# Preventing cardiovascular disease in primary care: Role of a national risk factor management program

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**Background** Heartwatch, a structured risk factor modification program for secondary prevention of cardiovascular (CV) disease (CVD) in primary care, is associated with improvements in CV risk factors in participating patients. However, it is not known whether Heartwatch translates into reductions in clinically important CV events.

**Objective** The aim of the study was to determine the association between participation in Heartwatch and future risk of CV events in patients with CVD.

**Methods** The study consisted of a prospective cohort of 1,609 patients with CVD in primary care practices. Of these, 97.5% had data available on Heartwatch participation status, of whom 15.2% were Heartwatch participants. Cox proportional hazards models were used to determine the association between Heartwatch participation and risk of the CV composite (CV death, nonfatal myocardial infarction, heart failure, and nonfatal stroke). All-cause mortality and CV mortality were secondary outcome measures.

**Results** During follow-up, the CV composite occurred in 208 patients (13.6%). Of Heartwatch participants, 8.4% experienced the CV composite compared with 14.5% of nonparticipants (P = .003). Participation in Heartwatch was associated with a significantly reduced risk of the CV composite (hazard ratio [HR] 0.52, 95% CI, 0.31-0.87), CV mortality (HR 0.31, 95% CI, 0.11-0.89), and all-cause mortality (HR 0.32, 95% CI, 0.15-0.68). Heartwatch participation was also associated with greater reductions in mean systolic blood pressure (P = .047), mean diastolic blood pressure (P < .001), and greater use of secondary preventative therapies for CVD, such as lipid-lowering agents (P < .001),  $\beta$ -blockers (P < .001), and angiotensin-converting enzyme inhibitors (P < .001).

**Conclusion** Heartwatch is associated with a reduced risk of major vascular events and improved risk factor modification, supporting its potential as a nationwide program for secondary prevention of CVD. (Am Heart J 2012;163:714-9.)

Cardiovascular (CV) disease (CVD) is one of the leading causes of mortality worldwide. Individuals with established CVD are at a significantly increased risk of subsequent CV events, such as stroke, myocardial infarction, and CV death.<sup>1</sup> Heartwatch, a structured primary care delivered program for the secondary prevention of coronary heart disease in Ireland, was introduced in 2003 and follows the recommendations of the European Joint Task Force on Coronary Prevention.<sup>2</sup> Previous studies evaluating the Heartwatch program have reported significant reductions in systolic blood pressure (SBP), diastolic blood pressure (DBP), proportion of individuals smoking, total cholesterol (TC), and lowdensity lipoprotein cholesterol levels as well as significant

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increases in the use of secondary preventative therapies, such as lipid-lowering agents and antihypertensive medications, in participating patients. However, neither of these studies included a control group for comparison.<sup>3,4</sup> Furthermore, there have been no studies to date that have evaluated whether Heartwatch-related improvements in vascular risk factors translate into reductions in clinically important CV events such as myocardial infarction, stroke, or CV-related mortality. Given the cost and logistic challenges associated with implementing the Heartwatch program, such information is important in informing policy for CVD prevention in primary care.

Within a population-based prospective cohort study, we determined the association between a primary carebased intervention (Heartwatch) and future risk of major vascular events in patients with established CVD followed up for approximately 3 years.

# Methods

# Study population

Our study sample consisted of a cohort of 1,609 patients with CVD identified in 2000 to 2002 via stratified random sampling of

35 general practices in Ireland. In each practice, patients with CVD were identified using general practice disease registers, patient database searches, prescribing records, prospective recording of patient attendance, and opportunistic practitioner recall. Patients were defined as having CVD in accordance with Heartwatch eligibility criteria<sup>5</sup>: history of myocardial infarction, angina pectoris, or a previous cardiac revascularization procedure, including percutaneous coronary intervention and coronary artery bypass grafting (CABG). Patients were included in the current study if data were available on Heartwatch participation status (97.5% of cohort). Information on participation in Heartwatch was systematically collected in all patients, and evidence of participation was based on documentary evidence in the medical chart. Prospective follow-up was completed after a mean of 2.9 years. A more detailed description of this study has previously been reported.<sup>6,7</sup>

#### Outcomes

The primary outcome was time to occurrence of the composite of CV death (defined as CVD included as either a primary or contributing factor on the death certificate),<sup>8</sup> nonfatal myocardial infarction, new-onset heart failure, and nonfatal stroke. Data on mortality were collected through searching practice records and the General Register Office, which is the central civil repository for records relating to births, marriages, and deaths in the Republic of Ireland. Secondary outcomes included CV mortality and all-cause mortality.

#### Heartwatch

The Heartwatch program is based on the recommendations of the European Joint Task Force on Coronary Prevention.<sup>2</sup> It consists of regular visits (maximum of 4 per annum) to a registered general practitioner participating in the Heartwatch program. At each visit, the primary focus is on CV risk factor assessment and modification.<sup>5</sup>

General practitioners are provided with educational study packs on CV risk factor interventions such as advice on lifestyle and behavior, pharmacologic management, and referral pathways for patients requiring specialist care.<sup>3</sup> Targeted risk factors include diet, exercise, obesity, smoking, blood pressure, cholesterol, and diabetes mellitus.

#### Statistical analysis

Patients were categorized according to Heartwatch participation status. Baseline characteristics were compared using  $\chi^2$  tests for categorical variables and Student *t* tests for continuous variables. Kaplan-Meier estimates of survival functions for the CV composite in Heartwatch and non-Heartwatch participants were generated, and a log-rank test was used to compare survival functions between the 2 groups.

Univariable and multivariable Cox proportional hazards models were fitted to determine the association between Heartwatch participation and time to occurrence of the composite end point. Confounders known or proposed to be associated with an increased risk of CV events were entered and retained in the multivariable models. Separate models were fitted for each outcome (CV composite, CV mortality, and all-cause mortality). The following variables were included in all models: age, sex, general medical services (GMS) scheme eligibility (eligibility for free medical care in Ireland), time from diagnosis of CVD (months), known diabetes mellitus, previous myocardial infarction, previous stroke, previous percutaneous transluminal coronary angioplasty, previous CABG, history of angina, history of heart failure, history of peripheral vascular disease (PVD), history of thromboembolic disease including deep venous thrombosis and pulmonary embolism, baseline SBP, baseline DBP, smoking status (current smokers or nonsmokers), location of general practice (rural/urban), presence of a practice nurse, and type of general practice (single-handed or partnership). Individuals whose smoking status was not available were classified as nonsmokers for the purposes of the analyses. A second multivariable model was also fitted, which included all the above covariates, with the addition of baseline medications (aspirin, lipid-lowering therapy, B-blocker, and angiotensinconverting enzyme [ACE] inhibitor therapy), to adjust for the effects of baseline secondary prevention therapies. We also carried out a subgroup analysis confined to non-single-handed general practices with a practice nurse to represent a more homogenous group of general practices with similar levels of access to specialized programs such as Heartwatch.

Patients who had not experienced the primary outcome were censored at follow-up. Data were also censored for those patients lost to follow-up (0.6%).

Assumptions underlying the final models were assessed using Schoenfeld residual plots. All tests of significance were 2 sided ( $\alpha = .05$  significance level), and a 95% CI that did not include 1.0 was considered to be significant. All statistical analyses were performed using commercially available software packages (SPSS version 18.0; SPSS Inc, Chicago, IL).

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# Results

#### **Baseline characteristics**

Among the entire cohort of 1,609 patients, 1,569 (97.5%) had data available on Heartwatch participation status, and 1,560 (97%) had follow-up data for the primary end point. Mean follow-up was 2.9 years (SD 1.47). The mean age of patients in the cohort was 66.3 years; 66.4% were male, and 45.9% had a previous history of myocardial infarction. A total of 239 patients (15.2%) participated in the Heartwatch program. Patients who participated in the Heartwatch program were younger; more likely to be male; living in an urban area; have a previous history of myocardial infarction, heart failure, or a coronary revascularization procedure; and were also more likely to be receiving lipid-lowering agents and  $\beta$ -blocker therapy compared with patients who were not participating in Heartwatch. Table I describes the baseline characteristics.

Changes in CV risk factor profiles and use of secondary prevention therapies: baseline to follow-up

Participation in Heartwatch, compared with nonparticipation, was associated with significantly larger reductions in mean SBP (3.7% vs 2.2%, P = .047), mean DBP

Table I. Baseline characteristics of Heartwatch and non-Heartwatch cohorts

Variable	All	Heartwatch	No Heartwatch	Р
n	1569	239	1330	
Demographics				
Female, n/N (%)	543/1569 (34.6)	45/239 (18.8)	498/1330 (37.4)	<.001
Age, mean, SD (n)	66.3, 9.1 (1568)	64.7, 8.8 (239)	66.5, 9.2 (1329)	.003
GMS scheme eligibility, n/N (%)	1240/1568 (79.0)	174/239 (72.8)	1066/1329 (80.2)	.01
General practice location, urban, n/N (%)	1215/1569 (77.4)	208/239 (87.0)	1007/1330 (75.7)	<.001
General practice type, single-handed, n/N (%)	721/1569 (46.0)	42/239 (17.6)	679/1330 (51.1)	<.001
General practice nurse, n/N (%)	839/1499 (56.0)	210/239 (87.9)	629/1260 (49.9)	<.001
Baseline CVD		· · ·		
Myocardial infarction, n/N (%)	717/1561 (45.9)	170/239 (71.1)	547/1322 (41.4)	<.001
Angina, n/N (%)	1328/1557 (85.3)	187/237 (78.9)	1141/1320 (86.4)	.007
Cardiac failure, n/N (%)	96/1564 (6.1)	25/237 (10.6)	71/1327 (5.4)	.013
Previous stroke, n/N (%)	75/1564 (4.8)	9/238 (3.8)	66/1326 (5)	.38
PVD, n/N (%)	88/1564 (5.6)	14/238 (5.9)	74/1326 (5.6)	.86
Thromboembolism, n/N (%)	169/1569 (10.8)	23/239 (9.6)	146/1330 (11)	.52
Cardiac interventions				
PTCA, n/N (%)	210/1563 (13.4)	47/237 (19.8)	163/1326 (12.3)	.006
CABG, n/N (%)	292/1567 (18.6)	71/239 (29.7)	221/1328 (16.6)	<.001
CV risk factors				
TC >5 mmol/L, n/N (%)	783/1216 (64.4)	110/211 (52.1)	673/1005 (67)	<.001
LDL-cholesterol >2 mmol/L, n/N (%)	423/456 (92.8)	72/80 (90)	351/376 (93.4)	.35
Hypertension, proportion with	873/1501 (58.2)	135/228 (59.2)	738/1273 (58.0)	.73
BP ≥140/90 mm Hg, n/N (%)				
Currently smoking, n/N (%)	322/1569 (20.5)	34/239 (14.2)	288/1330 (21.7)	.003
Diabetes mellitus, n/N (%)	176/1563 (11.3)	20/237 (8.4)	156/1326 (11.8)	.10
Baseline medications				
Aspirin, n/N (%)	1160/1544 (75.1)	179/233 (76.8)	981/1311 (74.8)	.51
β-Blocker, n/N (%)	718/1545 (46.4)	125/233 (53.7)	593/1312 (45.2)	.02
Lipid-lowering agent, n/N (%)	727/1542 (47.1)	141/232 (60.8)	586/1310 (44.7)	<.001
ACE inhibitor, n/N (%)	380/1540 (24.7)	68/233 (29.2)	312/1307 (23.9)	.10
Baseline measurements		. , /		
SBP, mean ± SD (n)	139.0 ± 19.5 (1501)	138.9 ± 18.9 (228)	139.0 ± 19.6 (1273)	.92
DBP, mean ± SD (n)	80.9 ± 9.1 (1501)	80.8 ± 8.6 (228)	80.9 ± 9.2 (1273)	.85

Patients whose Heartwatch participation status is unknown are excluded, -2.5% (40 patients).

Blood pressure  $\geq$ 140/90 includes SBP  $\geq$ 140 and/or DBP  $\geq$ 90 in line with British Hypertension Society guidelines for hypertension, 2004.

Test for an interaction between Heartwatch and general practice type, *P* = .95; Heartwatch and presence of practice nurse, *P* = .29. *PTCA*, Percutaneous transluminal coronary angioplasty; *LDL-cholesterol*, low-density lipoprotein cholesterol; *BP*, blood pressure.

Table II. Change in risk factors and secondary prevention medications from baseline to follow-up

	Heartwatch			No Heartwatch			
Variable	Baseline	Follow-up	% Change	Baseline	Follow-up	% Change	P
SBP, mean ± SD (n)	138.9 ± 18.9 (228)	133.7 ± 16.8 (236)	-3.7	139.0 ± 19.6 (1273)	135.9 ± 18.7 (1254)	-2.2	.047
DBP, mean ± SD (n)	80.9 ± 9.1 (228)	75.4 ± 10.5 (236)	-6.8	80.9 ± 9.2 (1273)	78.2 ± 9.7 (1255)	-3.3	<.001
BP ≥140/90, n/N (%)	135/228 (59.2)	90/236 (38.1)	-21.1	738/1273 (58.0)	612/1254 (48.8)	-9.2	<.001
TC >5 mmol/L, n/N (%)	110/211 (52.1)	47/234 (20.1)	-32.0	673/1005 (67.0)	540/1125 (48.0)	-19.0	<.001
Aspirin, n/N (%)	179/233 (76.8)	182/238 (76.5)	-0.3	981/1311 (74.8)	800/1286 (62.2)	-12.6	<.001
β-Blocker, n/N (%)	125/233 (53.7)	140/237 (59.1)	+5.4	593/1312 (45.2)	555/1281 (43.3)	-1.9	<.001
Lipid-lowering agent, n/N (%)	141/232 (60.8)	198/238 (83.2)	+22.4	586/1310 (44.7)	725/1284 (56.5)	+11.8	<.001
ACE-inhibitor, n/N (%)	68/233 (29.2)	113/238 (47.5)	+18.3	312/1307 (23.9)	432/1284 (33.6)	+9.7	<.001
Currently smoking, n/N (%)	34/239 (14.2)	36/239 (15.1)	+0.9	288/1330 (21.7)	262/1330 (19.7)	-2.0	<.001

Patients whose Heartwatch participation status is unknown are excluded, -2.5% (40 patients).

P value refers to the test of the difference in mean change in risk factors and medications between patients who participated in *Heartwatch* and those who did not. Blood pressure  $\geq 140/90$  includes SBP  $\geq 140$  and/or DBP  $\geq 90$  in line with British Hypertension Society guidelines for hypertension, 2004. Follow-up measurements were last date of follow-up recorded in chart.

(6.8% vs 3.3%, P < .001), and the proportion of patients with TC >5 mmol/L (32% vs 19%,  $P \le .001$ ) from baseline to last follow-up. Heartwatch participation was also associated with significantly greater increases in the proportion of patients prescribed secondary preventative therapies from baseline to last follow-up, for example,

Tab	le III.	Cardiovascul	ar events	at fol	low-up
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Variable	All (1569)	Heartwatch (239)	No Heartwatch (1330)
CV death, n/N (%)	110/1560 (7.1)	7/239 (2.9)	103/1321 (7.8)
Myocardial infarction, n/N (%)	43/1545 (2.8)	8/239 (3.3)	35/1306 (2.7)
Stroke, n/N (%)	40/1528 (2.6)	2/238 (0.8)	38/1290 (2.9)
Heart failure, n/N (%)	49/1526 (3.2)	7/237 (3.0)	42/1289 (3.3)
CV composite, n/N (%)	208/1530 (13.6)	20/237 (8.4)	188/1293 (14.5)
All-cause mortality, n/N (%)	208/1560 (13.3)	12/239 (5.0)	196/1321 (14.8)

Patients whose Heartwatch participation status is unknown are excluded, -2.5% (40 patients).

Figure 1



Kaplan-Meier estimates of survival function for time to CV composite according to Heartwatch participation status.

lipid-lowering agents (22.4% vs 11.8%, P < .001),  $\beta$ -blockers (5.4% vs -1.9%, P < .001), and ACE inhibitors (18.3% vs 9.7%, P < .001) and a significantly lower rate of cessation of aspirin therapy (0.3% vs 12.6%) (Table II).

# Cardiovascular events on follow-up

During follow-up, the CV composite occurred in 208 patients (13.6%). The frequency of new CV events in the

Table IV. Haz	zard ratios for the CV composite, CV mortality, and	ł
all-cause mortalit	ty for Heartwatch participants	

	CV composite, HR (95% CI)	CV mortality, HR (95% CI)	All-cause mortality, HR (95% CI)
Univariable analysis (Heartwatch)	0.62 (0.39-0.99)	0.35 (0.14-0.87)	0.35 (0.18-0.69)
Multivariable model 1	0.52 (0.31-0.87)	0.31 (0.11-0.89)	0.32 (0.15-0.68)
Multivariable model 2	0.54 (0.32-0.90)	0.32 (0.11-0.93)	0.34 (0.16-0.74)

Model 1 includes age, sex, GMS scheme eligibility, living location (rural/urban), time since diagnosis of CVD until entry into cohort (months), history of diabetes mellitus, previous myocardial infarction, previous stroke, previous percutaneous transluminal coronary angioplasty, previous CABG, history of angina, history of heart failure, history of PVD, history of thromboembolic disease (including deep venous thrombosis and pulmonary embolism), Heartwatch participation status, baseline SBP, general practice variables such as presence of a practice nurse and type of general practice (single-handed or partnership), and smoking status (current smokers or nonsmokers). Model 2 includes all covariates in model 1, with the addition of baseline medications (aspirin, lipid-lowering therapy, β-blocker, and ACE inhibitor therapy).

Heartwatch cohort was 8.4% compared with 14.5% in the non-Heartwatch cohort (P = .003) (Table III). The mean time to occurrence of the CV composite was 2.75 years for patients participating in Heartwatch and 2.65 years for those who were not participating in Heartwatch. Participation in Heartwatch was associated with a significantly reduced risk of the CV composite, unadjusted HR 0.62 (95% CI 0.39-0.99), and adjusted HR 0.52 (95% CI 0.31-0.87) (log-rank Mantel-Cox P = .04) (Figure 1).

On multivariable analyses, participation in Heartwatch was associated with a significantly reduced risk of CV mortality, adjusted HR 0.31 (95% CI 0.11-0.89) (log-rank Mantel-Cox P = .02), and all-cause mortality, adjusted HR 0.32 (95% CI 0.15-0.68) (log-rank Mantel-Cox P = .001). Inclusion of baseline medications in the multivariable models did not materially alter our findings (Table IV), and in a sensitivity analysis that restricted the population to partnership general practices with a practice nurse, results were also consistent.

# Discussion

#### Summary of main findings

We found that participation in the Heartwatch CVD prevention program, compared to non-participation, was associated with significantly greater improvements in CV risk factor profiles and use of secondary preventative therapies as well as significant reductions in the risks of the CV composite, CV death, and all-cause mortality on longterm follow-up.

### Comparison with the existing literature

Previous cohort studies evaluating the Heartwatch program have reported significant reductions in blood pressure, favorable changes in lipid profiles, increased smoking cessation rates, and significant increases in the use of secondary preventative therapies such as lipidlowering agents and antihypertensive medications. These benefits were maintained after 3.5 years of follow-up.<sup>3,4</sup> Our study extends these findings by reporting an association between Heartwatch and the incidence of major vascular events, meaning that benefits in intermediate outcomes (risk factor modification) appear to translate into benefits for clinically meaningful outcomes. Our results are consistent with a meta-analysis of 63 randomized, controlled trials of similar secondary prevention programs for CVD that reported a significant reduction in the risk of recurrent myocardial infarction for participating patients (summary relative risk 0.83, 95% CI 0.74-0.94). However, participants in clinical trials may not fully represent patients in real-life clinical practice. Our findings provide evidence that the benefits reported in clinical trials are likely to be generalized to an unselected population of patients with CVD in the community.

The results of our study are particularly important in light of the recent findings of the PURE study, an epidemiological survey of the use of secondary preventative drugs in patients with a history of coronary artery disease or stroke, in both high-income and lower-income countries. In high-income countries, only 62% of patients with a previous history of coronary artery disease or stroke were on aspirin, and only 73.8% were on statin therapy, with even lower rates of  $\beta$ -blocker (40%) and ACE-inhibitor/angiotensin receptor blocker use (49.8%).<sup>10</sup> Similar rates of prescription of these therapies were also observed in our cohort, aspirin (64.3%), lipidlowering agents (60.7%), β-blockers (45.7%), and ACEinhibitors (35.8%), with higher rates of prescription noted among Heartwatch participants (Table II). These results as well as those from other studies<sup>11,12</sup> highlight the need for more effective strategies to increase uptake of effective CV therapies in high-risk patients and promote their sustained use. Heartwatch has been shown to be a cost-effective intervention (cost per lifeyear gained of 7,987)<sup>5</sup> and is associated with a relatively low additional burden of work for general practices.

# Strengths and limitations of this study

There are several limitations that require mention. First, this is an observational study and not a randomized, controlled trial, so we cannot make direct inferences about the effectiveness of the Heartwatch intervention. Second, only 60% of the practices randomly selected to participate in this study actually agreed to participate. Practices with fewer resources, such as single-handed practices or those without the support of ancillary staff, may have been less likely to participate in this study because of the associated time and cost constraints. This could potentially limit the generalizability of our results. However, we used stratified random sampling, which allowed a broad representation of patients and clinicians from routine clinical practice, which enhances the external validity of our results.

Third, although we used multivariable models to adjust for the effect of known confounders, our results are still subject to residual confounding from unmeasured or inadequately measured predictors of CV events. We were unable to adjust for the effect of obesity (body mass index) because there was a large amount of missing data for this variable. Furthermore, patient behaviors such as dietary habits and levels of physical activity were unmeasured, and so, we could not include them in our analysis. Patients and practices that agree to participate in Heartwatch may differ from those who do not participate. However, our analyses did adjust for the most important risk factors for recurrent major vascular events. In a sensitivity analysis that restricted the population to partnership general practices with a practice nurse, results were not materially altered, and a formal test for an interaction between Heartwatch and type of general practice or presence of a practice nurse was not significant, adding strength to our findings (Table I).

Fourth, some deaths may have been incorrectly classified as cardiac related. However, we do not suspect that such misclassification would have systematically biased our results as the cause of death was reported independently of our study and unlikely to be influenced by knowledge of whether the patients were participating in Heartwatch.

Finally, patients joined the Heartwatch program at varying times after the initial diagnosis of CVD, which may have resulted in variations in the uptake of secondary preventative therapies. In addition, patients participating in the Heartwatch program may have been followed up more closely than nonparticipants (surveillance bias), and thus, the detection of events may have been greater in this group. However, both of these factors would likely have biased our results toward the null hypothesis.

The strengths of our study include its minimal losses to follow-up, the broad representation of patients from routine clinical practice, the use of clinically meaningful outcome measures, and the use of multivariable model risk adjustment to control for the effect of a multitude of confounders.

#### Conclusion

In patients with CVD, sustained use of secondary prevention therapies is poor even in high-income countries. Effective, generalizable, and cost-effective interventions to increase the proportion of patients who achieve risk factors target are urgently needed.<sup>13</sup> Heartwatch is associated with improved risk factor management and a significantly reduced risk of major vascular events, supporting its potential as a nationwide program for the secondary prevention of major vascular events.

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