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Implementing guidelines to routinely prevent chronic vascular disease in primary care: The Preventive Evidence into Practice cluster randomised controlled trial

Mark Fort Harris

University of New South Wales, m.f.harris@unsw.edu.au

Sharon M. Parker

University of New South Wales

John Litt

Flinders University

Mieke van Driel

University of Queensland

Grant Russell

Monash University

See next page for additional authors

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Abstract

Objective: To evaluate an intervention to improve implementation of guidelines for the prevention of chronic vascular disease. **Setting:** 32 urban general practices in 4 Australian states. **Randomisation:** Stratified randomisation of practices. **Participants:** 122 general practitioners (GPs) and practice nurses (PNs) were recruited at baseline and 97 continued to 12 months. 21 848 patient records were audited for those aged 40-69 years who attended the practice in the previous 12 months without heart disease, stroke, diabetes, chronic renal disease, cognitive impairment or severe mental illness. **Intervention:** The practice level intervention over 6 months included small group training of practice staff, feedback on audited performance, practice facilitation visits and provision of patient education and referral information. **Outcome measures:** Primary: 1. Change in proportion of patients aged 40-69 years with smoking status, alcohol intake, body mass index (BMI), waist circumference (WC), blood pressure (BP) recorded and for those aged 45-69 years with lipids, fasting blood glucose and cardiovascular risk in the medical record. 2. Change in the level of risk for each factor. Secondary: change in self-reported frequency and confidence of GPs and PNs in assessment. **Results:** Risk recording improved in the intervention but not the control group for WC (OR 2.52 (95% CI 1.30 to 4.91)), alcohol consumption (OR 2.19 (CI 1.04 to 4.64)), smoking status (OR 2.24 (1.17 to 4.29)) and cardiovascular risk (OR 1.50 (1.04 to 2.18)). There was no change in recording of BP, lipids, glucose or BMI and no significant change in the level of risk factors based on audit data. The confidence but not reported practices of GPs and PNs in the intervention group improved in the assessment of some risk factors. **Conclusions:** This intervention was associated with improved recording of some risk factors but no change in the level of risk at the follow-up audit. **Trial registration number:** Australian and New Zealand Clinical Trials Register (ANZCTR): ACTRN12612000578808, results.

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Authors

Mark Fort Harris, Sharon M. Parker, John Litt, Mieke van Driel, Grant Russell, Danielle Mazza, Upali W. Jayasinghe, Chris del Mar, Jane Lloyd, Jane Smith, Nicholas Arnold Zwar, Richard J. Taylor, and Gawaine Powell Davies

BMJ Open Implementing guidelines to routinely prevent chronic vascular disease in primary care: the Preventive Evidence into Practice cluster randomised controlled trial

Mark Fort Harris,¹ Sharon M Parker,¹ John Litt,² Mieke van Driel,³ Grant Russell,⁴ Danielle Mazza,⁵ Upali W Jayasinghe,¹ Chris Del Mar,⁶ Jane Lloyd,¹ Jane Smith,⁶ Nicholas Zwar,⁷ Richard Taylor,⁷ Gawaine Powell Davies,¹ On behalf of the Preventive Evidence into Practice (PEP) Partnership Group

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For numbered affiliations see end of article.

Correspondence to

Professor Mark Fort Harris;
m.f.harris@unsw.edu.au

ABSTRACT

Objective: To evaluate an intervention to improve implementation of guidelines for the prevention of chronic vascular disease.

Setting: 32 urban general practices in 4 Australian states.

Randomisation: Stratified randomisation of practices.

Participants: 122 general practitioners (GPs) and practice nurses (PNs) were recruited at baseline and 97 continued to 12 months. 21 848 patient records were audited for those aged 40–69 years who attended the practice in the previous 12 months without heart disease, stroke, diabetes, chronic renal disease, cognitive impairment or severe mental illness.

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Secondary: change in self-reported frequency and confidence of GPs and PNs in assessment.

Results: Risk recording improved in the intervention but not the control group for WC (OR 2.52 (95% CI 1.30 to 4.91)), alcohol consumption (OR 2.19 (CI 1.04 to 4.64)), smoking status (OR 2.24 (1.17 to 4.29)) and cardiovascular risk (OR 1.50 (1.04 to 2.18)). There was no change in recording of BP, lipids, glucose or BMI and no significant change in the level of risk factors based on audit data. The confidence but not reported practices of GPs and PNs in the intervention group improved in the assessment of some risk factors.

Strengths and limitations of this study

- This is a moderately large cluster randomised controlled trial in general practices in four Australian states.
- The intervention was developed in partnership with organisations involved in developing and implementing guidelines for the prevention of chronic vascular conditions in Australian general practice.
- The trial design involved blind random allocation but practitioners were not blinded to their allocation.
- Although provider questionnaires relied on self-report, medical records were electronically audited and not subject to selection bias.

Conclusions: This intervention was associated with improved recording of some risk factors but no change in the level of risk at the follow-up audit.

Trial registration number: Australian and New Zealand Clinical Trials Register (ANZCTR): ACTRN12612000578808, results.

INTRODUCTION

Chronic diseases and their risk factors account for most of the global burden of disease.¹ Nine in 10 adult Australians have at least one of the behavioural or physiological risk factors for chronic disease including smoking, poor nutrition, excessive alcohol consumption, physical inactivity, overweight or obesity, hypertension or dyslipidemia.² General practitioners (GPs) are well placed to work with patients to manage these risk factors because of their high population

coverage (over 80% of the population present in primary care at least once a year), and patient acceptance of their role in preventive care.^{3 4} They are thus in an ideal position to assess and provide advice about lifestyle-related behavioural risk factors.⁵

The roles of GPs in preventive care are reinforced in clinical guideline recommendations from a range of government and non-government organisations.^{6 7} A number of these recommendations are based on the '5As' (Ask, Assess, Advise/Agree, Assist and Arrange) framework for a multidisciplinary preventive care.^{8–10} There is evidence that this approach enhances patient motivation and behaviour change.¹¹ Despite wide dissemination of preventive guidelines, implementation barriers exist at various patient (eg, motivation and health literacy), practitioner (eg, beliefs about effectiveness), practice (eg, time and organisational capacity) and system (eg, funding and workforce) levels.^{12–14} These barriers contribute to low rates of clinical assessment of risk, lifestyle advice and referral.^{15–17}

The Preventive Evidence into Practice (PEP) partnership group developed and conducted a multicenter cluster randomised controlled trial of a practice facilitation and quality improvement intervention designed to support general practices to implement the recommendations of evidence-based clinical management guidelines for the prevention of cardiovascular disease (CVD) and type 2 diabetes. This paper reports on the primary outcome of the trial: the clinical assessment and recording of patient risk factors from audited records. We hypothesised that, for patients aged 40–69 years, the PEP intervention would improve the recording of patient risk factors by 20%, over 12 months.

MATERIALS AND METHODS

Design

We conducted a cluster randomised controlled trial in urban general practices in four Australian states (New South Wales, Victoria, South Australia and Queensland) over 12 months (2012–2013). The methods for the PEP trial were designed a priori, and have been described elsewhere.¹⁵

Randomisation

Blinded practice allocation was conducted (by UJ) independent of recruitment or data collection. Practices were randomly assigned to intervention and control groups after stratification into blocks by state and practice size (the number of general practitioners in a practice) using a computer-generated randomisation list. Participant practitioners were not blinded to allocation.

Participants

Thirty-two practices (eight from each state) were recruited to the study through regional primary care organisations responsible for coordinating quality improvement activities at the local practice level. A total

of 124 practices were approached to assess their eligibility. Eighty-one declined to participate; eight did not meet the inclusion criteria and three did not participate for other (various reasons). Eight practices in each of the four states provided consent.

Inclusion criteria were the use of computerised medical records that could be audited with the PCS Clinical Audit Tool (PENCAT) and employment of a practice nurse (PN). PNs are registered nurses (generally bachelor degree qualified) who work in general practice and in collaboration with GPs, coordinate and provide preventive and chronic illness care.¹⁸

De-identified medical record data were extracted for patients who were aged 40–69 years and had attended the practice in the previous 12 months. Records of patients with heart disease, stroke, diabetes or chronic renal disease, cognitive impairment or severe mental illness (psychoses) were excluded based on their need for specialised assessment and management.

Intervention

The intervention was targeted at the practice level and aimed to improve the assessment and management of smoking; nutrition and weight; alcohol and physical activity (SNAP),¹⁹ cardiovascular and diabetes risk; blood pressure (BP) and lipids.

The intervention occurred over 6 months and comprised (1) small group training of practice staff; (2) feedback on audited performance; (3) a series of practice facilitation visits; and (4) provision of patient education resources and referral information (see [box 1](#)). The facilitation was based on quality improvement (QI) whereby each practice reviewed their performance and set and reviewed goals specific to their individual circumstances and resources. Facilitators also provided telephone support as needed to practices over 12 months. Facilitators were sourced from a local primary care organisation and all had expertise providing QI to practices. Facilitators also underwent specific training to provide the PEP intervention and were in turn supported by the research team.

Outcomes

The primary outcomes were the assessment and recording in the electronic medical record of smoking status, alcohol use, body mass index (BMI), waist circumference (WC), systolic and diastolic BP, fasting blood glucose, lipids (total cholesterol, high-density lipoprotein, low-density lipoprotein, triglycerides) and absolute cardiovascular (CV) risk (base on Framingham risk score adjusted for the Australian population²⁰). Secondary outcomes were the self-reported assessment practices of GPs and PNs and their confidence when performing these assessments.

Data collection

Clinicians completed a questionnaire at baseline and 12 months. This questionnaire was based on work

Box 1 PEP Practice Intervention

1. Written feedback and practice-based discussion of clinical record audit of recording and levels of behavioural and physiological risk factors (BMI, waist circumference, systolic BP, alcohol consumption, smoking status, lipids, fasting glucose and absolute cardiovascular risk) for chronic vascular disease from the electronic medical record of each practice. These were compared with Australian evidence-based guidelines and standards.
2. Small group training (approximately 3 h duration) of all participating general practitioners and practice nurses based on the 5As for each of the risk factors using clinical scenarios and case studies to reflect on assessment, advice giving, goal setting, referral and follow-up of patients with abnormal risk factors. There was particular emphasis on the lifestyle management of these risk factors.
3. Trained practice facilitators visited and met with practice staff (for at least three 1–2 h) to develop and support the implementation of a plan to improve the prevention of vascular disease in the practice population. The plan for each practice was required to include improving the assessment and recording of risk factors. Practice goals to improve other aspects of vascular preventive care were flexibly determined for each practice based on need and the priority of participants. There were three structured visits over 3 months following the small group training.
4. Patient education resources for use by practice nurses and general practitioners and information on referral services and programmes within the local area were provided to each practice in written and electronic form for uploading into practice record systems. No specific prompts or templates for preventive care were used in the electronic record.

previously undertaken by the investigators with questions adapted from the Preventive Medicine Attitudes and Activities Questionnaire (PMAAQ).²¹ The instrument collected self-reported frequency of assessment of risk factors during clinical encounters, advice given and referral of patients identified to be at risk. We also asked clinicians about their confidence in assessing and managing risk factors. Principle component analysis was performed on the confidence questions which identified a single component with an Eigenvalue of 5.5 which explained 69% of the variance.

Deidentified clinical patient data were extracted using the PENCAT clinical audit software at baseline and 12 months. We extracted data related to recording and level of risk factors for BMI, WC, systolic BP, alcohol and smoking for patients aged 40–69 years and lipids, fasting blood glucose and absolute CV risk for patients aged 45–69 years (in accordance with the guidelines).

Sample size

The sample size calculation was based on the ability to detect an improvement of 10% between control and intervention groups in the recording of risk factors. For BMI with intra-cluster correlation coefficient (ICC) of 0.047 at 80% power at the 5% significance level, this

gave a sample of 8700 patient records in each group. The same assumptions produce sample size estimates of 10 800 and 11 300 for LDL-cholesterol (ICC=0.059) and systolic BP (ICC=0.062), respectively.

Analysis

Practice and provider characteristics at baseline were compared between groups for those participating over the 12 months using univariate statistical tests (χ^2).

Primary analysis evaluated the change in recording of risk factors and levels of risk factors. Levels were defined as elevated for BMI (>25), waist circumference (male ≥ 94 cm, female ≥ 80 cm), BP ($\geq 140/90$), alcohol (>2 standard drinks/day), smoking (current), blood glucose (>5.5 mmol/L), total cholesterol (≥ 4) and CV disease (CVD) risk (>10% over 5 years) based on evidence-based Australian guidelines. Secondary analysis evaluated the change in self-reported assessment and confidence in assessment by participating GPs and PNs.

Univariate statistical tests (χ^2 and t tests) were performed to examine difference between baseline and follow-up, and between intervention and control participants for the outcome variables at the level of $p < 0.05$.

Multilevel logistic regression models were used to examine those outcomes that were significant in the univariate analysis. This modelled dichotomous dependent variables for improvements in recording of CVD risk, BMI, WC, alcohol, BP and smoking at follow-up. These models examined the effect of the intervention on improved recording of risk factors adjusted for clustering of patients (level 1) within practices (level 2) and confounding effects of patient factors (age and gender) and practice characteristics (number of GPs and nurses and proportion of GPs/PNs working ≥ 10 years in primary care).

Initially we fitted a baseline variance component or empty multilevel model (no independent variables) for each of the dependent variables, followed by the multilevel model with independent variables. The significance of the fixed and random parameter variance estimates (practice variance) was assessed using the Wald joint χ^2 test statistic. The proportion of the practice level variance explained for each model was estimated as the difference in practice variance between baseline model (empty model) and each model with independent variables divided by the practice variance for the baseline model. All multilevel models were performed using MLwiN V.2.25.²²

Ethics and trial registration

All participants gave full informed written consent. Clinical Trial Registration was obtained via the Australian and New Zealand Clinical Trials Register (ANZCTR): ACTRN12612000578808. We started the trial registration process with ANZCTR on the 15 May 2012. We entered the CTR registration form on the 21 May 2012 and received notification of the registration on 29 May 2012.

RESULTS

Practice and provider characteristics

Of the 32 practices recruited, 16 were allocated to the PEP intervention and 16 to usual care (figure 1). Prior to baseline data collection, one intervention practice was excluded because of incompatibility between the electronic medical record and the data extraction programme and one control practice withdrew citing lack of capacity to continue participating in the study. A further three control practices were excluded later in the study when technical difficulties impeded the collection of audit data. The resulting sample comprised 15 intervention and 12 control practices. There was no difference between the two groups in relation to the number of

GPs in the practice (26% were solo, 30% 2–4 GPs, 44% 5 or more GPs).

There were 83 GPs and 40 PNs enrolled in the study at baseline. At baseline 122 of the 123 practitioners who were enrolled in the study completed the questionnaire, and 97 practitioners completed both the baseline and follow-up questionnaires (70 GPs and 27 PNs).

There were no significant differences between intervention and control groups with respect to gender or in the number of practices that had staff aged 55 years or older, or those who had been working in general practice for 10 or more years. There were significant differences in the years in general practice and years working

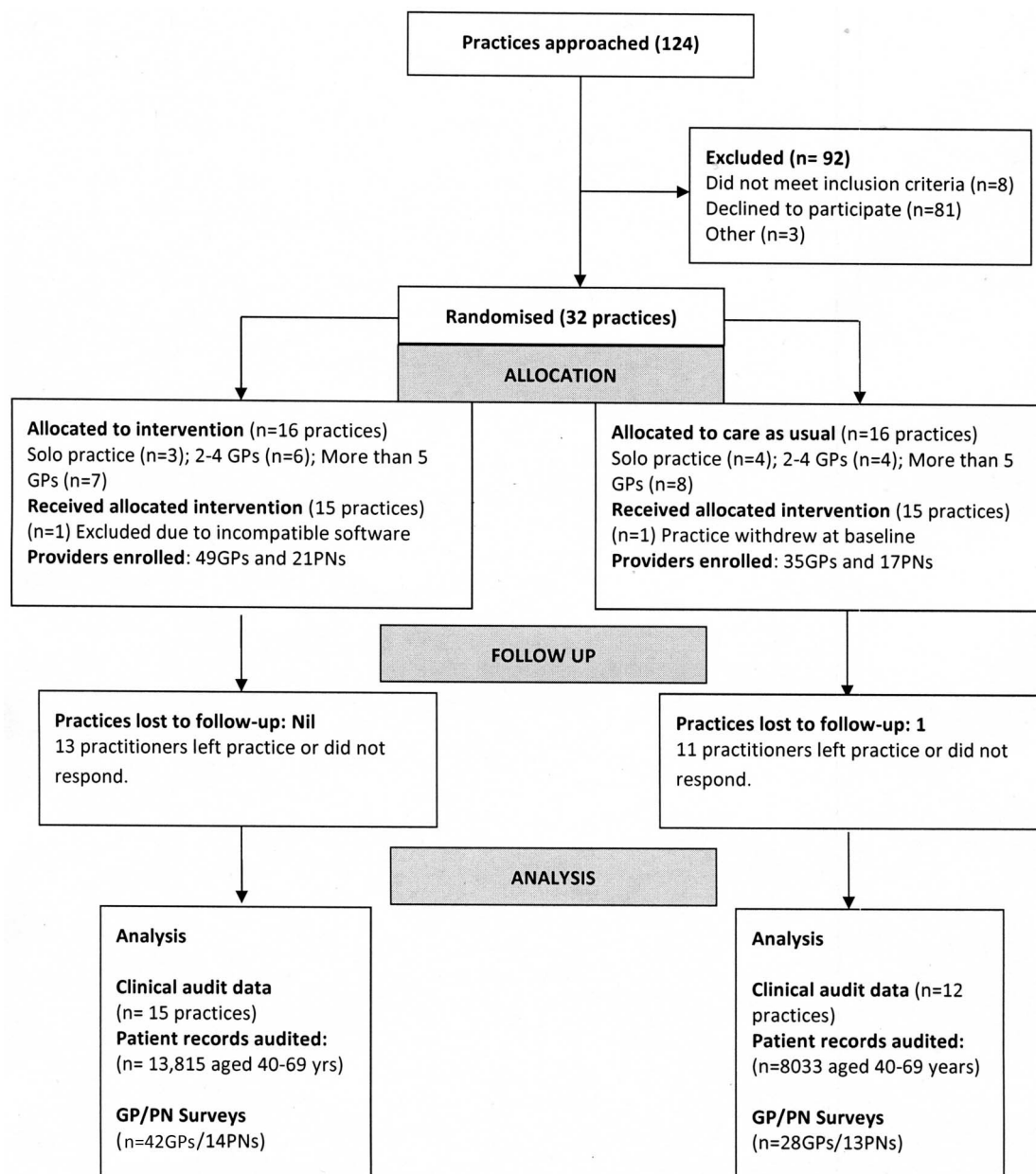


Figure 1. Consort flow chart. GP, general practitioners; PN, practice nurses.

Table 1 Clinician characteristics (general practitioners and practice nurses)

	Intervention N (%)	Control N (%)	Total N (%)	Comparison: intervention vs control
Gender				
Female	35 (62)	23 (56)	58 (60)	$\chi^2=0.18$, p=0.5
Male	21 (38)	18 (49)	39 (40)	
Age (years)				
20–34	7 (13)	2 (5)	9 (9)	$\chi^2=1.16$, p=0.3
35–44	17 (30)	8 (20)	25 (26)	
45–54	20 (36)	16 (39)	36 (37)	
55–64	11 (20)	13 (32)	24 (25)	
65+	0	2 (5)	2 (2)	
Missing	1 (2)	0	1 (1)	
Work				
Full-time equivalent	29 (52)	23 (56)	52 (54)	$\chi^2=0.06$, p=0.9
Part-time equivalent	26 (46)	17 (42)	43 (44)	
Missing	1 (2)	1 (2)	2 (2)	
Type				
Family practitioner	42 (75)	28 (68)	70 (72)	$\chi^2=0.25$, p=0.6
Practice nurse	14 (25)	13 (32)	27 (28)	
Years in GP				
<10	27 (48)	13 (32)	40 (42)	$\chi^2=2.4$, p=0.03
10–19	10 (18)	9 (23)	19 (20)	
20+	19 (34)	18 (45)	37 (38)	
Years in this practice				
<10	41 (74)	17 (42)	58 (60)	$\chi^2=11.0$, p=0.004
10–19	8 (15)	12 (29)	20 (21)	
20+	6 (11)	12 (29)	18 (19)	

GP, general practitioner.

Table 2 Proportion (%) of primary care providers self-reporting frequency of and confidence in assessments

Assessment	Intervention (n=56 baseline and follow-up)			Control (n=41 baseline and follow-up)			Comparison change intervention/control
	Baseline N (%)	Follow-up N (%)	Per cent change BL to FU	Baseline N (%)	Follow-up N (%)	Per cent change BL to FU	
Frequency of often, usually or always assess the risk (for more than 60% of their patients)							
Diet	32 (57.1)	35 (62.5)	5.4	28 (68.3)	26 (63.5)	–4.8	$\chi^2=1.5$, p=0.5
Physical activity	33 (58.9)	39 (69.6)	10.7	29 (70.7)	29 (70.7)	0	$\chi^2=1.4$, p=0.5
Smoking status	42 (75.0)	41 (73.2)	–1.8	35 (85.4)	37 (90.2)	4.8	$\chi^2=0.7$, p=0.7
Alcohol use	37 (66.1)	37 (66.1)	0	27 (65.9)	30 (73.2)	7.3	$\chi^2=1.0$, p=0.6
Blood pressure	55 (98.2)	51 (91.1)	–7.1	35 (85.4)	28 (92.7)	7.3	$\chi^2=4.3$, p=0.05
Fasting blood lipids	42 (75.0)	44 (78.6)	3.6	27 (65.9)	29 (70.7)	4.8	$\chi^2=0.1$, p=0.9
Fasting blood glucose	42 (75.0)	44 (78.6)	3.6	27 (65.9)	29 (68.3)	2.4	$\chi^2=0.1$, p=0.9
Body mass index	28 (50.0)	32 (57.1)	7.1	27 (65.9)	32 (78.0)	12.0	$\chi^2=2.3$, p=0.1
Absolute cardiovascular risk*	13 (23.2)	19 (33.9)	10.7	20 (48.8)	13 (31.7)	–17.1	$\chi^2=6.7$, p=0.03
Proportion of providers stating that they were very confident (on a five-point scale of not at all, minimally, somewhat, moderately and very confident)							
Smoking status	23 (41.1)	32 (57.1)	17.5	19 (46.3)	18 (43.9)	–2.4	$\chi^2=3.1$, p=0.08
Nutrition	12 (21.4)	17 (30.4)	9.0	13 (31.7)	10 (24.4)	–7.3	$\chi^2=0.9$, p=0.3
Risky drinking	18 (32.1)	20 (35.7)	3.6	14 (34.1)	10 (24.4)	–9.7	$\chi^2=2.5$, p=0.1
Physical activity	17 (30.4)	23 (41.1)	10.7	12 (29.3)	12 (29.3)	0	$\chi^2=1.0$, p=0.3
Readiness to change	8 (14.3)	16 (28.6)	14.3	9 (22.0)	5 (12.2)	–9.8	$\chi^2=5.5$, p=0.04
Absolute cardiovascular risk*	16 (28.6)	25 (44.6)	16.0	16 (39.0)	13 (31.7)	–7.3	$\chi^2=5.3$, p=0.03

*Australian 5-year Cardiovascular Risk based on Framingham Risk Equations modified for the Australian Population which take into account smoking status, blood pressure, lipids, age, gender, diabetes status and Aboriginality.³⁷

Bold indicates a statistical significant difference (p<0.05) between the amount of change from baseline to follow up in the intervention compared with the control group.

Table 3 Medical record audit: recording of risk factors (percentages of eligible population)

	Intervention				Control			
	Baseline		Follow-up		Baseline		Follow-up	
	N	Per cent (95% CI)	N	Per cent (95% CI)	N	Per cent (95% CI)	N	Per cent (95% CI)
40–69 years	N=13 815		N=13 815		N=8033		N=8033	
Body mass index	3125	22.6 (21.9 to 23.3)	3581	25.9 (25.2 to 26.6)*	2459	30.6 (29.6 to 31.6)	2520	31.4 (30.4 to 32.4)
Waist circumference	921	6.7 (6.3 to 7.1)	1243	9 (8.5 to 9.5)*	392	4.9 (4.4 to 5.4)	482	6 (5.5 to 6.5)*
Systolic blood pressure	10 319	74.7 (74.0 to 75.4)	10 675	77.3 (76.6 to 78.0)*	5604	69.8 (68.8 to 70.8)	5900	73.4 (72.4 to 74.4)*
Alcohol use	1842	13.3 (12.7 to 13.9)	2130	15.4 (14.8 to 16.0)*	1399	17.4 (16.6 to 18.2)	1307	16.3 (15.5 to 17.1)
Smoking status	9482	68.6 (67.8 to 69.4)	10 442	75.6 (74.9 to 76.3)*	6761	84.2 (83.4 to 85.0)	6973	86.8 (86.1 to 87.5)
45–69 years	N=10 985		N=10 985		N=6580		N=6580	
Cholesterol	6525	59.4 (58.5 to 60.3)	6151	56.0 (55.1 to 56.9)	4414	67.1 (66.0 to 68.2)	4423	67.2 (66.1 to 68.4)
Fasting blood glucose	1651	15.0 (14.4 to 15.7)	1649	15.0 (14.3 to 15.68)	1122	17.1 (16.2 to 18.0)	1176	17.9 (17.0 to 18.8)
Absolute cardiovascular risk	4561	41.5 (40.6 to 42.4)	6073	55.3 (54.4 to 56.2)*	3856	58.6 (57.4 to 59.8)	3958	60.2 (59.0 to 61.3)

*Increase from pre to post p<0.05.

at the enrolled practice (which was longer for the control group; table 1).

Provider self-reported quality of care

Table 2 shows clinician self-reported frequency of, and confidence in risk factor assessment for those providers who responded at both baseline and 12 months. At baseline, clinicians reported frequently (often, usually or always) assessing risk factors (except cardiovascular risk), and there was little change at 12 months (except for CVD risk which improved in the intervention but not the control group; table 2). At baseline clinician confidence levels were low and at 12 months these had improved in relation to the assessment of absolute CVD risk and patient's readiness to change (table 2).

Change in recording of risk factors at clinical record audit

From the clinical record audit, 21 848 patients aged 40–69 years had both baseline and follow-up audit data (73% of the total; 13 815 intervention and 8033 control). Of these, 17 565 were aged 45–69 years (10 985 and 6580 respectively). Sixty-one per cent were female with similar proportions in the intervention and control groups ($\chi^2=2.7$, $p=0.1$). At baseline the mean age overall was 52.9 years, 52.7 years in the intervention group compared to 53.2 years in the control group ($t=4.28$, $p<0.001$).

The baseline audits of all practices identified scope for at least a 10% improvement in the assessment and recording of all the risk factors except smoking which was also significantly higher for the control group compared to the intervention group at baseline ($\chi^2=641$, $p<0.0001$). In univariate analysis the proportion of records from the intervention practices with recorded BMI, WC, systolic BP, smoking, alcohol and CVD risk improved over the 12-month intervention period. In the control practices the percentage of records with waist circumference and systolic BP also improved (table 3). A greater proportion of gaps in recording for BMI, waist circumference, alcohol, smoking, cholesterol and absolute CVD risk were filled at follow-up in the intervention compared to the control group (table 4).

Multilevel, multivariate analyses were performed comparing the likelihood of a change in risk factor recording (ie, where risk factors were not recorded at baseline but were subsequently recorded at follow-up). After adjusting for age group and gender of patients, number of GPs and PNs in the practice and the proportion working in the practice for 10 or more years, the likelihood of change was significantly greater in the intervention compared to control group for WC (OR, 2.52 (95% CI 1.30 to 4.91)) alcohol consumption (OR, 2.19 (CI 1.04 to 4.64)), smoking status (OR, 2.24 (1.17 to 4.29)) and cardiovascular absolute risk (OR, 1.50 (1.04 to 2.18); table 5).

Patient age increased the likelihood of an improvement in recorded CVD risk and cholesterol. Younger patients had a higher probability of waist circumference

Table 4 Proportion (%) of records with missing baseline data but newly recorded risk factors at follow-up.

	Intervention % (95% CI)	Control % (95% CI)	Comparison of change between intervention/control
40–69 years	N=13 815	N=8033	
Body mass index	9.1 (6.9 to 11.3)	7.6 (5.3 to 9.8)	$\chi^2=14.8$, $p<0.0001$
Waist circumference	4.9 (2.8 to 7.1)	2.1 (0 to 4.2)	$\chi^2=110$, $p<0.0001$
Systolic blood pressure	9.8 (7.6 to 12.0)	9.1 (6.8 to 11.4)	$\chi^2=2.7$, $p=0.1$
Alcohol use	6.3 (4.1 to 8.5)	3.3 (1.1 to 5.4)	$\chi^2=95$, $p<0.0001$
Smoking status	6.9 (4.8 to 9.1)	2.6 (0.5 to 4.8)	$\chi^2=185$, $p<0.0001$
45–69 years	N=10 985	N=6580	
Cholesterol	16.4 (15.8 to 17.2)	13.5 (12.6 to 14.3)	$\chi^2=19.4$, $p<0.0001$
Fasting blood glucose	4.5 (4.1 to 4.9)	4.6 (4.1 to 5.1)	$\chi^2=0.7$, $p=0.4$
Absolute cardiovascular risk	14.9 (14.2 to 15.5)	8.9 (8.2 to 9.6)	$\chi^2=114$, $p<0.0001$

and BP being recorded. Smaller practices and practices with two or more nurses were more likely to improve assessment and recording of BP over the 12 months. However, significant interpractice variation remained unexplained by the variables included in the regression analysis (table 6).

Change in patient outcomes—clinical audit

While there was a significant burden of ‘risk’ across the whole audited population, where data was recorded no significant changes in the proportion of patients at increased risk between baseline and follow-up were found in either the intervention or control group (table 6).

DISCUSSION

In this multicenter cluster randomised controlled trial the PEP intervention was associated with an improved recording of CVD risk, WC, alcohol use and smoking status in comparison with the control group (by between 2% and 6% for individual risk factors). Small improvements in recording preventive care are consistent with previous evaluations of practice facilitation on preventive care^{23–25} underlining the challenge in achieving systemic quality improvement. While not specifically assessed in this trial, the failure to achieve better results with facilitation may also reflect the variable capacity of practices to alter their systems and routines^{26–27} or the perceived importance of preventive care. Achieving greater improvements may also require greater intervention effort or a different approach more closely tailored to the context of individual practice needs.²⁶

Those older patients, who are at greater risk, were appropriately more likely to have their CVD risk recorded. However, they were less likely to have documented BP and WC, both of which can be readily assessed during clinical encounters. Regular assessment of BP is no less important in older adults²⁸ and waist circumference is associated with significantly higher mortality in the elderly after adjusting for BMI.²⁹

We found a disparity between a high reported frequency of assessments by GPs and PNs with much lower

frequency of recording in the medical record. This is consistent with earlier research demonstrating inconsistency between the frequency of self-reported assessment and more objective measures.³⁰ Over half of the GPs and PNs reported not being confident in various preventive assessments at baseline, and remained so after a year, despite some improvement in the intervention group. This suggests the importance of developing provider skill and confidence as pre-requisites for further improvement.

The level of ‘risk’ in the patient population was high and comparable with that reported generally for Australians in this age group. Despite this, where recorded, no change was found during the trial in the proportion of patients who were at risk. This is an important negative finding and is potentially explained by a couple of intervention characteristics. The PEP intervention targeted the preventive care provided by practices and practitioners for their patients, rather than providing new services directly to patients. The intervention period was also relatively short being of 6 months duration only. We know that effective lifestyle interventions can require significant time.^{23–31} There are system barriers that may reduce the capacity of practices to improve the frequency of referral. Barriers to referral include patient (health literacy),³² practice (team roles and time)³³ and system level (cost and funding, information and communication systems) factors.^{34–35} The implication of this may be that more direct services to patients need to be provided in addition to practice improvement strategies to achieve change in health outcomes.

There are a number of limitations of our trial. Practices were urban and thus we cannot generalise these findings to rural or remote general practice. The trial design did not allow blinding of practitioners to their allocation. Practices were smaller than those participating in a national audit of general practices³⁶ with respect to size of practice (43% had four or more GPs compared with 62.8% in the national data). All practices in our study were urban or semiurban compared with 73.9% of those national data.

Table 5 Multilevel logistic regression models for being absent at baseline but recorded at follow-up in intervention compared to control group

	CVD risk OR (95% CI)	BMI OR (95% CI)	Waist circumference OR (95% CI)	Alcohol OR (95% CI)	Blood pressure OR (95% CI)	Smoking OR (95% CI)	Cholesterol OR (95% CI)
Allocation							
Control (reference) (n=8033)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Intervention (n=13 815)	1.50 (1.04 to 2.18)	1.28 (0.87 to 1.88)	2.52 (1.30 to 4.91)	2.19 (1.04 to 4.64)	1.12 (0.79 to 1.58)	2.24 (1.17 to 4.29)	1.29 (0.88 to 1.91)
Patient age							
<50-year (reference)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
50–59-year	1.15 (1.04 to 1.27)	0.95 (0.53 to 1.70)	0.68 (0.59 to 0.79)	1.10 (0.97 to 1.25)	0.85 (0.77 to 0.94)	0.97 (0.85 to 1.11)	1.22 (1.11 to 1.34)
>59 years	1.13 (1.01 to 1.26)	0.96 (0.85 to 1.08)	0.78 (0.66 to 0.92)	1.12 (0.97 to 1.29)	0.55 (0.49 to 0.63)	0.93 (0.80 to 1.08)	1.08 (0.97 to 1.20)
Patient gender							
Male (reference)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Female	0.99 (0.99 to 1.09)	0.96 (0.87 to 1.06)	0.94 (0.82 to 1.07)	0.98 (0.88 to 1.10)	1.04 (0.95 to 1.15)	0.93 (0.83 to 1.05)	1.06 (0.98 to 1.15)
Number of general practitioners (GP) in practice							
1–3 GPs (reference)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
>3 GPs	0.89 (0.58 to 1.37)	1.16 (0.78 to 1.72)	1.64 (0.75 to 3.59)	1.95 (0.81 to 4.68)	0.64 (0.43 to 0.96)	1.06 (0.54 to 2.06)	0.86 (0.54 to 1.35)
Number of practice nurses (PN) in practice							
1 or less PN (reference)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
>1 PN	1.51 (0.99 to 2.31)	1.28 (0.87 to 1.88)	1.32 (0.62 to 2.82)	0.83 (0.36 to 1.96)	1.61 (1.08 to 2.40)	0.92 (0.48 to 1.76)	1.35 (0.87 to 2.11)
Percentage of GPs/PNs working in primary care ≥ 10 years							
0 (reference)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
>0 or more	0.72 (0.37 to 1.40)	1.02 (0.55 to 1.88)	1.01 (0.30 to 3.36)	0.90 (0.24 to 3.41)	0.55 (0.30 to 1.03)	0.41 (0.15 to 1.14)	1.34 (0.67 to 2.71)
Between practice variance (SE)	0.201 (0.062)	0.159 (0.051)	0.640 (0.197)	0.869 (0.251)	0.174 (0.054)	0.482 (0.145)	0.231 (0.069)
Percentage of Variance explained*	14.8	32.3	46.9	33.1	11.7	0	37.2

Proportion of GPs/PNs working in primary care ≥ 10 years included as a continuous variable.

*Explained 'between practice' variance using the variance in the baseline model as reference.

Bold indicates a statistically significant difference ($p < 0.05$) in the OR for the independent variable compared with its reference variable.

Table 6 Proportion of patients at risk at baseline and follow up in intervention compared with control group

Risk	Intervention baseline (95% CI)		Intervention follow-up (95% CI)		Control baseline (95% CI)		Control follow-up (95% CI)	
	N	% (95% CI)	N	% (95% CI)	N	% (95% CI)	N	% (95% CI)
Body mass index (>25)	2296	73.5 (72.0 to 75.1)	2635	73.6 (72.2 to 75.0)	1855	75.4 (73.7 to 77.1)	1865	74.0 (72.3 to 75.7)
Waist circumference	752	81.7 (79.2 to 84.2)	1017	81.8 (79.7 to 84.0)	315	80.4 (76.4 to 84.3)	389	80.7 (77.2 to 84.2)
Male ≥94 cm								
Female ≥80 cm								
Blood pressure (>140/90)	2807	27.2 (26.3 to 28.1)	2979	27.9 (27.1 to 28.8)	1542	27.5 (26.4 to 28.7)	1703	28.9 (27.7 to 30.0)
Alcohol (>2 standard drinks/day)	374	20.3 (18.5 to 22.1)	417	19.6 (17.9 to 21.3)	344	24.6 (22.3 to 26.9)	327	25.0 (22.7 to 27.4)
Smoking (current)	1358	14.3 (13.6 to 15.0)	1436	13.8 (13.1 to 14.4)	1105	16.3 (15.5 to 17.2)	1093	15.7 (14.8 to 16.5)
Diabetes (BSL >5.5)	471	28.5 (26.4 to 30.7)	528	32.0 (29.8 to 34.3)	410	36.5 (33.7 to 39.4)	423	36.0 (33.2 to 38.7)
Cholesterol (TC >4)	6285	96.3 (95.9 to 96.8)	5849	95.1 (94.6 to 95.6)	4194	95.0 (94.4 to 95.7)	4213	95.3 (94.6 to 95.9)
Cardiovascular risk (10% or more)	458	10.0 (9.2 to 10.9)	654	10.8 (10.0 to 11.6)	398	10.3 (9.4 to 11.3)	457	11.6 (10.6 to 12.5)

BSL, blood sugar level; TC, total cholesterol.

Although largely comparable, there were some differences at baseline in practitioner years in general practice and in their current practice between intervention and control groups. Furthermore there were differences at baseline in the recorded frequency of smoking which made it more difficult to show improvement in this risk factor the control group. In addition, the provider questionnaire relied on self-report and as such was subject to recall and social desirability bias. While all practitioners agreed to the assessment goals, the implementation of the intervention with patients was constrained by their lack of confidence and other practical constraints. The number of practitioners was too small for multilevel analysis of their self-reported data.

The sample size was lower in the control practices due to the smaller number of practices and practitioners and thus it was insufficiently powered to show a 10% or less difference in BP and cholesterol recording between intervention and control practices. Patient medical record audits did not allow examination of other patient characteristics such as health literacy and did not allow for the measurement of assessments that had been recorded in other ways by the GP. Only a minority of the interpractice variance in CVD risk, BMI and BP recording was explained by variables included in the regression model suggesting that other factors need to be explored.

CONCLUSION

The PEP intervention involved clinical audit, provider training, practice facilitation visits and linkage to other services. It had a positive impact on provider behaviour, as evidenced by the improved assessment and recording of smoking, WC, alcohol and absolute CVD risk. Effective implementation of preventive care in PHC is however a complex iterative process that requires ongoing support and monitoring at the patient, provider, practice and system levels. This result is extremely relevant to the role of primary care organisations in Australia which are charged with improving the quality of care. Our trial did however show no impact on patient risk. Achieving the latter may require more intensive facilitation over a longer time frame, changes to the electronic medical record to prompt preventive care, additional support of practices to make changes to their work flow and providing interventions that directly involve patients (such as telephone or online coaching).

Author affiliations

¹Centre for Primary Health Care and Equity, University of New South Wales Australia, Sydney, New South Wales, Australia

²Discipline of General Practice, School of Medicine, Flinders University, Adelaide, South Australia, Australia

³Academic Discipline of General Practice, University of Queensland, Brisbane, Queensland, Australia

⁴Southern Academic Primary Care Research Unit, School of Primary Health Care, Monash University, Notting Hill, Victoria, Australia

⁵Department of General Practice, Monash University, Notting Hill, Victoria, Australia

⁶Faculty of Health Sciences and Medicine, Bond University, Gold Coast, Queensland, Australia

⁷School of Public Health and Community Medicine, University of New South Wales, Sydney, New South Wales, Australia

Contributors MFH led the development of the design of the study and its protocol and the implementation of the trial. MFH, JL, GR, DM, MvD, CDM, JS, JL, NZ, UWJ, SMP and GP-D contributed to the design of the trial, development of the data collection instruments and trial processes and coordination of the trial across sites. SMP coordinated the acquisition of trial data and MFH, SMP and UWJ collated and analysed the data. All authors contributed to the interpretation of the data and provided intellectual input to the manuscript and critical review of the content. All authors approved the final version for publication and agree to be accountable for the integrity of the content, and responsible for any issues that arise from publication of the trial data.

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REFERENCES

- Lim SS, Vos T, Flaxman AD, *et al.* A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2012;380:2224–60.
- Australian Institute of Health and Welfare. *Risk factors contributing to chronic disease*. Canberra: AIHW, 2012.
- Royal Australian College of General Practitioners (RACGP). *Guidelines for preventive activities in general practice*. 8th edn. East Melbourne: RACGP, 2012.
- Lu S, MF H. Prevention of diabetes and heart disease—patient perceptions on risk, risk assessment and the role of their GP in preventive care. *Aust Fam Physician* 2013;42:328–31.
- Hung DY, Rundall TG, Tallia AF, *et al.* Rethinking prevention in primary care: applying the chronic care model to address health risk behaviors. *Milbank Q* 2007;85:69–91.
- National Vascular Disease Prevention Alliance (NVDPA). *Guidelines for the management of absolute cardiovascular disease risk*. Canberra: Stroke Foundation, 2012.
- National Health and Medical Research Council (NHMRC). *Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia*. Melbourne National Health and Medical Research Council, 2013.
- Goldstein MG, Whitlock EP, DePue J. Multiple behavioral risk factor interventions in primary care. Summary of research evidence. *Am J Prev Med* 2004;27(2 Suppl):61–79.
- Vallis M, Piccinini-Vallis H, Sharma AM, *et al.* Clinical review: modified 5 As: minimal intervention for obesity counseling in primary care. *Can Fam Physician* 2013;59:27–31.
- Dosh SA, Holtrop JS, Torres T, *et al.* Changing organizational constructs into functional tools: an assessment of the 5 A's in primary care practices. *Ann Fam Med* 2005;3(Suppl 2):S50–2.
- Jay M, Gillespie C, Schlair S, *et al.* Physician's use of the 5As in counseling obese patients: is the quality of counseling associated with patients' motivation and intention to lose weight? *BMC Health Serv Res* 2010;10:159.
- Ampt A, Amoroso C, Harris MF, *et al.* Attitudes, norms and controls influencing lifestyle risk factor management in general practice. *BMC Fam Pract* 2009;10:59.
- Wolff S, Massett H, Weber D, *et al.* Opportunities and barriers to disease prevention counseling in the primary care setting: a multisite qualitative study with US health consumers. *Health Promot Int* 2010;25:265–76.
- Amoroso C, Harris MF, Ampt A, *et al.* The 45-year-old health check—feasibility and impact on practices and patient behaviour. *Aust Fam Physician* 2009;38:358–62.
- Harris MF, Lloyd J, Litt J, *et al.* Preventive evidence into practice (PEP) study: implementation of guidelines to prevent primary vascular disease in general practice protocol for a cluster randomised controlled trial. *Implement Sci* 2013;8:8.
- Harris MF, Lloyd J. *The role of Australian primary health care in the prevention of chronic disease*. Australian National Preventive Health Agency, 2012.
- Mazza D, Harris MF. Improving implementation of evidence-based prevention in primary care. *Med J Aust* 2010;193:101–2.
- Keleher H, Joyce C, Parker R, *et al.* Practice nurses in Australia: current issues and future directions. *Med J Aust* 2007;187:108–10.
- Royal Australian College of General Practitioners (RACGP). *Smoking, Nutrition, Alcohol and Physical activity (SNAP). A population health guide to behavioural risk factors in general practice*. Edited by Care TRACoGPNSCQ. Melbourne: RACGP, 2004.
- Alliance. *NVDP. Guidelines for the assessment of absolute cardiovascular disease risk*. Melbourne: National Heart Foundation of Australia, 2009.
- Murphy KA, Yeazel M, Center BA. Validity of residents' self-reported cardiovascular disease prevention activities: the Preventive Medicine Attitudes and Activities Questionnaire. *Prev Med* 2000;31:241–8.
- Rashbash J, Browne W, Healey M, *et al.* *A user's guide to MLwiN version 2.25*. Centre for Multilevel Modelling, University of Bristol, 2012.
- Litt JC. *Exploration of the delivery of prevention in the general practice setting*. Adelaide Flinders University, 2007.
- Lemelin J, Hogg W, Baskerville N. Evidence to action: a tailored multifaceted approach to changing family physician practice patterns and improving preventive care. *CMAJ* 2001;164:757–63.
- Hogg W, Lemelin J, Moroz I, *et al.* Improving prevention in primary care: evaluating the sustainability of outreach facilitation. *Can Fam Physician* 2008;54:712–20.
- Klabunde CN, Lanier D, Breslau ES, *et al.* Improving colorectal cancer screening in primary care practice: innovative strategies and future directions. *J Gen Intern Med* 2007;22:1195–205.
- Nutting PA, Crabtree BF, Miller WL, *et al.* Transforming physician practices to patient-centered medical homes: lessons from the national demonstration project. *Health Aff (Millwood)* 2011;30:439–45.
- Mancia G, Fargard R, Narkiewicz K, *et al.* 2013 ESH/ESC Guidelines for the management of arterial hypertension. *Eur Heart J* 2013;34:2159–219.
- Janssen I, Katzmarzyk PT, Ross R. Body mass index is inversely related to mortality in older people after adjustment for waist circumference. *J Am Geriatr Soc* 2005;53:2112–18.

30. Davis DA, Mazmanian PE, Fordis M, *et al*. Accuracy of physician self-assessment compared with observed measures of competence: a systematic review. *JAMA* 2006;296:1094–102.
31. Yarnall KS, Pollak KI, Østbye T, *et al*. Primary care: is there enough time for prevention? *Am J Public Health* 2003;93:635–41.
32. Taggart J, Williams A, Dennis S, *et al*. A systematic review of interventions in primary care to improve health literacy for chronic disease behavioral risk factors. *BMC Fam Pract* 2012;13:49.
33. Ghorob A, Bodenheimer T. Sharing the care to improve access to primary care. *N Engl J Med* 2012;366:1955–7.
34. Baker R, Camosso-Stefinovic J, Gillies C, *et al*. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev* 2010;(3):CD005470.
35. Baskerville NB, Liddy C, Hogg E. Systematic review and meta-analysis of practice facilitation within primary care settings. *Ann Fam Med* 2012;10:63–74.
36. Britt H, *Family medicine research C, university of S, beach: general practice activity in Australia 2011–12: BEACH, bettering the evaluation and care of health*. Sydney: Sydney University Press, 2012.
37. National Vascular Disease Prevention Alliance. *Guidelines for the management of absolute cardiovascular disease risk*. Canberra: Stroke Foundation, 2012.