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The MEDMAN study: a randomized controlled trial of community pharmacy-led medicines management for patients with coronary heart disease

The Community Pharmacy Medicines Management Project Evaluation Team

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Background. There have been recent moves to extend the role of the community pharmacist to include medicine management.

Methods. A randomized controlled trial was conducted in nine sites in England. Patients with coronary heart disease were identified from general practice computer systems, recruited and randomized (2:1) to intervention or control. The 12-month intervention comprised an initial consultation with a community pharmacist to review appropriateness of therapy, compliance, lifestyle, social and support issues. Control patients received standard care. The primary outcome measures were appropriate treatment [derived from the National Service Framework (NSF)], health status (SF-36, EQ-5D) and an economic evaluation. Secondary outcome measures were patient risk of cardiovascular death and satisfaction.

Results. The study involved 1493 patients (980 intervention and 513 control), 62 pharmacists and 164 GPs. No statistically significant differences between intervention and control groups were shown at follow-up for any of the primary outcome measures such as numbers on aspirin or lifestyle measures. There were few differences in quality of life (SF-36) between the intervention and control groups at baseline or follow-up or with overall EQ-5D score over time. The total National Health Service cost increased between baseline and at 12 months in both groups but to a greater extent in the intervention group. Significant improvements were found in the satisfaction score for patients' most recent pharmacy visit for prescription medicines among the intervention group, compared with control group. Self-reported compliance was good for both groups at baseline and no significant differences were shown at follow-up.

Conclusion. There was no change in the proportion of patients receiving appropriate medication as defined by the NSF. The pharmacist-led service was more expensive than standard care.

Keywords. Clinical outcomes, community pharmacy, coronary heart disease, RCT.

Introduction

Coronary heart disease (CHD) is a leading cause of morbidity and mortality in industrialized countries, with the UK having some of the highest age standardized mortality rates.[1] Individuals with CHD are at high risk of further coronary events, although this risk can be significantly reduced.[2–5] Organized provision of treatment in general practice has important short- and long-term benefits[6,7] but current care in general practice remains suboptimal.[8]

The role of community pharmacists within the UK is changing to include the management of patients' medicines.[9] A systematic review[10] of community pharmacist interventions in CHD provides some evidence of benefits, including improvements in blood pressure,[11,12] cholesterol,[13] anticoagulant control[14]and smoking cessation rates.[15–17] However, few large randomized controlled trials (RCTs) have been conducted of comprehensive, community pharmacy-led medicines management (MEDMAN) services. This paper presents the results of a RCT to test the hypothesis that

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a comprehensive MEDMAN service would (i) increase the proportion of patients receiving treatment according to the National Service Framework[18] (NSF) in England and Wales; (ii) improve overall patient health status; and (iii) be cost effective.

Methods

Study design

An RCT comparing patients with CHD, who received the community pharmacy-based medicines management service intervention, with control CHD patients, who received usual general practice-based care, was conducted between November 2002 and May 2004.

Participants

Nine study sites were purposively selected from a list of 33 volunteer primary care organizations in England, provided by the Pharmaceutical Services Negotiating Committee (PSNC), purposively selected on the basis of local knowledge to include a range of population, general practice and community pharmacy characteristics. Patients registered with the general practices, aged over 17 years, and with CHD (previous myocardial infarction, angina, coronary artery bypass graft and/or angioplasty) were eligible. Exclusion criteria (illiterate/innumerate, history of alcohol/drug misuse, terminal/serious illness, severe mental illness and unable to provide informed consent or otherwise unsuitable for the trial) were applied by the GP.

Recruitment of participants

The patient recruitment and intervention process are shown in Figure 1. Practices generated a list of all patients with CHD. GPs screened the list and sent invitation packs (invitation letter, trial information sheet and consent form) to eligible patients. Signed consent forms were returned directly to the researchers, and included the name of the preferred community pharmacy provider. Patients were randomized in a ratio of 2:1, intervention to control group. This was done independently of the research team using a password protected computer programme in permuted blocks stratified by practice. Community pharmacists were given an indicative allocation of 20 patients. If more than 20 patients chose one pharmacy, the pharmacist could choose to go 'over quota', or refuse the patient who was asked to choose another pharmacy, or was excluded (designated over quota in Fig. 1).

Audit clerks, blind to patient randomization status, extracted and recorded baseline data from general practice records [confirmation of inclusion criteria, relevant medical history (e.g. significant diagnoses and known allergies), clinical indicators (e.g. last blood pressure, lipid measurement, pulse rate, blood glucose, weight and height), current medication, documented use of over-the-counter (OTC) medicines and use of health service resources in the previous 12 months]. All forms were returned to the research team who forwarded copies of intervention patients' forms to their nominated pharmacist.

Patients' self-reported baseline data were collected by postal questionnaire (health status; compliance with treatment; experience of, and satisfaction with, community pharmacy services and the cost of accessing health care services).

Intervention patients received a study registration card and a letter asking them to visit their nominated pharmacy to initiate the service. Pharmacists were instructed to contact the patients if they were not contacted spontaneously. Patients in the control group received usual care from their GP and community pharmacist.

The intervention

The medicines management service was delivered from community pharmacy premises, by community pharmacists who had received training designed and delivered by the Centre for Pharmacy Post-Graduate Education. The intervention comprised an initial consultation informed by the extracted medical data supplied by the researchers. Further consultations were provided according to pharmacist-determined patient need. Consultations included assessments of the following: therapy, medication compliance, lifestyle (e.g. smoking cessation, exercise and diet) and social support (e.g. difficulties in collecting prescriptions and opening bottles). Recommendations were recorded on a referral form which was sent to the GP, who returned annotated copies to the pharmacists. Only pharmacies with private consultation areas were eligible to participate. Further information about the consultations is available in the final report to the funding body (available from the authors).

Follow-up

The follow-up period was 12 months from the date of the first pharmacy appointment, or estimated equivalent for controls. Follow-up data were collected by audit clerks and postal questionnaire as at baseline. Intervention patients were also asked about their experience of the medicine management service.

Outcome measures

Primary outcomes were as follows: proportion of patients receiving secondary prevention treatment for CHD in accordance with the NSF (2000) (Box 1); a cumulative score summarizing 'appropriate treatment' and advice (Box 2); health status (SF-36[19] EuroQOL[20]); and a health economic analysis. National Health Service (NHS) resource use was based on information extracted from general practice-held records at baseline and follow-up. The total NHS cost

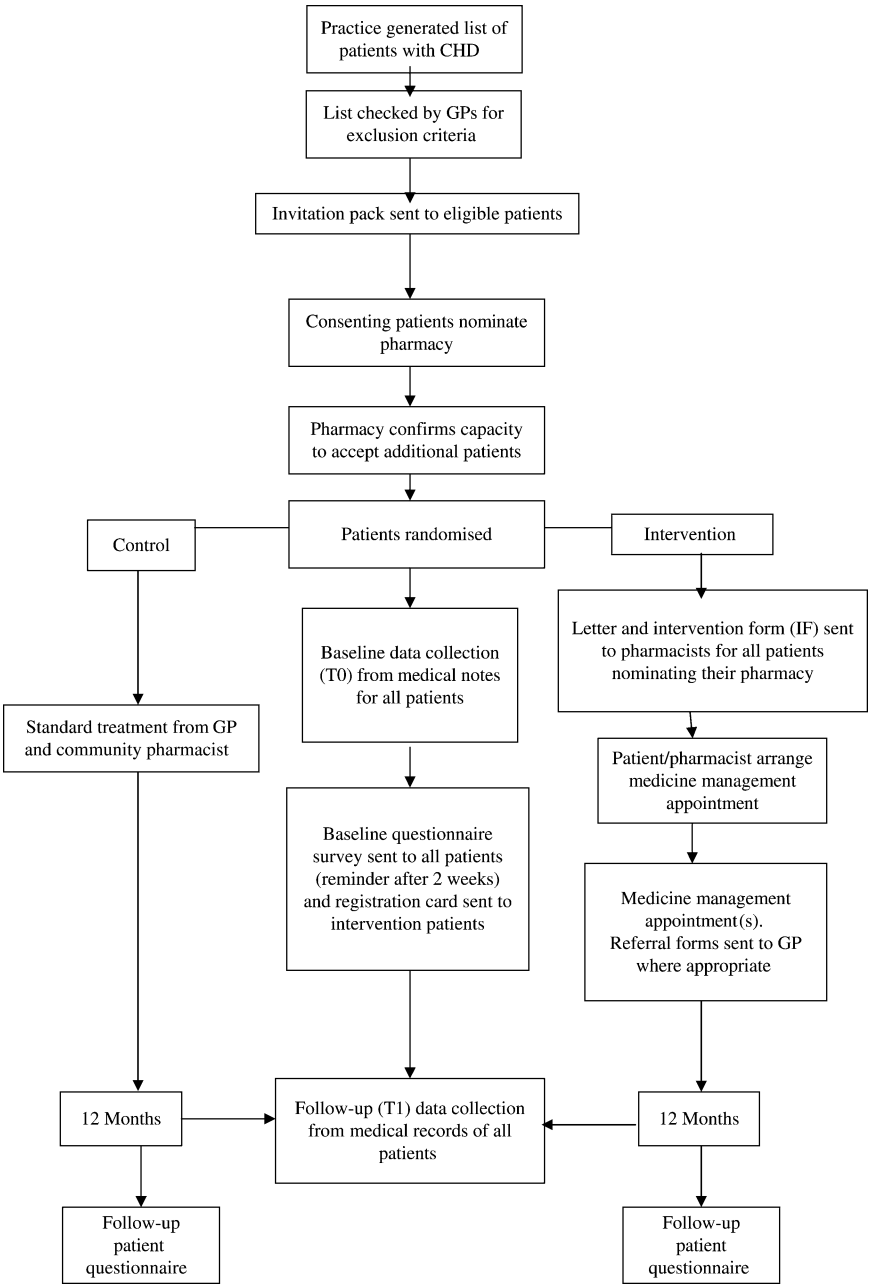


FIGURE 1 *Patient recruitment and intervention process. CP, community pharmacist; T0, time zero (baseline); T1, time one (baseline plus 12 months)*

was, for intervention patients only, the sum of the costs of delivering the intervention (training and intervention visits) and, for both intervention and control patients, NHS treatment costs (including cost of medicines, hospital and other health consultations). Training costs included direct (e.g. venue costs) and indirect (e.g. attendance fees) costs. Secondary outcomes were as follows: 5-year risk of cardiovascular death based on an existing score modified to allow for the absence of data on history of stroke and creatinine concentration,[21,22] patient satisfaction and compliance with treatment.

The final satisfaction score included experience of and satisfaction with the community pharmacy service and was assessed by measuring response to 15 positive and negative statements regarding their most recent pharmacy visit. Statements were derived from a review of the relevant patient satisfaction literature.[23] Possible responses ranged from 5 to 1 for strongly agree to strongly disagree for positive statements and from 1 to 5 for negative statements, summated to give an overall satisfaction score (range 15–75). Similarly, 12 statements about medicine taking were included and summated to derive a self-reported compliance score (range 12–60).

Box 1 *Operationalization of NSF guideline targets*

Guideline target	Criterion for target having been met
All patients with CHD	
Aspirin-related management	On aspirin (on prescription or prescribed OTC, another antiplatelet, anticoagulant, documented as aspirin intolerant, contraindicated or patient refused treatment
Lipid management	
Pragmatic	On statin or another lipid lowering agent
Optimal	On statin or another lipid lowering agent or no treatment; and last cholesterol in previous 12 months <5 mmol/l
Blood pressure management	Blood pressure measured in the previous 12 months; and last systolic blood pressure <140 mmHg and dystolic blood pressure <85 mmHg
Smoking management	Non-smoker or smoker who reports using nicotine replacement therapy
Physical activity	Participant reports: occurs on four or more days per week; and ⩾15 minutes duration; and moderate or vigorous intensity
Diet	Participant reports consuming ⩾5 portions of fruit or vegetables per day
Alcohol consumption	Participant reports consuming <21 units per week (men) or <14 per week (women)
Weight	Record BMI ⩽25 kg/m^2
Specific CHD circumstances	
β-blockers post-myocardial infarction	History of myocardial infarction recorded and receiving a β-blocker
Treatment of left ventricular dysfunction (LVD) or cardiac failure with an ACE inhibitor	History of LVH[a] or cardiac failure recorded on intervention form and receiving ACE-inhibitor
Treatment of AF in older patients with aspirin or warfarin	History of AF recorded; aged 60+ and receiving aspirin (on prescription or OTC) or warfarin
Management of diabetes	History of diabetes recorded; blood pressure measured in previous 12 months; last systolic blood pressure <130 mmHg and diastolic blood pressure <80 mmHg; glucose measured in previous 12 months and last glucose ⩽7 mmol/l

[a]LVD is not recorded routinely in general practice. Therefore, LVH and/or cardiac failure were used as a proxy measure for LVD.

Box 2 *Appropriate treatment score*

Criterion met	Score
Aspirin management	1
Lipid management	1
Blood pressure management	1
Smoking	1
Physical activity	1
Diet	1
Weight	1
Total score (range)	0–7

Blinding

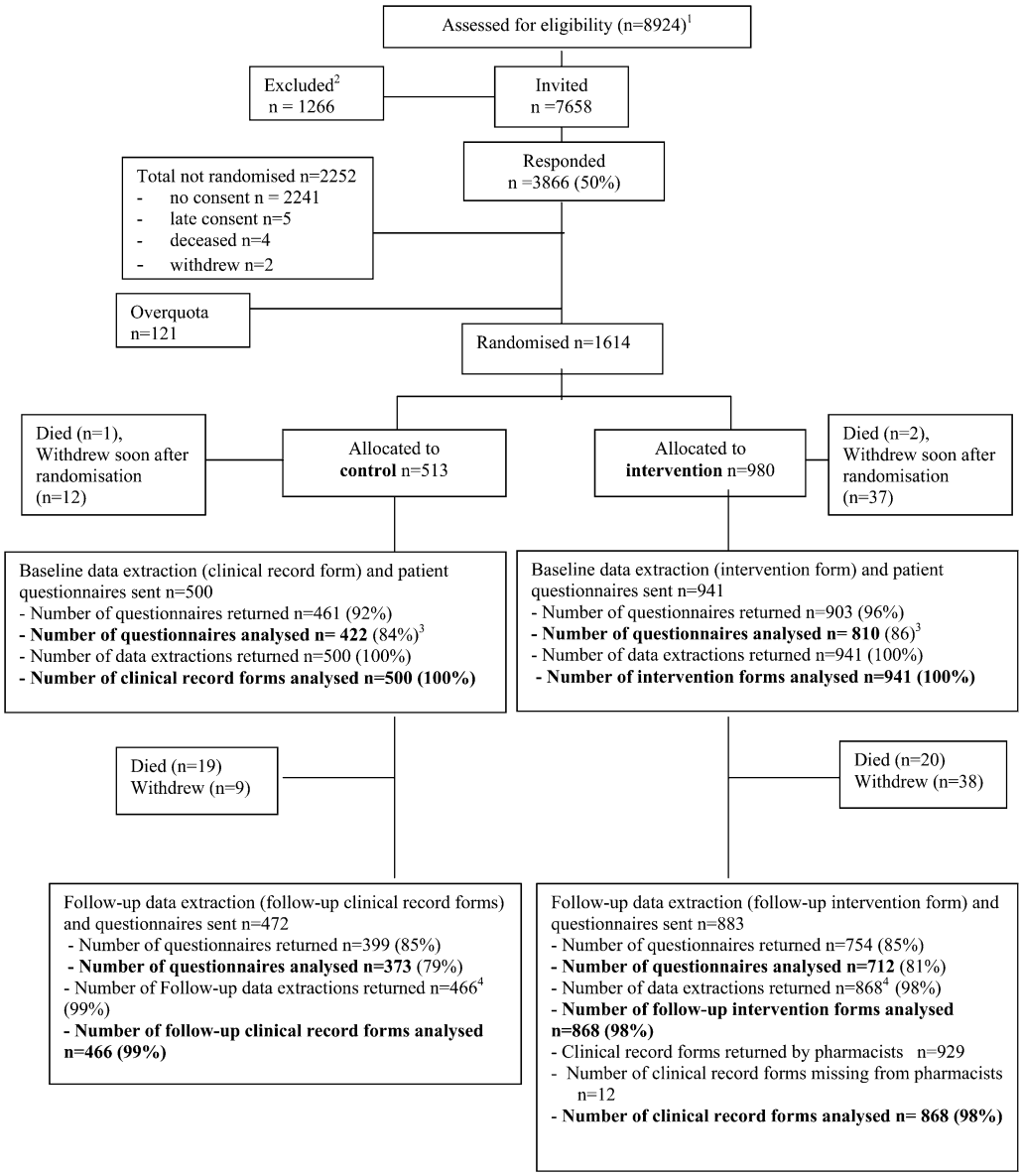
Patients could not be blind to trial intervention because of its nature. Community pharmacists were not informed which control patients had nominated their pharmacy. Audit clerks performing data extraction were blind to the randomization status of participants, as were the researchers conducting the statistical analyses.

Sample size

The power calculation was based on the NSF recommendations (Box 1) of aspirin-related management for all patients with CHD. From a local audit of 71 GP practices (Philip Hannaford, personal communication.), 80% of patients were estimated to be on aspirin. For a standard RCT using 2:1 randomization, a total of 1920 evaluable patients (1280 intervention and 640 control) were required to detect a change from 80% to 86% for the percentage of patients receiving aspirin, with 90% power and a 5% significance level.

Statistical methods

Data were analysed using SPSSv11.5 and STATA v8. Descriptive statistics are presented as means (SD) for normally distributed continuous data, medians [interquartile range (IQR)] for skewed continuous data and



[1] A total of 39 practices was in the study with a combined full CHD register of 10,769 patients. Thirty-three practices applied the exclusion criteria to their full CHD register and 6 practices applied exclusion criteria to a random sample of patients only; this means the exclusion criteria were applied to a total of 8924 patients

[2] Four practices were unable to say whether they excluded any patients. This figure is based on the assumption they made no exclusions and may under-estimate our response rate

[3] The total number of questionnaires analysed is less than the total received as 132 patients subsequently withdrew or had returned blank questionnaire

[4] Follow-up data extraction was completed for 1334 of the 1441 patients i.e. 107 did not have data extraction performed either because they had since deceased or had withdrawn from the study or they moved away and records were not available

FIGURE 2 *Consort diagram. [1]A total of 39 practices were in the study with a combined full CHD register of 10 769 patients. Thirty-three practices applied the exclusion criteria to their full CHD register and six practices applied exclusion criteria to a random sample of patients only; this means the exclusion criteria were applied to a total of 8924 patients. [2]Four practices were unable to say whether they excluded any patients. This figure is based on the assumption they made no exclusions and may under-estimate our response rate. [3]The total number of questionnaires analysed is less than the total received as 132 patients subsequently withdrew or had returned blank questionnaire. [4]Follow-up data extraction was completed for 1334 of the 1441 patients, i.e. 107 did not have data extraction performed because they had since deceased or had withdrawn from the study or they moved away and records were not available*

percentages (*n*) for categorical data. The main analysis was conducted on an intention-to-treat basis. Regression modelling was used to estimate the effect [odds ratios (ORs) or adjusted mean differences and their corresponding 95% CI] of the intervention on primary and secondary outcomes, while adjusting for baseline differences between groups and clustering by practice, pharmacy and area. Patients with missing data at

either time point were excluded from these analyses. Additional analysis using the chi-square test was also conducted to compare between groups the extent of patients' agreement with a series of statements about their experiences in the community pharmacy. Due to the large number of statistical tests conducted for this, a *P*-value of <0.01 was used to denote statistical significance.

Potential selection bias resulting from loss to follow-up or missing data was tested, and adjusted for, using the Heckman selection correction.[24] Where evidence of selection bias was found, the unbiased effect of the intervention (i.e. with the Heckman selection correction applied) is reported.

Costs were reported using the median and IQR for skewed data. Comparisons between groups were conducted using the Mann–Whitney test for independent groups and the Wilcoxon signed ranks test for related groups.

Data management

Data were entered into an Access database with 10% checked for accuracy. In this paper, we only report percentages for participants with a full set of available data at each time point.

TABLE 1 *Baseline characteristics of intervention and control groups*

	Intervention $n = 941$	Control $n = 500$
Age in years		
Mean (SD)	68.7 (9.2)	68.8 (9.1)
Range	39–92	41–92
Males		
% (*n*)	67.4 (634)	70.6 (353)
Height in metres		
Mean (SD)	1.69 (0.10)	1.69 (0.10)
Weight in kilograms		
Mean (SD)	79.4 (15.5)	78.8 (15.1)
BMI in kg/m^2		
Mean (SD)	27.8 (4.7)	27.6 (4.7)
BMI categories [% (*n*)]		
<20	1.2 (9)	2.1 (8)
20–24	22.5 (165)	23.1(87)
25–29	43.9 (322)	42.0 (158)
⩾30	32.3 (237)	32.7 (123)
Last blood pressure recorded in medical records [mean (SD)]		
Systolic blood pressure (mmHg)	138.8 (18.9)	138.6 (20.5)
Diastolic blood pressure (mmHg)	77.2 (10.3)	77.6 (10.8)
Last recorded total cholesterol (mmol/l)		
Mean (SD)	4.70 (0.98)	4.72 (1.01)

Results

Participants

In total, 1493 patients were randomized (980 intervention and 513 control). Data extraction was completed at baseline for 1441 patients and for 1334 patients at follow-up (Fig. 2). No substantial differences in the baseline characteristics of the trial groups (Table 1) were found. A total of 70 pharmacies (102 pharmacists) and 48 practices (208 GPs) were recruited, of which 50 (62 pharmacists) and 39 (164 GPs) completed.

TABLE 2 *Adjusted effect of the intervention on individual targets for appropriate treatment of CHD and on the global score*

	Effect of the intervention in all participants at baseline and follow-up				Effect of the intervention based on participants in both time points		
	Intervention		Control		Effect of the intervention[a]	95% CI	*P*-value
	Baseline % (*n*)	Follow-up % (*n*)	Baseline % (*n*)	Follow-up % (*n*)			
All patients with CHD: on target							
Aspirin-related management	94.6 (890)	93.5 (812)	90.6 (453)	93.3 (435)	0.66	0.33 to 1.31	0.24
Lipid-related management	59.2 (557)	58.2 (505)	56.8 (284)	54.7 (255)	0.99	0.67 to 1.48	1.00
Blood pressure management	46.9 (441)	48.5 (421)	42.6 (213)	46.8 (218)	0.90	0.67 to 1.21	0.49
Smoking management	68.8 (557)	94.2 (807)	66.8 (282)	92.5 (417)	1.53	0.85 to 2.75	0.15
Alcohol	85.3 (463)	95.5 (571)	85.2 (236)	93.1 (299)	1.08	0.39 to 2.99	0.87
Physical activity	34.9 (272)	73.2 (502)	35.8 (146)	72.9 (266)	1.02	0.74 to 1.42	0.90
Diet	20.9 (178)	44.1 (282)	23.2 (101)	41.5 (140)	1.10	0.82 to 1.49	0.52
BMI	85.5 (941)	36.5 (191)	82.8 (414)	33.7 (93)	1.21	0.82 to 1.79	0.33
Total score, mean (SD)	4.3 (1.1)	4.6 (1.2)	4.2 (1.2)	4.6 (1.1)	0.19	–0.07 to 0.46	0.15

[a]OR for binary outcomes or mean difference for continuous outcomes, using regression analysis to adjust for differences in outcomes at baseline, gender, age and previous CHD event and for cluster effects within pharmacies, general practices and areas; paired data only (i.e. with data at both baseline and follow-up).

TABLE 3 *Adjusted effect of the intervention on individual targets for appropriate treatment of CHD and on the global score*

	Effect of the intervention in all participants at baseline and follow-up				Effect of the intervention based on participants in both time points		
	Intervention		Control		Effect of the intervention[a]	95% CI	*P*-value
	Baseline % (*n*)	Follow-up % (*n*)	Baseline % (*n*)	Follow-up % (*n*)			
Specific CHD circumstances							
Patients with history of myocardial infarction (*n*)	423	397	236	227	1.16	0.62 to 2.17	0.64
Patients with myocardial infarction receiving β-blockers	48.7 (206)	47.6 (189)	50.8 (120)	49.3 (112)			
Patients with left ventricular hypertrophy (LVH) or cardiac failure (*n*)	119	115	61	54	0.69	0.22 to 2.10	0.51
Patients with LVH/cardiac failure receiving angiotensin-converting enzyme (ACE) inhibitors	58.0 (69)	59.1 (68)	68.9 (42)	63.0 (34)			
Patients with diabetes (*n*)	161	160	66	65	0.14	0.01 to 1.56	
Diabetic patients with systolic blood pressure <130 mmHg and diastolic blood pressure <80 mmHg and blood glucose ⩽7.0 mmol/l	4.3 (7)	0.6 (1)	4.5 (3)	4.6 (3)			
Patients with atrial fibrillation (AF) aged >60 years (*n*)	69	77	39	36	[b]		0.11
Patients with AF aged >60 years and receiving aspirin[c] or warfarin	89.9 (62)	88.3 (68)	97.4 (38)	97.2 (35)			

[a]OR for binary outcomes or mean difference for continuous outcomes, using regression analysis to adjust for differences in outcomes at baseline, gender age, and previous CHD event and for cluster effects within pharmacies, general practices and areas; paired data only (i.e. with data at both baseline and follow-up).
[b]OR not calculated due to unreliability of estimate because only one individual did not reach target in the control group.
[c]Prescribed or OTC.

Primary outcomes

No statistically significant differences were found for any of the (adjusted) main outcome measures between the two groups at follow-up (Tables 2–4).

There were no significant differences in lifestyle factors between the groups (Table 2) at baseline or at follow-up. A higher percentage of data regarding lifestyle was available at follow-up in both groups (because of better supply of information at follow-up by patients) compared with baseline. The global score for appropriateness of treatment was not significantly different between groups.

There were no significant differences between groups in individual SF-36 domains or in overall EQ-5D score (Table 4).

The economic evaluation was a cost-minimization analysis, in which all relevant *P*-values are from a multiple regression analysis to examine differences in costs at follow-up between the intervention and the control group, adjusted for differences in costs at baseline and clustering within pharmacy, GP practice and area (where necessary).[33] The difference at follow-up in total NHS-related cost was statistically significant (Table 5), due to the cost of providing pharmacist training.

Secondary outcomes

Five-year risk of cardiovascular death. The 5-year risk of cardiovascular death score at baseline could be calculated for 964 (66.5%) patients (Fig. 3). Apparent benefits in the intervention group at follow-up did not reach statistical significance.

Patients' perspectives: satisfaction, experience and attitudes. In the intervention group, statistically significant improvements ($P < 0.01$) were found in the single computed satisfaction score for patients' most recent pharmacy visit for prescription medicines compared with control patients (Table 4).

Patient compliance. At baseline, the median score for compliance for the intervention and control groups was high at 59 (IQR 56–60) and was little changed at follow-up (Table 3).

Discussion

This MEDMAN intervention for patients with CHD did not demonstrate any significant change in NSF-recommended treatment for the secondary prevention

TABLE 4 *Health status, quality of life (SF-36, EQ-5D) and patient satisfaction*

Dimensions	Intervention		Control		Mean difference[a] /effect[b]	95% CI	*P*-value
	Baseline median (IQR)	Follow-up median (IQR)	Baseline median (IQR)	Follow-up median (IQR)			
	n = 810	*n* = 712	*n* = 422	*n* = 373			
SF-36							
Physical functioning	60 (35–80)	60 (33–85)	65 (35–85)	65 (35–85)	–0.004[a]	–0.11 to 0.10	0.93
Role physical	50 (0–100)	50 (0–100)	50 (0–100)	50 (0–100)	–0.11[a]	–0.23 to 0.02	0.10
Bodily pain	62 (41–84)	62 (41–84)	62 (41–84)	61 (41–84)	–0.001[a]	–0.08 to 0.07	0.97
General health	52 (35–67)	52 (35–67)	50 (35–67)	52 (35–67)	0.05[a]	–0.03 to 0.13	0.23
Vitality	50 (35–65)	50 (35–65)	50 (35–70)	50 (35–70)	–0.03[a]	–0.12 to 0.04	0.34
Social functioning	87.5 (59–100)	75 (50–100)	87.5 (62–100)	88 (50–100)	0.02[a]	–0.05 to 0.01	0.52
Role emotional	100 (67–100)	100 (67–100)	100 (67–100)	100 (33–100)	0.04[a]	–0.01 to 0.11	0.11
Mental health	76 (64–88)	80 (64–88)	76 (64–88)	80 (64–88)	0.01[a]	–0.03 to 0.05	0.63
EQ-5D score	0.73 (0.6–0.8)	0.73 (0.7–0.9)	0.73 (0.6–0.9)	0.73 (0.7–0.9)	0.04[a]	–0.05 to 0.13	0.37
Patient satisfaction							
Total score	42.0	46.0	42.0	43.0	4.0[b]	1.7 to 6.3	<0.01
Median (IQR)	36–48	40–55	36–48	38–49			
Patient compliance							
Total score	59	59	59	59	1.0[b]	0.61 to 1.65	0.99
Median (IQR)	(56–60)	(57–60)	(56–60)	(57–60)			

Denominators are number of completed questionnaires returned and analysed at both time points in each group; SF-36 and EQ-5D scores are in natural logarithms.
[a]Adjusted for differences in outcome at baseline, gender, age and previous CHD, and for cluster effects within pharmacies, general practices and areas.
[b]Effect of the intervention: this column shows an OR for each of the binary outcomes and a mean difference for the overall satisfaction score, adjusted for differences in outcomes at baseline, gender, age and previous CHD event and for cluster effects within pharmacies, general practices and areas.

TABLE 5 *Summary of costs per patient*

	Intervention (£)		Control (£)		*P*-value
	Baseline median (IQR)	Follow-up median (IQR)	Baseline median (IQR)	Follow-up median (IQR)	
Cost of CHD medicines	347.7 (207.8–526.1)	422.6 (257.0–619.4)	325.7 (183.1–514.0)	411.6 (249.4–600.8)	0.92
Cost of non-CHD medicines	244.2 (71.2–589.3)	200.6 (50.8–401.0)	222.7 (75.4–446.6)	191.1 (54.0–416.9)	0.79
Cost of all medicines	597.5 (344.1–963.7)	605.2 (387.0–971.1)	513.6 (312.1–848.5)	584.9 (402.2–971.3)	0.04
NHS costs (GP and hospital visits)	139.7 (70.1–321.5)	127.4 (61.6–290.7)	138.7 (71.9–315.3)	120.2 (54.5–300.5)	0.65
Total cost of usual treatment (medicines plus NHS visits)[a]	852.4 (480.6–1694.2)	838.7 (544.1–1369.6)	737.8 (446.1–1239.7)	835.2 (534.4–1396.3)	0.22
Cost of the intervention (pharmacist time and training)	0	90 (60–118)	0	0	–
Total NHS-related study cost (medicines plus NHS visits plus intervention costs)[a]	852.4 (480.6–1694.2)	970.5 (667.0–1489.0)	737.8 (446.1–1239.7)	835.2 (534.4–1396.3)	<0.0001

[a]Total costs will not be the sum of presented components as these are all median values.

of CHD, or future risk of cardiovascular death. The cost of the intervention was more than that of standard care. Patient satisfaction in the intervention group increased significantly compared with controls.

Strengths and limitations

The study had a number of important strengths compared with many previous pharmacy intervention studies. It is the largest RCT in the British community pharmacy setting using established validated, primary outcomes. Data extraction and analysis were blind, and high follow-up rates were achieved. Limitations included the following: choice of condition (most patients at baseline were already receiving optimal treatment for aspirin-related outcomes), lack of information on the extent to which pharmacist recommendations were implemented by GPs, potential bias from the use of self-reported questionnaires and levels

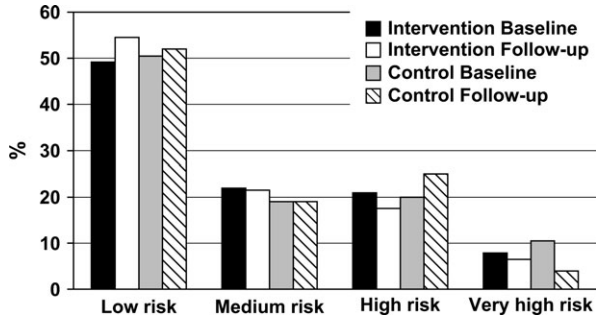


FIGURE 3 *Risk of cardiovascular death. Low, Medium, High and Very High Risk categories were assigned, based on the overall score and subjects' age and gender. The original overall score based on 11 factors was adapted to include the nine factors for which data were available: age, sex, systolic blood pressure, serum total cholesterol concentration, height, cigarette smoking, diabetes, LVH and history of myocardial infarction*

of missing data for some lifestyle components [e.g. body mass index (BMI) at follow-up]. Equal weighting of individual components of the appropriateness of treatment score did not necessarily reflect the contribution of these factors to CHD risk. In addition, the self-selection of the primary care organizations and practices within them and the low proportion of eligible patients consenting might have limited the trial's generalizability. For example, patients appeared to have a high compliance with medication taking, reducing the potential for improvements in care. Finally, target recruitment numbers were not achieved. A *post hoc* power calculation indicates that the study had a resulting power of 74% to detect the 6% difference in the percentage of patients receiving aspirin. The underpowering of the study may have increased the chance of a Type II error. The original sample size calculation was based on absolute risks (benefits) and this methodology is conventionally used in RCTs. However, in the analyses, as is also standard, the relative risk was used to assess the strength of association because the amount by which an intervention multiplies the risk of an event is interpretable regardless of the size of the risk.

Primary outcomes

The lack of observed change in this study, in the main outcome measures of appropriateness, may be explained by the high proportion of patients already receiving NSF-recommended treatment. This ceiling effect might have been avoided if pharmacists had identified patients whose treatment was not in line with the agreed guidelines and agreed individual patient goals with the responsible GP, as has been done in Australia.[2] GPs might have optimized patient care before the study commenced, possibly influenced by the imminent introduction of the quality and outcomes framework of the new General Medical Services contract, in which CHD outcomes are targets.[28] Differences in time frames and practices mean that direct comparisons of the proportions achieving targets would be inappropriate. Some baseline values such as aspirin were higher than previously reported[6] and studies have shown that there have been increases in their use recently.[8] Failure to achieve improvements in the main outcomes has been shown previously with MEDMAN studies[25] although others have demonstrated improvements in individual components of medicines management.[26,27]

Secondary outcomes

Despite high baseline satisfaction scores in both groups, there was a small but significant increase in the intervention group score at follow-up compared to the controls reflecting previous studies assessing satisfaction with the extended role for community pharmacists.[30–32] A full qualitative evaluation of the service is reported elsewhere.[33]

Policy implications

New services within health care can be difficult to implement, particularly, when they occur across traditional professional boundaries. Perceived 'boundary encroachment' may be met either by 'accommodation' or by attempts at 'exclusion'.[34] A study of collaboration between community pharmacists and family practitioners[35] demonstrated a need for clarification of the community pharmacist and physician roles. The extent to which GPs and community pharmacists worked together in this study is unclear. The importance of a systematic approach when changing professional practice, with careful planning, resourcing, implementation and monitoring has been emphasized.[36] All of these may not have been sufficiently addressed in the current study.

Conclusion

This community pharmacist-led intervention did not significantly improve NSF-defined management of CHD.

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