BMJ Open

Heartwatch: an Irish Cardiovascular Secondary Prevention programme in primary care, a secondary analysis of patient outcomes.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-063811
Article Type:	Original research
Date Submitted by the Author:	19-Apr-2022
Complete List of Authors:	Homeniuk, Robyn; Irish College of General Practitioners, Research Stanley, Fintan; Irish College of General Practitioners, Research Hub Gallagher, Joseph; Irish College of General Practitioners Collins, Claire; Irish College of General Practitioners, Research
Keywords:	PRIMARY CARE, CARDIOLOGY, Coronary intervention < CARDIOLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PREVENTIVE MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title Page:

Heartwatch: an Irish Cardiovascular Secondary Prevention programme in primary care, a secondary analysis of patient outcomes.

Authors

Robyn Homeniuk*[1]

- MSc
- https://orcid.org/0000-0002-5526-4113

Fintan Stanley*[2]

- PhD
- https://orcid.org/0000-0002-6740-3280

Joseph Gallagher[3]

- BA MB BCh BAO MRCPI MICGP MD
- https://orcid.org/0000-0002-5564-2890

Claire Collins[1]

- PhD
- https://orcid.org/0000-0001-8967-5159

*These authors contributed equally and should be joint first author.

Corresponding: Claire Collins, Research Centre, Irish College of General Practitioners, Dublin, Ireland, claire.collins@icgp.ie,

1. Research Centre, Irish College of General Practitioners, Dublin, Ireland
2. Research Hub, Irish College of General Practitioners, Dublin, Ireland
3. Cardiovascular Clinical Lead, Irish College of General Practitioners, Dublin, Ireland

Word count: 4,470 (main text)
Manuscript count: 6700

Abstract

Objectives: The objective of this secondary analysis was to investigate patient follow-up data from Heartwatch: Ireland's secondary prevention programme for cardiovascular disease delivered in general practice.

Design: Retrospective descriptive study based on secondary analysis of routinely collected data from a secondary prevention programme for cardiovascular disease.

Setting: Heartwatch targeted 20% of general practices in Ireland and recruited 475 GPs across 325 practices.

Participants: The patient population included people with a history of acute myocardial infarction (AMI), percutaneous transluminal coronary angioplasty (PTCA) or a coronary artery bypass graft (CABG). Over 16,000 patients entered the programme however, to assess the long-term progress of patients, we identified a cohort of 5,700 patients with at least 8 years in the programme.

Interventions: A standard protocol for continuing care of patients for the secondary prevention of cardiovascular disease was administered by general practices. The programme was designed using World Health Organisation (WHO) and European Society of Cardiology (ESC) guidelines on secondary prevention.

Outcome measures: A Continuing Care (CCare) score out of 8 was the primary outcome measure used. It was calculated based on programme targets for well-known cardiovascular risk factors: exercise, systolic blood pressure, LDL cholesterol, optimally controlled glucose, smoking status, and pharmacological treatment.

Results: After one year, 33% of the 8-year cohort had achieved a 5 CCare score increasing to 40% of patients scoring ≥6 after year 8. Patients who enrolled in Heartwatch sooner after their qualifying event achieved more targets, as did patients with more frequent visits, males, and younger patients.

Conclusions: Overall, patients are not likely to meet all targets set by secondary prevention guidelines, however, supporting patient self-management may impact on this. Early enrolment after a cardiac event and frequency of structured care visits should be priorities in the design and implementation of similar programmes and ongoing evaluation is necessary.

Keywords: secondary prevention, cardiovascular health, patient outcomes, primary care, general practice; continuing care score.

Strengths and limitations

- The key strength of Heartwatch is the volume of patient data and the length of time the program has been in existence with patients retained. Further to that, the data is geographically spread across general practices areas across Ireland.
- However, this is an active care program and not a randomised controlled trial, so no comparative or control group exists. Moreover, data is collected primarily for clinical monitoring, not research purposes, thus, some variables were calculated. For example, in our statistical models, visits per year is calculated retrospectively and so its value in a predictive model is constrained. A key strength is that this is real-world data.
- ESC guidelines on LDLc changed during the programme, so patients may have been treated towards different target levels. We retrospectively applied the most recent recommendations ergo some patients may have been designated out of target who would have been in target at the time.
- Another possible limitation could be a survivor bias on the available long-term information, as those with worse scores may have exited the programme earlier than 8 years.[25]
- Heartwatch does not collect outcome information such as mortality or further cardiac events, nor does it collect patient reported outcomes. This was a limitation which we have attempted to overcome by developing the CCare score method.

Introduction

Globally, cardiovascular diseases (CVD) are the leading cause of death, with 32% of all global deaths - 17.9 million - being attributed to them in 2019.[1] In Europe, cancer and circulatory diseases have been the leading causes of death since 2006.[2] Recent statistics have shown that from 2006-2016 the number of deaths from ischaemic heart disease fell by 28.4% for men and 34.2% for women.[2] In 2016, the standardised death rate from ischaemic heart disease in Ireland was 133 per 100,000 inhabitants, which was slightly more than the EU rate of 119.4 per 100,000 inhabitants.[2]

While the decline in deaths from ischaemic heart disease is promising, it is still a major cause of mortality in Ireland.[3] The Central Statistics Office state that circulatory system diseases made up 28.9% of all deaths in Ireland in 2019.[4] This was the second leading cause of death after malignant neoplasms.[4] As highlighted by the evidence review in the Sixth Joint European Society of Cardiology (ESC)[5], patients with a history of CVD may need long term support to change their behaviour and limit the risk of further cardiac events. Furthermore, evidence from clinical trials have shown the benefits of secondary prevention following acute myocardial infarction (AMI), percutaneous coronary intervention (PTCA) or coronary artery bypass grafting (CABG)[3,6,7]. Provision of comprehensive cardiac rehabilitation, similar to the comprehensive approach in Heartwatch, was shown to have more patients achieve risk factor targets.[8] Moreover, the World Health Organisation (WHO) has suggested that providing CVD management of risk factors under universal health coverage and at a primary care level can reduce the burden of CVD.[1] Ireland was the first country in the European Union to implement a standardised, national programme led by general practitioners (GPs) that strategically implemented the ESC.[9] Other countries have since also adopted secondary prevention programmes that monitor blood pressure, cholesterol, smoking status and physical activity.[10–12]

The stated aim of Heartwatch was to reduce the morbidity and mortality caused by cardiovascular diseases in Ireland. It has attempted to improve the care of patients with heart disease in the community at general practices across the country. It was an evidence-based programme, strategically designed to provide community-based care the integrates specialised disease management in general practice with referrals to other services as necessary. However, measuring the programme's success has been multifactorial and complex. This paper examines the follow-up results of patients over 8 years to determine if there are long term

benefits of this secondary prevention programme and what factors may influence or predict the types of patients who benefit.

Methods

Data Handling

Collection

Heartwatch is a national structured programme led by Irish GPs with a standard protocol for the continuing care of patients for the secondary prevention of cardiovascular disease. The programme has been reported on in 2004, 2005, 2008, 2011, and 2014[3,13–16] – this paper is the first that reviewed patients who have attended the program for at least 8 years.

In 2003, 475 GPs in 325 practices were recruited[17] to provide this national secondary prevention care programme. Heartwatch targeted 20% of general practices to review patients on a quarterly basis with care implemented according to defined clinical protocols. The patient population included men and women who had a history of AMI, PTCA, or a CABG.[13,14] In addition, diabetic patients from an established diabetes structured care programme were also invited into the programme – however, these patients are not included in the analysis in this paper due to differing treatment requirements. Heartwatch, was introduced as a collaborative national pilot programme[13] but was not expanded beyond 20% of practices. The program and its continuing care protocol are based on the internationally recognized cardiovascular prevention guidelines from 'Prevention of Coronary Disease in Clinical Practice 1998'[18] and those updated in 2003[18] and 2016 after the sixth Joint Taskforce guidelines were released.[5] In 2016, the target level for lipoprotein cholesterol (LDLc) for very high-risk patients was changed to 1.8mmol/l as a direct result of the change in guidelines.[5]

By employing the continuing care protocol of Heartwatch, eligible patients may have attended up to 4 visits per year with their GP practice after signup. Measurements of key risk factors were recorded at the signup visit and at each subsequent visit along with data related to medication changes and referrals[19] (See

supplementary Table 1). This information is securely uploaded directly from the practice patient management server in an anonymised format to the Independent National Data Centre(INDC)[19].

Table 1: *Components, target levels, and scoring used to calculate the Continuing Care (CCare) Score outcome measure.*

Outcome	Target	Score
Optimally controlled blood pressure	Systolic BP <140mmHg	+1
Optimally controlled cholesterol	LDL cholesterol <1.8mmol/L	+1
Optimally controlled glucose	Non-diabetic or Diabetic with HbA1c <53mmol/mol	+2 +1
Optimally controlled waist circumference	Female - waist circumference <80cm Male - waist circumference <94cm	+1
Regular physical activity	>210min / week of moderate exercise	+1
Smoking cessation	Non-smoking	+1
Pharmacological treatment	Prescribed an anti-coagulant or anti-platelet agent And Prescribed a lipid lowering agent	+1

Whether all factors were measured at every visit was dependent on whether the value was within target or not at the previous visit. For example, the target for total cholesterol is <5mmol/l – if a patient is within target, their GP only needed to measure at every other visit whereas if they were outside of the target their GP must repeat the test at the subsequent visit. However, the practice may choose to repeat all tests at each visit.[19]

During the analysis of medication data, patients were categorised as receiving or not receiving specific prescriptions - 'decreased dose', 'increased dose', 'maintained' and 'new' were considered as receiving; and 'not prescribed' and 'discontinued' as not receiving.

Access

The Heartwatch INDC acts as the primary collection point for all data returned by practices.[13] Within this structure there is a data management committee, which has the responsibility of reviewing access requests to the aggregated, anonymous version of the collected data. Data used here was released after such an access request. In the reporting, Strengthening the Reporting of Observational studies in Epidemiology (STROBE) cohort reporting guidelines were used.[20]

Processing

For this paper, data from all consultations January 2003-March 2020 were extracted in December 2021. For patients to be included in the overall analysis (Figures 1A-E), they must have had at least 1 valid initial visit (baseline) between January 2003 and March 2020. For the 8-year follow-up analysis, only those individuals who also had valid 2-, 4-, and 8-year follow-up visits were included. None of the patients recruited through the diabetes programme were included in the analyses presented here. Patients needed a minimum of 1 visit per year for those 8 years, but the intervals were not always the same because some patients attend more frequently than others. However, as part of the automated checks undertaken by the system, there must be a minimum of 10 weeks between visits for a practice to schedule a visit and upload data.[19]

Patients could have attended their GP up to 4 times per year under Heartwatch. However, as the number of visits per year and time between visits varied, the definition of what was the first visit of each year of follow up was applied retrospectively. The first-ever visit was defined as Year 1: Visit 1. The earliest date 1-year after this was defined as Year 2: Visit 1, however, given the variation in attendance a 30-day variance was given, so it would have been the earliest visit at least 335 days after the first visit. Later years were calculated similarly - Year 3: Visit 1 was the earliest visit 2 years (+/- 30 days) after Year 1: Visit 1.

Some patients had more than 1 recorded qualifying event (QE) - AMI, PTCA, or CABG. In these cases, counts and intervals were calculated based on the earliest recorded QE occurrence.

Patient and Public Involvement

Heartwatch was developed in collaboration with the Irish Heart Foundation Irish a national heart and stroke charity which supports and advocates for people who have been affected by heart and stroke. However, it was not possible to involve patients in this later secondary analysis due to data protection restrictions.

Outcome measure development and calculation

Rather than relying on individual targets to determine the success of the patient, a preliminary care outcome score was developed. It was based on EUROASPIRE studies[7,21,22] and the methods used by Ergatoudes et al.[10] They scored patients across six outcome measures derived from guidelines – exercise, systolic blood pressure, LDLc, optimally controlled glucose, smoking status and pharmacological treatment - then considered the number patients who met 6 guidelines, 5 guidelines, and so on.

This initial method was applied to a subset of the Heartwatch dataset to estimate the number of people meeting each metric. However, Ergatoudes et al.[10] only focused on patients in the 2 years after AMI, and the included targets needed to be adjusted for the Heartwatch context to include care guidelines for patients with PTCA and CABG. The methodology and preliminary results of this process were then scrutinised and refined with input from GP specialists in cardiology and diabetes, researchers and data experts.

Following this agreement, patient care outcome scores were calculated within the cohort with 8 years of follow-up recorded. Statistics were run on this cohort on the baseline and 8-year data. The metrics selected and their metric score varies from 1 – 2 (Table 1). For optimally controlled glucose, patients without a QE of diabetes mellitus (DM) were give 2 points because of the high prevalence of comorbidity of CVD and DM.[23] These scores have been called the Continuing Care Score (CCare score).

Statistics

Statistical analysis was carried out using R (4.1) and RStudio (1.4).[24] Regressions were run on individual's calculated outcome measure (range 0-8). Stepwise subset regression analysis was run using an exhaustive

search with all available factors that could have influenced patient outcomes(dummied as necessary). Minimised Bayesian Information Criterion (BIC) was used for model selection. Age was always included in each model as a control variable.

Variable of interest selection

The Heartwatch data is a highly dimensional dataset with a large number of records, therefore to avoid overfitted and complex models, a variable selection approach was taken to identify variables of interest, which would then be further investigated.

Once the CCare score was calculated for each patient in the 8-year follow-up cohort, exhaustive search subset regression was used to select variables for a model to quantify the strength of the relationship between CCare Scores and the explanatory variables. Automatic variable selection based on minimum BIC was used to create a separate model for baseline (year-1) and for the 8-year follow up data. That model was then applied to all patients with complete records for the selected variables.

Results

Heartwatch Overview: 2003-2020

Looking across all validated Heartwatch records between 2003 and March 2020. By the end the second year of Heartwatch there were over 20,000 GP visits annually, and attendance numbers stayed above 20,000 until 2012 (Figure 1A). While overall attendance has decreased since its peak in 2008, the proportion of patients attending once, twice, three or four times a year remained stable between 2004 and 2020 (Figure 1A). Over 16,000 patients had entered the programme and patients stayed in Heartwatch for an average of 7 years (Figure 1B). Over 7,000 patients (45%) have been in the programme for 8 years or more.

There were more male (76%) participants compared to female. The majority of Heartwatch patients were over 60 at signup, with 27% aged <60 years and 33% of all participants aged between 60-69 years at signup (Figure 1C). The median age at signup across all years was 67 and has not differed much over time (range: 63-67). The female group are typically older, with a median age of 70 compared to 65 for males (Figure 1C).

An AMI was the most common QE (40%), with PTCAs and CABGs accounting for 35% and 25% respectively (Figure 1D). Overall, 18% of patients were enrolled within 1 year of their QE (Figure 1E). Another 32% of patients enrolled between 1 and 2 years after their QE; with the rest singing up between 3 and 6 years (25%) or more than 6 years (26%) after their QE. Early signups on programme commencement tended to have longer intervals between event and signup (QE-Interval), (2003: mean 6 years) but the interval shortened and by 2006 stabilised (2006-2019: range 2-3).

The 8-Year Cohort from 2003-2020

To assess the progress of patients, we identified a cohort of 5,700 patients with at least 8 years in the programme (Figure 2A). These are patients who have had a minimum of at least 1 visit per year for 8 years between 2003-2020. The remainder of the analyses presented here pertains to this cohort. In this cohort, 77% were male and the median age at signup was 65 years (Figure 2C); 38% of patients in the 8-year cohort had a PTCA as their first QE and CABG was again the least common type of QE (26%) (Figure 2B). A third of patients in this cohort were referred to the programme within 1-2 years of experiencing their QE (34%), the median QE-interval was 2 years (Figure 2D).

The Continuing Care Scores

In year 1, the median CCare score was 5 (33% of patients), 30% of patients scored lower than this with the remaining 37% scoring greater than 5. The number of patients achieving scores above 5 increased to 44% in year 4 (Figure 3A). After 8 years of follow up, 40% of patients scored 6 or better. By year 4, 37% of patients had individual-level improvements in scores, 36% of scores had not changed and 27% decreased. By year 8, scores tended to be higher, although the ratio of higher-same-lower narrowed (36%:32%:32%) (Figure 3A). After 1, 2, 4 and 8 years of follow up, the median CCare score across the cohort was 5.

Components of the CCare Score and other metrics

At the start of the first year, 64% of the patient cohort was within the target for systolic blood pressure (Supplementary Table 1). This increased to 70% at year 4 but reverted to 67% in year 8. Exercise and anti-

platelet/anti-coagulant treatment showed a similar pattern of improvement up to year 4, with a degree of decline from year-4 to year-8 (Table 2).

Table 2: *Percentages of 8-year cohort within target under each score component, and by year of follow up (n = 5,729).*

Outcome	*Year 1*	*Year 2*	*Year 4*	*Year 8*
Systolic BP <140mmHg	64%	69%	70%	67%
LDL cholesterol <1.8mmol/L	21%	23%	26%	30%
Diabetic with HbA1c <53mmol/mol	5%	8%	10%	13%
Non-diabetic	90%	88%	85%	81%
Female - waist circumference <80cm *Male - waist circumference <94cm*	27%	27%	27%	25%
Moderate exercise >210min/week	37%	40%	41%	35%
Non-smoking	88%	89%	90%	92%
Prescribed anti-coagulant/antiplatelet and lipid lowering agents	88%	92%	94%	92%

The number of patients with co-morbid diabetes that had HbA1c readings within target increased over time. However, this occurred in tandem with an increased new diagnosis of diabetes in the rest of the cohort (Table 2).

LDLc started with only 21% of patients being in target but this steadily increased to 29% in year 8. Smoking rates likewise improved through to year 8. The rate of waist circumference within target did not change much through follow-up.

The values comprising the CCare score - as well as some not included in the score - demonstrated a similar pattern. Some risk factors showed continued improvement with follow-up - Total and LDL Cholesterol - others improved for the first 4 years of follow-up - Systolic BP, Exercise – while others did not improve - BMI, weight - and the prevalence of diabetes increased (Supplementary Table 2).

In terms of medication changes, fewer patients were prescribed aspirin from year 1 (91%) to year 8 (87%). This was the only tracked prescription that saw an overall reduction, however, it remained among the most commonly prescribed item. Beta-blockers and statins were also commonly prescribed items (year 8: 92% & 73%). Prescriptions of diuretics started at 18% and increased to 24% over time. There were 3 medications that had a 6% increase in being prescribed; ace inhibitors (started at 45%), Ca channel blockers (started at 16%), and ATII inhibitors (started at 10%). The prescription of diabetic medications also showed steady increases through follow-up (Table 3).

***Table 3**:Medications prescribed among the 8-year cohort by year of follow up (n = 5,729), with change from year 1 calculated for each later year of follow up. ACE, angiotensin-converting enzyme; ATII, angiotensin II; Ca, Calcium-channel blockers; Δ, delta (change).*

	Year 1		*Year 2*	*Δ*	*Year 4*	*Δ*	*Year 8*	*Δ*
Aspirin	91%	-	91%	0%	90%	-2%	87%	-4%
Beta blockers	69%	-	70%	1%	71%	2%	73%	4%
ACE inhibitors	45%	-	49%	4%	51%	6%	51%	6%
Anti-Coagulants	8%	-	7%	0%	8%	0%	12%	4%
Diuretics	18%	-	19%	2%	21%	3%	24%	6%
Ca channel blockers	16%	-	17%	1%	19%	3%	22%	6%
ATII inhibitors	10%	-	11%	1%	13%	3%	16%	6%
Other antihypertensive	9%	-	8%	-1%	8%	0%	10%	1%
Fibrate	2%	-	1%	-1%	2%	0%	2%	0%
Statin	88%	-	92%	4%	93%	5%	92%	4%
Other lipid lowering	5%	-	7%	1%	9%	4%	11%	6%
Insulin	1%	-	1%	0%	2%	0%	3%	1%
Sulphonylureas	4%	-	4%	1%	5%	2%	7%	3%
Biguanides	5%	-	6%	1%	7%	2%	10%	5%

Glucosidase	0%	-	0%	0%	0%	0%	0%	0%
Other hypoglycaemic	1%	-	1%	0%	1%	1%	3%	2%

Variables Selection

The variable selection procedure was run across available influencing factors; age at signup, year of signup , QE-Type, QE-Interval, public/private patient status, and employment status, additional average visits per year were considered in the year-8 model. With year 1 data considered, a 4-predictor model of CCare scores at signup was selected; QE-Interval, year of signup, and sex were selected as regression variables, age was also forced into the model. The selected model statistically significantly predicted CCare scores, $F(4, 14920) = 222.2$, $p < .0001$, adj. $R2 = .06$. All 4 variables added statistically significantly to the model's prediction ($p < .001$). Longer QE-intervals and higher age at signup predicted lower scores. Male patients and patients registered more recently in Heartwatch were predicted to have higher scores. In all cases, the effect sizes were small; the largest effect size showed males to have an average higher score by 0.3 (Supplementary Table 3).

Looking at data from year 8, a different model for CCare scores at signup was selected. Visits per year, year of signup, and sex were selected as regression variables, age was again forced into the model. The resulting model statistically significantly influenced CCare scores ($F(4, 6958) = 84.93$, $p < .0001$, adj. $R2 = .06$). All variables except age added statistically significantly to the model ($p < .001$) (age: $p= 0.07$)(Supplementary Table 4). More visits per year predicted lower CCare scores. Male patients and those registered more recently, were predicted to have higher CCare scores. Again, in all cases, the effect sizes were small (Supplementary Table 3 & 4).

Variables of Interest and CCare Scores

Sex was selected in both year-1 and year-8 models and showed female patients having lower scores in both cases. Female patients had lower CCare scores across all eight years of follow up, 26% had scores above 5 in year 1, which rose to a maximum of 33% in year 4 and fell again to 28% in year 8, which was 15% points lower than the equivalent in male patients (41%, 47% & 44% respectively) (Figure 3B). The increase amongst both sexes from year-1 to year-4 were similar (females: +7%, males: +6%) (Figure 3B).

Age was not selected in either model but was forced in given its known association with several of the metrics used in the CCare score. Higher age was predictive of lower scores at baseline but did not significantly statistically add to the 8-year model. More younger patients had a CCare score greater than 5 at signup (<60: 42%) compared to older patients (60-69: 38%, 70+: 34%)(Figure 3C). All age groups had more scores >5 after 4 years of follow up, (0-59: 46%, 60-69: 46%, 70+: 42%), but more older patients had improved scores to reach those levels (0-59: +4%, 60-69: +8%, 70+: +8%). The difference in the number of patients with a score above 5 narrowed after 8 years of follow up, and fewer patients achieved scores of ≥5 than they had after 4 years (0-59: 42%, 60-69: 42%, 70+: 38%)(Figure 3C).

Those who registered earlier in the programme had lower scores at signup. More recent registrants had stable outcomes in the first 4 years and then generally dropped, while those who signed up earlier saw improvement (Figure 3D). Despite this, earlier registrants never recovered to the same degree as later joining patients starting point.

Longer intervals between a patient's earliest cardiac event and first visit under HW was predictive of worse CCare scores in the year-1 model and was not selected in the year-8 model. Patients with shorter intervals were more likely to have scores above 5 (Figure 3E). Shorter QE-interval patients were stable in the first 4 years and then dropped, whereas those with longer QE-intervals saw continued improvement. Similar to the year of signup, the improvements that were seen in patients with longer QE-intervals to signup did not allow them to reach the same level of scores as the shorter QE-interval patients.

The number of Heartwatch visits per year was selected and predictive of higher CCare scores in the year-8 model and was not selected in the year-1 model. Looking at grouped figures, patients who visited more often were more likely to have scores above 5 (Figure 3F). All visit per year groups saw improvements throughout years of follow up, each achieving their highest CCare score after 4 years.

Discussion

In this investigation of patient data from a cardiovascular secondary prevention programme, we found that patients achieved moderate improvements in blood pressure (+3% within target), LDL cholesterol (+7% within target), and smoking status (+4% non-smokers). To develop a broader understanding of patient

success, an 8-point Continuing Care Score was created to monitor changes over 8 years. Less than 2% of patients achieved all targets, however by year 8, 71% of patients had achieved between 5 and 7 of the 8 targets.

Using statistical modelling, we found that longer time intervals between the qualifying cardiac event and starting the secondary prevention intervention predicted worse scores even after 8 years, but these patients can and do improve overtime, just not as rapidly as other patients. Female patients were also more likely to have worse CCare scores, both in the baseline and 8-year model. Moreover, patients who attended 3 or more visits per year had higher average CCare scores and maintained higher scores while patients who visited less frequently saw a decline in their outcomes. This could be a reason to promote attending secondary cardiac prevention as soon as possible following a cardiac event and maintaining a good level of contact with that intervention.

Comparison to other literature

It is difficult to draw a direct comparison with other literature because the programme is not a trial nor a survey of patients with a history of CVD but an ongoing care program with real-world data. The programme, Heartwatch, presents a much longer-term view of secondary prevention compared to most literature which focuses on the first six months,[26] first year or first 2 years following a cardiac event.[8,27] There is substantial research on secondary prevention of CVD and identifying and managing risk factors for these patients which we have compared with our results. In a review of clinical trials looking at primary and secondary prevention of coronary artery disease, Kantaria et al. found that reduction of LDLc, decrease in blood pressure and discontinuation resulted in reduced death rates and further cardiac events.[28] This is promising, as these are the key areas in which Heartwatch patients improved.

An international review of risk factor management for patients with CVD in Asia, Europe and the Middle East also found sex-based differences where female patients were less likely to achieve total cholesterol, LDLc, glucose, physical activity and weight targets compared to male counterparts.[29] These differences were smaller in Europe compared to Asia and the Middle East but persisted nevertheless which is congruent with our predictive model findings of sex-based outcome differences.

In 2009, the European Action on Secondary and Primary Prevention by Intervention to Reduce Events III (EUROASPIRE III)[21] survey sought to determine whether the European guidelines were being followed in everyday practice. This survey found that large proportions of patients do not achieve the targets, more than half did not meet the blood pressure or cholesterol targets[21] and they stated that European countries needed to raise the standard of preventive care. An Italian study of secondary prevention of coronary heart disease in primary care, which looked at health records of just under 6,000 patients found 153 patients with CVD.[9] This survey found that there was satisfactory adherence to guideline advice – 46% of patients achieved LDL targets and 83% achieved the systolic blood pressure target. They concluded that GPs are well placed to help people with a history of CVD to manage risk factors, but that care could be further optimised.

The Swedish study[10] that inspired the development of the CCare score, found only 3.5% of people were achieving all targets 2 years after AMI. This is similar to our finding here where just 2% of patients achieved all 8 targets at year 2. This highlights further the need for specific interventions of secondary prevention, as more Heartwatch patients achieved their systolic blood pressure (SBP), 69%, and LDL targets, 23%, after 2 years compared to the those in Sweden where 57% achieved the SBP and 18.5% achieved LDL targets. However, it should be noted that Heartwatch has a more diverse patient group compared to the Swedish patients, who had suffered an acute incident. A Norwegian study of cardiac rehabilitation patients, showed that patients who had an acute incident were more likely to participate in secondary prevention.[30]

Finally, in the more recent EUROASPIRE surveys, smoking, obesity, and exercise were persistent in their unlikeliness to change overtime but lifestyle changes were more successful if a patient was in a prevention programme.[31] However, in the same Norwegian study as above patients who were overweight were more likely to participate in the program, which shows a willingness to improve.[30] In Heartwatch, exercise and waist circumference did not show much improvement over 8 years. Patients in the EUROASPIRE surveys stated lack of confidence as their main barrier to address unhealthy behaviour.

Implications for policy and practice

In current secondary prevention research and guidelines, there is a focus on measurement and development of risk factor targets. However, research has repeatedly demonstrated that patients are not meeting these targets.[32,33] For example, results for males and females diverge under similar targets. The current evidence

base should be used as a foundation to refocus secondary prevention research away from target definitions and onto the implementation of these programmes with added public and patient involvement.

We, and others[34], have shown early enrolment after a cardiac event and frequency of structured care visits should be priorities in the design and implementation of similar programmes.

The evaluation of patient outcomes and cost-effectiveness should take into consideration that new programmes can experience an initial influx from a backlog of high-risk cases. Chronic disease programmes may evolve significantly in the initial few years. Planning and evaluation should take this into consideration.

Conclusion

Secondary prevention of CVD can have a positive impact even when patients start with poor outcomes. The sooner a patient can access a structured care program, the better but even with delays it is worth enrolling patients with a history of cardiac events regardless of age. Overall, patients are not likely to meet all targets set by secondary prevention guidelines – especially those related to lifestyle factors such as exercise and waist circumference. However, supporting patient self-management may impact on this and the inclusion of factors such as a patient-centred approach and regular training of health professionals to deliver same, as noted elsewhere.[22,31]

Acknowledgements

We thank Drs. Suzanne Kelly and Mike O'Callaghan, clinical leads in the ICGP for their support and clinical expertise. Our thanks also to Patricia Patton, ICGP library for bibliography assistance. This work uses data that have been provided by patients and collected by their GPs as part of their care and support, we acknowledge these contributions and thank Sally-Anne O'Neill and Colleen O'Neil for Heartwatch administrative support and advice.

Conflict of interest

The authors declare no conflicts of interest.

Author Contributions

All authors contributed to the research question development. FS carried out the re-coding of variables and undertook the analysis. All authors designed the analysis approach, interpreted the results and formulated the conclusions. JG contributed clinical expertise. CC is the PI and manager of the Heartwatch Programme and provided direction and oversight for this analysis and paper. RH and FS prepared the first draft of the manuscript. RH and FS contributed equally to this paper. All authors contributed to the manuscript and all authors read and approved the final manuscript. All named authors contributed sufficient work according to the COPE guidelines.

Funding

There was no additional funding obtained to undertake this secondary analysis. The Heartwatch programme is funded by the Irish Health Service Executive. The ICGP Research Hub is funded by the Irish Sláintecare Office.

Ethical Review Statement

The anonymous data used in this paper was provided through the agreed database access process and is in accordance with all GDPR requirements and is a legitimate use of the database and in compliance with the programme's ethical approval.[35]

Data Sharing Statement

Heartwatch data is managed by the Heartwatch INDC which has the responsibility of reviewing access requests to the aggregated, anonymous version of the collected data.

References

1. World Health Organization. Cardiovascular diseases (CVDs) - Key facts. 2021.

2. Eurostat. Causes of Death Statistics., 2021.

3. Fitzpatrick P, Fitz-Simon N, Lonergan M *et al.* Heartwatch: The effect of a primary care-delivered secondary prevention programme for cardiovascular disease on medication use and risk factor profiles. *Eur J Prev Cardiol* 2011;**18**:129–35.

4. Central Statistics Office. *Vital Statistics Yearly Summary 2019.*, 2020.

5. 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 (constituted by representati. *Eur Heart J* 2016;**37**:2315–81.

6. Wilt TJ, Bloomfield HE, MacDonald R *et al.* Effectiveness of statin therapy in adults with coronary heart disease. *Arch Intern Med* 2004;**164**:1427–36.

7. Collaboration AT. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. *BMJ* 2002;**324**:71–86.

8. Peersen K, Munkhaugen J, Gullestad L *et al.* The role of cardiac rehabilitation in secondary prevention after coronary events. *Eur J Prev Cardiol* 2017;**24**:1360–8.

9. De Backer G, Ambrosioni E, Borch-Johnsen K *et al.* European guidelines on cardiovascular disease prevention in clinical practice: third joint task force of European and other societies on cardiovascular disease prevention in clinical practice (constituted by representatives of eight societies and by invit. *Eur J Cardiovasc Prev Rehabil* 2003;**10**:S1–10.

10. Ergatoudes C, Thunström E, Rosengren A *et al.* Long-term secondary prevention of acute myocardial infarction (SEPAT) - guidelines adherence and outcome. *BMC Cardiovasc Disord* 2016;**16**:226.

11. Hall M, McGettigan M, O'Callaghan P *et al.* Comparison of secondary prevention of heart disease in Europe: lifestyle getting worse, therapy getting better in Ireland. *Ir Med J* 2002;**95**:272–4.

12. Modesti A, Del Papa C, Modesti L *et al.* Secondary prevention of coronary heart disease. A survey in an Italian primary care practice. *Minerva Cardioangiol* 2010;**58**:167–73.

13. Department of Health and Children, Health Boards, ICGP *et al. Heartwatch Clinical Report - V1*. Dublin, 2004.

14. Department of Health and Children, HSE, ICGP *et al. Heartwatch Clinical Report - V2*. Dublin, 2006.

15. Collins C, Finn C, Meade B *et al.* Strengthening the Foundation of General Practice Evidence in Ireland by Addressing the Data Quality Issues in a Structured Secondary Prevention Programme for Cardiovascular Disease. *JMED Res* 2014;**2014**:1–6.

16. Bennett K, Jennings S, Collins C *et al.* Heartwatch: A secondary prevention programme in primary care in Ireland. *Eur J Prev Cardiol* 2008;**15**:651–6.

17. Brett T, McGuire S, Meade B *et al.* Secondary prevention of cardiovascular disease: A possible model for Australian general practice. *Aust Fam Physician* 2006;**35**:157–9.

18. Wood D, De Backer G, Faergeman O *et al.* Prevention of coronary heart disease in clinical practice. Summary of recommendations of the Second Joint Task Force of European and other Societies on Coronary Prevention. *Blood Press* 1998;**7**:262–9.

19. Irish College of General Practitioners. *Heartwatch Summary Guide*., 2003.

20. Elm E von, Altman DG, Egger M *et al.* Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;**335**:806–8.

21. Kotseva K, Wood D, De Backer G *et al.* EUROASPIRE III: a survey on the lifestyle, risk factors and use of cardioprotective drug therapies in coronary patients from 22 European countries. *Eur J Cardiovasc Prev Rehabil* 2009;**16**:121–37.

22. Kotseva K, De Backer G, De Bacquer D *et al.* Lifestyle and impact on cardiovascular risk factor control in coronary patients across 27 countries: Results from the European Society of Cardiology ESC-EORP EUROASPIRE V registry. *Eur J Prev Cardiol* 2019;**26**:824–35.

23. Leon BM, Maddox TM. Diabetes and cardiovascular disease: Epidemiology, biological mechanisms, treatment recommendations and future research. *World J Diabetes* 2015;**6**:1246.

24. Team RC. R: A language and environment for statistical computing. 2021.

25. Saracci R. Survival-related biases survive well. *Int J Epidemiol* 2007;**36**:244–6.

26. Urbinati S, Olivari Z, Gonzini L *et al.* Secondary prevention after acute myocardial infarction: drug adherence, treatment goals, and predictors of health lifestyle habits. The BLITZ-4 Registry. *Eur J Prev Cardiol* 2015;**22**:1548–56.

27. Jankowski P, Kosior DA, Sowa P *et al.* Secondary prevention of coronary artery disease in Poland. Results from the POLASPIRE survey. *Cardiol J* 2020;**27**:533–40.

28. Kantaria M, Buleishvili M, Kipiani N V *et al.* Risk factors of Coronary Artery Disease (review). *Georgian Med News* 2020:78–82.

29. Zhao M, Vaartjes I, Graham I *et al.* Sex differences in risk factor management of coronary heart disease across three regions. *Heart* 2017;**103**:1587–94.

30. Olsen SJ, Schirmer H, Bønaa KH *et al.* Cardiac rehabilitation after percutaneous coronary intervention: Results from a nationwide survey. *Eur J Cardiovasc Nurs* 2018;**17**:273–9.

31. De Bacquer D, Astin F, Kotseva K *et al.* Poor adherence to lifestyle recommendations in patients with coronary heart disease: results from the EUROASPIRE surveys. *Eur J Prev Cardiol* 2021, DOI: 10.1093/eurjpc/zwab115.

32. Vogel B, Acevedo M, Appelman Y *et al.* The Lancet women and cardiovascular disease Commission: reducing the global burden by 2030. *Lancet* 2021;**397**:2385–438.

33. Murphy AW, Cupples ME, Murphy E *et al.* Six-year follow-up of the SPHERE RCT: secondary prevention of heart disease in general practice. *BMJ Open* 2015;**5**:e007807.

34. Murchie P. Secondary prevention clinics for coronary heart disease: four year follow up of a randomised controlled trial in primary care. *BMJ* 2003;**326**:84–84.

35. Irish College of General Practitioners. Research Ethics Committee. *Irish Coll Gen Pract* 2022.

Figure legends

Figure 1 – Heartwatch overview 2003-2020

A - All Heartwatch visits graphed by year of visit.
B – Each year of follow up with total number of patients graphed.
C – Population pyramid of all patients.
D – All patients grouped by earliest qualifying event type.
E – All patients grouped by interval from earliest qualifying event to date of first Heartwatch visit.
AMI, acute myocardial infarction; PTCA, percutaneous coronary intervention; CABG, coronary artery bypass grafting; * Jan 2003 to March 2020.

Figure 2 – Heartwatch 8-year cohort overview 2003-2020

A – Patient records graphed by year of follow up. The records of the 8yr-cohort are highlighted in pink.
B - 8-year cohort grouped by earliest qualifying event type.
C - Population pyramid of 8-year cohort.
D - 8-year cohort grouped by interval from earliest qualifying event to date of first Heartwatch visit.
8-year cohort n= 5729.

Figure 3 – The CCare for the 8-year cohort in follow up years 1, 2, 4 & 8.

A – The CCare scores for the 8-year cohort; proportion of cohort by number of metrics met.
B – The CCare scores by grouped age bands.
C - The CCare scores by grouped recorded sex.
D - The CCare scores by grouped year of first visit.
E - The CCare scores by grouped by number of visits per year.
F - The CCare scores by grouped by interval from earliest qualifying event to date of first Heartwatch visit.
QE, Qualifying event.

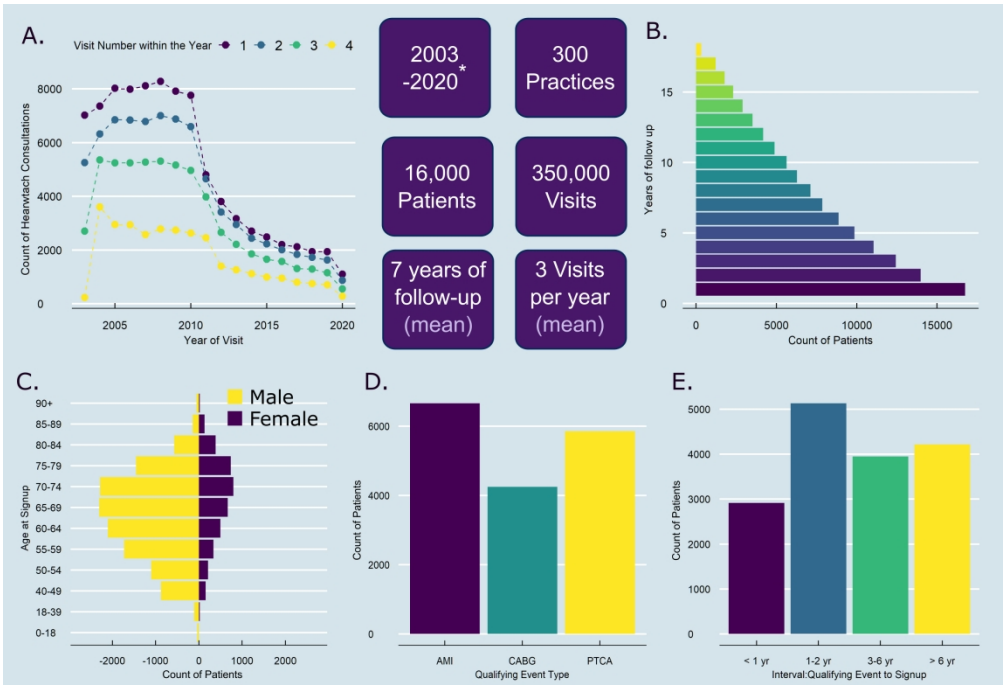

Figure 1 – Heartwatch overview 2003-2020.
A - All Heartwatch visits graphed by year of visit. B - Each year of follow up with total number of patients graphed. C - Population pyramid of all patients. D - All patients grouped by earliest qualifying event type. E - All patients grouped by interval from earliest qualifying event to date of first Heartwatch visit. AMI, acute myocardial infarction; PTCA, percutaneous coronary intervention; CABG

464x316mm (164 x 164 DPI)

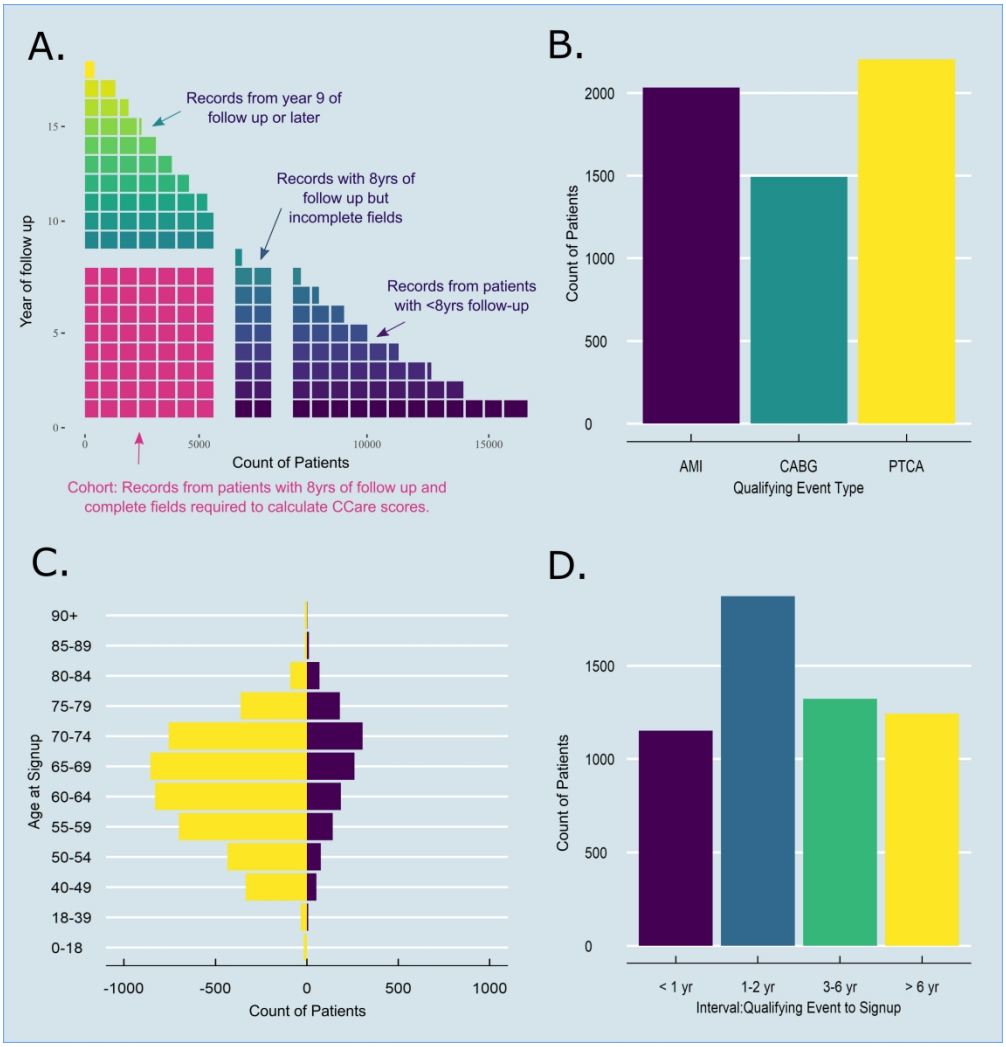

Figure 2 – Heartwatch 8-year cohort overview 2003-2020
A - Patient records graphed by year of follow up. The records of the 8yr-cohort are highlighted in pink. B - 8-year cohort grouped by earliest qualifying event type.
C - Population pyramid of 8-year cohort. D - 8-year cohort grouped by interval from earliest qualifying event to date of first Heartwatch visit. 8-year cohort n= 5729.

698x725mm (105 x 105 DPI)

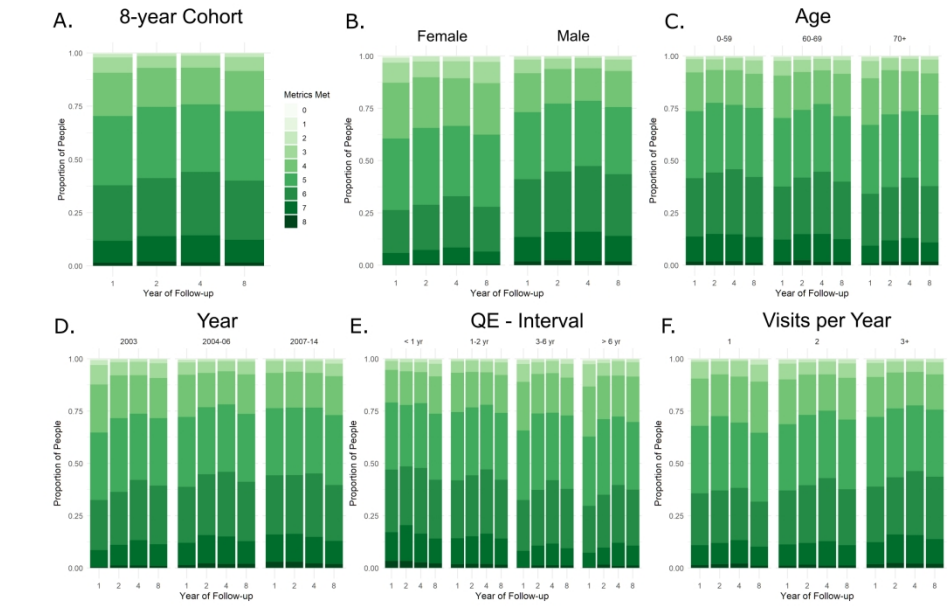

Figure 3 – The CCare for the 8-year cohort in follow up years 1, 2, 4 & 8.
A - The CCare scores for the 8-year cohort; proportion of cohort by number of metrics met. B - The CCare scores by grouped age bands. C - The CCare scores by grouped recorded sex. D - The CCare scores by grouped year of first visit. E - The CCare scores by grouped by number of visits per year. F - The CCare scores by grouped by interval from earliest qualifying event to date of first Heartwatch visit. QE, Qualifying event.

1058x726mm (72 x 72 DPI)

Supplementary Table 1

	Mandatory Fields	Units	Targets	Min/Max
Systolic Blood Pressure	y	mmHg	<140	60/240
Diastolic blood pressure	y	mmHg	<90	30/150
Total Cholesterol	y	mmol/L	<5	1/12
LDL Cholesterol	y	mmol/L	<1.8	0/11
Exercise Total	n	min/week	>210	
Height	y	cm		135/195
Weight	y	kg		40/200
Waist Circumference	y	cm	Male: <94 Female: <80	40/200
Body Mass Index	y	kg/cm2	<25	15/60
Diabetes Status	y			
Fasting Glucose	y	mmol/L	Non-Diabetics: <5.5 Diabetics: <6	2/30
HbA1c	y - (Type 1,Type 2 & IGT)	mmol/mol	<45	20/140
Serum Creatinine	y - (Type 1,Type 2 & IGT)	mmol/L	<115	10/999

Legend

Supplemental Table 1 – Heartwatch measures, targets, and minimum and maximum valid values allowed for each.

IGT, Impaired glucose tolerance.

Supplementary Table 2

	Year 1			*Year 2*			*Year 4*			*Year 8*		
	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD	n
BP Systolic	133	18	5729	132	17	5729	131	16	5729	132	16	5729
BP diastolic	77	10	5729	76	9	5726	75	9	5728	75	9	5729
Cholesterol total	4.3	1.0	5728	4.2	1.0	5724	4.1	0.9	5729	4.0	0.9	5728
Cholesterol LDL	2.5	0.9	5729	2.3	0.8	5729	2.2	0.8	5729	2.2	0.9	5729
Weight	81	15	5725	81	15	5725	82	15	5729	82	16	5729
Waist Circumference	97	13	5729	97	13	5729	97	13	5729	98	14	5729
BMI	28	4	5710	28	4	5677	28	4	5729	28	5	5729
Diabetes (T1,T2,IGT)	10%		5729	12%		5729	15%		5729	19%		5729
Fasting Glucose	5.5	1.7	4870	5.7	2.8	4937	5.6	1.8	4957	5.7	1.8	5101
HbA1c	50	14	738	49	12	872	49	12	1015	50	12	1235
Serum Creatinine	99	82	1034	99	73	1170	98	66	1274	97	41	1466
Weekly Exercise	227	152	5729	235	135	5729	237	136	5729	215	141	5729
Smoking Status	12%		5729	11%		5729	10%		5729	8%		5729

Legend:

Table 2 – Means, standard deviations (SD) and sample sizes of Heartwatch programme measures for the 8-year cohort in follow up years 1,2,4,and 8.

Supplementary Table 3

Term	*Coefficient*	*SE*	*T-statistic*	*P-value*
(Intercept)	-52.941	4.435	-11.938	< 0.001
QE-Interval	-0.035	0.002	-16.043	< 0.001
Sex	0.339	0.024	14.33	< 0.001
Year of signup	0.029	0.002	13.132	< 0.001
Age at signup	-0.006	0.001	-6.483	< 0.001

Legend

Supplemental Table 3 – coefficients table from the year-1 model: the multiple linear regression run on data from the first Heartwatch visit of the 8-year cohort (n = 5,729).

QE, qualifying event; SE, standard error.

Supplementary Table 4

Term	*Coefficient*	*SE*	*T-statistic*	*P-value*
(Intercept)	-16.941	10.762	-1.574	0.12
Visits per year	0.161	0.021	7.74	< 0.001
Sex	0.387	0.035	11.114	< 0.001
Year of signup	0.011	0.005	1.988	0.047
Age at signup	-0.001	0.001	-0.576	0.56

Legend

Supplemental Table 4 – coefficients table from the year-8 model: the multiple linear regression run on data from the earliest visit from the eighth year of follow up of the 8-year cohort (n = 5,729).

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1	'secondary analysis'
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2	See abstract
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5	See Introduction
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5	See introduction
Methods				
Study design	4	Present key elements of study design early in the paper	6-9	Se methods
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-9	See methods, with specific sections on data collection, access, and processing
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6-9	See methods, data collection mentions how patients are recruited to secondary prevention programme and how their data is collected, section on data processing dictates how patients were selected for secondary analysis
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9	In methods, outcome measure development and calculation, stats, and variables of interest
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-9	Methods and supplemental table 1
Bias	9	Describe any efforts to address potential sources of bias	6-9	methods
Study size	10	Explain how the study size was arrived at	7-8	Method > data handling > processing

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-9	Data handling and variables of interest
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9	
		(*b*) Describe any methods used to examine subgroups and interactions	9	
		(*c*) Explain how missing data were addressed	6-9	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a secondary analysis	
		(*e*) Describe any sensitivity analyses	n/a	
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10	Results section
		(b) Give reasons for non-participation at each stage	n/a	
		(c) Consider use of a flow diagram		
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10-14	results
		(b) Indicate number of participants with missing data for each variable of interest	n/a	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)		
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	10-14	results
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures		
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-14 15-16	Results Discussion
		(*b*) Report category boundaries when continuous variables were categorized	supplemental table 1	Target values/limits are included in supplemental table 1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		n/a

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10-14	All analyses in results
Discussion				
Key results	18	Summarise key results with reference to study objectives	15	first section of discussion
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15	Second section of discussion 'strengths and limitations'
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15-18	Discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results	15-18	Discussion
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Heartwatch: an Irish Cardiovascular Secondary Prevention programme in primary care, a secondary analysis of patient outcomes.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-063811.R1
Article Type:	Original research
Date Submitted by the Author:	24-Aug-2022
Complete List of Authors:	Homeniuk, Robyn; Irish College of General Practitioners, Research Stanley, Fintan; Irish College of General Practitioners, Research Hub Gallagher, Joseph; Irish College of General Practitioners Collins, Claire; Irish College of General Practitioners, Research
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Cardiovascular medicine, General practice / Family practice
Keywords:	PRIMARY CARE, CARDIOLOGY, Coronary intervention < CARDIOLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PREVENTIVE MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title Page:

Heartwatch: an Irish Cardiovascular Secondary Prevention programme in primary care, a secondary analysis of patient outcomes.

Authors

Robyn Homeniuk*[1]

- MSc
- https://orcid.org/0000-0002-5526-4113

Fintan Stanley*[2]

- PhD
- https://orcid.org/0000-0002-6740-3280

Joseph Gallagher[3]

- BA MB BCh BAO MRCPI MICGP MD
- https://orcid.org/0000-0002-5564-2890

Claire Collins[1]

- PhD
- https://orcid.org/0000-0001-8967-5159

*These authors contributed equally and should be joint first author.

Corresponding: Claire Collins, Research Centre, Irish College of General Practitioners, Dublin, Ireland, claire.collins@icgp.ie

1. Research Centre, Irish College of General Practitioners, Dublin, Ireland
2. Research Hub, Irish College of General Practitioners, Dublin, Ireland
3. Cardiovascular Clinical Lead, Irish College of General Practitioners, Dublin, Ireland

The work for this paper was completed at the Irish College of General Practitioners (remotely)

Word count: 4,634 (main text)

Manuscript count: 7074

Abstract

Objectives: To investigate patient follow-up data from Heartwatch: Ireland's secondary prevention programme for cardiovascular disease delivered in general practice.

Design: Retrospective descriptive study based on secondary analysis of routinely collected data from Heartwatch.

Setting: Heartwatch targeted 20% of general practices in Ireland and recruited 475 GPs across 325 practices.

Participants: The patient population included people with a history of acute myocardial infarction (AMI), percutaneous transluminal coronary angioplasty (PTCA) or a coronary artery bypass graft (CABG). Over 16,000 patients entered the programme however, to assess the long-term progress of patients, we identified a cohort of 5,700 patients with at least 8 years in the programme.

Interventions: A standard protocol for continuing care of patients for the secondary prevention of cardiovascular disease was administered by general practices. The programme was designed using World Health Organisation (WHO) and European Society of Cardiology (ESC) guidelines on secondary prevention.

Outcome measures: A Continuing Care (CCare) score out of eight was the primary outcome measure used. It was calculated based on programme targets for well-known cardiovascular risk factors: exercise, systolic blood pressure, LDL cholesterol, optimally controlled glucose, smoking status, and pharmacological treatment.

Results: After one year, 37% of the 8-year cohort had achieved a CCare score >5 increasing to 44% after year-8. Patient sex was predictive of better scores; male patients had almost a half-point advantage (0.432, CI: 0.335-0.509). Patients who enrolled earlier following their qualifying event and patients with more frequent visits were also more likely to achieve higher CCare scores.

Conclusions: Overall, patients are not likely to meet all targets set by secondary prevention guidelines, however, supporting patient self-management may impact on this. Early enrolment after a cardiac event and frequent structured care visits should be priorities in the design and implementation of similar programmes. Ongoing evaluation of them is necessary to improve outcomes.

Keywords: secondary prevention, cardiovascular health, patient outcomes, primary care, general practice; continuing care score

Strengths and limitations

- The key strength of Heartwatch is the volume of patient data and the length of time the program has been in existence with patients retained.
- The data comes from an active clinical program. There is no comparative or control group
- LDLc guideline targets changed during the program so guidelines initially would have suggested a higher target, although we retrospectively applied the most recent guideline target. Hence, as a stricter target is applied, we have underestimated the number achieving the desired active target prior to 2016.
- There is likely a survivor bias on the available long-term information, as those with worse scores may have exited the programme earlier than 8 years and we do not have access to outcomes such as death or major adverse cardiovascular events.

Introduction

Globally, cardiovascular diseases (CVD) are the leading cause of death, with 32% of all global deaths - 17.9 million - being attributed to them in 2019.[1] In Europe, cancer and circulatory diseases have been the leading causes of death since 2006.[2] Recent statistics have shown that from 2006-2016 the number of deaths from ischaemic heart disease fell by 28.4% for men and 34.2% for women.[2] In 2016, the standardised death rate from ischaemic heart disease in Ireland was 133 per 100,000 inhabitants, which was slightly more than the EU rate of 119.4 per 100,000 inhabitants.[2]

While the decline in deaths from ischaemic heart disease is promising, it is still a major cause of mortality in Ireland.[3] The Central Statistics Office state that circulatory system diseases made up 28.9% of all deaths in Ireland in 2019.[4] This was the second leading cause of death after malignant neoplasms.[4] As highlighted by the evidence review in the Sixth Joint European Society of Cardiology (ESC)[5], patients with a history of CVD may need long term support to change their behaviour and limit the risk of further cardiac events. Furthermore, evidence from clinical trials have shown the benefits of secondary prevention following acute myocardial infarction (AMI), percutaneous coronary intervention (PTCA) or coronary artery bypass grafting (CABG)[3,6,7].

Provision of comprehensive cardiac rehabilitation, similar to the comprehensive approach in Heartwatch, was shown to have more patients achieve risk factor targets.[8] As of 2013, nearly 80% of Irish patients were compliant with cardiac rehabilitation recommendations.[9] Moreover, the World Health Organisation (WHO) has suggested that providing CVD management of risk factors under universal health coverage and at a primary care level can reduce the burden of CVD.[1] Ireland was the first country in the European Union to implement a standardised, national programme led by general practitioners (GPs) – called Heartwatch – that strategically implemented the ESC guidelines.[10] Other countries have since also adopted secondary prevention programmes that monitor blood pressure, cholesterol, smoking status and physical activity.[11–13]

In Ireland, GPs work as private healthcare professionals charging private patients per visit and receiving government payments on a capitation basis for eligible public patients. Around 43% of

people in Ireland qualify for free GP care, either through the General Medical Scheme card (32.4%) or GP-visit card(10.4%).[14] GPs have a central role in the Irish health system, and they are critical in the management of long-term conditions with 80% of all GP visits relating to chronic disease management.[14] A fifth of Irish general practices were recruited to deploy the specially developed secondary prevention program, which enabled patients to attend up to four specialised visits per year, with a payment made per visit to the GP from the State. The stated aim of Heartwatch was to reduce the morbidity and mortality caused by cardiovascular diseases in Ireland. It has attempted to improve the care of patients with heart disease in the community at general practices across the country. It was an evidence-based programme, strategically designed to provide community-based care the integrates specialised disease management in general practice with referrals to other services as necessary. However, measuring the programme's success has been multifactorial and complex. This paper examines the follow-up results of patients over eight years to determine if there are long term benefits of this secondary prevention programme and what factors may influence or predict the types of patients who benefit.

Methods

Data Handling

Collection

Heartwatch is a national structured programme led by Irish GPs with a standard protocol for the continuing care of patients for the secondary prevention of cardiovascular disease. The programme has been reported on in 2004, 2005, 2008, 2011, and 2014[3,15–18] – this paper is the first that reviewed patients who have attended the program for at least eight years.

In 2003, 475 GPs in 325 practices were recruited[19] to provide this national secondary prevention care programme. Heartwatch targeted 20% of GPs to review patients on a quarterly basis with care implemented according to defined clinical protocols. Practices from each health board area were recruited with the aim of having national coverage of the program. Each area employed a regional GP co-ordinator and nurse facilitator to assist with the deployment of Heartwatch care protocol. Upon been granted a contract to provide the programme, the clinical staff in the GP's practice underwent specific training to enable a standardised approach to applying the care protocol and performing the required checks at each visit. The patient population included men and women who had a history of AMI, PTCA, or a CABG.[15,16] In addition, diabetic patients from an established diabetes structured care programme were also invited into the programme – however, these patients are not included in the analysis in this paper due to differing treatment requirements.

Heartwatch, was introduced as a collaborative national pilot programme[15] but was not expanded beyond 20% of GPs. The program and its continuing care protocol are based on the internationally recognized cardiovascular prevention guidelines from 'Prevention of Coronary Disease in Clinical Practice 1998'[20] and those updated in 2003[20] and 2016 after the sixth Joint Taskforce guidelines were released.[5] In 2016, the target level for lipoprotein cholesterol (LDLc) for very high-risk patients was changed to 1.8mmol/l (from 3.0mmol/L) as a direct result of the change in

guidelines.[5]

By employing the standard continuing care protocol of Heartwatch, eligible patients may have attended up to four visits per year with their GP practice after signup. Measurements of key risk factors were recorded at the signup visit and at each subsequent visit along with data related to medication changes and referrals[21] (See supplementary Table 1). This information is securely uploaded directly from the practice patient management server in an anonymised format to the Independent National Data Centre(INDC)[21].

Whether all factors were measured at every visit was dependent on whether the value was within target or not at the previous visit. For example, the target for total cholesterol is <5mmol/l – if a patient is within target, their GP only needed to measure at every other visit whereas if they were outside of the target their GP must repeat the test at the subsequent visit. However, the GP/practice nurse may have chosen to repeat all tests at each visit.[21]

During the analysis of medication data, patients were categorised as receiving or not receiving specific prescriptions - 'decreased dose', 'increased dose', 'maintained' and 'new' were considered as receiving; and 'not prescribed' and 'discontinued' as not receiving.

Access

The Heartwatch INDC acts as the primary collection point for all data returned by practices.[15] Within this structure there is a data management committee, which has the responsibility of reviewing access requests to the aggregated, anonymous version of the collected data. Data used here was released after such an access request. In the reporting, the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) cohort reporting guidelines were used.[22]

Processing

For this paper, data from all consultations January 2003-March 2020 were extracted in December 2021. For patients to be included in the overall analysis (Figures 1A-E), they must have had at least one valid initial visit (baseline) between January 2003 and March 2020. For the 8-year follow-up analysis, only those individuals who also had valid 2-, 4-, and 8-year follow-up visits were included. None of the patients recruited through the diabetes programme were included in the analyses presented here. Patients needed a minimum of one visit per year for those eight years, but the intervals were not always the same because some patients attend more frequently than others. However, as part of the automated checks undertaken by the system, there must be a minimum of 10 weeks between visits for a practice to schedule a visit and upload data.[21] Patients could have attended their GP up to four times per year under Heartwatch. However, as the number of visits per year and time between visits varied, the definition of what was the first visit of each year of follow up was applied retrospectively. The first-ever visit was defined as Year-1: Visit-1. The earliest date one year after this was defined as Year-2: Visit-1, however, given the variation in attendance a 30-day variance was given, so it would have been the earliest visit at least 335 days after the first visit. Later years were calculated similarly – Year-3: Visit-1 was the earliest visit two years (+/- 30 days) after Year-1: Visit-1.

Some patients had more than one recorded qualifying event (QE) - AMI, PTCA, or CABG. In these cases, counts and intervals were calculated based on the earliest recorded QE occurrence.

Outcome measure development and calculation

Rather than relying on individual targets to determine the success of the patient, a preliminary care outcome score was developed. It was based on EUROASPIRE studies[7,23,24] and the methods used by Ergatoudes et al.[11] They scored patients across six outcome measures derived from guidelines – exercise, systolic blood pressure, LDLc, optimally controlled glucose, smoking status and

pharmacological treatment - then considered the number patients who met six guidelines, five guidelines, and so on.

This initial method was applied to a subset of the Heartwatch dataset to estimate the number of people meeting each metric. However, Ergatoudes et al.[11] only focused on patients in the two years after AMI, and the included targets needed to be adjusted for the Heartwatch context to include care guidelines for patients with PTCA and CABG. The methodology and preliminary results of this process were then scrutinised and refined with input from GP specialists in cardiology and diabetes, researchers, and data experts.

Following this agreement, patient care outcome scores were calculated within the cohort with eight years of follow-up recorded. Statistics were run on this cohort on the baseline and 8-year data. The metrics selected and their metric score varies from 1 – 2 (Table 1). For optimally controlled glucose, patients without a QE of diabetes mellitus (DM) were give two points because of the high prevalence of comorbidity of CVD and DM.[25] These scores have been called the Continuing Care Score (CCare score).

Outcome	Target	Score
Optimally controlled blood pressure	Systolic BP <140mmHg	+1
Optimally controlled cholesterol	LDL cholesterol <1.8mmol/L	+1
Optimally controlled glucose	Non-diabetic or Diabetic with HbA1c <53mmol/mol	+2 +1
Optimally controlled waist circumference	Female - waist circumference <80cm Male - waist circumference <94cm	+1

Regular physical activity	>210min / week of moderate exercise	+1
Smoking cessation	Non-smoking	+1
Pharmacological treatment	Prescribed an anti-coagulant or anti-platelet agent And Prescribed a lipid lowering agent	+1

Table 1: Components, target levels, and scoring used to calculate the Continuing Care (CCare) Score outcome measure.

Statistics

Statistical analysis was carried out using R (4.1) and RStudio (1.4).[26]

Given the repeated measures structure of the data (repeated visits per patient) a linear mixed effects model was used, with maximum likelihood estimation of fixed and random effects. Fixed effects included patient level demographics (sex, age), program adherence (average visits per year, visit number), signup context (qualifying event type (dummied) and qualifying even interval), as well as possible two-way interactions. The model also considered random effects at the patient level, which allows individual patients to vary randomly in terms of their intercept (accounting for differing baseline readings). The mixed effects model was estimated using the lme4 package [27], confidence intervals were calculated at 99%, and conditional and marginal coefficient of determination were also calculated(See supplementary Table 2 for full model estimates). [28,29]

Patient and public involvement

Heartwatch was developed in collaboration with the Irish Heart Foundation Irish a national heart and stroke charity which supports and advocates for people who have been affected by heart and

stroke. However, it was not possible to involve patients in this later secondary analysis due to data protection restrictions.

Results

Heartwatch Overview: 2003-2020

Looking across all validated Heartwatch records between 2003 and March 2020. By the end the second year of Heartwatch, there were over 20,000 visits per year; annual attendance remained above 20,000 until 2012 (Figure 1A). While overall attendance has decreased since the peak in 2008, the proportion of patients attending once, twice, three or four times a year remained stable between 2004 and 2020 (Figure 1A). Over 16,000 patients had entered the programme, patients remained in Heartwatch for an average of seven years (Figure 1B). Over 7,000 patients (45%) have been in the programme for eight years or more.

There were more male (76%) participants compared to females. The majority of Heartwatch patients were over 60 years old when they signed up, with 27% aged <60 years old and 33% of all participants aged between 60-69 years old at signup (Figure 1C). The median age at signup across all years of the program was 67 and has not differed much over time (range: 63-67). The female group were typically older, with a median age of 70 compared to 65 for males (Figure 1C).

An AMI was the most common QE (40%), with PTCAs and CABGs accounting for 35% and 25% respectively (Figure 1D). Overall, 18% of patients were enrolled within one year of their QE (Figure 1E). Another 32% of patients enrolled between one and two years after their QE; with the rest singing up between three and six years (25%) or more than six years (26%) after their QE. Early signups on programme commencement tended to have longer intervals between event and signup (QE-Interval), (2003: mean 6 years) but the interval shortened and by 2006 stabilised (2006-2019: range 2-3 years).

The 8-Year Cohort from 2003-2020

In the assessment of patients' progress, we identified a cohort of 5,700 patients with at least eight years in the programme (Figure 2A). The included patients had a minimum of one visit per year for eight years between 2003-2020. The remainder of the analyses presented pertains to this cohort. In this cohort, 38% of patients in the 8-year cohort had a PTCA as their first QE and CABG was again the least common type of QE (26%) (Figure 2B); 77% were male and the median age at signup was 65 years old (Figure 2C). A third of patients in this cohort were referred to the programme within 1-2 years of experiencing their QE (34%), the median QE-interval was two years (Figure 2D).

The Continuing Care Scores (CCare Score)

After one year in Heartwatch , the median CCare score was five (33% of patients), 30% of patients scored lower than this and the remainder scored > 5. After four years, 37% of patients had individual-level improvements in their score, 36% of scores had not changed and 27% decreased. The number of patients who achieved scores >5 increased to 44% at this point (Figure 3A). After eight years of follow up, 40% of patients scored ≥6. By the eighth year, patients' scores were higher, although the ratio of higher-same-lower narrowed (36%:32%:32%) (Figure 3A). At each time point, the median CCare score for the cohort was five.

Components of the CCare Score and other metrics

At the start of the first year, 64% of the patient cohort was within the target for systolic blood pressure (Supplementary Table 1). This increased to 70% at year-4 but reverted to 67% in year-8. Exercise and anti-platelet/anti-coagulant treatment showed a similar pattern of improvement up to year-4, with a degree of decline from year-4 to year-8 (Table 2).

Outcome	*Year 1*	*Year 2*	*Year 4*	*Year 8*

Systolic BP <140mmHg	64%	69%	70%	67%
LDL cholesterol <1.8mmol/L	21%	23%	26%	30%
Diabetic with HbA1c <53mmol/mol	5%	8%	10%	13%
Non-diabetic	90%	88%	85%	81%
Female - waist circumference <80cm Male - waist circumference <94cm	27%	27%	27%	25%
Moderate exercise >210min/week	37%	40%	41%	35%
Non-smoking	88%	89%	90%	92%
Prescribed anti-coagulant/antiplatelet and lipid lowering agents	88%	92%	94%	92%

Table 2 – Percentages of 8-year cohort within target under each score component, and by year of follow up (n = 5,729).

The number of patients with co-morbid diabetes that had HbA1c readings within target increased over time. However, this occurred in tandem with an increased new diagnosis of diabetes in the rest of the cohort (Table 2). LDLc started with only 21% of patients being in target but steadily increased to 29% in year-8. Smoking rates likewise improved through to year-8. The rate of waist circumference within target did not change much through follow-up.

The values comprising the CCare score - as well as some not included in the score - demonstrated a similar pattern. Some risk factors showed continued improvement with follow-up - Total and LDL Cholesterol - others improved for the first four years of follow-up - Systolic BP, Exercise – while others did not improve - BMI, weight - and the prevalence of diabetes increased (Supplementary Table 3).

In terms of medication changes, fewer patients were prescribed aspirin from year one (91%) to year eight (87%). This was the only recorded prescription that had an overall reduction, however, it remained among the most frequently prescribed items. Beta-blockers and statins were also frequently prescribed items (year-8: 92% & 73%). Prescriptions of diuretics started at 18% and increased to 24% over time. There were three medications that had a 6% increase in being prescribed; ace inhibitors (started at 45%), Ca channel blockers (started at 16%), and ATII inhibitors (started at 10%). The prescription of diabetic medications also increased through follow-up (Table 3).

	Year 1		*Year 2*	*Δ*	*Year 4*	*Δ*	*Year 8*	*Δ*
Aspirin	91%	-	91%	0%	90%	-2%	87%	-4%
Beta blockers	69%	-	70%	1%	71%	2%	73%	4%
ACE inhibitors	45%	-	49%	4%	51%	6%	51%	6%
Anti-Coagulants	8%	-	7%	0%	8%	0%	12%	4%
Diuretics	18%	-	19%	2%	21%	3%	24%	6%
Ca channel blockers	16%	-	17%	1%	19%	3%	22%	6%
ATII inhibitors	10%	-	11%	1%	13%	3%	16%	6%
Other antihypertensive	9%	-	8%	-1%	8%	0%	10%	1%
Fibrate	2%	-	1%	-1%	2%	0%	2%	0%
Statin	88%	-	92%	4%	93%	5%	92%	4%
Other lipid lowering	5%	-	7%	1%	9%	4%	11%	6%
Insulin	1%	-	1%	0%	2%	0%	3%	1%
Sulphonylureas	4%	-	4%	1%	5%	2%	7%	3%
Biguanides	5%	-	6%	1%	7%	2%	10%	5%
Glucosidase	0%	-	0%	0%	0%	0%	0%	0%

Other hypoglycaemic	1%	-	1%	0%	1%	1%	3%	2%

Table 3 – Medications prescribed among the 8-year cohort by year of follow up (n = 5,729), with change from year 1 calculated for each later year of follow up.
ACE, angiotensin-converting enzyme; ATII, angiotensin II; Ca, Calcium-channel blockers; Δ, delta (change).

Patient Demographics and the CCare score

The patients' sex was predictive of better scores; male patients had almost a half point advantage on females (0.432, CI: 0.335-0.509, p<.0001). Female patients had lower CCare scores across all eight years of follow up, 26% had scores >5 in year-1, which rose to a maximum of 33% in year-4 and fell again to 28% in year-8, which was 15% points lower than the equivalent in male patients (41%, 47% & 44% respectively) (Figure 3B). The increase amongst both sexes from year-1 to year-4 were similar (females: +7%, males: +6%) (Figure 3B).

A patient's age at signup does not appear to predict CCare scores in the 8-year cohort. The effect size was small and not found to be significant (0, CI: -0.004 to 0.003, p=0.737). While not significant there were some differences across age groups. More younger patients had a CCare score >5 at signup (<60: 42%) compared to older patients (60-69: 38%, 70+: 34%)(Figure 3C). All age groups had more scores >5 after four years of follow up, (0-59: 46%, 60-69: 45%, 70+: 42%), but more older patients had improved scores to reach those levels (0-59: +4%, 60-69: +7%, 70+: +8%). The difference in the number of patients with a score >5 narrowed after eight years of follow up, and fewer patients achieved scores of >5 than they had after four years (0-59: 42%, 60-69: 40%, 70+: 38%)(Figure 3C).

Signup, attendance patterns, and the CCare score

Th year of patient's signup does not appear to predict CCare scores in the 8-year cohort, but those who registered earlier in the programme had generally lower scores at signup (Figure 3D). Patients

who had a CABG as a qualifying event were predicted to have better scores than patients qualifying from an AMI(0.106, CI: 0.028 to 0.183, p<.0001). Patients qualifying from a PTCA events do not differ much from AMI (0.038, CI: -0.045 to 0.121, p=0.234).

Longer intervals between a patient's earliest cardiac event and first visit under Heartwatch were predictive of worse CCare scores (-0.031, CI: -0.040 to -0.023), although the effect size is small; an interval of over 16 years (2.5% of patients) would be required to predict a half point lower score. Patients with shorter intervals were more likely to have scores >5 (Figure 3E). Shorter QE-interval patients were stable in the first four years and then dropped, whereas those with longer QE-intervals saw continued improvement. Similar to the year of signup, the improvements that were seen in patients with longer QE-intervals to signup were insufficient to allow them to reach the same level of scores as the shorter QE-interval patients. A two-interaction effect of QE-interval and visit number predicts that the negative effects of long intervals diminish with attendance (0.001, CI: 0.001 to 0.002, p<.0001), at that effect size it might take over seven years of visits to erase the negative effect of a 1-year interval.

The number of Heartwatch visits per year was predictive of higher CCare scores(0.109, CI: 0.051 to 0.168, p<.0001). Looking at frequencies, patients who visited more often were more likely to have scores >5 (Figure 3F). However, when grouped by visit per year, all groups still saw improvements throughout years of follow up, each achieving their highest CCare score after four years. A two-interaction effect of visits per year and visit number predicts that the positive effects of regular attendance compound with time (0.003, CI: 0.001 to 0.006, p=0.002).

While the descriptive statistics indicate improvements/stability up to year-4 followed by decline/return to baseline (Figure 3A), the model of 8-years predicted marginally worse scores over time (-0.014, CI: -0.022 to -0.005, p<.0001). The marginal R2, representing the variance explained by the fixed effects was calculated at 0.04. The conditional R2, representing the fixed effects and the random intercept (individual patient baseline effects) was 0.57. This would indicate that the patient

level variables only account for a fraction of the variance compared to the patient's initial health status upon signup.

Discussion

In this investigation of patient data from a cardiovascular secondary prevention programme, we found that patients achieved moderate improvements in blood pressure (+3% within target), LDL cholesterol (+7% within target), and smoking status (+4% non-smokers). To develop a broader understanding of patient success, an 8-point Continuing Care Score was created to monitor changes over eight years. Less than 2% of patients achieved all targets, however by year-8, 71% of patients had achieved between five and seven of the eight targets.

Using statistical modelling, we found that longer time intervals between the qualifying cardiac event and starting the secondary prevention intervention predicted worse scores even after eight years, but these patients can and do improve overtime, just not as rapidly as other patients. Female patients were also more likely to have worse CCare scores, both in the baseline and 8-year model. Moreover, patients who attended three or more visits per year had higher average CCare scores and maintained higher scores while patients who visited less frequently saw a decline in their outcomes. This could be a reason to promote attending secondary cardiac prevention as soon as possible following a cardiac event and maintaining a good level of contact with that intervention.

Strengths and limitations

The key strength of Heartwatch is the volume of patient data and the length of time the program has been in existence with patients retained. Further to that, the data is geographically spread across general practices areas across Ireland.

However, this is an active care program and not a randomised controlled trial, so no comparative or control group exists. Moreover, data is collected primarily for clinical monitoring, not research purposes, thus, some variables were calculated. For example, in our statistical models, visits per year

is calculated retrospectively and so its value in a predictive model is constrained. A key strength is that this is real-world data.

ESC guidelines on LDLc changed during the programme, so patients may have been treated towards different target levels. We retrospectively applied the most recent recommendations ergo some patients may have been designated out of target who would have been in target at the time. Hence, we may have underestimated the number achieving the target as a stricter more recent guideline is being applied.

Another possible limitation could be a survivor bias on the available long-term information, as those with worse scores may have exited the programme earlier than eight years.[30]

Heartwatch does not collect outcome information such as mortality or further cardiac events, nor does it collect patient reported outcomes. This was a limitation which we have attempted to overcome by developing the CCare score method.

Comparison to other literature

It is difficult to draw a direct comparison with other literature because the programme is not a trial nor a survey of patients with a history of CVD but an ongoing care program with real-world data. The programme, Heartwatch, presents a much longer-term view of secondary prevention compared to most literature which focuses on the first six months,[31] first year or first two years following a cardiac event.[8,32] There is substantial research on secondary prevention of CVD and identifying and managing risk factors for these patients which we have compared with our results. In a review of clinical trials looking at primary and secondary prevention of coronary artery disease, Kantaria et al. found that reduction of LDLc, decrease in blood pressure and discontinuation of smoking resulted in reduced death rates and further cardiac events.[33] This is promising, as these are the key areas in which Heartwatch patients improved.

An international review of risk factor management for patients with CVD in Asia, Europe and the Middle East also found sex-based differences where female patients were less likely to achieve total

cholesterol, LDLc, glucose, physical activity and weight targets compared to male counterparts.[34] These differences were smaller in Europe compared to Asia and the Middle East but persisted nevertheless which is congruent with our predictive model findings of sex-based outcome differences.

In 2009, the European Action on Secondary and Primary Prevention by Intervention to Reduce Events III (EUROASPIRE III)[23] survey sought to determine whether the European guidelines were being followed in everyday practice. This survey found that large proportions of patients do not achieve the targets, more than half did not meet the blood pressure or cholesterol targets[23] and they stated that European countries needed to raise the standard of preventive care. An Italian study of secondary prevention of coronary heart disease in primary care, which looked at health records of just under 6,000 patients found 153 patients with CVD.[10] This survey found that there was satisfactory adherence to guideline advice – 46% of patients achieved LDL targets and 83% achieved the systolic blood pressure target. They concluded that GPs are well placed to help people with a history of CVD to manage risk factors, but that care could be further optimised.

The Swedish study[11] that inspired the development of the CCare score, found only 3.5% of people were achieving all targets two years after AMI. This is similar to our finding here where just 2% of patients achieved all eight targets at year-2. This highlights further the need for specific interventions of secondary prevention, as more Heartwatch patients achieved their systolic blood pressure (SBP), 69%, and LDL targets, 23%, after two years compared to the those in Sweden where 57% achieved the SBP and 18.5% achieved LDL targets. However, it should be noted that Heartwatch has a more diverse patient group compared to the Swedish patients, who had suffered an acute incident. A Norwegian study of cardiac rehabilitation patients, showed that patients who had an acute incident were more likely to participate in secondary prevention.[35]

Finally, in the more recent EUROASPIRE surveys, smoking, obesity, and exercise were persistent in their unlikeliness to change overtime but lifestyle changes were more successful if a patient was in a prevention programme.[36] However, in the same Norwegian study as above patients who were

overweight were more likely to participate in the program, which shows a willingness to improve.[35] In Heartwatch, exercise and waist circumference did not show much improvement over eight years. Patients in the EUROASPIRE surveys stated lack of confidence as their main barrier to address unhealthy behaviour.

Implications for policy and practice

In current secondary prevention research and guidelines, there is a focus on measurement and development of risk factor targets. However, research has repeatedly demonstrated that patients are not meeting these targets.[37,38] For example, results for males and females diverge under similar targets. The current evidence base should be used as a foundation to refocus secondary prevention research away from target definitions and onto the implementation of these programmes with added public and patient involvement.

We, and others[39], have shown early enrolment after a cardiac event and frequency of structured care visits should be priorities in the design and implementation of similar programmes.

The evaluation of patient outcomes and cost-effectiveness should take into consideration that new programmes can experience an initial influx from a backlog of high-risk cases. Chronic disease programmes may evolve significantly in the initial few years. Planning and evaluation should take this into consideration.

Conclusion

Secondary prevention of CVD can have a positive impact even when patients start with poor outcomes. The sooner a patient can access a structured care program, the better but even with delays it is worth enrolling patients with a history of cardiac events regardless of age. Overall, patients are not likely to meet all targets set by secondary prevention guidelines – especially those related to lifestyle factors such as exercise and waist circumference. However, supporting patient self-management may impact on this and the inclusion of factors such as a patient-centred approach

and regular training of health professionals to deliver same, as noted elsewhere.[24,36] Ongoing evaluation and improvement of secondary prevention programmes is needed to help more patients successfully reach targets.[40]

Acknowledgements

We thank Drs. Suzanne Kelly and Mike O'Callaghan, clinical leads in the ICGP for their support and clinical expertise. Our thanks also to Patricia Patton, ICGP library for bibliography assistance. This work uses data that have been provided by patients and collected by their GPs as part of their care and support, we acknowledge these contributions and thank Sally-Anne O'Neill and Colleen O'Neil for Heartwatch administrative support and advice.

Conflict of interest

The authors declare no conflicts of interest.

Author Contributions

All authors contributed to the research question development. FS carried out the re-coding of variables and undertook the analysis. All authors designed the analysis approach, interpreted the results and formulated the conclusions. JG contributed clinical expertise. CC is the PI and manager of the Heartwatch Programme and provided direction and oversight for this analysis and paper. RH and FS prepared the first draft of the manuscript. RH and FS contributed equally to this paper. All authors contributed to the manuscript and all authors read and approved the final manuscript. All named authors contributed sufficient work according to the COPE guidelines.

Funding

There was no additional funding obtained to undertake this secondary analysis. The Heartwatch programme is funded by the Irish Health Service Executive. The ICGP Research Hub is funded through the Irish Sláintecare initiative .

Ethical Review Statement

not applicable

Data Sharing Statement

The Heartwatch INDC acts as the primary collection point for all HeartWatch data returned by practices. Within this structure there is a data management committee, which has the responsibility of reviewing access requests to the aggregated, anonymous version of the collected data. Data used here was released after such an access request.

References

1. World Health Organization. Cardiovascular diseases (CVDs) - Key facts. 2021.

2. Eurostat. *Causes of Death Statistics*., 2021.

3. Fitzpatrick P, Fitz-Simon N, Lonergan M *et al.* Heartwatch: The effect of a primary care-delivered secondary prevention programme for cardiovascular disease on medication use and risk factor profiles. *Eur J Prev Cardiol* 2011;**18**:129–35.

4. Central Statistics Office. *VITAL STATISTICS YEARLY SUMMARY 2019*., 2020.

5. 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 (constituted by representati. *Eur Heart J* 2016;**37**:2315–81.

6. Wilt TJ, Bloomfield HE, MacDonald R *et al.* Effectiveness of statin therapy in adults with coronary heart disease. *Arch Intern Med* 2004;**164**:1427–36.

7. Collaboration AT. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. *BMJ* 2002;**324**:71–86.

8. Peersen K, Munkhaugen J, Gullestad L *et al.* The role of cardiac rehabilitation in secondary prevention after coronary events. *Eur J Prev Cardiol* 2017;**24**:1360–8.

9. Irish Association of Cardiac Rehabilitation. *Cardiac Rehabilitation Guidelines 2013* . Dublin, 2013.

10. De Backer G, Ambrosioni E, Borch-Johnsen K *et al.* European guidelines on cardiovascular disease prevention in clinical practice: third joint task force of European and other societies on cardiovascular disease prevention in clinical practice (constituted by representatives of eight societies and by invit. *Eur J Cardiovasc Prev Rehabil* 2003;**10**:S1–10.

11. Ergatoudes C, Thunström E, Rosengren A *et al.* Long-term secondary prevention of acute myocardial infarction (SEPAT) - guidelines adherence and outcome. *BMC Cardiovasc Disord* 2016;**16**:226.

12. Hall M, McGettigan M, O'Callaghan P *et al.* Comparison of secondary prevention of heart disease

in Europe: lifestyle getting worse, therapy getting better in Ireland. *Ir Med J* 2002;**95**:272–4.

13. Modesti A, Del Papa C, Modesti L *et al.* Secondary prevention of coronary heart disease. A survey in an Italian primary care practice. *Minerva Cardioangiol* 2010;**58**:167–73.

14. Homeniuk R, Collins C. How COVID-19 has affected general practice consultations and income: general practitioner cross-sectional population survey evidence from Ireland. *BMJ Open* 2021;**11**, DOI: 10.1136/bmjopen-2020-044685.

15. Department of Health and Children, Health Boards, ICGP *et al. Heartwatch Clinical Report - V1*. Dublin, 2004.

16. Department of Health and Children, HSE, ICGP *et al. Heartwatch Clinical Report - V2*. Dublin, 2006.

17. Collins C, Finn C, Meade B *et al.* Strengthening the Foundation of General Practice Evidence in Ireland by Addressing the Data Quality Issues in a Structured Secondary Prevention Programme for Cardiovascular Disease. *JMED Res* 2014;**2014**:1–6.

18. Bennett K, Jennings S, Collins C *et al.* Heartwatch: A secondary prevention programme in primary care in Ireland. *Eur J Prev Cardiol* 2008;**15**:651–6.

19. Brett T, McGuire S, Meade B *et al.* Secondary prevention of cardiovascular disease: A possible model for Australian general practice. *Aust Fam Physician* 2006;**35**:157–9.

20. Wood D, De Backer G, Faergeman O *et al.* Prevention of coronary heart disease in clinical practice. Summary of recommendations of the Second Joint Task Force of European and other Societies on Coronary Prevention. *Blood Press* 1998;**7**:262–9.

21. Irish College of General Practitioners. *Heartwatch Summary Guide*., 2003.

22. Elm E von, Altman DG, Egger M *et al.* Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;**335**:806–8.

23. Kotseva K, Wood D, De Backer G *et al.* EUROASPIRE III: a survey on the lifestyle, risk factors and use of cardioprotective drug therapies in coronary patients from 22 European countries. *Eur J*

Cardiovasc Prev Rehabil 2009;**16**:121–37.

24. Kotseva K, De Backer G, De Bacquer D *et al.* Lifestyle and impact on cardiovascular risk factor control in coronary patients across 27 countries: Results from the European Society of Cardiology ESC-EORP EUROASPIRE V registry. *Eur J Prev Cardiol* 2019;**26**:824–35.

25. Leon BM, Maddox TM. Diabetes and cardiovascular disease: Epidemiology, biological mechanisms, treatment recommendations and future research. *World J Diabetes* 2015;**6**:1246–58.

26. Team RC. R: A language and environment for statistical computing. 2022.

27. Bates D, Mächler M, Bolker B *et al.* Fitting Linear Mixed-Effects Models Using lme4. *J Stat Softw* 2015;**67**, DOI: 10.18637/jss.v067.i01.

28. Burnham KP, Anderson DR. *Model Selection and Multimodel Inference*. Burnham KP, Anderson DR (eds.). New York, NY: Springer New York, 2004.

29. Nakagawa S, Johnson PCD, Schielzeth H. The coefficient of determination R 2 and intra-class correlation coefficient from generalized linear mixed-effects models revisited and expanded. *J R Soc Interface* 2017;**14**:20170213.

30. Saracci R. Survival-related biases survive well. *Int J Epidemiol* 2007;**36**:244–6.

31. Urbinati S, Olivari Z, Gonzini L *et al.* Secondary prevention after acute myocardial infarction: drug adherence, treatment goals, and predictors of health lifestyle habits. The BLITZ-4 Registry. *Eur J Prev Cardiol* 2015;**22**:1548–56.

32. Jankowski P, Kosior DA, Sowa P *et al.* Secondary prevention of coronary artery disease in Poland. Results from the POLASPIRE survey. *Cardiol J* 2020;**27**:533–40.

33. Kantaria M, Buleishvili M, Kipiani N V *et al.* RISK-FACTORS OF CORONARY ARTERY DISEASE (REVIEW). *Georgian Med News* 2020:78–82.

34. Zhao M, Vaartjes I, Graham I *et al.* Sex differences in risk factor management of coronary heart disease across three regions. *Heart* 2017;**103**:1587–94.

35. Olsen SJ, Schirmer H, Bønaa KH *et al.* Cardiac rehabilitation after percutaneous coronary intervention: Results from a nationwide survey. *Eur J Cardiovasc Nurs* 2018;**17**:273–9.

36. De Bacquer D, Astin F, Kotseva K *et al.* Poor adherence to lifestyle recommendations in patients with coronary heart disease: results from the EUROASPIRE surveys. *Eur J Prev Cardiol* 2021, DOI: 10.1093/eurjpc/zwab115.

37. Vogel B, Acevedo M, Appelman Y *et al.* The Lancet women and cardiovascular disease Commission: reducing the global burden by 2030. *Lancet* 2021;**397**:2385–438.

38. Murphy AW, Cupples ME, Murphy E *et al.* Six-year follow-up of the SPHERE RCT: secondary prevention of heart disease in general practice. *BMJ Open* 2015;**5**:e007807.

39. Murchie P. Secondary prevention clinics for coronary heart disease: four year follow up of a randomised controlled trial in primary care. *BMJ* 2003;**326**:84–84.

40. Farkouh ME, Boden WE, Bittner V *et al.* Risk factor control for coronary artery disease secondary prevention in large randomized trials. *J Am Coll Cardiol* 2013;**61**:1607–15.

Figure 1 – Heartwatch overview 2003-2020

A - All Heartwatch visits graphed by year of visit. B – Each year of follow up with total number of patients graphed. C – Population pyramid of all patients. D – All patients grouped by earliest qualifying event type. E – All patients grouped by interval from earliest qualifying event to date of first Heartwatch visit.
AMI, acute myocardial infarction; PTCA, percutaneous coronary intervention; CABG, coronary artery bypass grafting; * Jan 2003 to March 2020.

Figure 2 – Heartwatch 8-year cohort overview 2003-2020

A – Patient records graphed by year of follow up. The records of the 8yr-cohort are highlighted in pink. B - 8-year cohort grouped by earliest qualifying event type. C - Population pyramid of 8-year cohort. D - 8-year cohort grouped by interval from earliest qualifying event to date of first Heartwatch visit.
8-year cohort n= 5729.

Figure 3 – The CCare for the 8-year cohort in follow up years 1, 2, 4 & 8.

A – The CCare scores for the 8-year cohort; proportion of cohort by number of metrics met. B – The CCare scores by grouped age bands. C - The CCare scores by grouped recorded sex. D - The CCare scores by grouped year of first visit. E - The CCare scores by grouped by number of visits per year. F - The CCare scores by grouped by interval from earliest qualifying event to date of first Heartwatch visit.
QE, Qualifying event.

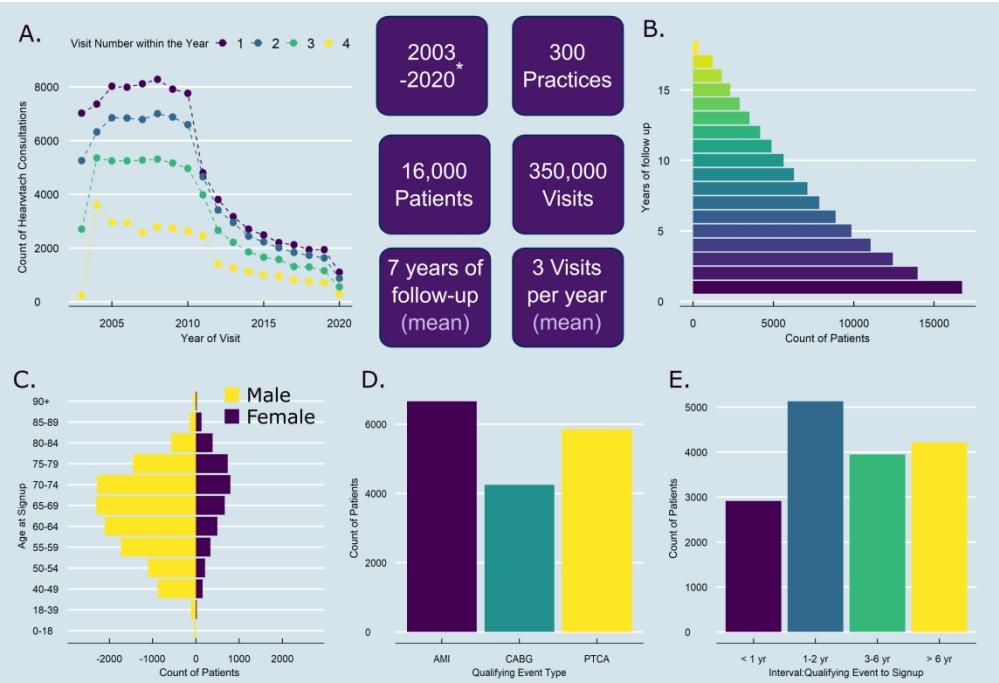

Figure 1 – Heartwatch overview 2003-2020.
A - All Heartwatch visits graphed by year of visit. B - Each year of follow up with total number of patients graphed. C - Population pyramid of all patients. D - All patients grouped by earliest qualifying event type. E - All patients grouped by interval from earliest qualifying event to date of first Heartwatch visit. AMI, acute myocardial infarction; PTCA, percutaneous coronary intervention; CABG

464x316mm (164 x 164 DPI)

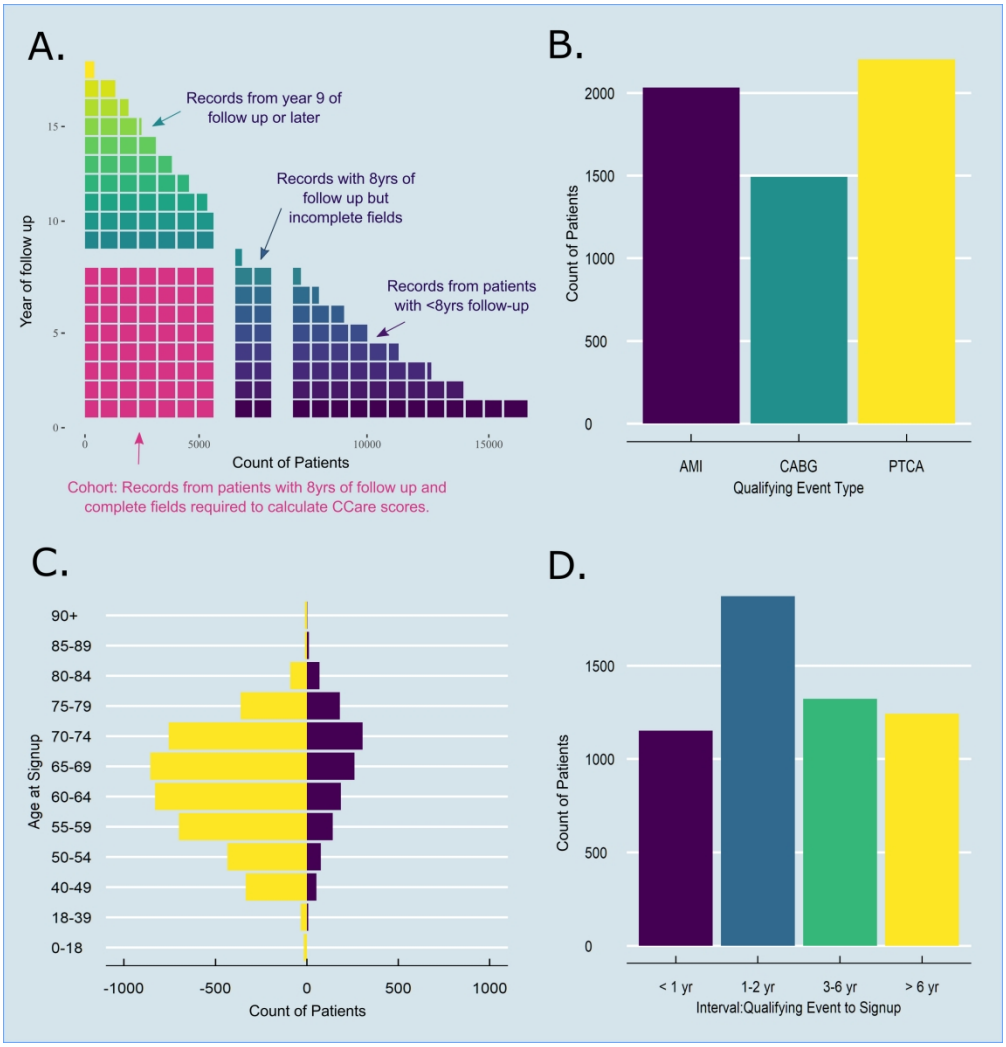

Figure 2 – Heartwatch 8-year cohort overview 2003-2020
A - Patient records graphed by year of follow up. The records of the 8yr-cohort are highlighted in pink. B - 8-year cohort grouped by earliest qualifying event type.
C - Population pyramid of 8-year cohort. D - 8-year cohort grouped by interval from earliest qualifying event to date of first Heartwatch visit. 8-year cohort n= 5729.

698x725mm (105 x 105 DPI)

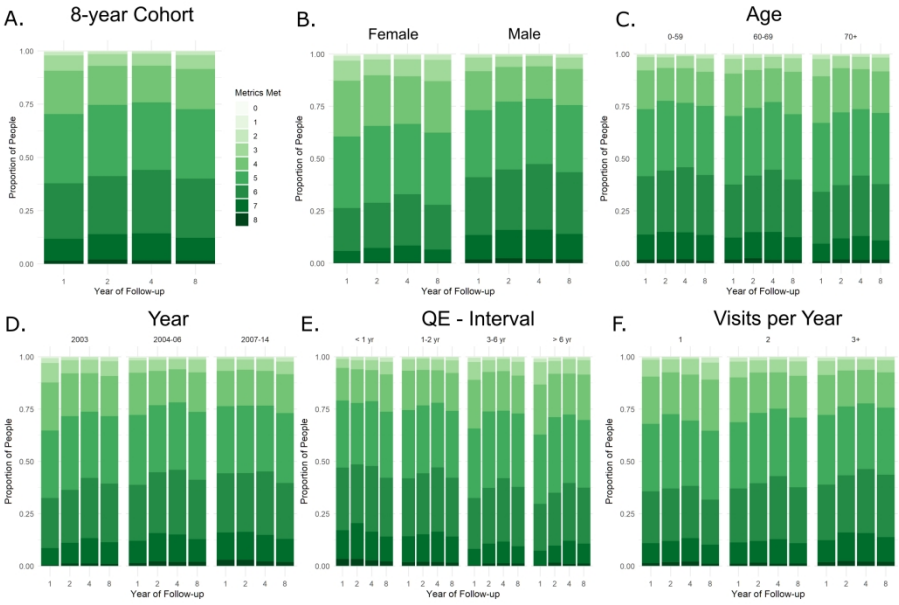

Figure 3 – The CCare for the 8-year cohort in follow up years 1, 2, 4 & 8.
A - The CCare scores for the 8-year cohort; proportion of cohort by number of metrics met. B - The CCare scores by grouped age bands. C - The CCare scores by grouped recorded sex. D - The CCare scores by grouped year of first visit. E - The CCare scores by grouped by number of visits per year. F - The CCare scores by grouped by interval from earliest qualifying event to date of first Heartwatch visit. QE, Qualifying event.

1058x726mm (72 x 72 DPI)

Supplementary Data File

Supplementary Table 1

	Mandatory Fields	Units	Targets	Min/Max
Systolic Blood Pressure	y	mmHg	<140	60/240
Diastolic blood pressure	y	mmHg	<90	30/150
Total Cholesterol	y	mmol/L	<5	1/12
LDL Cholesterol	y	mmol/L	<1.8	0/11
Exercise Total	n	min/week	>210	
Height	y	cm		135/195
Weight	y	kg		40/200
Waist Circumference	y	cm	Male: <94 Female: <80	40/200
Body Mass Index	y	kg/cm2	<25	15/60
Diabetes Status	y			
Fasting Glucose	y	mmol/L	Non-Diabetics: <5.5 Diabetics: <6	2/30
HbA1c	y - (Type 1,Type 2 & IGT)	mmol/mol	<45	20/140
Serum Creatinine	y - (Type 1,Type 2 & IGT)	mmol/L	<115	10/999

Legend

Supplemental Table 1 – Heartwatch measures, targets, and minimum and maximum valid values allowed for each.

IGT, Impaired glucose tolerance.

Supplementary Table 2

Effect	*Estimate*	*Error*	*z*	*p*
Intercept	4.668	0.106	43.844	<.0001
Main effects				
SEX	0.432	0.030	14.443	<.0001
Visit count	-0.014	0.003	-4.111	<.0001
Vpa	0.109	0.023	4.810	<.0001
QE - Interval	-0.031	0.003	-9.471	<.0001
QE -PTCA	0.038	0.032	1.190	.234
QE - CABG	0.106	0.030	3.502	<.0001
Age at signup	0.000	0.001	-0.336	.737
Year of signup	0.432	0.030	14.443	<.0001
Two-way interactions				
Vpa : Visit count	0.003	0.001	3.107	.002
QEV - Interval : Visit count	0.001	0.000	10.430	<.0001

Legend

Supplemental Table 2 – effect estimates table from the mixed effects model of data from Heartwatch visits of the 8-year cohort (n = 5,729).

Note: Sex coding Female =0, Male = 1; QE, qualifying event; Vpa – visits per annum

Supplementary Table 3

	Year 1			*Year 2*			*Year 4*			*Year 8*		
	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD	n
BP Systolic	133	18	5729	132	17	5729	131	16	5729	132	16	5729
BP diastolic	77	10	5729	76	9	5726	75	9	5728	75	9	5729
Cholesterol total	4.3	1.0	5728	4.2	1.0	5724	4.1	0.9	5729	4.0	0.9	5728
Cholesterol LDL	2.5	0.9	5729	2.3	0.8	5729	2.2	0.8	5729	2.2	0.9	5729
Weight	81	15	5725	81	15	5725	82	15	5729	82	16	5729
Waist Circumference	97	13	5729	97	13	5729	97	13	5729	98	14	5729
BMI	28	4	5710	28	4	5677	28	4	5729	28	5	5729
Diabetes (T1,T2,IGT)	10%		5729	12%		5729	15%		5729	19%		5729
Fasting Glucose	5.5	1.7	4870	5.7	2.8	4937	5.6	1.8	4957	5.7	1.8	5101
HbA1c	50	14	738	49	12	872	49	12	1015	50	12	1235
Serum Creatinine	99	82	1034	99	73	1170	98	66	1274	97	41	1466
Weekly Exercise	227	152	5729	235	135	5729	237	136	5729	215	141	5729
Smoking Status	12%		5729	11%		5729	10%		5729	8%		5729

Legend:

Supplemental Table 3 – Means, standard deviations (SD) and sample sizes of Heartwatch programme measures for the 8-year cohort in follow up years 1,2,4,and 8.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1	'secondary analysis'
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2	See abstract
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5	See Introduction
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5	See introduction
Methods				
Study design	4	Present key elements of study design early in the paper	6-9	Se methods
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-9	See methods, with specific sections on data collection, access, and processing
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6-9	See methods, data collection mentions how patients are recruited to secondary prevention programme and how their data is collected, section on data processing dictates how patients were selected for secondary analysis
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9	In methods, outcome measure development and calculation, stats, and variables of interest
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-9	Methods and supplemental table 1
Bias	9	Describe any efforts to address potential sources of bias	6-9	methods
Study size	10	Explain how the study size was arrived at	7-8	Method > data handling > processing

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-9	Data handling and variables of interest
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9	
		(*b*) Describe any methods used to examine subgroups and interactions	9	
		(*c*) Explain how missing data were addressed	6-9	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a secondary analysis	
		(*e*) Describe any sensitivity analyses	n/a	
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10	Results section
		(b) Give reasons for non-participation at each stage	n/a	
		(c) Consider use of a flow diagram		
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10-14	results
		(b) Indicate number of participants with missing data for each variable of interest	n/a	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)		
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	10-14	results
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures		
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-14 15-16	Results Discussion
		(*b*) Report category boundaries when continuous variables were categorized	supplemental table 1	Target values/limits are included in supplemental table 1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		n/a

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10-14	All analyses in results
Discussion				
Key results	18	Summarise key results with reference to study objectives	15	first section of discussion
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15	Second section of discussion 'strengths and limitations'
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15-18	Discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results	15-18	Discussion
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Heartwatch: an Irish Cardiovascular Secondary Prevention programme in primary care, a secondary analysis of patient outcomes.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-063811.R2
Article Type:	Original research
Date Submitted by the Author:	03-Nov-2022
Complete List of Authors:	Homeniuk, Robyn; Irish College of General Practitioners, Research Stanley, Fintan; Irish College of General Practitioners, Research Hub Gallagher, Joseph; Irish College of General Practitioners Collins, Claire; Irish College of General Practitioners, Research
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Cardiovascular medicine, General practice / Family practice
Keywords:	PRIMARY CARE, CARDIOLOGY, Coronary intervention < CARDIOLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PREVENTIVE MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title Page:

Heartwatch: an Irish Cardiovascular Secondary Prevention programme in primary care, a secondary analysis of patient outcomes.

Authors

Robyn Homeniuk*[1]

- MSc
- https://orcid.org/0000-0002-5526-4113

Fintan Stanley*[2]

- PhD
- https://orcid.org/0000-0002-6740-3280

Joseph Gallagher[3]

- BA MB BCh BAO MRCPI MICGP MD
- https://orcid.org/0000-0002-5564-2890

Claire Collins[1]

- PhD
- https://orcid.org/0000-0001-8967-5159

*These authors contributed equally and should be joint first author.

Corresponding: Claire Collins, Research Centre, Irish College of General Practitioners, Dublin, Ireland, claire.collins@icgp.ie

1. Research Centre, Irish College of General Practitioners, Dublin, Ireland
2. Research Hub, Irish College of General Practitioners, Dublin, Ireland
3. Cardiovascular Clinical Lead, Irish College of General Practitioners, Dublin, Ireland

The work for this paper was completed at the Irish College of General Practitioners (remotely)

Word count: 4900 (main text)
Manuscript count: 7300

Abstract

Objectives: To investigate patient follow-up data from Heartwatch: Ireland's secondary prevention programme for cardiovascular disease delivered in general practice.

Design: Retrospective descriptive study based on secondary analysis of routinely collected data from Heartwatch.

Setting: Heartwatch targeted 20% of general practices in Ireland and recruited 475 GPs across 325 practices.

Participants: The patient population included people with a history of acute myocardial infarction (AMI), percutaneous transluminal coronary angioplasty (PTCA) or a coronary artery bypass graft (CABG). Over 16,000 patients entered the programme however, to assess the long-term progress of patients, we identified a cohort of 5,700 patients with at least 8 years in the programme.

Interventions: A standard protocol for continuing care of patients for the secondary prevention of cardiovascular disease was administered by general practices. The programme was designed using World Health Organisation (WHO) and European Society of Cardiology (ESC) guidelines on secondary prevention.

Outcome measures: A Continuing Care (CCare) score out of eight was the primary outcome measure used. It was calculated based on programme targets for well-known cardiovascular risk factors: exercise, systolic blood pressure, LDL cholesterol, optimally controlled glucose, smoking status, and pharmacological treatment.

Results: After one year, 37% of the 8-year cohort had achieved a CCare score >5 increasing to 44% after year-8. Patient sex was predictive of better scores; male patients had almost a half-point advantage (0.432, CI: 0.335-0.509). Patients who enrolled earlier following their qualifying event and patients with more frequent visits were also more likely to achieve higher CCare scores.

Conclusions: Overall, patients are not likely to meet all targets set by secondary prevention guidelines, however, supporting patient self-management may impact on this. Early enrolment after a cardiac event and frequent structured care visits should be priorities in the design and implementation of similar programmes. Ongoing evaluation of them is necessary to improve outcomes.

Keywords: secondary prevention, cardiovascular health, patient outcomes, primary care, general practice; continuing care score

Strengths and limitations

- The key strength of Heartwatch is the volume of patient data and the length of time the program has been in existence with patients retained.
- The data comes from an active clinical program. There is no comparative or control group
- LDLc guideline targets changed during the program so guidelines initially would have suggested a higher target, although we retrospectively applied the most recent guideline target. Hence, as a stricter target is applied, we have underestimated the number achieving the desired active target prior to 2016.
- There is likely a survivor bias on the available long-term information, as those with worse scores may have exited the programme earlier than 8 years and we do not have access to outcomes such as death or major adverse cardiovascular events.

Introduction

Globally, cardiovascular diseases (CVD) are the leading cause of death, with 32% of all global deaths - 17.9 million - being attributed to them in 2019.[1] In Europe, cancer and circulatory diseases have been the leading causes of death since 2006.[2] Recent statistics have shown that from 2006-2016 the number of deaths from ischaemic heart disease fell by 28.4% for men and 34.2% for women.[2] In 2016, the standardised death rate from ischaemic heart disease in Ireland was 133 per 100,000 inhabitants, which was slightly more than the EU rate of 119.4 per 100,000 inhabitants.[2]

While the decline in deaths from ischaemic heart disease is promising, it is still a major cause of mortality in Ireland.[3] The Central Statistics Office state that circulatory system diseases made up 28.9% of all deaths in Ireland in 2019.[4] This was the second leading cause of death after malignant neoplasms.[4] As highlighted by the evidence review in the Sixth Joint European Society of Cardiology (ESC)[5], patients with a history of CVD may need long term support to change their behaviour and limit the risk of further cardiac events. Furthermore, evidence from clinical trials have shown the benefits of secondary prevention following acute myocardial infarction (AMI), percutaneous coronary intervention (PTCA) or coronary artery bypass grafting (CABG)[3,6,7]. Provision of comprehensive cardiac rehabilitation, similar to the comprehensive approach in Heartwatch, was shown to have more patients achieve risk factor targets.[8] As of 2013, nearly 80% of Irish patients were compliant with cardiac rehabilitation recommendations.[9] Moreover, the World Health Organisation (WHO) has suggested that providing CVD management of risk factors under universal health coverage and at a primary care level can reduce the burden of CVD.[1] Ireland was the first country in the European Union to implement a standardised, national programme led by general practitioners (GPs) – called Heartwatch – that strategically implemented the ESC guidelines.[10] Other countries have since also adopted secondary prevention programmes that monitor blood pressure, cholesterol, smoking status and physical activity.[11–13]

In Ireland, GPs work as private healthcare professionals charging private patients per visit and receiving government payments on a capitation basis for eligible public patients. Around 43% of

people in Ireland qualify for free GP care, either through the General Medical Scheme card (32.4%) or GP-visit card(10.4%).[14] GPs have a central role in the Irish health system, and they are critical in the management of long-term conditions with 80% of all GP visits relating to chronic disease management.[14] A fifth of Irish general practices were recruited to deploy the specially developed secondary prevention program, which enabled patients to attend up to four specialised visits per year, with a payment made per visit to the GP from the State. The stated aim of Heartwatch was to reduce the morbidity and mortality caused by cardiovascular diseases in Ireland. It has attempted to improve the care of patients with heart disease in the community at general practices across the country. It was an evidence-based programme, strategically designed to provide community-based care the integrates specialised disease management in general practice with referrals to other services as necessary. However, measuring the programme's success has been multifactorial and complex. This paper examines the follow-up results of patients over eight years to determine if there are long term benefits of this secondary prevention programme and what factors may influence or predict the types of patients who benefit.

Methods

Data Handling

Collection

Heartwatch is a national structured programme led by Irish GPs with a standard protocol for the continuing care of patients for the secondary prevention of cardiovascular disease. The programme has been reported on in 2004, 2005, 2008, 2011, and 2014[3,15–18] – this paper is the first that reviewed patients who have attended the program for at least eight years.

In 2003, 475 GPs in 325 practices were recruited[19] to provide this national secondary prevention care programme. Heartwatch targeted 20% of GPs to review patients on a quarterly basis with care implemented according to defined clinical protocols. Practices from each health board area were recruited with the aim of having national coverage of the program. Each area employed a regional GP co-ordinator and nurse facilitator to assist with the deployment of Heartwatch care protocol. Upon been granted a contract to provide the programme, the clinical staff in the GP's practice underwent specific training to enable a standardised approach to applying the care protocol and performing the required checks at each visit. The patient population included men and women who had a history of AMI, PTCA, or a CABG.[15,16] In addition, diabetic patients from an established diabetes structured care programme were also invited into the programme – however, these patients are not included in the analysis in this paper due to differing treatment requirements.

Heartwatch, was introduced as a collaborative national pilot programme[15] but was not expanded beyond 20% of GPs. The program and its continuing care protocol are based on the internationally recognized cardiovascular prevention guidelines from 'Prevention of Coronary Disease in Clinical Practice 1998'[20] and those updated in 2003[20] and 2016 after the sixth Joint Taskforce guidelines were released.[5] In 2016, the target level for lipoprotein cholesterol (LDLc) for very high-risk patients was changed to 1.8mmol/l (from 3.0mmol/L) as a direct result of the change in

guidelines.[5]

By employing the standard continuing care protocol of Heartwatch, eligible patients may have attended up to four visits per year with their GP practice after signup. Measurements of key risk factors were recorded at the signup visit and at each subsequent visit along with data related to medication changes and referrals[21] (See supplementary Table 1). This information is securely uploaded directly from the practice patient management server in an anonymised format to the Independent National Data Centre(INDC)[21].

Whether all factors were measured at every visit was dependent on whether the value was within target or not at the previous visit. For example, the target for total cholesterol is <5mmol/l – if a patient is within target, their GP only needed to measure at every other visit whereas if they were outside of the target their GP must repeat the test at the subsequent visit. However, the GP/practice nurse may have chosen to repeat all tests at each visit.[21]

During the analysis of medication data, patients were categorised as receiving or not receiving specific prescriptions - 'decreased dose', 'increased dose', 'maintained' and 'new' were considered as receiving; and 'not prescribed' and 'discontinued' as not receiving.

Access

The Heartwatch INDC acts as the primary collection point for all data returned by practices.[15] Within this structure there is a data management committee, which has the responsibility of reviewing access requests to the aggregated, anonymous version of the collected data. In the reporting, the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) cohort reporting guidelines were used.[22]

Processing

For this paper, data from all consultations January 2003-March 2020 were extracted in December 2021. For patients to be included in the overall analysis (Figures 1A-E), they must have had at least one valid initial visit (baseline) between January 2003 and March 2020. For the 8-year follow-up analysis, only those individuals who also had valid 2-, 4-, and 8-year follow-up visits were included. None of the patients recruited through the diabetes programme were included in the analyses presented here. Patients needed a minimum of one visit per year for those eight years, but the intervals were not always the same because some patients attend more frequently than others. However, as part of the automated checks undertaken by the system, there must be a minimum of 10 weeks between visits for a practice to schedule a visit and upload data.[21] Patients could have attended their GP up to four times per year under Heartwatch. However, as the number of visits per year and time between visits varied, the definition of what was the first visit of each year of follow up was applied retrospectively. The first-ever visit was defined as Year-1: Visit-1. The earliest date one year after this was defined as Year-2: Visit-1, however, given the variation in attendance a 30-day variance was given, so it would have been the earliest visit at least 335 days after the first visit. Later years were calculated similarly – Year-3: Visit-1 was the earliest visit two years (+/- 30 days) after Year-1: Visit-1.

Some patients had more than one recorded qualifying event (QE) - AMI, PTCA, or CABG. In these cases, counts and intervals were calculated based on the earliest recorded QE occurrence.

Outcome measure development and calculation

Rather than relying on individual targets to determine the success of the patient, a preliminary care outcome score was developed. It was based on EUROASPIRE studies[7,23,24] and the methods used by Ergatoudes et al.[11] They scored patients across six outcome measures derived from guidelines – exercise, systolic blood pressure, LDLc, optimally controlled glucose, smoking status and

pharmacological treatment - then considered the number patients who met six guidelines, five guidelines, and so on.

This initial method was applied to a subset of the Heartwatch dataset to estimate the number of people meeting each metric. However, Ergatoudes et al.[11] only focused on patients in the two years after AMI, and the included targets needed to be adjusted for the Heartwatch context to include care guidelines for patients with PTCA and CABG. The methodology and preliminary results of this process were then scrutinised and refined with input from GP specialists in cardiology and diabetes, researchers, and data experts.

Following this agreement, patient care outcome scores were calculated within the cohort with eight years of follow-up recorded. Statistics were run on this cohort on the baseline and 8-year data. The metrics selected and their metric score varies from 1 – 2 (Table 1). For optimally controlled glucose, patients without a QE of diabetes mellitus (DM) were give two points because of the high prevalence of comorbidity of CVD and DM.[25] These scores have been called the Continuing Care Score (CCare score).

Outcome	Target	Score
Optimally controlled blood pressure	Systolic BP <140mmHg	+1
Optimally controlled cholesterol	LDL cholesterol <1.8mmol/L	+1
Optimally controlled glucose	Non-diabetic or Diabetic with HbA1c <53mmol/mol	+2 +1
Optimally controlled waist circumference	Female - waist circumference <80cm Male - waist circumference <94cm	+1
Regular physical activity	>210min / week of moderate exercise	+1
Smoking cessation	Non-smoking	+1
Pharmacological treatment	Prescribed an anti-coagulant or anti-platelet agent And Prescribed a lipid lowering agent	+1

Table 1: Components, target levels, and scoring used to calculate the Continuing Care (CCare) Score outcome measure.

Statistics

Statistical analysis was carried out using R (4.1) and RStudio (1.4).[26]

Given the repeated measures structure of the data (repeated visits per patient) a linear mixed effects model was used, with maximum likelihood estimation of fixed and random effects. Fixed effects included patient level demographics (sex, age), program adherence (average visits per year, visit number), signup context (qualifying event type (dummied) and qualifying even interval), as well

as possible two-way interactions. The model also considered random effects at the patient level, which allows individual patients to vary randomly in terms of their intercept (accounting for differing baseline readings). The mixed effects model was estimated using the lme4 package [27], confidence intervals were calculated at 99%, and conditional and marginal coefficient of determination were also calculated(See supplementary Table 2 for full model estimates). [28,29]

Patient and public involvement

Heartwatch was developed in collaboration with the Irish Heart Foundation Irish a national heart and stroke charity which supports and advocates for people who have been affected by heart and stroke. However, it was not possible to involve patients in this later secondary analysis due to data protection restrictions.

Results

Heartwatch Overview: 2003-2020

Looking across all validated Heartwatch records between 2003 and March 2020. By the end the second year of Heartwatch, there were over 20,000 visits per year; annual attendance remained above 20,000 until 2012 (Figure 1A). While overall attendance has decreased since the peak in 2008, the proportion of patients attending once, twice, three or four times a year remained stable between 2004 and 2020 (Figure 1A). Over 16,000 patients had entered the programme, patients remained in Heartwatch for an average of seven years (Figure 1B). Over 7,000 patients (45%) have been in the programme for eight years or more.

There were more male (76%) participants compared to females. The majority of Heartwatch patients were over 60 years old when they signed up, with 27% aged <60 years old and 33% of all participants aged between 60-69 years old at signup (Figure 1C). The median age at signup across all years of the program was 67 and has not differed much over time (range: 63-67). The female group were typically older, with a median age of 70 compared to 65 for males (Figure 1C).

An AMI was the most common QE (40%), with PTCAs and CABGs accounting for 35% and 25% respectively (Figure 1D). Overall, 18% of patients were enrolled within one year of their QE (Figure 1E). Another 32% of patients enrolled between one and two years after their QE; with the rest singing up between three and six years (25%) or more than six years (26%) after their QE. Early signups on programme commencement tended to have longer intervals between event and signup (QE-Interval), (2003: mean 6 years) but the interval shortened and by 2006 stabilised (2006-2019: range 2-3 years).

The 8-Year Cohort from 2003-2020

In the assessment of patients' progress, we identified a cohort of 5,700 patients with at least eight years in the programme (Figure 2A). The included patients had a minimum of one visit per year for eight years between 2003-2020. The remainder of the analyses presented pertains to this cohort. In this cohort, 38% of patients in the 8-year cohort had a PTCA as their first QE and CABG was again the least common type of QE (26%) (Figure 2B); 77% were male and the median age at signup was 65 years old (Figure 2C). A third of patients in this cohort were referred to the programme within 1-2 years of experiencing their QE (34%), the median QE-interval was two years (Figure 2D).

The Continuing Care Scores (CCare Score)

After one year in Heartwatch , the median CCare score was five (33% of patients), 30% of patients scored lower than this and the remainder scored > 5. After four years, 37% of patients had individual-level improvements in their score, 36% of scores had not changed and 27% decreased. The number of patients who achieved scores >5 increased to 44% at this point (Figure 3A). After eight years of follow up, 40% of patients scored ≥6. By the eighth year, patients' scores were higher, although the ratio of higher-same-lower narrowed (36%:32%:32%) (Figure 3A). At each time point, the median CCare score for the cohort was five.

Components of the CCare Score and other metrics

At the start of the first year, 64% of the patient cohort was within the target for systolic blood pressure (Supplementary Table 1). This increased to 70% at year-4 but reverted to 67% in year-8. Exercise and anti-platelet/anti-coagulant treatment showed a similar pattern of improvement up to year-4, with a degree of decline from year-4 to year-8 (Table 2).

Outcome	*Year 1*	*Year 2*	*Year 4*	*Year 8*

Systolic BP <140mmHg	64%	69%	70%	67%
LDL cholesterol <1.8mmol/L	21%	23%	26%	30%
Diabetic with HbA1c <53mmol/mol	5%	8%	10%	13%
Non-diabetic	90%	88%	85%	81%
Female - waist circumference <80cm Male - waist circumference <94cm	27%	27%	27%	25%
Moderate exercise >210min/week	37%	40%	41%	35%
Non-smoking	88%	89%	90%	92%
Prescribed anti-coagulant/antiplatelet and lipid lowering agents	88%	92%	94%	92%

Table 2: Percentages of 8-year cohort within target under each score component, and by year of follow up (n = 5,729).

The number of patients with co-morbid diabetes that had HbA1c readings within target increased over time. However, this occurred in tandem with an increased new diagnosis of diabetes in the rest of the cohort (Table 2). LDLc started with only 21% of patients being in target but steadily increased to 29% in year-8. Smoking rates likewise improved through to year-8. The rate of waist circumference within target did not change much through follow-up.

The values comprising the CCare score - as well as some not included in the score - demonstrated a similar pattern. Some risk factors showed continued improvement with follow-up - Total and LDL Cholesterol - others improved for the first four years of follow-up - Systolic BP, Exercise – while others did not improve - BMI, weight - and the prevalence of diabetes increased (Supplementary Table 3).

In terms of medication changes, fewer patients were prescribed aspirin from year one (91%) to year eight (87%). This was the only recorded prescription that had an overall reduction, however, it remained among the most frequently prescribed items. Beta-blockers and statins were also frequently prescribed items (year-8: 92% & 73%). Prescriptions of diuretics started at 18% and increased to 24% over time. There were three medications that had a 6% increase in being prescribed; ace inhibitors (started at 45%), Ca channel blockers (started at 16%), and ATII inhibitors (started at 10%). The prescription of diabetic medications also increased through follow-up (Table 3).

	Year 1		*Year 2*	*Δ*	*Year 4*	*Δ*	*Year 8*	*Δ*
Aspirin	91%	-	91%	0%	90%	-2%	87%	-4%
Beta blockers	69%	-	70%	1%	71%	2%	73%	4%
ACE inhibitors	45%	-	49%	4%	51%	6%	51%	6%
Anti-Coagulants	8%	-	7%	0%	8%	0%	12%	4%
Diuretics	18%	-	19%	2%	21%	3%	24%	6%
Ca channel blockers	16%	-	17%	1%	19%	3%	22%	6%
ATII inhibitors	10%	-	11%	1%	13%	3%	16%	6%
Other antihypertensive	9%	-	8%	-1%	8%	0%	10%	1%
Fibrate	2%	-	1%	-1%	2%	0%	2%	0%
Statin	88%	-	92%	4%	93%	5%	92%	4%
Other lipid lowering	5%	-	7%	1%	9%	4%	11%	6%
Insulin	1%	-	1%	0%	2%	0%	3%	1%
Sulphonylureas	4%	-	4%	1%	5%	2%	7%	3%
Biguanides	5%	-	6%	1%	7%	2%	10%	5%
Glucosidase	0%	-	0%	0%	0%	0%	0%	0%
Other hypoglycaemic	1%	-	1%	0%	1%	1%	3%	2%

Table 3: Medications prescribed among the 8-year cohort by year of follow up (n = 5,729), with change from year 1 calculated for each later year of follow up.
ACE, angiotensin-converting enzyme; ATII, angiotensin II; Ca, Calcium-channel blockers; Δ, delta (change).

Patient Demographics and the CCare score

The patients' sex was predictive of better scores; male patients had almost a half point advantage on females (0.432, CI: 0.335-0.509, p<.0001). Female patients had lower CCare scores across all eight years of follow up, 26% had scores >5 in year-1, which rose to a maximum of 33% in year-4 and fell again to 28% in year-8, which was 15% points lower than the equivalent in male patients (41%, 47% & 44% respectively) (Figure 3B). The increase amongst both sexes from year-1 to year-4 were similar (females: +7%, males: +6%) (Figure 3B).

A patient's age at signup does not appear to predict CCare scores in the 8-year cohort. The effect size was small and not found to be significant (0, CI: -0.004 to 0.003, p=0.737). While not significant there were some differences across age groups. More younger patients had a CCare score >5 at signup (<60: 42%) compared to older patients (60-69: 38%, 70+: 34%)(Figure 3C). All age groups had more scores >5 after four years of follow up, (0-59: 46%, 60-69: 45%, 70+: 42%), but more older patients had improved scores to reach those levels (0-59: +4%, 60-69: +7%, 70+: +8%). The difference in the number of patients with a score >5 narrowed after eight years of follow up, and fewer patients achieved scores of >5 than they had after four years (0-59: 42%, 60-69: 40%, 70+: 38%)(Figure 3C).

Signup, attendance patterns, and the CCare score

Th year of patient's signup does not appear to predict CCare scores in the 8-year cohort, but those who registered earlier in the programme had generally lower scores at signup (Figure 3D). Patients who had a CABG as a qualifying event were predicted to have better scores than patients qualifying from an AMI(0.106, CI: 0.028 to 0.183, p<.0001). Patients qualifying from a PTCA events do not differ much from AMI (0.038, CI: -0.045 to 0.121, p=0.234).

Longer intervals between a patient's earliest cardiac event and first visit under Heartwatch were predictive of worse CCare scores (-0.031, CI: -0.040 to -0.023), although the effect size is small; an

interval of over 16 years (2.5% of patients) would be required to predict a half point lower score. Patients with shorter intervals were more likely to have scores >5 (Figure 3E). Shorter QE-interval patients were stable in the first four years and then dropped, whereas those with longer QE-intervals saw continued improvement. Similar to the year of signup, the improvements that were seen in patients with longer QE-intervals to signup were insufficient to allow them to reach the same level of scores as the shorter QE-interval patients. A two-interaction effect of QE-interval and visit number predicts that the negative effects of long intervals diminish with attendance (0.001, CI: 0.001 to 0.002, p<.0001), at that effect size it might take over seven years of visits to erase the negative effect of a 1-year interval.

The number of Heartwatch visits per year was predictive of higher CCare scores(0.109, CI: 0.051 to 0.168, p<.0001). Looking at frequencies, patients who visited more often were more likely to have scores >5 (Figure 3F). However, when grouped by visit per year, all groups still saw improvements throughout years of follow up, each achieving their highest CCare score after four years. A two-interaction effect of visits per year and visit number predicts that the positive effects of regular attendance compound with time (0.003, CI: 0.001 to 0.006, p=0.002).

While the descriptive statistics indicate improvements/stability up to year-4 followed by decline/return to baseline (Figure 3A), the model of 8-years predicted marginally worse scores over time (-0.014, CI: -0.022 to -0.005, p<.0001). The marginal R2, representing the variance explained by the fixed effects was calculated at 0.04. The conditional R2, representing the fixed effects and the random intercept (individual patient baseline effects) was 0.57. This would indicate that the patient level variables only account for a fraction of the variance compared to the patient's initial health status upon signup.

Discussion

In this investigation of patient data from a cardiovascular secondary prevention programme, we found that patients achieved moderate improvements in blood pressure (+3% within target), LDL cholesterol (+7% within target), and smoking status (+4% non-smokers). To develop a broader understanding of patient success, an 8-point Continuing Care Score was created to monitor changes over eight years. Less than 2% of patients achieved all targets, however by year-8, 71% of patients had achieved between five and seven of the eight targets.

Using statistical modelling, we found that longer time intervals between the qualifying cardiac event and starting the secondary prevention intervention predicted worse scores even after eight years, but these patients can and do improve overtime, just not as rapidly as other patients. Female patients were also more likely to have worse CCare scores, both in the baseline and 8-year model. Moreover, patients who attended three or more visits per year had higher average CCare scores and maintained higher scores while patients who visited less frequently saw a decline in their outcomes. This could be a reason to promote attending secondary cardiac prevention as soon as possible following a cardiac event and maintaining a good level of contact with that intervention.

Strengths and limitations

The key strength of Heartwatch is the volume of patient data and the length of time the program has been in existence with patients retained. Further to that, the data is geographically spread across general practices areas across Ireland.

However, this is an active care program and not a randomised controlled trial, so no comparative or control group exists. Moreover, data is collected primarily for clinical monitoring, not research purposes, thus, some variables were calculated. For example, in our statistical models, visits per year is calculated retrospectively and so its value in a predictive model is constrained. A key strength is that this is real-world data.

ESC guidelines on LDLc changed during the programme, so patients may have been treated towards different target levels. We retrospectively applied the most recent recommendations ergo some patients may have been designated out of target who would have been in target at the time. Hence, we may have underestimated the number achieving the target as a stricter more recent guideline is being applied.

Another possible limitation could be a survivor bias on the available long-term information, as those with worse scores may have exited the programme earlier than eight years.[30]

Heartwatch does not collect outcome information such as mortality or further cardiac events, nor does it collect patient reported outcomes. This was a limitation which we have attempted to overcome by developing the CCare score method.

Comparison to other literature

It is difficult to draw a direct comparison with other literature because the programme is not a trial nor a survey of patients with a history of CVD but an ongoing care program with real-world data. The programme, Heartwatch, presents a much longer-term view of secondary prevention compared to most literature which focuses on the first six months,[31] first year or first two years following a cardiac event.[8,32] There is substantial research on secondary prevention of CVD and identifying and managing risk factors for these patients which we have compared with our results. In a review of clinical trials looking at primary and secondary prevention of coronary artery disease, Kantaria et al. found that reduction of LDLc, decrease in blood pressure and discontinuation of smoking resulted in reduced death rates and further cardiac events.[33] This is promising, as these are the key areas in which Heartwatch patients improved.

An international review of risk factor management for patients with CVD in Asia, Europe and the Middle East also found sex-based differences where female patients were less likely to achieve total cholesterol, LDLc, glucose, physical activity and weight targets compared to male counterparts.[34] These differences were smaller in Europe compared to Asia and the Middle East but persisted

nevertheless which is congruent with our predictive model findings of sex-based outcome differences.

In 2009, the European Action on Secondary and Primary Prevention by Intervention to Reduce Events III (EUROASPIRE III)[23] survey sought to determine whether the European guidelines were being followed in everyday practice. This survey found that large proportions of patients do not achieve the targets, more than half did not meet the blood pressure or cholesterol targets[23] and they stated that European countries needed to raise the standard of preventive care. An Italian study of secondary prevention of coronary heart disease in primary care, which looked at health records of just under 6,000 patients found 153 patients with CVD.[10] This survey found that there was satisfactory adherence to guideline advice – 46% of patients achieved LDL targets and 83% achieved the systolic blood pressure target. They concluded that GPs are well placed to help people with a history of CVD to manage risk factors, but that care could be further optimised.

The Swedish study[11] that inspired the development of the CCare score, found only 3.5% of people were achieving all targets two years after AMI. This is similar to our finding here where just 2% of patients achieved all eight targets at year-2. This highlights further the need for specific interventions of secondary prevention, as more Heartwatch patients achieved their systolic blood pressure (SBP), 69%, and LDL targets, 23%, after two years compared to the those in Sweden where 57% achieved the SBP and 18.5% achieved LDL targets. However, it should be noted that Heartwatch has a more diverse patient group compared to the Swedish patients, who had suffered an acute incident. A Norwegian study of cardiac rehabilitation patients, showed that patients who had an acute incident were more likely to participate in secondary prevention.[35]

Finally, in the more recent EUROASPIRE surveys, smoking, obesity, and exercise were persistent in their unlikeliness to change overtime but lifestyle changes were more successful if a patient was in a prevention programme.[36] However, in the same Norwegian study as above patients who were overweight were more likely to participate in the program, which shows a willingness to improve.[35] In Heartwatch, exercise and waist circumference did not show much improvement

over eight years. Patients in the EUROASPIRE surveys stated lack of confidence as their main barrier to address unhealthy behaviour.

Implications for policy and practice

In current secondary prevention research and guidelines, there is a focus on measurement and development of risk factor targets. However, research has repeatedly demonstrated that patients are not meeting these targets.[37,38] For example, results for males and females diverge under similar targets. The current evidence base should be used as a foundation to refocus secondary prevention research away from target definitions and onto the implementation of these programmes with added public and patient involvement.

We, and others[39], have shown early enrolment after a cardiac event and frequency of structured care visits should be priorities in the design and implementation of similar programmes.

The evaluation of patient outcomes and cost-effectiveness should take into consideration that new programmes can experience an initial influx from a backlog of high-risk cases. Chronic disease programmes may evolve significantly in the initial few years. Planning and evaluation should take this into consideration.

While twenty percent of Irish GPs were recruited to Heartwatch, the demographics and location of the practices is not available for analysis. As mentioned above, recruitment of patients was at the GPs' discretion. As Heartwatch was not primarily designed for research, it did not capture socioeconomic status or cultural behaviours such as diet. Better prior design of the recruitment and data collection would be required to fully assess of how valid our findings would be to the wider Irish population . However, in other justifications, the model has been cited to inform the design of local programs, particularly in areas with similar general practice systems (e.g., Australia).[19,40,41]

Our results on sex-based differences and earlier recruitment into the programme may apply to the broader Irish population, or other similar populations with CVD, as these are previously demonstrated factors which impact secondary prevention of CVD.[34,39,42] Another finding likely to

be true for similar programmes is the need to carefully consider monitoring and evaluation of patient outcomes whilst the programme and its data collection is designed.[17]

Conclusion

Secondary prevention of CVD can have a positive impact even when patients start with poor outcomes. The sooner a patient can access a structured care program, the better but even with delays it is worth enrolling patients with a history of cardiac events regardless of age. Overall, patients are not likely to meet all targets set by secondary prevention guidelines – especially those related to lifestyle factors such as exercise and waist circumference. However, supporting patient self-management may impact on this and the inclusion of factors such as a patient-centred approach and regular training of health professionals to deliver same, as noted elsewhere.[24,36] Ongoing evaluation and improvement of secondary prevention programmes is needed to help more patients successfully reach targets.[40]

Acknowledgements

We thank Drs. Suzanne Kelly and Mike O'Callaghan, clinical leads in the ICGP for their support and clinical expertise. Our thanks also to Patricia Patton, ICGP library for bibliography assistance. This work uses data that have been provided by patients and collected by their GPs as part of their care and support, we acknowledge these contributions and thank Sally-Anne O'Neill and Colleen O'Neil for Heartwatch administrative support and advice.

Conflict of interest

The authors declare no conflicts of interest.

Author Contributions

All authors contributed to the research question development. FS carried out the re-coding of variables and undertook the data analysis. All authors designed the analysis approach, interpreted the results and formulated the conclusions. JG contributed clinical expertise. CC is the PI and manager of the Heartwatch Programme and provided direction and oversight for this analysis and paper. RH and FS prepared the first draft of the manuscript. RH and FS contributed equally to this paper. All authors contributed to the manuscript and all authors read and approved the final manuscript. All named authors contributed sufficient work according to the COPE guidelines.

Funding

There was no additional funding obtained to undertake this secondary analysis. The Heartwatch programme is funded by the Irish Health Service Executive. The ICGP Research Hub is funded through the Irish Sláintecare initiative .

Ethical Review Statement

The anonymous data used in this paper was provided through the agreed database access process and is in accordance with all GDPR requirements and is a legitimate use of the database and in compliance with the programme's ethical approval.

Data Sharing Statement

The Heartwatch INDC acts as the primary collection point for all HeartWatch data returned by practices. Within this structure there is a data management committee, which has the responsibility of reviewing access requests to the aggregated, anonymous version of the collected data. Data used here was released after such an access request.

References

1. World Health Organization. Cardiovascular diseases (CVDs) - Key facts. 2021.

2. Eurostat. *Causes of Death Statistics*., 2021.

3. Fitzpatrick P, Fitz-Simon N, Lonergan M *et al.* Heartwatch: The effect of a primary care-delivered secondary prevention programme for cardiovascular disease on medication use and risk factor profiles. *Eur J Prev Cardiol* 2011;**18**:129–35.

4. Central Statistics Office. *VITAL STATISTICS YEARLY SUMMARY 2019*., 2020.

5. 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 (constituted by representati. *Eur Heart J* 2016;**37**:2315–81.

6. Wilt TJ, Bloomfield HE, MacDonald R *et al.* Effectiveness of statin therapy in adults with coronary heart disease. *Arch Intern Med* 2004;**164**:1427–36.

7. Collaboration AT. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. *BMJ* 2002;**324**:71–86.

8. Peersen K, Munkhaugen J, Gullestad L *et al.* The role of cardiac rehabilitation in secondary prevention after coronary events. *Eur J Prev Cardiol* 2017;**24**:1360–8.

9. Irish Association of Cardiac Rehabilitation. *Cardiac Rehabilitation Guidelines 2013* . Dublin, 2013.

10. De Backer G, Ambrosioni E, Borch-Johnsen K *et al.* European guidelines on cardiovascular disease prevention in clinical practice: third joint task force of European and other societies on cardiovascular disease prevention in clinical practice (constituted by representatives of eight societies and by invit. *Eur J Cardiovasc Prev Rehabil* 2003;**10**:S1–10.

11. Ergatoudes C, Thunström E, Rosengren A *et al.* Long-term secondary prevention of acute myocardial infarction (SEPAT) - guidelines adherence and outcome. *BMC Cardiovasc Disord* 2016;**16**:226.

12. Hall M, McGettigan M, O'Callaghan P *et al.* Comparison of secondary prevention of heart disease

in Europe: lifestyle getting worse, therapy getting better in Ireland. *Ir Med J* 2002;**95**:272–4.

13. Modesti A, Del Papa C, Modesti L *et al.* Secondary prevention of coronary heart disease. A survey in an Italian primary care practice. *Minerva Cardioangiol* 2010;**58**:167–73.

14. Homeniuk R, Collins C. How COVID-19 has affected general practice consultations and income: general practitioner cross-sectional population survey evidence from Ireland. *BMJ Open* 2021;**11**, DOI: 10.1136/bmjopen-2020-044685.

15. Department of Health and Children, Health Boards, ICGP *et al. Heartwatch Clinical Report - V1*. Dublin, 2004.

16. Department of Health and Children, HSE, ICGP *et al. Heartwatch Clinical Report - V2*. Dublin, 2006.

17. Collins C, Finn C, Meade B *et al.* Strengthening the Foundation of General Practice Evidence in Ireland by Addressing the Data Quality Issues in a Structured Secondary Prevention Programme for Cardiovascular Disease. *JMED Res* 2014;**2014**:1–6.

18. Bennett K, Jennings S, Collins C *et al.* Heartwatch: A secondary prevention programme in primary care in Ireland. *Eur J Prev Cardiol* 2008;**15**:651–6.

19. Brett T, McGuire S, Meade B *et al.* Secondary prevention of cardiovascular disease: A possible model for Australian general practice. *Aust Fam Physician* 2006;**35**:157–9.

20. Wood D, De Backer G, Faergeman O *et al.* Prevention of coronary heart disease in clinical practice. Summary of recommendations of the Second Joint Task Force of European and other Societies on Coronary Prevention. *Blood Press* 1998;**7**:262–9.

21. Irish College of General Practitioners. *Heartwatch Summary Guide*., 2003.

22. Elm E von, Altman DG, Egger M *et al.* Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;**335**:806–8.

23. Kotseva K, Wood D, De Backer G *et al.* EUROASPIRE III: a survey on the lifestyle, risk factors and use of cardioprotective drug therapies in coronary patients from 22 European countries. *Eur J*

Cardiovasc Prev Rehabil 2009;**16**:121–37.

24. Kotseva K, De Backer G, De Bacquer D *et al.* Lifestyle and impact on cardiovascular risk factor control in coronary patients across 27 countries: Results from the European Society of Cardiology ESC-EORP EUROASPIRE V registry. *Eur J Prev Cardiol* 2019;**26**:824–35.

25. Leon BM, Maddox TM. Diabetes and cardiovascular disease: Epidemiology, biological mechanisms, treatment recommendations and future research. *World J Diabetes* 2015;**6**:1246–58.

26. Team RC. R: A language and environment for statistical computing. 2022.

27. Bates D, Mächler M, Bolker B *et al.* Fitting Linear Mixed-Effects Models Using lme4. *J Stat Softw* 2015;**67**, DOI: 10.18637/jss.v067.i01.

28. Burnham KP, Anderson DR. *Model Selection and Multimodel Inference*. Burnham KP, Anderson DR (eds.). New York, NY: Springer New York, 2004.

29. Nakagawa S, Johnson PCD, Schielzeth H. The coefficient of determination R 2 and intra-class correlation coefficient from generalized linear mixed-effects models revisited and expanded. *J R Soc Interface* 2017;**14**:20170213.

30. Saracci R. Survival-related biases survive well. *Int J Epidemiol* 2007;**36**:244–6.

31. Urbinati S, Olivari Z, Gonzini L *et al.* Secondary prevention after acute myocardial infarction: drug adherence, treatment goals, and predictors of health lifestyle habits. The BLITZ-4 Registry. *Eur J Prev Cardiol* 2015;**22**:1548–56.

32. Jankowski P, Kosior DA, Sowa P *et al.* Secondary prevention of coronary artery disease in Poland. Results from the POLASPIRE survey. *Cardiol J* 2020;**27**:533–40.

33. Kantaria M, Buleishvili M, Kipiani N V *et al.* RISK-FACTORS OF CORONARY ARTERY DISEASE (REVIEW). *Georgian Med News* 2020:78–82.

34. Zhao M, Vaartjes I, Graham I *et al.* Sex differences in risk factor management of coronary heart disease across three regions. *Heart* 2017;**103**:1587–94.

35. Olsen SJ, Schirmer H, Bønaa KH *et al.* Cardiac rehabilitation after percutaneous coronary intervention: Results from a nationwide survey. *Eur J Cardiovasc Nurs* 2018;**17**:273–9.

36. De Bacquer D, Astin F, Kotseva K *et al.* Poor adherence to lifestyle recommendations in patients with coronary heart disease: results from the EUROASPIRE surveys. *Eur J Prev Cardiol* 2021, DOI: 10.1093/eurjpc/zwab115.

37. Vogel B, Acevedo M, Appelman Y *et al.* The Lancet women and cardiovascular disease Commission: reducing the global burden by 2030. *Lancet* 2021;**397**:2385–438.

38. Murphy AW, Cupples ME, Murphy E *et al.* Six-year follow-up of the SPHERE RCT: secondary prevention of heart disease in general practice. *BMJ Open* 2015;**5**:e007807.

39. Murchie P. Secondary prevention clinics for coronary heart disease: four year follow up of a randomised controlled trial in primary care. *BMJ* 2003;**326**:84–84.

40. Farkouh ME, Boden WE, Bittner V *et al.* Risk factor control for coronary artery disease secondary prevention in large randomized trials. *J Am Coll Cardiol* 2013;**61**:1607–15.

Figure Legends

Figure 1 – Heartwatch overview 2003-2020

A – All Heartwatch visits graphed by year of visit.
B – Each year of follow up with total number of patients graphed.
C – Population pyramid of all patients.
D – All patients grouped by earliest qualifying event type.
E – All patients grouped by interval from earliest qualifying event to date of first Heartwatch visit.

AMI, acute myocardial infarction; PTCA, percutaneous coronary intervention; CABG, coronary artery bypass grafting; * Jan 2003 to March 2020.

Figure 2 – Heartwatch 8-year cohort overview 2003-2020

A – Patient records graphed by year of follow up. The records of the 8yr-cohort are highlighted in pink.
B – 8-year cohort grouped by earliest qualifying event type.
C – Population pyramid of 8-year cohort.
D – 8-year cohort grouped by interval from earliest qualifying event to date of first Heartwatch visit.

8-year cohort n= 5729.

Figure 3 – The CCare for the 8-year cohort in follow up years 1, 2, 4 & 8.

A – The CCare scores for the 8-year cohort; proportion of cohort by number of metrics met.
B – The CCare scores by grouped age bands.
C – The CCare scores by grouped recorded sex.
D – The CCare scores by grouped year of first visit.
E – The CCare scores by grouped by number of visits per year.
F – The CCare scores by grouped by interval from earliest qualifying event to date of first Heartwatch visit.

QE, Qualifying event.

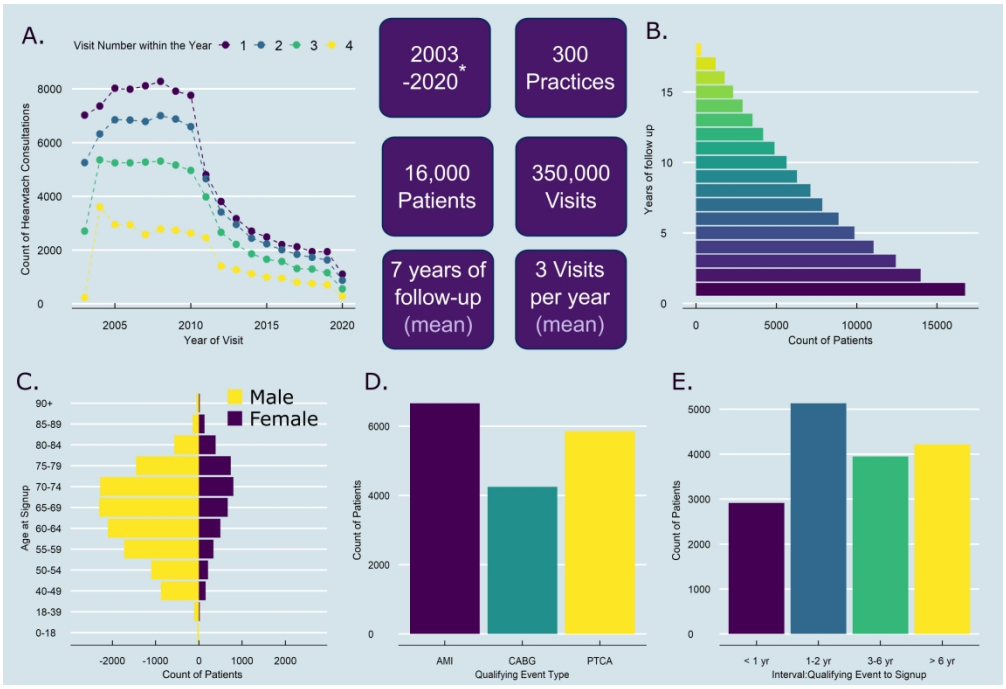

Figure 1 – Heartwatch overview 2003-2020.
A - All Heartwatch visits graphed by year of visit. B - Each year of follow up with total number of patients graphed. C - Population pyramid of all patients. D - All patients grouped by earliest qualifying event type. E - All patients grouped by interval from earliest qualifying event to date of first Heartwatch visit. AMI, acute myocardial infarction; PTCA, percutaneous coronary intervention; CABG

464x316mm (164 x 164 DPI)

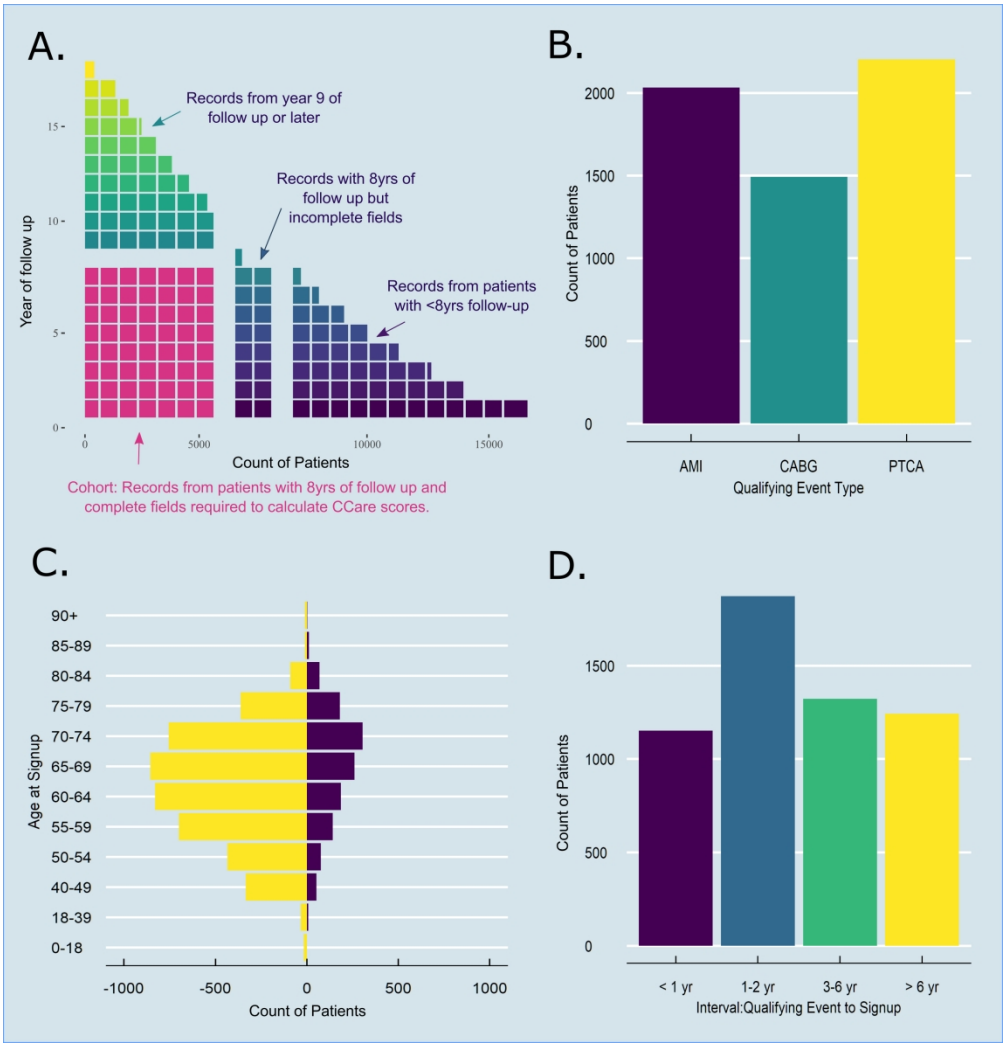

Figure 2 – Heartwatch 8-year cohort overview 2003-2020
A - Patient records graphed by year of follow up. The records of the 8yr-cohort are highlighted in pink. B - 8-year cohort grouped by earliest qualifying event type.
C - Population pyramid of 8-year cohort. D - 8-year cohort grouped by interval from earliest qualifying event to date of first Heartwatch visit. 8-year cohort n= 5729.

698x725mm (105 x 105 DPI)

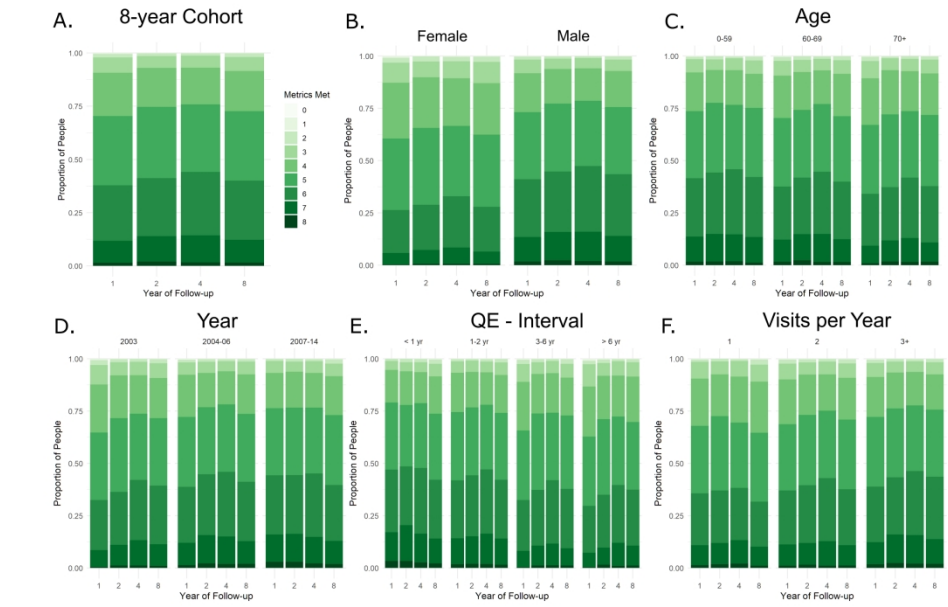

Figure 3 – The CCare for the 8-year cohort in follow up years 1, 2, 4 & 8.
A - The CCare scores for the 8-year cohort; proportion of cohort by number of metrics met. B - The CCare scores by grouped age bands. C - The CCare scores by grouped recorded sex. D - The CCare scores by grouped year of first visit. E - The CCare scores by grouped by number of visits per year. F - The CCare scores by grouped by interval from earliest qualifying event to date of first Heartwatch visit. QE, Qualifying event.

1058x726mm (72 x 72 DPI)

Supplementary Data File

Supplementary Table 1

Effect	*Estimate*	*Error*	*z*	*p*
Intercept	4.668	0.106	43.844	<.0001
Main effects				
SEX	0.432	0.030	14.443	<.0001
Visit count	-0.014	0.003	-4.111	<.0001
Vpa	0.109	0.023	4.810	<.0001
QE - Interval	-0.031	0.003	-9.471	<.0001
QE -PTCA	0.038	0.032	1.190	.234
QE - CABG	0.106	0.030	3.502	<.0001
Age at signup	0.000	0.001	-0.336	.737
Two-way interactions				
Vpa : Visit count	0.003	0.001	3.107	.002
QEV - Interval : Visit count	0.001	0.000	10.430	<.0001

Legend

Supplemental Table 3 – effect estimates table from the mixed effects model of data from Heartwatch visits of the 8-year cohort (n = 5,729).

Note: Sex coding Female = 0, Male = 1; QE = qualifying event; Vpa = visits per annum

Supplementary Table 2

	Mandatory Fields	Units	Targets	Min/Max
Systolic Blood Pressure	y	mmHg	<140	60/240
Diastolic blood pressure	y	mmHg	<90	30/150
Total Cholesterol	y	mmol/L	<5	1/12
LDL Cholesterol	y	mmol/L	<1.8	0/11
Exercise Total	n	min/week	>210	
Height	y	cm		135/195
Weight	y	kg		40/200
Waist Circumference	y	cm	Male: <94 Female: <80	40/200
Body Mass Index	y	kg/cm2	<25	15/60
Diabetes Status	y			
Fasting Glucose	y	mmol/L	Non-Diabetics: <5.5 Diabetics: <6	2/30
HbA1c	y - (Type 1,Type 2 & IGT)	mmol/mol	<45	20/140
Serum Creatinine	y - (Type 1,Type 2 & IGT)	mmol/L	<115	10/999

Legend

Supplemental Table 1 – Heartwatch measures, targets, and minimum and maximum valid values allowed for each.

IGT, Impaired glucose tolerance.

Supplementary Table 3

	Year 1			*Year 2*			*Year 4*			*Year 8*		
	mean	SD	n	mean	SD	n	mean	SD	n	mean	SD	n
BP Systolic	133	18	5729	132	17	5729	131	16	5729	132	16	5729
BP diastolic	77	10	5729	76	9	5726	75	9	5728	75	9	5729
Cholesterol total	4.3	1.0	5728	4.2	1.0	5724	4.1	0.9	5729	4.0	0.9	5728
Cholesterol LDL	2.5	0.9	5729	2.3	0.8	5729	2.2	0.8	5729	2.2	0.9	5729
Weight	81	15	5725	81	15	5725	82	15	5729	82	16	5729
Waist Circumference	97	13	5729	97	13	5729	97	13	5729	98	14	5729
BMI	28	4	5710	28	4	5677	28	4	5729	28	5	5729
Diabetes (T1,T2,IGT)	10%		5729	12%		5729	15%		5729	19%		5729
Fasting Glucose	5.5	1.7	4870	5.7	2.8	4937	5.6	1.8	4957	5.7	1.8	5101
HbA1c	50	14	738	49	12	872	49	12	1015	50	12	1235
Serum Creatinine	99	82	1034	99	73	1170	98	66	1274	97	41	1466
Weekly Exercise	227	152	5729	235	135	5729	237	136	5729	215	141	5729
Smoking Status	12%		5729	11%		5729	10%		5729	8%		5729

Legend:

Table 3 – Means, standard deviations (SD) and sample sizes of Heartwatch programme measures for the 8-year cohort in follow up years 1,2,4,and 8.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1	'secondary analysis'
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2	See abstract
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5	See Introduction
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5	See introduction
Methods				
Study design	4	Present key elements of study design early in the paper	6-9	Se methods
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-9	See methods, with specific sections on data collection, access, and processing
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6-9	See methods, data collection mentions how patients are recruited to secondary prevention programme and how their data is collected, section on data processing dictates how patients were selected for secondary analysis
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9	In methods, outcome measure development and calculation, stats, and variables of interest
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-9	Methods and supplemental table 1
Bias	9	Describe any efforts to address potential sources of bias	6-9	methods
Study size	10	Explain how the study size was arrived at	7-8	Method > data handling > processing

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-9	Data handling and variables of interest
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9	
		(*b*) Describe any methods used to examine subgroups and interactions	9	
		(*c*) Explain how missing data were addressed	6-9	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a secondary analysis	
		(*e*) Describe any sensitivity analyses	n/a	
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10	Results section
		(b) Give reasons for non-participation at each stage	n/a	
		(c) Consider use of a flow diagram		
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10-14	results
		(b) Indicate number of participants with missing data for each variable of interest	n/a	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)		
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	10-14	results
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures		
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-14 15-16	Results Discussion
		(*b*) Report category boundaries when continuous variables were categorized	supplemental table 1	Target values/limits are included in supplemental table 1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		n/a

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10-14	All analyses in results
Discussion				
Key results	18	Summarise key results with reference to study objectives	15	first section of discussion
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15	Second section of discussion 'strengths and limitations'
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15-18	Discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results	15-18	Discussion
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	21	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.