non fasting), serum total and HDL cholesterol	Limited effect in experimental region
El Fakiri et al. (submitted2006)	30-70 years Dutch, Turkish, Surinamese etc. Low SES; at high risk the Hague & Rotterdam	RCT, 1 year-follow-up intervention	Intensified preventive care by primary care team (including GP, peer health educator and GP assistant) led by a practice nurse	10 year absolute CVD risk other CVD risk factors	No effect of intervention

recently conducted in the Netherlands in the so-called deprived neighbourhoods that aimed to prevent cardiovascular risk factors or CVD (Table 1).
The project 'South East-Drenthe Good and Heart-y', one of the first large community-based interventions in the Netherlands, covered the period 1991 to1999 and aimed to promote a healthy lifestyle among the population in that region in order to reduce the incidence of CVD [3]. A longitudinal and a cross-sectional study design were combined. The focus was on four lifestyle themes: nutrition, exercise, smoking and stress, whereby changes in knowledge, attitude and behaviour among the regional population were examined. In the first years of the project a few minor changes were observed in the steps toward change in behaviour regarding the themes of the project (favourable changes for nutrition and exercise only; while no consistent results were found with regard to other health-related behaviour). Throughout the entire project period, however, no significant effects of the intervention were demonstrated.

The study of Kloek et al. [4] investigated the impact of a community intervention on health-related behaviour (fruit and vegetable consumption, smoking, physical activity and alcohol consumption) and intermediate outcomes of health-related behaviour (including knowledge, attitudes, self-efficacy expectations and awareness of one's behaviour and the intention to change behaviour (stages of change)) among people living in deprived neighbourhoods in the city of Eindhoven. The study consisted of a quasi-experimental design, with 3 deprived neighbourhoods assigned to receive the intervention programme and 3 comparison neighbourhoods matched according to socio-demographic and baseline health-related behaviour variables.
After an implementation period of 2 years, during which more than 40 intervention activities were planned and delivered, the effects of the intervention programme was small. The investigators found evidence for a small impact on fruit consumption; and a small impact on awareness of one's own physical activity. However, no effect was found on vegetable consumption, physical activity, smoking and alcohol consumption and no impact on most intermediate outcomes of vegetable consumption or physical activity. The authors conclude that this intervention could only have a minimal contribution to reduce socio-economic inequalities in health-related behaviour.

The study by Uitewaal et al. [5] aimed to assess the effect and feasibility of an ethnic-specific peer-led education programme in Turkish type 2 diabetes patients. The study followed a prospective controlled experimental design, carried out in general practices in Rotterdam. Compared with the control group, mean HbA1c in the intervention group decreased by 0.3% (95% CI -0.8 to 0.2) and fasting plasma glucose decreased by 0.9 mmol/l (95% CI -2.2 to 0.3). A significant intervention effect was found in women (with increased plasma levels at baseline), but not in the other subgroups. The "effect" in these

women may, however, have been a chance finding. Although tailored to the traditions and specific habits of the Turkish diabetes patients, this study showed that such an ethnic-specific education programme has no clear beneficial effect on glycaemic control or other cardiovascular risk factors in Turkish diabetes patients.

Finally, the 'Hartslag Limburg' project is a community-based CVD prevention programme integrated with a high-risk group approach in general practices and the local hospital cardiology department [6]. The project aimed at decreasing the prevalence of CVD in the general population of the Maastricht region, particularly low SES groups, by encouraging the inhabitants to become more physically active, reduce their fat intake, and stop smoking. During the 5-year follow-up, cardiovascular risk factors changed unfavourably in the reference group while changes were less pronounced or absent in the intervention group. Body Mass Index, waist circumference, and blood pressure were more favourable in the intervention group than in the control group. This study also showed that the difference in change in risk factors between the intervention and control group was similar in subjects with low SES compared to the other participants (after adjustment for gender, age, smoking, and the mean of the individual's pre- and post intervention measurement of the variable under study). It should be noted that the 'Hartslag Limburg' study focused on indigenous Dutch persons with a low SES and did not include persons from other ethnic origins. This raises questions about the generalisability of findings from this project to ethnic minorities.

As far as process evaluations were embedded in the above-mentioned intervention studies, process evaluation data revealed that, in general, intervention activities were well appreciated by the target population and the participating (healthcare) professionals or organisations [3,7,8]. Nevertheless, those with a low SES, the ethnic minority groups, the less well educated, and males were less often reached by the intervention activities or were more likely to dropout during the intervention programme [7,8].

On the basis of these findings, we concluded that there is little evidence for the effectiveness of interventions aimed at reducing cardiovascular risk in deprived neighbourhoods, particularly those targeting multi-ethnic populations: the interventions had no or only limited benefits in reducing the burden of CVD for the population in deprived neighbourhoods and that (albeit originally designed to target individuals with low SES) these interventions did not succeed in reaching relevant subgroups in the community. This finding confirms the idea that people who are in most need are the hardest to reach.

In conclusion, the most likely answer to the question that we posed at the beginning of this chapter (i.e. Are all interventions based on health education to prevent CVD in deprived neighbourhoods doomed to fail?) is 'yes'.

A NEW APPROACH TO PREVENT CVD IN DEPRIVED NEIGHBOURHOODS?

Based on the earlier studies and the results from our trial, it seems that alternative interventions focusing on health education should be carried out in deprived neighbourhoods, and that novel methods should be applied to ensure that multiple ethnic groups at risk of developing CVD are reached. Which interventions should be implemented and which "novel methods" should be applied to reach these relevant populations is, however, unknown; even when known, one doubts whether they would be effective because of: 1) the heterogeneity of subjects living in deprived neighbourhoods, and 2) the multifactorial causality of CVD in deprived neighbourhoods.

Heterogeneity of those in deprived neighbourhoods

In the Netherlands, most deprived neighbourhoods are situated in the four largest cities (i.e. Amsterdam, Rotterdam, the Hague and Utrecht). By the year 2002, 12.5% of the Dutch population was living in these cities compared to 37.6% of people belonging to ethnic minorities. By the year 2010, the proportion of ethnic minorities in these areas is expected to grow to approximately 64% [9]. Currently, in some deprived neighbourhoods, the proportion of people from ethnic minorities exceeds 50%.

As noted above, the heterogeneity of the population living in deprived neighbourhoods complicates the tailoring of intervention activities not only because the risk profiles differ (Chapter 2), but also because of the varying socio-demographic, ethnic and cultural backgrounds of the inhabitants (Table 2) which implies, for example, different languages, religions, level of acculturation and, thus, varying knowledge of the Dutch language and participation rate in the community.

This diversity confronts healthcare professionals with serious dilemmas concerning the intervention activities to be chosen and for whom, as well as which communication channels should be used to reach these people. For example, it is practically impossible to address all ethnic groups living in deprived neighbourhoods in their mother tongue.

To further clarify this complex tailoring process, we present the following simplified overview with reference to our study findings reported in Chapter 2 (Table 3).

An important prerequisite to effectively tailor interventions is a gradual and well-balanced provision of health education according to the specific needs of the target population and phases in the behavioural change model. Obviously, this aspect will be difficult to achieve in deprived neighbourhoods due to the diversity between and within the different ethnic groups.

Last but not least, to serve all these subgroups with health education interventions, substantial knowledge is required about the characteristics of the different target groups to adequately tailor the health education message; in practice an unfeasible task.

Table 2. Population composition in the large (G4) and medium-sized Dutch cities (G21) and the rest of the Netherlands

	G4	G21	rest of the Netherlands
Age in years (%)			
0-14	16.3	16.9	19.6
15-34	33.5	30,6	25.2
35-64	35.4	38.3	41.8
≥ 65	13.8	14.2	13.4
Low income (%)	20.7	16.7	10.7
Unemployed (%)	9.5	8.0	6.0
Single (%)	46.9	43.0	35.3
Ethnic minorities (%)	37.6	20.0	10.3
Turks	14.3	7.0	6.9
Moroccans	17.4	7.8	6.1
Surinamese	19.3	6.0	4.8
Antilleans/Arubans	4.1	4.2	2.6
others non-western	15.0	23.3	10.0
other western	29.9	51.7	69.6
Educational level (%)			
Low	20.6	23.0	19.6
lower secondary	30.4	30.9	34.9
higher secondary	24.4	25.2	28.1
higher	24.6	20.8	17.4

Reprinted from: Lucht F van der, Verkleij H. Health in the cities. RIVM Rapport/ VTV 2002 [9]

Table 3: an example of tailoring intervention to reduce CVD in deprived neighbourhoods

Ethnic group	**Intervention focus on**	**Language**
Dutch	hypercholesterolemia, smoking	Dutch
Turkish	diabetes, smoking, obesity	Turkish, (Dutch)
Moroccan	diabetes, obesity	Arabic, Berbers, (Dutch)
Surinamese	diabetes, (hypertension)	different languages, Dutch
Antillean	diabetes, (obesity)	different languages, Dutch
Other ethnic groups	no information available	different languages

Multifactorial causality of CVD in deprived neighbourhoods

In addition to the conventional cardiovascular risk factors (e.g. smoking, high levels of blood pressure and cholesterol), which independently and in interaction influence cardiovascular risk, the environment in which people live should also be taken into account. In deprived neighbourhoods the social and environmental conditions in which individuals live are far from favourable, including problems associated with low income, unemployment, psychological stress, housing conditions and low education level. The

duration of exposure to deprivation is also associated with an adverse cardiovascular risk profile [10]. Therefore, focusing exclusively on achieving changes in an individual's lifestyle/behaviour will have no or only a limited effect unless other previously mentioned factors associated with the deprived status are also addressed [11,12].

This implies that broader approaches that include dealing with the root causes (e.g. social, economic and cultural/ethnic) of health inequalities are necessary to achieve health for all subgroups in the society and to reduce inequalities. However, because these broader approaches require not only mega investment in terms of resources such as manpower and finance but also collaboration of the various partners involved, these recommendations are not easily put into practice.

The fact that health education focusing on lifestyle changes requires enormous effort but lacks substantial results, might imply that we are expecting too much from health education in relation to behavioural changes in people in deprived neighbourhoods; especially given the fact that the neighbourhood environment can influence behavioural changes in various ways, including social cohesion, access to information, quality and cost of goods, services, and resources [10]. Alternatively, more simple and effective interventions should be considered which make the individuals less dependent on their environment than interventions related to smoking cessation, healthy diets and physical activity - while being acceptable to the target group.

In conclusion, given the expected failure of interventions based on health education in a deprived neighbourhood and the complex composition of the target population, we need to reconsider the current approach to prevention of CVD in deprived neighbourhoods and transform our way of thinking. An alternative intervention should be simple, acceptable and less dependent on the environment in which these people live.

PREVENTION OF CVD IN DEPRIVED NEIGHBOURHOODS: THE POLYPILL?

Persistent inequalities in cardiovascular health between deprived and non-deprived neighbourhoods necessitate effective solutions. In the near future, we think that in practice only a pharmacological solution may yield improvements. A pill that has gained much attention recently, is the multi-component Polypill.

We believe that the Polypill (proposed by Wald and Law in 2003) [13] offers an opportunity to reduce CVD in high-risk individuals among multi-ethnic populations living in a deprived neighbourhood. This pill combines four different active agents: a statin; three blood pressure lowering drugs; folic acid, and aspirin - which individually (except folic acid) have been shown to decrease cardiovascular events by 20-35% in primary prevention interventions, secondary prevention interventions, or both [14]. This combination has

been suggested to reduce CVD by more than 80% when taken by all adults aged 55 years and older.
Although this proposed intervention may raise more questions than it provides answers, it may stimulate discussions as to why there is still an urgent need for prevention of CVD in deprived neighbourhoods and could stimulate future research.

Arguments for use of the Polypill

Several arguments to support use of the Polypill should be addressed. First, the Polypill is designed to influence four cardiovascular risk factors simultaneously: LDL cholesterol, blood pressure, serum homocysteine and platelet function. In deprived areas there is an accumulation of risk factors (related to the population heterogeneity in terms of ethnicity and age: Chapter 2) suggesting the need for a combined treatment strategy, such as the Polypill, which is easier to administer than other interventions and influences multiple cardiovascular risk factors.
Second, although cardiovascular risk factors in deprived areas are predominantly modifiable (e.g. smoking, overweight, physical inactivity) the effect of health education is lacking despite the high costs. Use of the Polypill places less focus on health education among individuals with a low SES and may promote a reduction in mortality due to CVD [16]. In contrast to the use of a pill, even tailored health education necessitates an adequate level of school education to understand the information, and the effects may be visible on the long term. Furthermore, in line with many guidelines, pharmacological intervention should be initiated in case health education did not succeed in achieving the treatment targets.
Third, according to previous studies, ethnic and socio-economic disparities still exist in treatment of hypertension, hypercholesterolemia or CVD. For example the most affluent patients with coronary heart diseases and ethnic minorities were significantly less likely to receive statins [17, 18]; and diuretic use was lowest in ethnic minorities compared to Caucasians in the USA [19]. The simplicity of administrating a multiple-component pill to an at-risk population might limit the gap between treatment guidelines and daily practice [14].

Arguments against the use of the Polypill

These include doubts about the effectiveness of such therapy, possible low adherence, side effects of the Polypill components, and the need for multiple Polypills.
Randomised controlled trials of the single interventions of lipid and blood pressure lowering and antiplatelet therapy have shown their efficacy in the prevention of CVD [16]. The effectiveness and cost effectiveness of the Polypill (i.e. the multiple interventions combined) has, however, never been established in a formal RCT. The 80% reduction in cardiovascular diseases mentioned by Wald and Law [13] was estimated based on the

individual components of the Polypill and modelling techniques. To demonstrate the (cost) effectiveness of the Polypill, an RCT in daily practice including different ethnic groups is required. For instance, instead of a placebo comparison, one could also choose a more pragmatic approach and compare the Polypill with usual care [14].
Since patient-related characteristics such socio-economic status and ethnicity have been correlated with nonadherence [20], nonadherence to the Polypill might be a serious problem, notably in the low SES individuals and ethnic minorities. Nevertheless adherence to the Polypill is supposed to be higher than it would be if all components were to be taken as an individual pill [21,16]. Sleight et al. [16] reported on the easy use of a Polypill among elderly patients; we believe that the same can apply to persons with a low SES and to ethnic minorities.
The side effects of the Polypill are unknown. However, using half-doses of multiple drugs in the Polypill is likely to exert fewer side effects than the full dose. Also, according to Wald and Law 's estimations [13], adverse events would only warrant discontinuation of the pill in 1-2% of patients, and fatal side effects would occur in less than one in 10,000 users. Precise estimates of side effects should preferably be obtained in a large-scale RCT. Regarding ethnic-specific side effects of the Polypill components, a recently published systematic review and meta-analysis showed that patients from different ethnic groups have different risks for important adverse drugs reactions to cardiovascular drugs [22]. However, this latter study was criticised because of its approach to ethnic classification [23], and the insufficiency of the used medical approach to explain ethnic differences [24].
The availability of a pharmacological solution to cardiovascular health may send the wrong message to the population at large that there is a "universal cardiovascular panacea" to solve or restore adverse lifestyle choices [25]. However, the Polypill is not an alternative to adopting a healthy lifestyle such as not smoking or not becoming overweight [26]. It is a complementary means of prevention and it may be a substitute to health education based interventions.

Lastly, the problem with this "one-size-fits-all" approach is that some people would be undertreated, and others would be overtreated [25]. Therefore, the need for separate titration of individual components of the Polypill may be important in a number of situations. This may require the development of several Polypills with different dosages and possibly drugs in order to cover different patients' risk profiles, for primary prevention and for secondary prevention, for special subgroups such as patients with diabetes mellitus, hypertension or with prior myocardial infarction.

Implementation of the Polypill

To implement this strategy in an adequate way, several conditions have to be fulfilled. First, periodical assessments of patients receiving the Polypill may be necessary because (as shown in Chapter 7) structured follow-up and assessment of cardiovascular risk are known to be beneficial in improving the cardiovascular risk profile of patients at high cardiovascular risk; and the recent guideline for Diabetes Mellitus [27] and the Multidisciplinary Guideline for Cardiovascular Management [28] also recommends periodical risk assessments.

It should be noted that according to the original Wald & Law study, monitoring to prevent rare serious adverse effects of treatment might be considered.

Second, a recall system using the GP electronic information system is also useful to monitor the patient's risk profiles, compliance, improvements in cardiovascular risk and possible side effects.

Lastly, for some ethnic minorities, even with the introduction of the Polypill, there is still a need to involve intermediary professionals or peer health educators to bridge any language and/or cultural differences between the GP or other healthcare professionals and the patients from ethnic minorities. However, in this case the message will become less complicated, implying that more people will be compliant.

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Chapter 9

Summary

SUMMARY

Cardiovascular diseases (CVD) are still the most important cause of mortality and disability in the Netherlands. Although improvements have been made in reducing cardiovascular mortality and morbidity on the national level, people living in deprived neighbourhoods have a greater risk of developing CVD than the general population.
The population in deprived neighbourhoods is a heterogeneous group including an indigenous population of low socio-economic status and a large proportion of people from different ethnic backgrounds.
To achieve health gain, future interventions to prevent CVD should be targeted to people living in deprived neighbourhoods. This thesis describes such an intervention and deals with the major issues related to the design, implementation and evaluation of this intervention. These include: identification of high-risk individuals that should be targeted by intervention activities, assessment of the prevalence of cardiovascular risk factors, and tailoring intervention to specific needs of the target population.

Chapter 1 introduces the background, the aim, and the outline of the thesis.
The general aim of this thesis is to contribute to and expand previous research on prevention of CVD in deprived neighbourhoods.
Chapters 2 and 3 deal with the issues concerning the identification of individuals at high risk of developing CVD.
In **chapter 2** we compared the distribution of cardiovascular risk factors between indigenous Dutch and individuals from other ethnic backgrounds. In this study we found that ethnic monitories (i.e. Turks, Moroccans, Surinamese and Antilleans) have a significantly greater chance of being diabetic than the Dutch (OR 3.2 to 19.4) but a lower prevalence of hypercholesterolemia than the Dutch. Compared to the Dutch, people with a Turkish background were more likely to be obese (OR=2.4). All ethnic minorities had a lower prevalence of reported smoking than the Dutch population (OR=0.10 to 0.53), but Turkish males and Dutch females were more likely to smoke than males and females from other ethnic groups. The prevalence of hypertension was comparable between ethnic groups.
This study shows the heterogeneity of the patient population from general practices located in deprived neighbourhoods in terms of ethnic composition, age and education level, as well as the prevalence of cardiovascular risk factors. Our findings provide additional evidence for the need to tailor interventions in general practices specifically for different ethnic groups at risk of developing CVD.

According to several national and international guidelines for the prevention of cardiovascular risk factors, individuals should be the target of prevention and treatment strategies if their absolute risk to develop CVD within the next 10 years is ≥ 20%.
In **chapter 3** we determined whether the use of this inclusion criterion (absolute risk ≥ 20% based on the Framingham risk formula) leads to the exclusion of individuals with a substantial modifiable part of this risk (≥ 5%). This modifiable risk can be reduced by influencing modifiable risk factors such as smoking, and elevated levels of blood pressure and lipids. This study showed that using an absolute risk threshold ≥ 20% resulted in the exclusion of individuals with a large potential reduction in absolute risk. Of those at ≥ 20% absolute risk, 98% had a modifiable risk ≥ 5%. Among those with an absolute risk <20%, 43% still had a modifiable risk ≥ 5%. This latter group (who were relatively young and predominantly female) constituted 29% of the entire study population and might benefit from intervention strategies to prevent CVD on the long term.
Use of the proposed modifiable part of the absolute risk is of particular importance for people living in deprived neighbourhoods because of their greater risk of developing CVD than the general population, as well as their heterogeneity in terms of ethnicity and age distribution.

In **chapter 4** we examined whether the assessment of cardiovascular risk factors using self- reported data is accurate in a multi-ethnic patient population.
We compared the accuracy of self-reported diabetes, hypertension and hypercholesterolemia with information based on the general practitioner's (GP) medical records, and with a gold standard based on measurements and medication use. The level of accuracy was measured with the Cohen's kappa method. Further, we investigated whether ethnicity is associated with the accuracy of self-reports.
The accuracy of self-reported diabetes, hypertension and hypercholesterolemia varied per risk factor and depended on the data source with which they were compared. In general, the overall agreement of self-reported diabetes was substantial to almost perfect (kappa: 0.84 to 0.76). For hypertension and hypercholesterolemia the agreement was moderate to substantial (kappa: 0.63 to 0.51) and fair to moderate (0.55 to 0.48), respectively.
We did not find a significant association between ethnicity and accuracy of self-reports, except for self-reporting of diabetes among Surinamese versus Dutch indigenous patients (OR= 0.37; 95%CI: 0.14 to 0.97). Surinamese were more likely to be inaccurate in reporting diabetes than Dutch.
In conclusion, there is no marked evidence for ethnic differences in agreement between self-reported cardiovascular risk factors and medical records, or between self-reports and the defined gold standard. To confirm these findings, larger studies including multiple ethnic groups are needed.

GPs play an important role in the prevention and treatment of (risk factors for) CVD. Secondary prevention strategies in general practice based on GP guidelines could be more effective. Because of the highly experienced workload of the GPs in deprived neighbourhoods, additional personnel is required to organise this preventive care in an optimal and effective way. In addition to the general practice assistant, some new disciplines have recently been introduced, such as peer health educators and, more recently, practice nurses.

We conducted a randomised controlled trial (RCT) to examine the effectiveness of a structured collaboration of a practice nurse, a peer health educator, a general practice assistant and the GP in the general practice in reducing cardiovascular risk in patients at high risk of developing CVD.

Chapters 5, 6 and 7 present the results of this trial, carried out in three large healthcare centres (consisting of five general practices with a total of 18 GPs) located in deprived neighbourhoods of Rotterdam and the Hague.

In each general practice, two randomisations at patient level took place resulting in an intervention group and two control groups. The intervention group received intensified preventive care to develop a healthier lifestyle (more exercise, stop smoking, healthier diet, and medication compliance) and was invited to the practice for the re-assessment of the cardiovascular risk profile every three months. The first control group received usual GP care and was, like the intervention group, invited to the practice for the re-assessment of their risk profile every three months. The second control group underwent no baseline measurements, and was invited at the end of the trial in order to assess the risk profile; this patient group was kept blind during the trial to avoid any disruption of the usual care.

The intervention was based on the formation of a primary care team (GP team) in each general practice consisting of the four above-mentioned disciplines - in which the practice nurse had the coordinating role. The intervention protocol was based on the current guidelines of the Dutch College of General Practitioners for hypertension, hypercholesterolemia, diabetes and smoking cessation and described the procedures for the GP (treatment task), practice nurse (risk assessment, health education, coordination and informative task), general practice assistant (logistic task including measurements, patient recall and follow-up), and peer health educator (ethnic-specific health education).

According to this protocol, the intervention patients should be: 1) discussed during four team meetings; 2) invited for four individual health education sessions carried out by the practice nurse and/or peer health educator; 3) invited for three re-assessments of the cardiovascular risk profile. The intervention lasted for a period of 9 months; subsequently, a final measurement of the cardiovascular risk profile was performed.

Chapter 5 presents the results of a study on the effectiveness of the structured collaboration of the primary care team (Quattro care), which compared the intervention group with the first control group. A total of 275 men and women aged 30-70 years from different ethnic groups at high risk of developing CVD (i.e. having a modifiable part of risk ≥ 5%) were randomly allocated to the intervention group (n=137) and the control group (n=138). After one-year follow-up, significant reductions in cardiovascular risk were observed in the intervention group [1.76% (SE: 0.81; p=0.032)] and the control group [2.27% (SE: 0.69; p=0.001)]. However, no significant treatment effect was found between the study groups [0.88% (95%: -1.16 to 2.93)]. Most of the individual risk factors were also improved: i.e. total cholesterol, total cholesterol to HDLc ratio, and LDLc (in both study groups), HDLc and body mass index (in the intervention group only), diastolic blood pressure (in the control group only). There were, however, no relevant differences between the study groups.
We conclude that the risk profile of the intervention and the (first) group of control patients improved after one year follow-up, but no extra effect of the structured preventive care provided by the practice nurse and peer health educator on the risk for CVD was achieved.

To better understand the above-mentioned findings, we conducted a process evaluation to investigate to what extent the target group was reached regarding the intervention activities, whether the intervention was carried out as planned, and how the participants actually experienced the intervention programme. **Chapter 6** presents the results of this process evaluation.
This evaluation showed that at first instance 91% of the target group was reached; however, the subsequent reach of the different subgroups was not uniform and dropout was relatively high, particularly among younger individuals, males and ethnic minorities. The intervention activities were not completely carried out according to plan: the number of intervention components actually carried out was on average 5.66 out of 11 activities (SD: 2.8) and there were clear differences between the centres [4.84 (SD: 2.7) to 7.40 (SD: 2.80)] and between ethnic groups [4.89 (SD: 2.6) to 7.38 (SD: 2.2)] with Turkish and Moroccan participants having the lowest score for protocol completion. With regard to implementing the core of the intervention, the number of structured team meetings was relatively low and difficult to organise in daily practice; this differed between the healthcare centres. The centres adapted the intervention to suit their own conditions by adopting some of the intervention activities (e.g. periodic risk assessments and individual education sessions) and leaving out others (e.g. team meetings). Despite the low implementation rate of the intervention, healthcare personnel and the patients were generally satisfied with the intervention activities.

Based on these findings it is difficult to draw firm conclusions about the lack of effectiveness of this intervention in general practice. However, we may claim that it is relatively difficult to implement a complex intervention (such as the Quattro care) and consequently to determine its effectiveness using an RCT design in general practice.
Based on the results reported in chapters 5 and 6, we hypothesised that periodic measurements of the risk profile (offered to both the intervention group and the first control group) were responsible for the improvements observed in the cardiovascular risk profile achieved in this trial.
In **chapter 7** we aimed to quantify the effect of these periodic measurements by comparing the changes in cardiovascular risk after one year follow-up in the first control group that received usual care plus periodic measurements (UC & PM group), and the second control group that received usual care only (UC group) and in whom no baselines measurements of the risk profile were performed to avoid disruption of the usual care in general practices. At one year follow-up the 10-year absolute risk deceased by 1.33% (95% CI: -2.87 to 0.21) in the UC& PM group compared to an increase of 3.43% (95% CI: 0.93 to 5.93) in the UC group. Individual cardiovascular risk factors also showed a similar trend: i.e. a reduction in the first group and an unfavourable change in the latter group.
Although these findings should be interpreted with some caution because of various methodological limitations, they provide additional evidence that the improvements in the risk profile achieved in the parental RCT study were predominantly due to the periodic measurements and follow-up of high-risk patients.

Given the results of the studies presented in this thesis, and the fact that there is still a substantial gap in cardiovascular health between deprived and non-deprived neighbourhoods, we discuss in **chapter 8** whether all interventions (based on health education) to prevent CVD in deprived neighbourhoods are doomed to fail.
Based on previous intervention studies conducted in deprived neighbourhoods in the Netherlands, we concluded that there is little evidence for the effectiveness of interventions aimed at reducing CVD, particularly those targeting multi-ethnic populations. The interventions had no or only limited benefits in reducing the burden of CVD for the populations in deprived neighbourhoods and, although originally designed to target individuals with low socio-economic status, these interventions did not succeed in reaching relevant subgroups in the community.
Taking into account the disappointing results of the existing intervention strategies, the heterogeneity of populations living in deprived neighbourhoods and the multifactorial causality of CVD in deprived neighbourhoods, we plead for a reconsideration of the approach to the prevention of CVD in deprived neighbourhoods which until now has been based on health education. We have proposed the introduction of a pharmacological solution (i.e. the Polypill) as an alternative strategy to the 'health education' type

of intervention. This 'pharmacological' intervention is much less dependent on environmental factors related to CVD and may be effective in closing the gap in CVD between populations on the short term. Finally, we have addressed the potential of this latter intervention strategy taking into consideration the arguments both for and against its use in general practice.

SAMENVATTING

Hart- en vaatziekten zijn nog steeds de belangrijkste oorzaak van sterfte en ziekte in Nederland. Hoewel er grote vooruitgang is geboekt in de preventie van hart- en vaatziekten op nationaal niveau, lopen bewoners van achterstandswijken een groter risico op het ontwikkelen van hart- en vaatziekten (HVZ) dan de totale bevolking. Achterstandswijken worden gekenmerkt door relatief veel mensen met een lagere sociaal- en economische status. Veel mensen in achterstandswijken vooral in grote steden behoren tot etnische minderheidgroeperingen.
Een groot deel van de gezondheidswinst die door preventie kan worden bereikt, is te behalen door toekomstige interventies op het gebied van preventie van HVZ te richten op bewoners van achterstandswijken. Dit proefschrift beschrijft een dergelijke interventie en zal uitgebreid ingaan op de problemen rondom de opzet, implementatie en evaluatie van deze interventie. In het bijzonder zal worden ingegaan op de identificatie van mensen met een verhoogd risico op het ontwikkelen van een hart- of vaatziekte, de vaststelling van de prevalentie van cardiovasculaire risicofactoren en de ontwikkeling van een interventie gericht op de specifieke behoeftes van de doelgroep.

Hoofdstuk 1 beschrijft de achtergrond van het proefschrift. De opbouw en de doelstelling van het proefschrift worden in dit hoofdstuk uitgewerkt.
Hoofdstuk 2 en **3** hebben betrekking op het vaststellen welke individuen een verhoogd risico hebben op het krijgen van een hart- of vaatziekte.
In hoofdstuk 2 wordt de prevalentie van risicofactoren voor HVZ van autochtone Nederlanders vergeleken met mensen uit andere etnische groeperingen. Deze studie laat zien dat mensen uit etnische minderheden (Turken, Marokkanen, Surinamers en Antillianen) een veel groter risico (OR=3.2 tot 19.4) op diabetes hebben dan autochtone Nederlanders. En verhoogd cholesterolgehalte (hypercholesterolemie) komt bij deze groepen minder vaak voor dan bij autochtone Nederlanders. Vergeleken met autochtone Nederlanders komt extreem overgewicht (obesitas) bij mensen met een Turkse achtergrond 2.4 vaker voor. Ook rapporteren mensen met een niet-Nederlandse achtergrond minder vaak dan Nederlanders dat ze roken (OR=0.10-0.53). Van alle mannen bevinden zich onder de Turken het grootste aantal rokers en onder alle vrouwen zijn het de Nederlandse vrouwen die het meeste roken. Wat betreft hoge bloeddruk (hypertensie) komen de verschillende etnische groeperingen ongeveer overeen.
Deze studie toont aan dat er een grote heterogeniteit is in de patiëntenpopulatie in de huisartspraktijk in achterstandswijken, niet alleen qua etnische samenstelling, leeftijdsopbouw, opleidingsniveau, maar ook in de mate waarin risicofactoren voor HVZ voorkomen. De resultaten laten zien dat er meer aandacht moet worden besteed aan preventieve activiteiten in de huisartspraktijk toegespitst op diabetes (alle

etnische minderheidsgroeperingen), roken (Turkse mannen en Nederlandse vrouwen), overgewicht (Turken) en hypercholesterolemie (Nederlanders).

Volgens allerlei nationale en internationale richtlijnen voor de preventie van risicofactoren voor HVZ komen patiënten pas in aanmerking voor preventie en behandeling wanneer hun risico op het ontwikkelen van een hart- of vaatziekte binnen de komende 10 jaar gelijk is aan of groter dan 20%. Het absolute risico is het risico dat iemand zelf werkelijk loopt en is opgebouwd uit een zogenaamd niet modificeerdaar deel en een modificeerbaar deel. Dit modificeerbaar deel kan beïnvloed worden door te interveniëren op modificeerbare risicofactoren voor HVZ zoals roken en verhoogde waardes van de bloeddruk en het cholesterol. Echter door het gebruiken van het 10 jaar absolute risico als criterium voor inclusie van mensen in preventieve activiteiten, kan een grote groep mensen met een relatief hoog (modificeerbaar) risico worden gemist.
Hoofdstuk 3 behandelt de vraag hoe hoog het percentage individuen is met een hoog modificeebaar risico (≥ 5%) dat niet in aanmerking komt voor preventie bij het gebruiken van het criterium van een absoluut risico ≥ 20%.
De resultaten van deze studie laten zien dat onder de patiënten met een absoluut risico op een HVZ ≥ 20%, 98% een modificeerbaar deel ≥ 5% heeft. Van de groep met een 10-jaars absoluut risico < 20%, heeft 43% een modificeerbaar deel van het risico ≥ 5%. Deze laatste groep, bestaande uit relatief jonge mensen en vrouwen, vormt maar liefst 29% van de totale studiepopulatie en zou kunnen profiteren van interventie strategieën.
Het toepassen van het voorgestelde modificeerbare deel van het absolute risico in plaats van het absolute risico is vooral van belang voor bewoners van achterstandswijken aangezien zij een groter risico lopen op het krijgen van HVZ dan de totale bevolking, vanwege hun etnische samenstelling en leeftijdsopbouw.

Hoofdstuk 4 beantwoordt de vraag of het vaststellen van de prevalentie van cardiovasculaire risicofactoren door middel van zelfrapportage bij mensen uit verschillende etnische groeperingen betrouwbaar is. Onderzocht werd of zelfrapportage van diabetes, hoge bloeddruk en hoge cholesterol overeenkomt met geregistreerde data in medische dossiers van huisartsen en met een gouden standaard van de betreffende risicofactoren die is gebaseerd op metingen en medicijnengebruik. De mate van overeenstemming werd berekend volgens de Cohen's Kappa methode. Verder is nagegaan of er een verband is tussen de etnische achtergrond van de patiënt en de mate waarin zelfrapportage van deze cardiovasculaire risicofactoren overeenkomt met de andere databronnen.
Deze studie laat zien dat de mate van overeenstemming van zelfrapportage verschilt per risicofactor en afhankelijk is van de databron waarmee de zelfrapportage vergeleken wordt. Over het algemeen was er een (zeer) goede overeenstemming van

zelfgerapporteerde diabetes met andere databronnen (kappa: 0.84-0.76), een redelijk goede overeenstemming voor hoge bloeddruk (kappa: 0.63-0.51) en een matige overeenstemming voor hoge cholesterol (0.55-0.48).
Er werd geen statistisch significant verband gevonden tussen etnische achtergrond en mate van overeenstemming, met één uitzondering; Surinamers zijn meer geneigd tot het over of onderrapporteren van diabetes dan autochtone Nederlanders (OR= 0.37; 95%CI: 0.14 tot 0.97).
Concluderend kan gesteld worden dat er geen hard bewijs is gevonden in deze studie voor de aanwezigheid van etnische verschillen in de mate van overeenstemming van zelfgerapporteerde cardiovasculaire risicofactoren vergeleken met medische dossiers of de gouden standaard. Aanvullend grootschalig onderzoek waarin verschillende etnische groeperingen vertegenwoordigd zijn, is noodzakelijk om deze bevindingen te bevestigen.

Behandeling van risicofactoren voor HVZ (secundaire preventie) neemt binnen de huisartsenzorg een belangrijke plaats in. Het naleven van de hiervoor verschenen richtlijnen en protocollen vergt een flinke inspanning van de huisarts waardoor de noodzaak tot het delegeren van een deel van de taken steeds groter is geworden. Naast de praktijkassistente is de laatste jaren extra hulp gekomen in de vorm van allochtone zorgconsulenten (AZC) en praktijkondersteuners huisartsen (POH).
Volgens het design van een gerandomiseerde gecontroleerde trial (RCT) is de effectiviteit van een gestructureerde samenwerking in de huisartspraktijk tussen een POH, AZC, de huisartsassistente en de huisarts (zgn. Quattro-zorg) onderzocht op het verlagen van het risico op hart-en vaatziekten bij mensen met een verhoogd risico.
In de hoofdstukken 5, 6 en 7 worden de resultaten van dit experiment dat is uitgevoerd in drie grote gezondheidscentra (5 huisartspraktijken met in totaal 18 huisartsen) geselecteerd uit achterstandwijken van Rotterdam en Den Haag gepresenteerd.
In elke huisartspraktijk zijn de geselecteerde patiënten gesplitst in één interventie groep en twee controle groepen. De interventie groep kreeg na zorgvuldig onderzoek intensieve medische begeleiding en hulp bij het bereiken van een gezondere leefstijl (meer bewegen, gezond eten, stoppen met roken) en werd drie maandelijks opgeroepen voor het vaststellen van het cardiovasculair risicoprofiel. De eerste controle groep kreeg normale zorg van de huisarts, maar werd daarnaast evenals de patiënten uit de interventie groep iedere drie maanden zorgvuldig onderzocht. De tweede controle groep is een "geblindeerde" groep die geen voor-meting heeft ondergaan, maar na afloop van het onderzoek eenmalig is onderzocht. Patiënten uit deze groep zijn mensen die ook in aanmerking zouden kunnen komen voor deze interventie maar omdat de huisarts gedurende het onderzoek niet wist welke patiënten dit waren, zal hij/zij deze niet anders behandeld hebben dan zoals dit normaal gebeurt.

De interventie bestond uit het samenstellen van een eerstelijns team in elk huisartspraktijk bestaande uit de vier bovengenoemde disciplines waarbij als leidraad voor de behandeling van patiënten een protocol is ontwikkeld gebaseerd op NHG standaarden hypertensie, hypercholesterolemie, diabetes mellitus type 2 en de Minimale Interventie Strategie voor stoppen met roken. Volgens dit protocol zouden interventie patiënten: 1) vier maal besproken worden (individueel of als groep) door het eerstelijns team onder leiding van de POH tijdens teamvergaderingen georganiseerd in de huisartspraktijk; 2) vier maal individueel opgeroepen worden naar de huisartspraktijken voor een begeleidingssessie door de POH en/of AZC (inclusief een intakegesprek); 3) drie maal opgeroepen worden voor bepalingen van het cardiovasculaire risicoprofiel. De interventieperiode die 9 maanden duurde, werd afgesloten met een nameting in zowel de interventie en als controle groep patiënten.

Hoofdstuk 5 beschrijft de resultaten van de extra inzet van de praktijkondersteuner en de allochtone zorgconsulente door de interventie groep te vergelijken met de eerste controle groep (die periodieke metingen ontving naast normale huisartsenzorg). In totaal werden 275 mannen en vrouwen tussen 30-70 jaar uit verschillende etnische groepen en met een verhoogd cardiovasculair risico (een modificeerbaar deel van het 10-jaar absolute risico ≥ 5%) verdeeld over de interventie (n=137) en de (eerste) controle groep (n=138).

Na een vervolg periode van één jaar, is zowel binnen de interventie groep als de controle groep een significante daling van het absolute risico waargenomen. De veranderingen waren resp. 1.76% (SE: 0.81; p=0.032) voor de interventie groep en 2.27% (SE: 0.69; p=0.001) voor de controle groep. Er kon echter geen significant verschil tussen beide onderzoeksgroepen [0.88% (95%: -1.16 tot 2.93)] worden aangetoond.
De meeste individuele risico factoren voor HVZ zijn eveneens gunstiger geworden: totale cholesterol, totale cholesterol/HDLc, and LDLc (in beide groepen), HDL-c en Body Mass Index (alleen de interventiegroep), diastolische bloeddruk (alleen controle groep). Ook hier zijn geen statistische significante verschillen gevonden tussen beide onderzoeksgroepen.
Op basis van deze resultaten concluderen we dat het risicoprofiel van zowel de interventie als de controle groep was verbeterd na één jaar gevolgd te zijn en dat gestructureerde preventieve zorg door een praktijkondersteuner en een allochtone zorgconsulente geen extra gunstig effect had boven periodieke bepalingen van het cardiovasculair risicoprofiel.

Om de onderzoeksresultaten beter te kunnen begrijpen is een procesevaluatie uitgevoerd met als doel 1) het bereik onder de doelgroep te beschrijven, 2) na te gaan of de interventie volgens plan is uitgevoerd en 3) de ervaringen te inventariseren van

de deelnemers met betrekking tot het interventie programma. In **hoofdstuk 6** wordt hierover gerapporteerd.
De resultaten laten zien dat weliswaar in eerste instantie 91% van de doelgroep werd bereikt maar dat niet alle verschillende subdoelgroepen even adequaat werden bereikt en dat de uitval met name onder jongeren, mannen en allochtonen groot was. De interventie activiteiten waren niet geheel volgens plan uitgevoerd. De gemiddelde score voor de uitvoering van de interventie activiteiten was 5.7 van de 11 activiteiten (SD 2.8) waarbij er duidelijke verschillen aanwezig waren tussen de centra [4.8 (SD 2.7) tot 7.4 (SD 2.8)] en etnische groepen [4.9 (SD 2.6) tot 7.34 (SD 2.2)]. Hierbij was het aantal uitgevoerde activiteiten het laagst onder Turkse en Marokkaanse patiënten. De uitvoerbaarheid van de kernactiviteit van de interventie, namelijk de gestructureerde team bijeenkomsten was beperkt en bleek moeilijk in de dagelijkse praktijk, maar verschilde wel per huisartspraktijk.
Ondanks de beperkte implementatie van het interventieprogramma, waren zowel het personeel van de huisartspraktijk als de patiënten over het algemeen tevreden over de interventie activiteiten.
Gelet op het feit dat de interventie niet geheel volgens plan is uitgevoerd, is het moeilijk op basis van deze bevindingen harde uitspraken te doen over de afwezigheid van een effect ervan in de huisartspraktijk. In het algemeen kan gesteld worden dat de dagelijkse praktijk veel te weerbarstig is om een complexe interventie zoals de Quattro-zorg interventie uit te voeren en de effectiviteit hiervan door middel van een RCT design te bepalen.

Gebaseerd op de resultaten uit hoofdstuk 5 en 6 formuleerden we de hypothese dat periodieke metingen van het risicoprofiel (aangeboden aan zowel de interventie als de eerste controle groep) verantwoordelijk waren voor de gunstige veranderingen in het cardiovasculair risicoprofiel aangetoond in deze trial.
In **hoofdstuk 7** hebben we geprobeerd het effect van deze periodieke metingen te kwantificeren door een vergelijking te maken van de veranderingen in het cardiovasculair risico na één jaar follow-up tussen de controle groep die periodieke metingen naast normale huisartsen ontving en de tweede controle groep, die alleen normale huisartsenzorg heeft gehad en waarbij geen voormeting is uitgevoerd om verstoring van de dagelijkse gang van zaken in de huisartsenpraktijk te vermijden.
Na afloop van het onderzoek bleek het 10-jaars absolute risico op HVZ bij de eerste groep te zijn gedaald met 1,33% (95% CI: -2.87 tot 0.21) terwijl er sprake was van een toename van dit risico van 3.43% (95% CI: 0.93 tot 5.93) in de tweede controle groep. Ook andere risicofactoren leken ongunstiger te zijn ontwikkeld in de laatste groep terwijl in de eerste groep wel een verbetering optrad.

Hoewel deze bevindingen met enige voorzichtigheid geïnterpreteerd dienen te worden wegens methodologische beperkingen van het gekozen RCT design, kan gesteld worden dat de gunstige ontwikkeling van het risicoprofiel in de eerste controle groep er niet zou zijn geweest wanneer er geen periodieke metingen zijn uitgevoerd.
Deze studie levert extra bewijs om te concluderen dat het gunstige effect op het risicoprofiel aangetoond in dit experiment toegeschreven kan worden aan de periodieke bepalingen van het cardiovasculair risicoprofiel en het volgen van hoogrisico patiënten in de huisartspraktijk.

Tot slot wordt in **hoofdstuk 8** bediscussieerd of alle interventies gericht op de preventie van (risicofactoren voor) hart-en vaatziekten welke gebaseerd zijn op gezondheidsvoorlichting en -educatie in achterstandswijken gedoemd zijn te mislukken. Ondanks de grote investeringen in preventie, is er nog steeds sprake van een grote kloof in de mate waarin risicofactoren voor HVZ voorkomen in achterstandswijken in vergelijking met meer welgestelde wijken.
Gebaseerd op de resultaten van de in dit proefschrift beschreven interventie en eerdere recent uitgevoerde interventie studies in Nederlandse achterstandswijken, concluderen we dat er weinig bewijs is voor de effectiviteit van interventies die als doel hebben (risicofactoren op) HVZ in achterstandswijken te verlagen. De beschikbare informatie liet bovendien zien dat de interventies geen of slechts een beperkt effect hadden. Over het algemeen werden allochtonen, mensen met de laagste opleiding en mannen het minst bereikt met de interventieactiviteiten en was de uitval onder deze groeperingen het grootst.
Rekening houdend met de teleurstellende resultaten van de bestaande interventiestrategieën die gebaseerd zijn op gezondheidsvoorlichting en -educatie, de (etnische) heterogeniteit van de bewoners van achterstandswijken en de multifactoriële oorzaken van HVZ in achterstandswijken, pleiten we voor een herziening van de benadering en de aanpak van de preventie van hart-en vaatziekten in zulke wijken. In plaats van een strategie die weer gebaseerd is op gezondheidsvoorlichting en educatie, wordt een farmaceutische oplossing voorgesteld (Polypill) welke niet afhankelijk is van omgevingsfactoren en die op korte termijn de grote kloof in het voorkomen van HVZ tussen achterstandswijken en welgestelde wijken kan verkleinen. Tevens worden de argumenten voor en tegen het toepassen van deze alternatieve strategie bediscussieerd.

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Curriculum vitae

Fatima El Fakiri was born in 1966 in Imzouren (Alhoceima region), Morocco. After passing her secondary school examination (baccalaureate *Sciences Experimentales*) at the Lyceum in Imzouren, in 1985 she emigrated to the Netherlands in the framework of family reunification. After passing the university entrance examination (*colloquium doctum*) and learning the Dutch language, in 1987 she started her studies on Human Nutrition at the Wageningen Agricultural University and graduated from there in 1993. At that same time she followed several courses at Leiden University related to ethnic minorities in Dutch society. After working for some years in the field of welfare work, in 1996 she started her research career at the NIVEL institute in Utrecht where she conducted and participated in various research projects focusing on the access to and quality of healthcare for ethnic minorities. From 2001 to the end of 2005 she worked at the Institute of Health Policy and Management of the Erasmus Medical Centre Rotterdam on the studies that resulted in this thesis. The author is currently working for the National Institute for Public Health and the Environment (RIVM) in Bilthoven.