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# Is a targeted and planned GP intervention effective in cardiovascular disease prevention? A randomized controlled trial

Authors' Contribution:  
Study Design A  
Data Collection B  
Statistical Analysis C  
Data Interpretation D  
Manuscript Preparation E  
Literature Search F  
Funds Collection G

ABCDE 1 **Ksenija Kranjčević**  
ADE 2 **Biserka Bergman Marković**  
ABE 3 **Dragica Ivezić Lalić**  
ABCE 4 **Davorka Vrdoljak**  
ABE 5 **Jasna Vučak**

1 General Practice Office, Zagreb-Zapad Health Care Center, Zagreb, Croatia  
2 Department of Family Medicine, University of Zagreb, School of Medicine, Zagreb, Croatia  
3 General Practice Office, Kutina Health Care Center, Novska, Croatia  
4 Department of Family Medicine, University of Split, School of Medicine, Split, Croatia  
5 General Practice Office, Sukošan, Croatia

**Corresponding Author:** Ksenija Kranjčević, e-mail: [ksenija.kranjcevic@inet.hr](mailto:ksenija.kranjcevic@inet.hr)

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**Background:** The optimal intensity and duration of the intervention to achieve sustained risk reduction in patients at high and very high cardiovascular (CV) risk still need to be established. The aim of this study was to evaluate the impact of general practitioner's (GP's) systematic and planned intervention on total CV risk reduction and a change in individual CV risk factors.

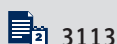
**Material/Methods:** This was a cluster-randomized trial (ISRCTN31857696) including 64 practices and 3245 patients aged  $\geq 40$ . The participating GPs and their examinees were randomized into an intervention or to a control group (standard care). Intervention group practitioners followed up their examinees during 1, 3, 6, 12, and 18 months. The main outcome measures were change in proportion of patients with low, moderate, high, and very high CV risk, and change in individual CV risk factors from the first to the second registration.

**Results:** The proportion of patients with very high CV risk was lower in the intervention group, the same as of patients with high blood pressure, total and LDL cholesterol, and increased intake of alcohol. The mean systolic ( $-1.49$  mmHg) and diastolic ( $-1.57$  mmHg) blood pressure, triglycerides ( $-0.18$  mmol/L), body mass index ( $-0.22$ ), and waist ( $-0.4$  cm) and hip circumference ( $-1.08$  cm) was reduced significantly in the intervention group. There was no additional impact in the intervention group of other tested CV risk factors.

**Conclusions:** Systematic and planned GP's intervention in CVD prevention reduces the number of patients with very high total CV risk and influences a change in lifestyle habits.

**MeSH Keywords:** **Preventive Medicine • General Practitioner • Cardiovascular Diseases • Advance Care Planning**

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## Background

Because cardiovascular diseases (CVD) are still the leading cause of mortality in the world, the World Health Organization in 2011 agreed to take concerted action to reduce mortality from CVD by 25% by 2025 [1]. Primary and secondary prevention of CVD is a high priority, and it is reflected in current guidelines of many national societies such as the European Society of Cardiology (ESC) and the National Institute for Health and Care Excellence [2,3]. Optimal screening strategies for identifying patients at high risk for developing CVD have been studied extensively and various sorts of interventions have been undertaken [4]. Assessment of CVD risk is a key to efficient cardiovascular prevention. It is important that individuals at risk of developing CVD can be effectively identified and appropriately stratified. The ESC recommended the Systematic Coronary Risk Evaluation (SCORE) chart for the total cardiovascular (CV) risk assessment. Change in lifestyle habits is recommended to all patients except to those with low CV risk, and pharmacotherapy is recommended to patients with high and very high CV risk [2].

The evidence shows that general practitioners (GPs) are the key persons to initiate, coordinate, and provide long-term follow-up for CVD prevention because in most countries they take care of >90% of the population [2]. The strength of general practice is its accessibility to the population. It has been proven that in most European countries, more than 60% of the population consults their GP at least once a year [5]. According to ESC guidelines, a GP should assess the total CV risk for every adult man  $\geq 40$ , and woman  $\geq 50$  years of age or the postmenopausal [2]. There are multiple barriers to the implementation of risk-adjusted prevention in a general practice setting, especially the fact that prevention is time-consuming [6]. The use of risk scoring based on an electronic patient record is promising [7]. In Croatia, where this study was conducted, all GPs had been electronically recording patient data with an integrated total CV risk calculator since 2005. Systematized and precisely planned intervention by a GP leads to a reduction of total CV risk. Considering single risk factors included in the charts for total CV risk assessment, the best outcome has been achieved in the regulation of dyslipidemia and hypertension. The aim of this study was to evaluate the impact of GP's systematic and planned intervention on total cardiovascular risk reduction and change in individual CV risk factors.

## Material and Methods

### Study design

The study was conducted as part of the Cardiovascular Risk and Intervention Study in Croatia – family medicine (CRISIC-fm). It was a multicentric, randomized, prospective, cohort and

intervention study, conducted in 2 phases (cross-sectional and intervention) and registered as clinical research (International Standard Randomized Controlled Trial Number Register – ISRCTN31857696). Sixty-four GPs from all over Croatia participated in the study and every GP included up to 55 patients aged  $\geq 40$ , who had visited their office for any reasons from May to July 2008 and signed the informed consent to participate. The representative sample of GP offices was selected by the 4-stage stratification method: district (21 districts), region (coastal and continental), town size (up to 3999 inhabitants, 4000–9999, 10 000–29 999, 30 000–89 999, and 90 000 inhabitants and more) and the number of insured subjects contracted between GPs and the Croatian Institute for Health Insurance in 2007 (national compulsory health insurance system covering 97% of the population). General practitioners (N=64) and patients were randomly allocated to usual care as a control group (N=32) and to an active and planned intervention group (N=32). The sample size of 55 participants included by each GP was obtained by the statistical power analysis (minimum 80% with 95% confidence interval [CI]). Exclusion criteria were the inability to communicate (e.g., dysphasia and aphasia), dementia, and expected survival under 6 months. All examinees were prospectively followed up. At 18 months after the first visit, they filled in a questionnaire identical to the one used at the beginning of the study, including anthropometric measurements and blood analyses. The study was approved by the Ethics Committee of the Medical Faculty in Zagreb.

### Questionnaire

We used the CRISIC-fm, which is a standardized, validated questionnaire with 140 questions, designed for the study, including socio-demographic, socio-economic, personal and family history data, psychological determinants, data about the diet and lifestyle habits, physical activity, and pharmacological therapy of the participants.

### Guidelines

We used the SCORE chart from 2012 for total CV risk assessment to group the examinees aged 40–69. The SCORE system estimates the 10-year risk of the first fatal atherosclerotic event by considering the effect of the major factors: age, sex, smoking, systolic blood pressure, total cholesterol, and high-density lipoprotein cholesterol. Subjects with a SCORE  $< 1\%$  were categorized as low risk, those with a SCORE was  $\geq 1\%$  and  $< 5\%$  were categorized as moderate risk, and all those with a calculated SCORE  $\geq 5\%$  and  $< 10\%$  were categorized as high risk. Participants who at the time of study had CVD, diabetes, or chronic kidney disease (CKD), or had a SCORE  $\geq 10\%$  were considered as very high-risk subjects. CVD was defined as previous myocardial infarction, acute coronary syndrome, coronary and other arterial revascularization, ischemic stroke,

angina pectoris, and peripheral arterial disease. Moderate-to-severe CKD was considered as glomerular filtration rate  $<60$  ml/min/1.73 m<sup>2</sup> [2]. All participants who smoked or had stopped smoking within a year before the beginning of the study were considered to be smokers. Blood pressure was measured (arithmetic mean of 2 measurements with a mercury sphygmomanometer), and a fasting blood sample for the analysis of total cholesterol concentration, HDL and LDL cholesterol, triglycerides, glucose, and creatinine was taken from each participant. Target values of blood pressure were  $\leq 140/90$  mmHg in examinees with low or moderate risk and  $\leq 130/80$  mmHg in examinees with high or very high risk. Target values of total cholesterol in patients at low and moderate CV risk were considered to be  $\leq 5.0$  mmol/L, HDL-cholesterol  $\geq 1.03$  mmol/L for men and  $\geq 1.29$  mmol/L for women, and those of LDL-cholesterol  $\leq 3.0$  mmol/L. Target values of total cholesterol in patients at high and very high total CV risk were considered to be  $\leq 4.0$  mmol/L, and of LDL-cholesterol  $\leq 2.5$  mmol/L. Target value of triglycerides in all examinees was  $\leq 1.7$  mmol/L, body mass index (BMI) 20–24.99 kg/m<sup>2</sup>, and waist circumference  $\leq 90$  cm for men and  $\leq 80$  cm for women [8].

### Intervention group

Treatment of examinees in the intervention group was based on the ESC guidelines for the CVD prevention from 2007, which were adopted by the Croatian Cardiac Society [8]. GPs in the intervention group received printed educational materials, with precise and standardized protocols for counselling on healthy life style habits and pharmacotherapy, as well as tables for following up the examinees (at 1, 3, 6, 12, and 18 months) and educational leaflets for the examinees. GPs drafted individual personal plans with precise goals to correct the CV risk factors for each examinee in the intervention group that could be achieved in a given period. GPs in the intervention group participated in 2 repeated case-based training during a 6-month period.

### Control group

GPs in the control group received general information about the study and instructions about filling in the questionnaires, and they followed up and provided their examinees with the same standard care they had applied in the treatment of such patients before. GPs in the control group did not have printed educational materials and tables to follow up the patients, nor did they have educational leaflets for the examinees and additional organized workshops.

### Statistical analyses

Pre-study power calculation indicated that a trial with 64 GPs each including up to 55 patients had a power of 80% to detect

a difference between the intervention and control group. The GP population in this study was very similar with respect to age, sex, and education. Multifactor analysis of variance (ANOVA) was used to detect differences before and after the intervention in intervention and control groups by assessing differences between repeated measurements (total CV risk according to SCORE chart, blood pressure, total cholesterol, HDL and LDL cholesterol, and triglycerides). Differences between the values of nominal variables (smoking) before and after the intervention were tested by McNemar's dependent test. Test results for both groups (the intervention and the control) were calculated for each variable and the conclusion on the efficacy of GP's intervention was inferred on the basis of the pattern of results. All obtained values were interpreted according to their level of significance of 95% (CI 95%,  $p < 0.05$ ). The SAS U statistical program was used for data processing (licence of Ministry of Science, Education, and Sport).

## Results

Out of 1957 examinees included at the beginning (N=59 GPs), 1497 examinees aged 40–69 years completed this study (N=51 GPs), giving a response rate of 76.5% (Figure 1.).

At the beginning of this study, out of the total number of examinees (N=1957), 25.9% were at low, 40.2% were at moderate, 18.6% were at high, and 15.5% were at very high risk of fatal CVD according to the SCORE chart. Examinees at low risk were more often female and aged 40–49, unlike examinees at high and very high risk, who were more often male and older. Most of the patients with hypertension, elevated values of total and LDL cholesterol, lower values of HDL cholesterol, and smokers were at moderate risk for fatal CVD (Table 1).

At the beginning of the study, the intervention and the control group had almost identical distribution of total CV risk, sex, hypertension, elevated values of total cholesterol, lower values of HDL cholesterol, smokers, those who abused alcohol, and those who were physically active, while the participation of subjects with elevated values of LDL cholesterol was slightly higher in the intervention group (Table 2).

After 18 months, the study was completed with 1497 examinees aged 40–69, with 832 (55.6%) in the intervention group and 665 (44.4%) in the control group. regarding the total CV risk, 15.0% of examinees were at low, 41.1% at moderate, 19.4% at high, and 24.5% at very high risk. We found a significant difference in the distribution of the total CV risk between the examinees in the intervention group and those in the control group at very high risk ( $P < 0.001$ ). Although there was an increase in the participation of examinees with very high risk in both test groups, it was significantly higher in the

**Table 1.** Baseline characteristics of all examinees regarding total CV risk.

Risk factors	SCORE risk							
	Low N (%)		Moderate N (%)		High N (%)		Very high N (%)	
Sex								
Male	67	(9.0)	277	(37.4)	214	(28.9)	183	(24.7)
Female	437	(36.0)	509	(41.9)	147	(12.1)	121	(10.0)
Age								
40–49	336	(67.2)	106	(21.2)	28	(5.6)	30	(6.0)
50–54	128	(31.7)	194	(48.0)	41	(10.1)	41	(10.1)
55–59	27	(6.1)	252	(56.5)	98	(22.0)	69	(15.5)
60–64	13	(3.6)	166	(46.2)	99	(27.6)	81	(22.6)
65–69	2	(0.8)	68	(27.4)	95	(38.3)	83	(33.5)
High blood pressure (mmHg)	161	(14.0)	439	(38.2)	275	(23.9)	275	(23.9)
High total cholesterol (mmol/L)	304	(20.4)	646	(43.4)	288	(19.4)	249	(16.7)
Low HDL-cholesterol (mmol/L)	77	(21.1)	150	(41.1)	74	(20.3)	64	(17.5)
High LDL-cholesterol (mmol/L)	233	(21.4)	502	(46.1)	192	(17.6)	161	(14.8)
Smokers	133	(29.6)	179	(39.8)	81	(18.0)	57	(12.7)

control group. Examinees at low and moderate risk were more represented in the intervention group, while the incidence of high risk examinees was equal in both groups. Regarding single risk factors, the intervention group was more successful in blood pressure regulation, hypercholesterolemia, reaching target values of LDL cholesterol, and reduced consumption of alcohol. Thus, the planned intervention did not prove efficient in reducing smoking, increasing physical activity, and reaching target values of HDL cholesterol (Table 3).

Significant differences in average values of the examined risk factors showed in blood pressure, triglycerides, BMI, and waist and hip circumference. Values of systolic and diastolic blood pressure, triglycerides, BMI, and waist and hip circumference at the end of the study were lower in the intervention group, while in the control group these values increased. Although at the end of the study, average values of total, HDL, and LDL cholesterol were lower in the intervention group, no significant difference was found compared to the control group (Table 4).

## Discussion

Results of our study showed that in the planned GP intervention in CV risk factors at defined periods of 1, 3, 6, 12, and 18 months, efficacy was achieved only in examinees with very high CV risk. These results may be because GPs are more focused

on reaching target values of CV risk factors in patients with very high risk, and that these patients are also more motivated and persevering in following their doctor's advice and in taking their medicines more regularly. Intervention planned this way did not show a difference in high risk patients compared to the control group, so we may assume that the education of GPs was insufficient, but it proved its efficacy in achieving target values of blood pressure and total and LDL cholesterol. Among the CV risk factors that change with a change of lifestyle, efficacy was demonstrated in the reduction of BMI and alcohol consumption, but the participation of smokers and physically active subjects did not change. Short motivating interview of patients conducted by the GP, followed by printed educational materials, had no or only marginal impact. Several studies proved the need for including local communities, public health resources, the media, and legislation in solving the massive problem posed by unhealthy lifestyles [9].

In most intervention studies in the prevention of CVD, the best results were achieved in high-risk patients with diagnosed CVD (at very high risk according to ESC/ESH guidelines from 2012), but not in subjects at moderate and low total cardiovascular risk, which conforms to the results of our study [10]. Results of a 1-year prospective study of prevention activities to reduce CVD in Canada with obligatory follow-up of the subjects every 6 months, showed a 24.5% reduction of CV risk in the intervention group, as compared to

**Table 2.** Baseline characteristics of patients between intervention and control group.

	Intervention group (N=1086) N (%)		P	Control group (N=871) N (%)	
SCORE risk					
Low	295	(27.2)	0.515	211	(24.2)
Moderate	451	(41.5)	0.537	335	(38.5)
High	186	(17.1)	0.055	175	(20.1)
Very high	154	(14.2)	0.449	150	(17.2)
Sex					
Females	679	(62.5)	0.079	535	(61.4)
Males	407	(37.5)	0.088	336	(38.6)
High blood pressure (mmHg)	613	(56.4)	0.693	537	(61.7)
High total cholesterol (mmol/L)	821	(75.6)	0.184	666	(76.5)
Low HDL-cholesterol (mmol/L)	188	(17.3)	0.690	177	(20.3)
High LDL-cholesterol (mmol/L)	667	(61.4)	0.025	421	(48.3)
Smokers	261	(24.0)	0.833	189	(21.7)
High alcohol intake	288	(26.5)	0.153	208	(23.9)
Physically active	922	(84.9)	0.483	713	(81.9)

only 9.9% in the control group (in which the reduction was in the primary prevention, without differences in the secondary) [11]. Planned 1-year follow-up of physical activity according to ESC guidelines in Sweden showed significant decreases in BMI, waist-hip ratio, systolic and diastolic blood pressure, triglycerides, and glycosylated hemoglobin [12]. Our study, in which subjects were followed up throughout 1, 3, 6, 12, and 18 months, showed similar results, which leads to the conclusion that a precisely defined approach to preventive activities and the evaluation of GP's work are needed in the prevention of CVD. A randomized and controlled study by Björknäs from 2003 to 2006 about the cost-effectiveness and efficacy of a systematized and planned intervention in the primary health care in high risk patients during 3, 12, 24, and 36 months also showed significant reduction of CV risk factors [13]. Similar results were shown by a study conducted in Finland [14]. In addition to the accepted national guidelines, aggressive application of nationally recommended prevention activities could prevent a high proportion of CVD. A simple decision based on calculating absolute individual CVD risk and promoting shared decision-making in CVD prevention can be disseminated through continuing medical education of family physicians groups and may lead to higher patient satisfaction [15,16]. It was demonstrated that the use of case-based training to implement evidence-based practice

in primary care was associated with decreased mortality at 10 years in patients with CHD [17].

With regard to single CV risk factors, intervention achieved best results in lowering and reaching target blood pressure. A 12-month Canadian intervention study also showed significant decrease of systolic blood pressure in the intervention group compared to the control group, as well as reduced total cholesterol values in subjects at high and very high risk [11]. Results of our study showed the intervention efficacy by the decreased number of subjects with elevated values of total and lowered values of LDL cholesterol, but not of HDL cholesterol. A similar intervention study was conducted in the Netherlands, where examinees were followed up at 3, 9, and 18 months, which also showed a significant decrease in LDL cholesterol values in the intervention group [18]. Efficacy in the regulation of these CV risk factors are explained by better availability of drugs on the market and because patients find it easier to take medicines than to change their lifestyle habits. Nevertheless, in the long term, patients who are subjective-ly not feeling any effects are often inclined to stop taking prescribed drugs. Additionally, there is "practitioners' inertia" in changing the drug and/or its dosage. Successful treatment of arterial hypertension and dyslipidemia depends, among other things, on adverse effects and the number of drugs a patient

**Table 3.** Effect of the intervention on the change in the proportion of patients with CV risk.

	Intervention group (N=832)			P*	Control group (N=665)		
	2010 N (%)	Change from 2008 to 2010 (%)	Test for change from 2008 to 2010		2010 N (%)	Change from 2008 to 2010 (%)	
<b>SCORE risk</b>							
Low	139 (16.7)	-10.5	0.900		85 (12.8)	-11.4	
Moderate	361 (43.4)	+1.9	0.461		255 (38.3)	-0.2	
High	162 (19.5)	+2.4	0.822		128 (19.2)	-0.9	
Very high	170 (20.4)	+6.2	<0.001		197 (29.6)	+12.4	
<b>Sex</b>							
Females	534 (64.2)	+1.7	0.079		416 (62.6)	+1.2	
Males	298 (35.8)	-1.7	0.052		249 (37.4)	-1.2	
↑ blood pressure (mmHg)	520 (62.5)	+6.1	0.014		483 (72.6)	+10.9	
↑ total cholesterol	657 (78.9)	+3.3	<0.001		501 (75.3)	-1.2	
↓ HDL-cholesterol (mmol/L)	179 (21.5)	+4.2	0.332		145 (21.8)	+1.5	
↑ LDL-cholesterol (mmol/L)	548 (65.9)	+1.07	<0.001		399 (60.0)	+11.7	
Smokers	210 (25.2)	+1.2	0.094		141 (21.2)	-0.5	
↑ alcohol intake	132 (15.7)	-10.8	0.016		132 (19.9)	-4.0	
Physically active	690 (82.9)	-2.0	0.483		529 (79.5)	-2.4	

\* Difference between intervention and control group.

**Table 4.** Efficacy of intervention regarding average values of examined CV risk factors.

	Intervention group		P*	Control group	
	2008 mean	2010 mean		2008 mean	2010 mean
Total cholesterol mmol/L	5.94	5.64	0.584	5.75	5.67
HDL-cholesterol mmol/L	1.51	1.48	0.287	1.48	1.45
LDL- cholesterol mmol/L	3.63	3.35	0.136	3.42	3.27
Triglycerides mmol/L	1.92	1.74	0.014	1.94	1.95
Systolic BP mmHg	129.65	128.16	<0.001	129.82	132.65
Diastolic BP mmHg	81.15	79.58	<0.001	80.73	81.67
BMI	28.71	28.49	<0.001	29.25	29.64
Waist circumference (cm)	94.93	94.83	0.044	96.11	98.83
Hip circumference (cm)	107.21	106.13	0.022	107.29	107.49
WHR	0.89	0.91	0.216	0.89	1.06

\* Difference between intervention and control group.

takes. Studies show that 90% of patients regularly take anti-hypertensives and statins in the first year, but only 33% do so after 3 years of therapy [18].

According to studies conducted in various populations, 44–76% of mortality reduction is attributable to prevention and changed risk behavior, while 23–47% of the reduction is attributable to

therapeutic interventions [1]. Our planned intervention was efficacious in the reduction of alcohol consumption and BMI, but not in the increase of physical activity and reduction of smoking. In Switzerland, only 2 years after smoking in public places was banned, the number of acute myocardial infarction patients dropped by 21%, and similar results were obtained in the U.S. (17%) and in Germany (8.6%) [19]. Change in the above-mentioned CV risk factors depends on practitioners' motivation, interests, and expertise, as well as on patients [20,21]. The PERCRO study, which sought to understand CV risk factors and the awareness of their impact on fatal CVD in the Croatian general population, showed that 53.2% of examinees had never talked about the issue with their physician [22]. The same study showed that practitioners considered the professional associations' guidelines were useful, but only 56.9% of them applied the guidelines. It is extremely difficult to motivate a patient to stop smoking and increase physical activity, which often frustrates GPs and certainly influences their work with such patients. Active follow-up of patients appeared to depend on the GPs' orientation to preventive care, the patient's motivation, and cost and accessibility of services to patients.

### Strengths and limitations of the study

The strength of this study is that it shows the effectiveness of a well-educated GP's systematized intervention. A potential weakness of the study is the absence of investigation into patients' attitudes towards prevention activities.

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### Conclusions

GP's systematic and planned intervention in the prevention of CVD, along with their permanent education, reduces the number of patients with increased total CV risk, which in turn leads to reduced CVD mortality. To motivate patients to change behavior risk factors, besides the GP, the whole society needs to be included via efforts such as media campaigns and pro-health legislation.

### Competing interest

There are no financial or other conflicts of interest.

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