

Longitudinal effects of a nurse-managed comprehensive cardiovascular disease prevention program for hospitalized coronary heart disease patients and primary care high-risk patients

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ABSTRACT

BACKGROUND The EUROACTION study (nurse-coordinated multidisciplinary, family-based cardiovascular disease prevention program) documented the efficacy of a nurse-managed, comprehensive prevention program in reducing risk factors for cardiovascular disease (CVD). No information was available on survival. **AIMS** The aim of the study was to assess the effects of EUROACTION intervention on CVD risk factors and 12-year survival in the Polish component of the study.

METHODS Two district hospitals and 2 primary care practices were allocated randomly to intervention (INT) or usual care (UC). The primary endpoints were lifestyle and risk factors changes at 1-year follow-up. Differences in survival were analyzed using the multivariable Cox proportional hazards regression models.

RESULTS The study involved 628 patients with coronary heart disease (CHD) and 711 high-risk patients. Compared to UC, INT patients achieved healthier lifestyles and a larger reduction of risk factors at 1 year but these differences were not maintained 12 years after the intervention. Less deaths occurred in patients from the INT hospital and from INT primary practice (hazard ratio [HR], 0.58; 95% CI, 0.42–0.82 and HR, 0.53; 95% CI, 0.3–0.95, respectively). Adjustment for the covariates slightly attenuated the estimates and removed significance (HR, 0.74; 95% CI, 0.52–1.04 and HR, 0.66; 95% CI, 0.36–1.24, respectively). For combined CHD and high-risk patient groups, compared with UC, INT patients had a 36% lower risk of death after adjustment for age, sex, and history of CHD (HR, 0.64; 95% CI, 0.48–0.86).

CONCLUSIONS The impact of the EUROACTION intervention on lifestyle and CVD risk factors could have contributed to lower mortality in INT coronary and high-risk patients. These results emphasize the need for sustaining the interventions to help patients maintain a healthy lifestyle.

INTRODUCTION Prevention is the most efficient and economically justified method to reduce cardiovascular disease (CVD) morbidity and mortality.¹ Earlier estimates suggested that

in Poland, the reduction in mortality from coronary heart disease (CHD) could be mostly explained by favorable changes in CVD risk factors but the most recent observations in the general

WHAT'S NEW?

This is the first study showing the reduction of mortality (by around 36%) in relation to improvement in the lifestyle and reduction of risk factors achieved by a structured, comprehensive, primary and secondary prevention program, the EUROACTION study (nurse-coordinated multidisciplinary, family-based cardiovascular disease prevention program). Further, the study documented that with no sustained interventions, favorable lifestyle and risk factors changes disappear in longitudinal observation.

population and in patients with CHD indicate that there is still great potential to reduce CVD incidence and mortality by lifestyle intervention, risk factor management, and cardioprotective medication. Two-thirds of Polish general adult population have hypercholesterolemia (61% are unaware and only 6% controlled), 40% of the adult population have hypertension (41% not aware and only 23% controlled), and 33% of men and 24% of women smoke cigarettes.²⁻⁴ Further, risk factors accumulate in the same persons and socially disadvantaged groups receive less intensive care^{5,6} and primary care does not provide sufficient counselling on risk factors and lifestyle.⁷ Results of the Polish component of the EUROASPIRE (European Action on Secondary and Primary prevention through Intervention to Reduce Events) study showed that, despite significant improvements in the use of cardioprotective drugs, mainly an increase in the use of statins and blood pressure lowering agents in patients with CHD, control of risk factors is still not sufficient. Only one-third of patients with CHD with hypercholesterolemia and 40% of patients with hypertension achieve the treatment goals and no considerable change was observed in smoking, diet, and physical activity for over 15 years.⁸ It is obvious that lifestyle modification requires well-organized and well-managed, structured prevention and rehabilitation program which would be applied to all in need, but in particular to patients with CHD and persons at high risk. Regrettably, there is evidence that only one-third of Polish patients with CHD who were hospitalized due to the acute manifestation of CHD are offered the opportunity to participate in rehabilitation programs. This proportion has remained unchanged for over 15 years and is one of the worst among the 24 centers who participated in the EUROASPIRE IV study.⁹ Further, the national prevention program funded by the Polish National Health Fund (Narodowy Fundusz Zdrowia) which was directed to primary care practices, appeared to be not accepted broadly and not effective in the control of risk factors.¹⁰

Since 2012, the European guidelines for CVD prevention recommend the integration of nurse-coordinated prevention programs into health-care system¹¹ and nurses together with general practitioners and allied health professionals should deliver CVD prevention programs for

high-risk patients within primary care.¹ One model of an effective prevention program was developed in the international EUROACTION study (nurse-coordinated multidisciplinary, family-based cardiovascular disease prevention program). It was shown that this ambulatory program increased the proportions of patients and their families who achieve the goals for CVD prevention in terms of lifestyle, risk factors control, and use of cardioprotective medications.¹²

The aim of the present paper was to describe the effects of the EUROACTION intervention on risk factors in a Polish sample who participated in the study, and to investigate whether the program which improved standards of preventive care in routine clinical practice could have an impact on the longitudinal survival in patients with CHD and high-risk individuals and whether the survivors maintain positive lifestyle changes and risk factors control long term.

METHODS The design and methods used in the EUROACTION project (trial registered in the ISRCTN registry of clinical trials, ISRCTN71715857), with special attention to the details of the intervention program were described earlier.¹² Below is a brief description relevant to the present study and to the specific aspects of the Polish component of the study.

The EUROACTION was a matched, cluster-randomized, controlled trial in 8 European countries, 6 pairs of hospitals and 6 pairs of primary practices were assigned to an intervention program (INT) or usual care (UC) for patients with CHD or those at high risk of developing CVD. This report is focused on the Polish component of the study which involved 2 district hospitals (Chrzanów and Olkusz) and 2 primary practices from Kraków. In hospitals, patients aged 80 years or younger who were hospitalized due to myocardial infarction or unstable or stable angina were recruited. In general practices, patients aged from 50 to 79 years, who were free of CVD, who were on treatment with antihypertensive or lipid-lowering drugs started in the year prior to the recruitment or were diagnosed with diabetes mellitus within the 3 years prior the recruitment or at high risk of CVD death (SCORE [Systematic Coronary Risk Estimation] $\geq 5\%$ either at the time of recruitment or projected to age 60 years) and not on any treatment, were recruited.

Hospitals and primary practices were centrally randomly allocated to INT or UC. In the INT hospitals and primary practices, after baseline assessment of lifestyle, risk factors, and drug treatment, patients and their partners were invited to attend a structured intervention program, which consisted of 8 group workshops and a supervised exercise class in hospitals and 3 workshops followed by individual

consultations in primary practices. Nurses monitored risk factors and adherence to drug treatments at each session and reported their observations to the doctors who could initiate or change the dose of cardioprotective medication. Additionally, printed leaflets on risk factors and a personal record card for lifestyle and risk factor targets were handed out to patients and their families were supplied with family support packs.

The primary endpoints were lifestyle change, management of blood pressure, lipids, and blood glucose to target concentrations, and prescription of cardioprotective drugs measured at 1 year and assessed by intention to treat.¹² Further, all eligible patients and their partners in the INT hospital were invited for reassessment at 16 weeks. In the UC hospital and primary practice, a random subsamples of eligible patients had baseline assessment and in the UC hospital a random subsample had an assessment after 16 weeks. According to the original EUROACTION protocol, assessment after 16 weeks was not done in primary practices. The study used highly standardized methods and participating centers were subjected to central quality control measures. Frozen blood samples were used in biochemical analysis in one central laboratory.¹²

Follow-up observation after at least over 10 years was attempted only for the Polish sample. Survival status was assessed from the residential registry and by personal contacts with participants or their relatives. Participants were interviewed during at-home visits according to the same questionnaire as at 1-year assessment and invited for a visit to the clinic for physical examination and blood collection. All

the procedures at the clinic including separation and freezing of plasma samples followed the original EUROACTION protocol. Biochemical analyses were carried out in the laboratory of the University Hospital in Kraków which is covered by the international quality control program.

Statistical analysis Results of the lifestyle, risk factors, and cardioprotective treatments assessment were presented as means (SD) or as numbers and percentages. The differences were tested using the χ^2 and the *t* test or the Mann-Whitney test. The survival analysis was based on intention to treat. Differences in survival were presented by Kaplan-Meier curves and tested by the log-rank test. Then, they were analyzed using the multivariable Cox proportional hazards regression model. Testing for the proportionality assumption of Cox regression was performed for each covariate and globally using a formal significance test based on the unscaled and scaled Schoenfeld residuals.¹³ The analyses were conducted using the STATA, version 14.2 (StataCorp LP, College Station, Texas, United States).

The study was approved by the bioethics committee of Jagiellonian University Medical College.

RESULTS In the Polish arm of the EUROACTION study, there were 331 eligible patients with CHD identified in the INT hospital and 297 patients with CHD in the UC hospital. Patients from the INT and UC hospitals had similar mean age, but there were more women in the INT hospital. At recruitment, the proportion of patients with clinical diagnosis of myocardial

TABLE 1 Baseline characteristics of the intervention and usual care patients

	Hospitals			Primary care			
	INT (n = 331)	UC (n = 297)	<i>P</i> value	INT (n = 325)	UC (n = 386)	<i>P</i> value	
Age, y, mean (SD)	58 (9.91)	59.2 (9.31)	0.12	56.1 (6.25)	58.2 (7.15)	<0.001	
Sex, n (%)	Male	176 (53.2)	185 (62.3)	0.02	138 (42.5)	167 (43.3)	0.83
	Female	155 (46.8)	112 (37.7)		187 (57.5)	219 (56.7)	
Diagnostic category at recruitment, n (%)	Myocardial infarction	93 (28.1)	129 (44.2)	<0.001	–	–	–
	Unstable angina	35 (10.6)	32 (11)		–	–	
	Stable angina	203 (61.3)	131 (44.8)		–	–	
Risk factors at recruitment, n (%)	Smoking	–	–	–	137 (42.3)	92 (24.2)	<0.001
	Hypertension	–	–	–	228 (68.5)	225 (57.7)	0.01
	Dyslipidemia	–	–	–	265 (79.6)	256 (65.6)	<0.001
	Diabetes	–	–	–	38 (11.4)	120 (30.8)	<0.001
Time of observation, y, mean (SD)	12.1 (2.79)	11.6 (3.78)	0.09	12.6 (1.4)	12.1 (2.49)	0.01	
Person years, n	3992	3440	<0.001	3480	3870	<0.001	
Deaths, n	61	92	<0.001	25	51	0.02	

Abbreviations: INT, intervention; UC, usual care

infarction was higher in UC patients (TABLE 1). Out of the identified patients, 199 in the INT hospital and 56 in the UC hospital (random sample) underwent the initial assessment, and 169 and 38 respectively (random sample) participated in the assessment after 16 weeks. A total of 198 patients in the INT hospital and 191 in the UC hospital participated in the 1-year follow-up, which was addressed to all patients identified. A total of 100 patients in the INT hospital and 71 in the UC hospital participated in the 12-year follow-up.

In the primary practices, 325 eligible high-risk patients were identified in the INT practice and 386 in the UC practice. There was no difference in the proportion of women, but patients from the INT practice were slightly younger and were exposed more frequently to smoking, hypercholesterolemia, and hypertension, and less often to diabetes as compared with UC practice (TABLE 1). Out of the identified high-risk patients, 256 underwent the initial assessment in the INT practice and 44 (random sample) in the UC practice; 234 and 160 respectively participated in the assessment after 1 year (addressed to all patients identified). A total of 149 patients in the INT practice and 81 in the UC practice participated in the 12-year follow-up.

Exposure to risk factors at baseline visit and subsequent follow-up (after 16 weeks in the case of hospitals, 1 year, and 12 years) for INT and UC hospitals and primary practices are presented in TABLE 2.

Patients with coronary heart disease

At baseline, the important difference was that, compared with UC, patients from INT hospital were less active, had higher mean blood total cholesterol, presented higher level of anxiety and depression, and were taking antiplatelet agents less frequently. Small difference in favor of INT patients was found in waist circumference. No differences were found in smoking rates, blood pressure, body mass index (BMI), characteristics of diet and use of ACE-inhibitors and statins.

On completion of the intervention program (16-week assessment), the most striking changes were observed in physical activity which resulted in over 3-fold more frequent recommended physical activity levels in patients from the INT hospital. INT patients also reported more frequent consumption of recommended amounts of oily fish and fresh vegetables compared with UC patients. Also, there was a decrease in low-density lipoprotein cholesterol (LDL-C) levels in patients from the INT hospital and in consequence, the baseline difference between them and patients from the UC hospital reversed. At 16-week follow-up, the differences in anxiety and depression as well as in the use of antiplatelet agents which were observed at the initial assessment were no longer significant.

At 1-year follow-up, compared with UC patients, patients from the INT hospital were more active, had higher high-density lipoprotein cholesterol (HDL-C) levels and were leaner. However, the baseline difference in the level of anxiety reappeared. No significant differences between the UC and INT hospitals were found in smoking rates, blood pressure, BMI, consumption of antiplatelet agents, and the use of ACE-inhibitors and statins.

The 12-year survivors among patients from the INT hospital did not maintain the favorable physically active lifestyle but consumed recommended amounts of fresh fruit and vegetables more frequently and were less anxious. However, they had higher mean total cholesterol and LDL-C compared with UC patients. No significant differences were found in smoking rates, blood pressure, parameters of obesity, and other assessed parameters.

High-risk primary care patients At baseline, the important difference was that compared with UC, patients from INT practice smoked more frequently, had higher mean blood total cholesterol and LDL-C but also slightly higher HDL-C, presented higher levels of anxiety and depression and were taking antiplatelet agents less frequently. No differences were found in blood pressure, BMI, or waist circumference, characteristics of diet and use of angiotensin-converting enzyme (ACE) inhibitors or statins.

At the 1-year follow-up, compared with UC patients, patients from the INT practice were more active, more likely to consume favorable amounts of fruit and vegetables more frequently, and had lower mean systolic and diastolic blood pressure. The differences in total cholesterol and LDL-C, which were unfavorable for patients from the INT practice at the initial assessment, disappeared. However, the favorable difference in the mean HDL-C was also not significant and patients from the INT practice had higher levels of anxiety and depression. Smoking rates decreased in both practices but prevalence of smoking remained higher in the INT practice. Patients from UC used ACE-inhibitors less frequently. No significant differences between the UC and INT practices were found in BMI or waist circumference, and consumption of antiplatelet agents or statins.

The 12-year survivors among patients from the INT primary practice did not maintain most of the favorable lifestyle and risk factors characteristics as compared with UC care patients with an exception of more frequent consumption of fruit and vegetables.

Mortality For patients with CHD, the mean time of follow-up was slightly shorter in the UC hospital as compared with the INT hospital (11.6 vs 12.1 years) but the difference was not

TABLE 2 Cardiovascular disease risk factors in intervention and usual care hospitals and primary care practices

		Hospitals								Primary care					
		Baseline		16-week follow-up		1-year follow-up		12-year follow-up		Baseline		1-year follow-up		12-year follow-up	
		INT (n = 199)	UC (n = 56)	INT (n = 169)	UC (n = 38)	INT (n = 198)	UC (n = 191)	INT (n = 100)	UC (n = 71)	INT (n = 256)	UC (n = 44)	INT (n = 234)	UC (n = 160)	INT (n = 149)	UC (n = 81)
Current smoker, %		14.6	14.3	21.9	21.1	19.7	25.1	17	21.1	45.7	25 ^a	38.5	18.8 ^c	21.5	14.8
Diet	Oily fish ≥ 3 times a week, %	4	3.6	19.5	5.3 ^a	18.1	0 ^b	4	5.6	2	4.6	4.3	4.4	2.7	0
	Fruit and vegetables ≥ 400 g per day, %	35.2	42.4	63.3	33.3 ^c	56.4	48.2	72	14.1 ^c	49.2	45.5	77.8	39.4 ^c	37.6	19.8 ^b
Physical activity ≥ 30 min, ≥ 4 times a week, %		13.5	46.4 ^c	63.3	18.4 ^c	38.2	24.6 ^b	33	32.4	34.4	29.6	66.2	5.6 ^c	17.7	13
BMI, kg/m ² , mean (SD)		29.3 (4.01)	29 (3.85)	29.3 (4.16)	29.5 (3.61)	28.9 (4.23)	29.1 (4.65)	30.3 (4.81)	29.4 (4.04)	28.2 (5.07)	28.3 (4.61)	27.8 (4.79)	27.5 (4.56)	28.9 (4.89)	28.2 (4)
Waist circumference, cm, mean (SD)		97 (11.4)	101 (9.5) ^a	96 (11.9)	102 (9.66) ^b	95 (11.6)	100 (11.3) ^c	104 (12.6)	102 (12.8)	93 (12.6)	92 (11.3)	92 (11.9)	90 (14.1)	99 (13.8)	96 (11.3)
SBP, mm Hg, mean (SD)		138 (20.9)	138 (16.6)	139 (19)	141 (13.7)	141 (21.4)	144 (20.4)	140 (21.9)	144 (22.7)	140 (17.3)	141 (15.5)	130 (11.9)	137 (16.7) ^c	131 (15.3)	132 (15.7)
DBP, mm Hg, mean (SD)		84 (10.7)	85 (10.5)	84 (10.3)	83 (7.3)	84 (11.2)	85 (11.2)	86 (13)	84 (15.7)	85 (8.4)	87 (5.8)	80 (6.9)	85 (8.3) ^c	81 (9.3)	80 (9.3)
Total cholesterol, mmol/l, mean (SD)		5.23 (1.21)	4.69 (0.87) ^b	5.22 (1.28)	5.19 (1.14)	5.36 (1.23)	5.42 (1.41)	5 (1.24)	4.41 (1.34) ^a	6.04 (0.97)	5.54 (1.01) ^c	5.71 (0.93)	5.55 (0.99)	4.84 (1.25)	4.83 (1.11)
LDL-C, mmol/l, mean (SD)		3.23 (1.03)	2.99 (0.71)	2.78 (0.86)	4.28 (1.5) ^c	3.47 (1.25)	3.57 (1.41)	2.9 (1.05)	2.45 (1.08) ^a	3.74 (0.91)	3.39 (0.93) ^a	3.63 (0.93)	3.47 (3.33)	2.54 (1.11)	2.68 (0.96)
HDL-C, mmol/l, mean (SD)		1.26 (0.4)	1.15 (0.25)	1.35 (0.36)	1.26 (0.31)	1.46 (0.45)	1.34 (0.42) ^a	1.35 (0.36)	1.23 (0.4)	1.56 (0.39)	1.43 (0.36) ^a	1.35 (0.26)	1.39 (0.27)	1.63 (0.72)	1.49 (0.37)
Anxiety (HADS), n, mean (SD)		9.4 (4.25)	7.9 (4.25) ^a	8.3 (3.76)	7 (3.58)	7.5 (4.18)	6.2 (3.97) ^b	11.6 (2.29)	12.6 (2.73) ^a	7.9 (3.89)	4.2 (3.99) ^c	7.1 (3.69)	5.4 (3.96) ^c	13 (2.17)	12.7 (2.14)
Depression (HADS), n, mean (SD)		7.7 (3.58)	6.3 (4.07) ^a	6.9 (3.27)	6.1 (3.68)	5.8 (3.69)	4.9 (3.66)	9.2 (2.17)	9.1 (2.02)	6.3 (3.37)	3.4 (4.33) ^c	5.9 (3.26)	4.9 (3.42) ^b	9.1 (1.75)	8.8 (1.86)
Cardioprotective drugs	Antiplatelet drugs, %	88.4	98.2 ^a	92.2	97.3	89	91.3	49	53.5	8.6	18.2 ^a	17.5	17.4	17.5	28.4
	ACEIs, %	68.2	55.4	68.9	56.8	69.5	74.3	48.4	30.8 ^a	0	0	65.5	52 ^a	38	41.3
	Statins, %	65.2	76.8	74.9	83.8	71.1	69.1	54.8	55.4	20.7	22.7	45.9	34.7	44.2	50.7

^a $P < 0.05$
^b $P < 0.01$
^c $P < 0.001$

Abbreviations: ACEIs, angiotensin-converting enzyme inhibitors; BMI, body mass index; DBP, diastolic blood pressure; HADS, Hospital Anxiety and Depression Scale; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; SBP, systolic blood pressure; others, see TABLE 1

significant (TABLE 1). There were 61 deaths identified in patients from the INT hospital and 92 deaths in patients from the control hospital (hazard ratio [HR], 0.58; 95% CI, 0.42–0.82). After adjustment for sex and baseline diagnosis of myocardial infarction (unequally distributed variables), the risk of death was still lower in patients from the INT hospital (HR, 0.7; 95% CI, 0.5–0.99). Adding age to the model did not change the estimate but removed the significance (TABLE 3).

For high-risk patients, the average time of follow-up was slightly shorter in the UC practice (12.1 vs 12.6 years; $P = 0.01$) and there were 25 deaths identified in patients from the INT practice and 51 deaths in patients from the UC practice (HR, 0.53; 95% CI, 0.3–0.95). Adjustment for age, sex, and risk factors resulted in the slight change of the hazard ratio and the statistical significance was lost (HR, 0.66; 95% CI, 0.36–1.24).

For combined CHD and high-risk patients, after adjustment for age, sex, and history of myocardial infarction or other CHD, patients from the INT centers appeared to have 36% lower risk of death compared with UC patients (HR, 0.64; 95% CI, 0.48–0.86) (TABLE 3).

DISCUSSION With the exception of the multifactorial primary prevention program which was carried out in 1970s,¹⁴ findings from the EUROACTION remain the only evidence from Poland which is based on experimental design and which confirm the effectiveness of the well designed and well executed cardiac prevention programs. Previous EUROACTION reports focused on the effects on exposure to risk factors and cost effectiveness.^{12,15} This report expands our understanding by the observation of mortality reduction in relation to reduction

in exposure to risk factors both in the hospital and primary care patients in one setting of the study. Our results, although cannot be regarded as a strong supportive evidence, are clearly in line with guidelines for cardiac prevention for clinical practice, which recommend nurse-led, simple outpatient cardiac prevention and rehabilitation programs as an effective tool in primary and secondary CVD prevention.¹

In general, the assessment just after finalizing the intervention program suggested a positive effect on blood lipids (mainly on LDL-C), increase of physical activity, some favorable changes in diet and by decrease of depression and anxiety. Although not every positive change persisted until 1 year after the intervention program, patients from the INT hospital and primary practice remained more active, had more healthy diet, improved lipid profile, and in case of primary care, had lower blood pressure as compared with UC patients. Cardiologists and primary care physicians tend to focus on cardioprotective medication.¹⁶ Similar to the observation from all sites from the EUROACTION, in the Polish component of the study, the effect of the intervention on the use of cardioprotective medications was modest and it seems that lifestyle changes, mainly in physical activity and diet, were more important.¹²

It is likely that favorable effect of the EUROACTION intervention persisted for longer than 1 year and gradually deteriorated afterwards. Further, it is likely that the effect of decreased exposure to risk factors and favorable lifestyle on mortality persisted until the end of observation, as observed in many prospective studies.

There is an extensive body of evidence on the effectiveness of nurse-led secondary prevention clinics. Gains were reported not only as a reduction of CVD risk factors but reduction was shown for recurrent events, all-cause

TABLE 3 Risk of death in the intervention hospital and primary care practice compared with usual care centers

	Hospitals		Primary care		Hospitals and primary care	
	HR	95% CI	HR	95% CI	HR	95% CI
Not adjusted	0.58	0.42–0.82	0.53	0.3–0.95	0.53	0.4–0.71
Adjusted for age	0.6	0.43–0.84	0.67	0.37–1.21	0.62	0.46–0.83
Adjusted for age and sex	0.67	0.48–0.93	0.65	0.36–1.18	0.64	0.48–0.86
Adjusted for sex and MI	0.7	0.5–0.99	–	–	0.66	0.49–0.88
Adjusted for sex and MI or other CHD	–	–	–	–	0.55	0.41–0.74
Adjusted for age, sex, and MI	0.74	0.52–1.04	–	–	0.71	0.53–0.95
Adjusted for age, sex, and MI or other CHD	–	–	–	–	0.64	0.48–0.86
Adjusted for age, sex, and RFs	–	–	0.66	0.36–1.24	–	–

Abbreviations: CHD, coronary heart disease; HR, hazard ratio; MI, myocardial infarction; RFs, risk factors

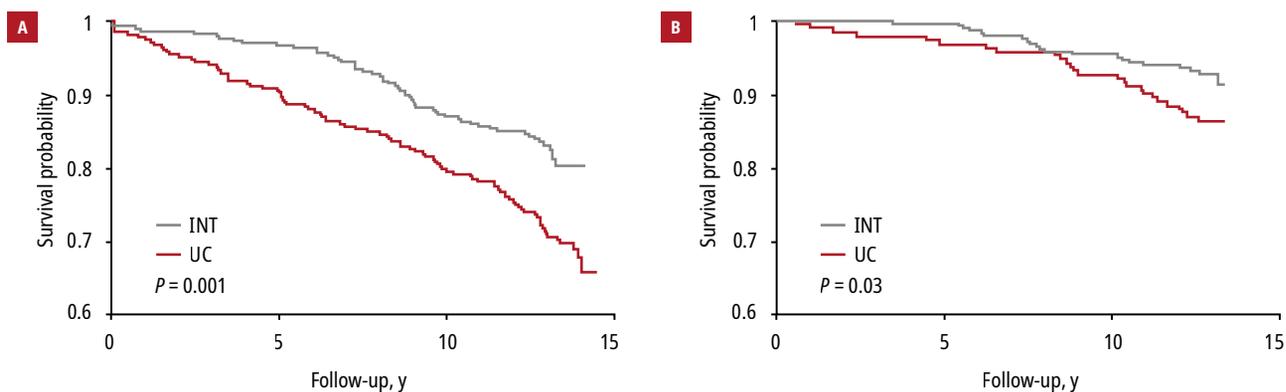


FIGURE 1 Kaplan–Meier survival curves illustrating the risk of death for intervention (INT; **A**) and usual care (UC; **B**) centers

and cardiovascular readmission rates, and the duration of hospitalization.¹⁷ However, some trials showed no effect of nurse-led care as compared with UC for all-cause mortality.^{18,19} For secondary prevention, in the meta-analysis of 12 randomized clinical trials,¹⁷ out of which 9 reported all-cause mortality, most had short time observation (1–2 years) and only 2 continued observation for longer periods, that is, 4 and 10 years.^{20,21} Our estimate for HR is very close to the average of the whole meta-analysis (odds ratio, 0.78; 95% CI, 0.65–0.95) and to the study with 10 years of observation (odds ratio, 0.74; 95% CI, 0.55–0.98). Further, we have provided some information on the beneficial effect of primary prevention on mortality in primary care high-risk patients which is scarce in the literature.

Since 2012, the European guidelines for CVD prevention recommend the integration of nurse-coordinated prevention programs into healthcare systems¹¹ and nurses together with general practitioners and allied health professionals should deliver CVD prevention programs for high-risk patients within the primary care.¹ In Poland, prevention was introduced as an important part of the work of nurses and nurse-led clinics (individual and group nursing practices) in law over 20 years ago.^{22,23} However, no CVD prevention program was targeted (and funded) for nurses at the national level. This might be a reason why the effectiveness of CVD prevention program supported by the Polish National Health Fund and targeted at general practitioners was less effective than expected.¹⁰

In 2019, the Polish National Health Fund introduced a new nation-wide system of coordinated care after myocardial infarction, which makes hospitals responsible for the care of the patient for up to 1 year after hospitalization due to myocardial infarction.^{24,25} The EUROACTION model might be ideal to ensure better outcomes at the most reasonable costs.

There are several important limitations for the interpretation of the results

presented. The most important is that although the EUROACTION was designed as a cluster randomized controlled trial, a study which involves centers from only 1 country is observational. Recruitment on the level of hospitals and primary practices affected negatively the comparability of the study samples and made the comparisons vulnerable for confounding. Although we attempted to control the most important unequally distributed confounders (diagnosis of myocardial infarction and sex, major risk factors) including the other variables in the statistical model, even equally distributed in the study samples (like age in hospitals) could eliminate significance of the association with no considerable change of the average estimate. In the EUROACTION, the sample size was initially planned for the assessment of differences in the prevalence of risk factors between the study groups.¹² The problem of low statistical power affected both hospital and primary care part of the project, but it is worth noting that in both settings, the effects of intervention on reduction in mortality and in primary care countered the initial unequal exposure to some CVD risk factors, which was lower in the UC practice. The second reservation would be that the study group after 12 years differed from the original EUROACTION sample by natural elimination (deaths) of persons at high risk, which was unequal in study groups (more persons died in the UC groups). It is likely that persons who died could be more exposed to risk factors and this could decrease the differences in mortality between the study groups. Further, the effect of intervention led by nurses is related to their expertise as well as differences in the conditions of the patients, but also depends on what care is provided in the control patients.¹⁷ It is likely that EUROACTION UC centers were stimulated to pay more attention to prevention measures than average healthcare centers in Poland. Finally, shortly after the EUROACTION, the population of Małopolska Province was exposed to the population intervention, that is, broadcasting of the educational materials on CVD prevention in the local television.²⁶

It could reduce the difference in impact between the INT and UC centers; however, it is unlikely that this would have had an impact on differences in survival.

Nevertheless, besides of being the only more recent, mortality-based observation in Poland, which is in line with expectations from primary and secondary CVD prevention programs, this study has some important strengths. First, hospitals served the districts which had similar morality from all causes and from cardiovascular diseases (Supplementary material, *Figure S1*) and primary practices served the same community. Both hospitals and primary practices were randomly allocated to INT and UC. Second, all data collection was done according to the same protocol. Third, we were able to assess survival status for all participants of the Polish part of the EUROACTION. The original EUROACTION intervention was not effective in reducing smoking in the whole study. However, intensifying counselling and using optional varenicline increased smoking abstinence and reduced cardiovascular risk in the later EUROACTION Plus study.²⁷ This all allows us to suggest that in Poland, the EUROACTION-type, nurse-managed, comprehensive education and rehabilitation program has the best available evidence for its effectiveness^{12,15,28} and it is worth considering to implement it in to clinical practice unless the evidence for more efficacious and cost-effective type of intervention appears. Furthermore, this study identified the need for repeated intervention in patients with CVD and individuals at high risk to encourage them to maintain healthy lifestyle and adhere to medication over subsequent years.

Conclusions In the Polish component of the study, the effect of the EUROACTION intervention program on classic risk was considerable. Mainly, there was a strong effect on lifestyles, that is, an increase of physical activity and favorable changes in diet were observed, which persisted at (1-year) longitudinal observation. These changes could have contributed to lower mortality in patients from the INT centers, despite that, with the exception of more frequent fruit and vegetables consumption, 12-year survivors did not maintain favorable lifestyle characteristics and risk factors pattern. These results emphasize the need for sustaining the interventions to help patients maintain a healthy lifestyle.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

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The full list of EUROACTION investigators was provided in Wood et al.¹²

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CONFLICT OF INTEREST None declared.

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REFERENCES

- 1 Piepoli MF, Hoes AW, Agewall S, et al. 2016 European guidelines on cardiovascular disease prevention in clinical practice: the Sixth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice. *Eur Heart J.* 2016; 37: 2315-2381.
- 2 Pająk A, Szafraniec K, Polak M, et al. Changes in the prevalence, treatment, and control of hypercholesterolemia and other dyslipidemias over 10 years in Poland: the WOBASZ study. *Pol Arch Med Wewn.* 2016; 126: 642-652.
- 3 Niklas A, Flotyńska A, Puch-Walczak A, et al. Prevalence, awareness, treatment and control of hypertension in the adult Polish population - Multi-center National Population Health Examination Surveys - WOBASZ studies. *Arch Med Sci.* 2018; 14: 951-961.
- 4 Polakowska M, Kaleta D, Piotrowski W, et al. Tobacco smoking in Poland in the years from 2003 to 2014. Multi-centre National Population Health Examination Survey (WOBASZ). *Pol Arch Intern Med.* 2017; 127: 91-99.
- 5 Kozela M, Polak M, Doryńska A, et al. Socioeconomic and sex differences in health care utilisation, counseling on cardiovascular disease (CVD) risk factors, and CVD factors control in the Polish population. The WOBASZ II Study. *Kardiologia Pol.* 2018; 76: 1516-1524.
- 6 Niklas A, Marcinkowska J, Kozela M, et al. Blood pressure and cholesterol control in patients with hypertension and hypercholesterolemia: the results from the Polish multicenter national health survey WOBASZ II. *Pol Arch Intern Med.* 2019; 129: 864-873.
- 7 Kozela M, Doryńska A, Misiowiec S, et al. Do participants with depression receive more counseling on cardiovascular disease risk factors? The results of the WOBASZ II study. *Kardiologia Pol.* 2019; 77: 1176-1181.
- 8 Jankowski P, Czarnecka D, Badacz L, et al. Practice setting and secondary prevention of coronary. *Arch Med Sci.* 2018; 14: 979-987.
- 9 Kotseva K, Wood D, De Bacquer D, et al. EUROASPIRE IV: a European Society of Cardiology survey on the lifestyle, risk factor and therapeutic management of coronary patients from 24 European countries. *Eur J Prev Cardiol.* 2016; 23: 636-648.
- 10 Pająk A, Szafraniec K, Janion M, et al. The impact of the national Program of Cardiovascular Disease Prevention (PCVDP) on the quality of primary CVD prevention in clinical practice. *Kardiologia Pol.* 2010; 68: 1332-1341.
- 11 Perk J, De Backer G, Gohlke H, et al. European Guidelines on cardiovascular disease prevention in clinical practice (version 2012). The Fifth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice. *Eur Heart J.* 2012; 33: 1635-1701.
- 12 Wood DA, Kotseva K, Connolly S, et al. Nurse-coordinated multidisciplinary, family-based cardiovascular disease prevention programme (EUROACTION) for patients with coronary heart disease and asymptomatic individuals at high risk of cardiovascular disease: a paired, cluster-randomised controlled trial. *Lancet.* 2008; 371: 1999-2012.
- 13 Grambsch PM, Therneau TM. Proportional hazards tests and diagnostics based on weighted residuals. *Biometrika.* 1994; 81: 515-526.

- 14 Rywik S, Sznajd J, Magdoń M, et al. "Polish trial on Coronary Heart Disease Prevention." Part I: influence of the programme on risk factors level of general population [in Polish]. *Przegl Lek.* 1986; 43: 581-587.
- 15 Šović N, Pajak A, Jankowski P, et al. Cost-effectiveness of a cardiovascular disease primary prevention programme in a primary health care setting. Results of the Polish part of the EUROACTION project. *Kardiol Pol.* 2013; 71: 702-711.
- 16 Hasenfuß G. Secondary prevention of cardiovascular diseases: current state of the art. *Kardiol Pol.* 2018; 76: 1671-1679.
- 17 Al-Mallah MH, Farah I, Al-Madani W, et al. The impact of nurse-led clinics on the mortality and morbidity of patients with cardiovascular diseases. a systematic review and meta-analysis. *J Cardiovasc Nurs.* 2015; 31: 89-95.
- 18 Allison TG, Farkouh ME, Smars PA, et al. Management of coronary risk factors by registered nurses versus usual care in patients with unstable angina pectoris (a chest pain evaluation in the emergency room [CHEER] substudy). *Am J Cardiol.* 2000; 86: 133-138.
- 19 Carrington MJ, Carrington MJ, Chan YK, et al. A multicenter, randomized trial of a nurse-led, home-based intervention for optimal secondary cardiac prevention suggests some benefits for men but not for women: the young at heart study. *Circ Cardiovasc Qual Outcomes.* 2013; 6: 379-389.
- 20 Haskell WL, Alderman EL, Fair JM, et al. Effects of intensive multiple risk factor reduction on coronary atherosclerosis and clinical cardiac events in men and women with coronary artery disease. The Stanford Coronary Intervention Project (SCRIP). *Circulation.* 1994; 89: 975-990.
- 21 Delany EK, Murchie P, Lee AJ, et al. Secondary prevention clinics for coronary heart disease: a 10-year follow-up of randomised controlled trial in primary care. *Heart.* 2008; 94: 1419-1423.
- 22 Act on the professions of nurse and midwife of July 15, 2011 [in Polish]. *Journal of Laws of 2011: No. 174. Item 1039.*
- 23 Act amending the Act on health care institutions, the medical profession, the profession of a nurse and midwife, on higher education and on the amendment of some other acts of December 10, 1998 [in Polish]. *Journal of Laws of 1998. No. 165. Item 1115.*
- 24 Directive No 10/2019/DSOZ of the President of The National Health Fund of January 3, 2019 [in Polish]. <http://www.nfz.gov.pl/zarzadzenia-prezesa/zarzadzenia-prezesa-nfz/zarzadzenie-nr-102019dsoz,6874.html>. Accessed June, 20, 2019.
- 25 Jankowski P, Gąsior M, Gierlotka M, et al. Coordinated care after myocardial infarction. The statement of the Polish Cardiac Society and the Agency for Health Technology Assessment and Tariff System. *Kardiol Pol.* 2016; 74: 800-811.
- 26 Waśniowska A, Kopeć G, Podolec J, et al. Relationship between knowledge of cardiovascular disease risk factors and watching educational television materials. *Małopolska Cardiovascular Preventive Intervention Study (M CAPRI).* *Pol Arch Intern Med.* 2017; 127: 608-613.
- 27 Jennings C, Kotseva K, De Bacquer D, et al. Effectiveness of a preventive cardiology programme for high CVD risk persistent smokers: the EUROACTION PLUS varenicline trial *Eur Heart J.* 2014, 35: 1411-1420.
- 28 Mistry H, Morris S, Dyer M, et al. Cost-effectiveness of a European preventive cardiology programme in primary care: a Markov modelling approach. *BMJ Open.* 2012; 2: e001029.