Randomised controlled trial of follow up care in general practice of patients with myocardial infarction and angina: final results of the Southampton heart integrated care project (SHIP)

Kate Jolly, Fiona Bradley, Stephen Sharp, Helen Smith, Simon Thompson, Ann-Louise Kinmonth, David Mant for the SHIP Collaborative Group

Editorial by Hobbs and Murray

Primary Medical Care, University of Southampton, Aldermoor Health Centre, Southampton SO16 5ST

Kate Jolly, *senior registrar*

Fiona Bradley, *research fellow*

Helen Smith, *senior lecturer*

David Mant, *professor*

Medical Statistics Unit, London School of Hygiene and Tropical Medicine, London WC1E 7HT

Stephen Sharp, *lecturer*

Department of Medical Statistics and Evaluation, Imperial College School of Medicine, Hammersmith Hospital, London W12 0NN

Simon Thompson, *professor*

General Practice and Primary Care Research Unit, Institute of Public Health, University of Cambridge, Cambridge CB2 2SR

Ann-Louise Kinmonth, *professor*

continued over

BMJ 1999;318:706–11

Abstract

Objective To assess the effectiveness of a programme to coordinate and support follow up care in general practice after a hospital diagnosis of myocardial infarction or angina.

Design Randomised controlled trial; stratified random allocation of practices to intervention and control groups.

Setting All 67 practices in Southampton and south west Hampshire, England.

Subjects 597 adult patients (422 with myocardial infarction and 175 with a new diagnosis of angina) who were recruited during hospital admission or attendance at a chest pain clinic between April 1995 and September 1996.

Intervention Programme to coordinate preventive care led by specialist liaison nurses which sought to improve communication between hospital and general practice and to encourage general practice nurses to provide structured follow up.

Main outcome measures Serum total cholesterol concentration, blood pressure, distance walked in 6 minutes, confirmed smoking cessation, and body mass index measured at 1 year follow up.

Results Of 559 surviving patients at 1 year, 502 (90%) were followed up. There was no significant difference between the intervention and control groups in smoking (cotinine validated quit rate 19% *v* 20%), lipid concentrations (serum total cholesterol 5.80 *v* 5.93 mmol/l), blood pressure (diastolic pressure 84 *v* 85 mm Hg), or fitness (distance walked in 6 minutes 443 *v* 433 m). Body mass index was slightly lower in the intervention group (27.4 *v* 28.2; P = 0.08).

Conclusions Although the programme was effective in promoting follow up in general practice, it did not improve health outcome. Simply coordinating and supporting existing NHS care is insufficient. Ischaemic heart disease is a chronic condition which requires the same systematic approach to secondary prevention applied in other chronic conditions such as diabetes mellitus.

Introduction

Although preventive care in patients with proved ischaemic heart disease is important and cost effective,[1 2] audits of follow up care after myocardial infarction in hospitals and general practices in the United Kingdom have shown inadequate management of risk factors and low rates of prescription of preventive treatment.[3 4] The results of two trials suggest that nurse led intervention in general practice may be effective.[5 6] Both trials, however, focused on prevalent cases, and the benefits were restricted to outcomes reported by patients. The more recent Scottish trial did not report objective measures of risk,[5] whereas the earlier study from Belfast reported risk outcomes but showed that the intervention had no significant effect on them.[6] In an editorial accompanying the Scottish study, van der Weijden and Grol described the results as "encouraging" but acknowledged the limitations of the study design and emphasised the need to examine the external validity of the findings.[7]

The Southampton heart integrated care project (SHIP) is similar in some ways to these two studies.[5 6] The intervention was assessed in a randomised trial and sought to improve the secondary preventive care of patients with ischaemic heart disease in general practice and to promote the role of practice nurses in coordinating care.[8] Results about self reported outcomes and the process of care were encouraging.[9] The study, however, also has important differences. It recruited only patients with a new diagnosis; the specialist nurses did not provide clinical care but coordinated care at hospital discharge and supported existing rehabilitation and community based services; and the main outcome measures were objective markers of cardiac risk. We report the impact of the intervention on these main outcome measures.

Participants and methods

Design

Each of the 67 practices in the Southampton and south west Hampshire health district was randomised (independently of the local organisation and before seeking

consent) to the intervention (33 practices) or control group (34 practices) after stratification by size of practice (number of whole time equivalent partners) and distance from the district general hospital. Details of recruitment and intervention have been described previously.[9] All 723 patients admitted to hospitals in the district who had survived a first or subsequent myocardial infarction and all patients with angina of recent onset (less than 3 months) who had been seen in a direct access chest pain clinic or admitted were systematically identified over a period of 18 months and considered for inclusion in the trial. Of the 686 patients judged by the medical and nursing staff on the ward to be well enough to participate in the trial, 597 (87%) gave their consent. Baseline data, including measurement of body mass index, blood pressure, and blood total cholesterol concentration, were collected before hospital discharge.

Patients were followed up by self administered questionnaire at 1 month, 4 months, and 1 year after recruitment. The 1 year questionnaire asked about lifestyle factors (smoking, exercise, and diet), current drug treatment, attendance at cardiac rehabilitation courses and other use of health services over the previous 3 months, and current symptoms of chest pain and breathlessness. Psychological state was assessed by the hospital anxiety and depression scale[10] and quality of life by the EuroQol visual analogue scale.[11] At 1 year patients were also assessed clinically by a liaison nurse. This clinical examination was carried out by a nurse who had not been responsible for delivering the intervention to the patient's practice, but we could not exclude the possibility of the nurse becoming aware during the examination of which group the patient's practice was in. The clinical examination included a 6 minute walking test and measurement of blood cotinine concentrations (in those who had ever smoked), as well as repeat measurement of baseline variables. The walking test followed the protocol devised by Guyatt et al and was performed in an enclosed corridor along a 25 m course with standard encouragement.[12]

In conjunction with the trial, a parallel qualitative study examined patients' experiences of myocardial infarction and the care they received during the intervention.[13 14] Ethical approval for both studies was obtained from the local research ethics committee.

Study population

Of the 597 patients, 422 were recruited after myocardial infarction and 175 after being given a diagnosis of angina alone. In total, 277 patients were registered with practices in the intervention group and 320 with practices in the control group. No selection bias was evident as this imbalance was not explained by different reported practice referral pathways or access to the chest pain clinics. Loss to follow up was low (10%) and was the same for intervention and control groups (table 1). The intervention and control groups at study entry were similar in terms of age, sex, smoking status, body mass index, total cholesterol concentration, and blood pressure (table 2).

The power of the study to detect clinically important differences at a 5% significance level was anticipated to be reasonably high for continuous variables (about 95% for a difference of 0.35 mmol/l in blood total cholesterol concentration and of 40 m in the distance walked); it was less for dichotomous outcomes (about 90% to detect a one third reduction in the proportion of patients with untreated blood cholesterol concentration >5.5 mmol/l or to detect a doubling of validated smoking cessation rates).

Intervention

The intervention was led by three specialist cardiac liaison nurses who were responsible for coordinating follow up care for patients, particularly the transfer of responsibility for care between hospital and general practice at the time of discharge and the support of practice nurses. A liaison nurse telephoned the practice (speaking to the practice nurse if possible) shortly before patients were to be discharged to discuss the care of each patient and to book the first follow up visit to the practice. Practice nurses were encouraged to telephone back to discuss problems or to seek advice on clinical or organisational issues. Evidence based guidance on clinical management was attached to each discharge communication, which was given to each patient (or relative) to give to the general practitioner. Each patient was also given a patient held record, which prompted and guided follow up at standard intervals. The liaison nurses did not provide individual clinical care after discharge but provided support to practice staff both by telephone and by visiting each practice every 3-6 months. They also encouraged practice nurses to attend both initial training on behavioural change and an ongoing support group to tackle their information needs as they arose. The initial training was based on the stages of change model adopted nationally by the Health Education Authority.[15]

Seventeen nurses from 13 practices attended the initial training; 27 nurses from 19 practices attended the support group at least once. One practice did not employ a practice nurse; two practices formally declined the participation of their practice nurses in the project; two practices referred patients mainly to hospitals outside the health district.

Correspondence to: Professor D Mant, Department of Primary Health Care, University of Oxford, Institute of Health Sciences, Oxford OX3 7LF

Members of the SHIP Collaborative group are listed at the end of the paper

Table 1 Numbers (percentages) of patients at entry into study and at 1 year follow up

	All patients		Patients with myocardial infarction		Patients with angina	
Detail	Control	Intervention	Control	Intervention	Control	Intervention
At study entry	320	277	218	204	102	73
At 1 year:						
Followed up	267	235	178	170	89	65
Died*	23	15	20	13	3	2
Lost to follow up†	30 (9)	27 (10)	20 (9)	21 (10)	10 (10)	6 (8)

*Difference between deaths in intervention and control group not significant (7% *v* 5%; P=0.4).

†Five patients were too ill or dying, 23 refused, and 29 were uncontactable.

Table 2 Baseline characteristics of patients in intervention and control groups. Values are means (SD) unless stated otherwise

Detail	Control (n=320)	Intervention (n=277)
Age (years)	64 (10)	63 (10)
No (%) of men	237 (74)	189 (68)
No (%) of smokers*	87 (27)	89 (32)
Serum total cholesterol (mmol/l)	6.1 (1.3)	6.1 (1.3)
Systolic blood pressure (mm Hg)	129 (21)	128 (19)
Diastolic blood pressure (mm Hg)	81 (14)	81 (13)
Body mass index (kg/m^2)	28 (3.7)	27 (4.2)

*Smokers at entry into study or in the two weeks before entry.

Table 3 Difference between intervention and control groups in primary outcome measures at 1 year follow up.* Values are means unless stated otherwise

Outcome measure	All patients			Patients with myocardial infarction		Patients with angina	
	Control (n=267)	Intervention (n=235)	Difference (95% CI) between intervention and control	Control (n=178)	Intervention (n=170)	Control (n=87)	Intervention (n=65)
Total cholesterol (mmol/l)	5.93	5.80	–0.14 (–0.33 to 0.06)	5.93	5.82	5.95	5.73
Systolic blood pressure (mm Hg)	139.1	136.9	–2.2 (–5.9 to 1.5)	135.7	137.1	145.6	136.4
Diastolic blood pressure (mm Hg)	85.0	83.7	–1.3 (–3.6 to 0.9)	84.0	84.3	87.1	82.2
Distance walked in 6 minutes (m)	433	443	11 (–13 to 34)	429	446	439	437
Body mass index (kg/m^2)†	28.2	27.4	–0.3 (–0.6 to 0.0)	28.3	27.3	28.0	27.5
Proportion (%) who stopped smoking‡	17/84 (20)	16/85 (19)	–1% (–13% to 11%)	13/66 (20)	16/73 (22)	4/18 (22)	0/12

*Risk factor measurements unavailable for 29-40 of the 502 subjects (6%-8%), except for distance walked which was unavailable for 92 subjects (18%). †Body mass index also adjusted for baseline measurement. ‡Smokers at baseline who were confirmed non-smokers at 1 year (serum cotinine concentration ≤78 nmol/l (≤13.7 ng/ml)). Subjects who were not assessed were assumed to be smokers.

Statistical analysis

Before the data were analysed the trial outcomes were designated as primary risk factor outcomes (see table 3), prescribing outcomes (see table 4), and secondary outcomes (see table 5). The data were analysed on an intention to treat basis but excluded deaths. We compared the outcome measures between the randomised groups by using differences in means or proportions. Body mass index was adjusted for baseline with analysis of covariance. The baseline characteristics of the 95 subjects who died or who were lost to follow up at 1 year were similar at baseline to those of the subjects who were followed up. To safeguard against bias, however, patients lost to follow up were assumed to have continued their baseline behaviour for smoking and prescribing outcomes.

A failure to allow for potential variability between practices may result in the overstatement of significance of differences between the intervention and control groups as the unit of randomisation was the general practice.[16] To allow for this, we calculated results from generalised estimating equations.[17] These equations incorporated robust standard errors and an exchangeable working correlation matrix for patients within the same general practice. Allowance for the cluster randomisation, however, seemed to make little difference to the results. For example, the difference in blood total cholesterol concentrations was −0.14 mmol/l (95% confidence interval −0.33 to 0.06 mmol/l) without adjustment and −0.13 mmol/l (−0.34 to 0.07 mmol/l) after adjustment for the practice effect. As it was also desirable to present absolute differences in proportions rather than odds ratios for binary outcomes, we have presented results without such an adjustment.

Results

At 1 year follow up the primary trial outcomes were not significantly different between the intervention and control groups, although there was some evidence of a difference in favour of the intervention for body mass index (P=0.08; table 3). The effect of the intervention on the primary outcomes was similar in both patients with angina and patients after myocardial infarction except in relation to blood pressure, when a difference in both systolic and diastolic pressures favouring the intervention was seen in patients with angina but not in those with myocardial infarction (tests for interaction P<0.05).

The reported rate of not smoking in all patients at 1 year was 84% in the control group and 81% in the intervention group. The mean reported number of times current smokers at 1 year had tried to give up was 2.3 in both intervention and control groups. Self reported intake of healthy foods was higher in the intervention group, but the mean difference in score for intake was not significant for any individual dietary category (fruit and vegetables P=0.06, olive oil P=0.11, fish P=0.75).

Table 4 reports prescribed drug treatment and use of health services. There were no significant differences in prescribing between the intervention and control groups. In both groups the proportion of patients with untreated high blood pressure was much lower than the proportion of untreated patients with blood total cholesterol concentration ≥5.5 mmol/l. More patients in the intervention group had attended at least one rehabilitation session (difference 18%, P<0.001). Attendance among patients in the intervention group was similar irrespective of diagnosis (angina 43%, myocardial infarction 41%). The reported mean number of sessions attended during the 12 months by patients with myocardial infarction was 3.1 and 2.2 and by patients with angina 3.8 and 0.7 in the intervention and control groups, respectively. The pattern of consulting for heart related problems reported at 4 month follow up was also seen at 1 year: the mean number of consultations with the practice nurse during the previous 3 months was about twice as high in the intervention than the control group (0.7 *v* 0.3 compared with a recommended frequency of 1.0), with no significant difference in the number of consultations with a general practitioner.

Table 5 reports the effect of the intervention on symptom control, anxiety, and depression measured by the hospital anxiety and depression scale and on the quality of life measured by the EuroQol visual analogue scale. About half of the patients in both groups reported chest pain and about two thirds reported shortness of breath. Chest pain interfered with activity to the same extent in both groups, but patients with angina or myocardial infarction in the intervention group reported significantly more interference with activity caused by shortness of breath (P=0.03). Anxiety and depression scores and the proportion of patients scoring over 10 on the subscales were not significantly different between the two groups. The mean score for patients with angina in the intervention group, however, was 1.8 points higher than in control subjects on the anxiety subscale (test for interaction P=0.03) and 1.3 points higher on the depression subscale (test for interaction P=0.07).

Table 4 Difference between intervention and control groups in prescribed drugs and use of health services at 1 year follow up. Values are numbers (percentages) of patients unless stated otherwise

Detail	All patients			Patients with myocardial infarction		Patients with angina	
	Control (n=297)	Intervention (n=262)	Difference (95% CI) between intervention and control	Control (n=198)	Intervention (n=191)	Control (n=99)	Intervention (n=71)
Antihypertensive drugs							
All patients treated*	230 (77)	210 (80)	3% (–4% to 10%)	161 (81)	165 (86)	69 (70)	45 (63)
Patients with untreated high blood pressure†	10 (3)	5 (2)		4 (2)	2 (1)	6 (6)	3 (4)
Cholesterol lowering agent							
All patients treated*	85 (29)	79 (30)	1% (–7% to 9%)	59 (30)	58 (30)	26 (26)	21 (30)
Patients with cholesterol ⩾5.5mmol/l but not receiving treatment	122 (41)	100 (38)		79 (40)	73 (38)	43 (43)	27 (38)
Angiotensin converting enzyme inhibitors							
All patients treated*	91 (31)	95 (36)	6% (0% to 13%)	83 (42)	90 (47)	8 (8)	5 (7)
Aspirin							
All patients treated*	252 (85)	228 (87)	2% (–4% to 8%)	177 (89)	171 (90)	75 (76)	57 (80)
Rehabilitation							
Patients attending at least one session	70 (24)	109 (42)	18% (10% to 26%)	60 (30)	79 (41)	10 (10)	30 (42)
Practice attendance‡							
Mean No of visits to practice nurse	0.3	0.7	0.4 (0.2 to 0.6)	0.3	0.7	0.2	0.8
Mean No of visits to GP	0.9	1.1	0.2 (–0.1 to 0.4)	0.9	1.0	0.7	1.2

GP=general practitioner.
*Those not followed up assumed to be continuing baseline behaviour. †High blood pressure defined as systolic pressure ⩾60 mm Hg or diastolic pressure ⩾100 mm Hg.
‡For issues related to ischaemic heart disease in previous 3 months.

Table 5 Difference between intervention and control groups in secondary outcomes: symptom control and quality of life at 1 year follow up. Values are means unless stated otherwise*

Detail	All patients			Patients with myocardial infarction		Patients with angina	
	Control (n=267)	Intervention (n=235)	Difference (95% CI) between intervention and control	Control (n=178)	Intervention (n=170)	Control (n=89)	Intervention (n=65)
Chest pain at rest or on exercise							
No (%) reporting pain	138 (52)	123 (53)	1% (–8% to 10%)	88 (49)	83 (49)	50 (56)	40 (64)
Interference with activity†	2.2	2.4	0.3 (–0.4 to 0.9)	2.2	2.3	2.2	2.8
Severity†	2.9	2.8	0.0 (–0.6 to 0.6)	2.7	2.5	3.1	3.5
Shortness of breath at rest or on exercise							
No (%) reporting shortness of breath	179 (68)	160 (69)	1% (–7% to 10%)	118 (67)	109 (65)	61 (69)	51 (80)
Interference with activity†	2.3	3.1	0.7 (0.1 to 1.4)	2.5	3.3	2.1	2.6
Severity†	3.4	3.5	0.1 (–0.4 to 0.7)	3.5	3.5	3.2	3.5
Anxiety‡							
Score on subscale	6.5	7.0	0.5 (–0.3 to 1.3)	6.9	6.7	5.9	7.7
No (%) scoring >10	50 (21)	51 (24)		36 (23)	32 (20)	14 (17)	19 (33)
Depression‡							
Score on subscale	4.5	5.0	0.4 (–0.3 to 1.0)	4.9	4.8	4.0	5.3
No (%) scoring >10	17 (7)	24 (11)		12 (7)	17 (10)	5 (6)	7 (12)
Quality of life							
EuroQol score¶	68.4	66.9	–1.5 (–5.1 to 2.1)	67.9	66.8	69.4	67.1

*Values are missing for 2-10 of the 502 subjects (0-2%); percentages are calculated exactly and vary slightly from those calculable with numerators and column denominators shown in table.
†Maximum 10 (visual analogue scale). ‡Hospital anxiety and depression scale. ¶Maximum 100 (visual analogue scale).

Discussion

Interpretation of results

From a methodological and logistic perspective the trial was successful. Loss to follow up was small (10%) and was similar in the intervention and control groups. All general practices in the health district were included in the study, yet only three of the 33 practices randomised to the intervention group refused to collaborate fully. The intervention was implemented effectively and the increase in general practice follow up and attendance for rehabilitation reported at 4 months[9] was still apparent at 1 year. There was some imbalance in the number of patients with angina recruited from intervention and control practices, but this is most likely to reflect the difficulty of adequately predicting patient flow from the stratifying parameters of practice size and geographical location.

So why was the intervention apparently ineffective in reducing risk? An important factor is sampling error. The confidence intervals in table 3 indicate that we cannot exclude the possibility of small but clinically important reductions in total cholesterol concentration, blood pressure, and smoking. For total cholesterol concentration, this interval includes a reduction of 0.3 mmol/l (5%), which could be crudely extrapolated as about a 10% fall in cardiac risk. Nevertheless, the intervention was certainly less effective than we had hoped on the basis of the known effects of preventive treatment, behavioural change, and exercise rehabilitation in non-pragmatic clinical trials.

Improvement in the standard of follow up care in the control group in response to other external factors must also be considered. The general level of prescribing of aspirin for patients with ischaemic heart disease may have increased in the United Kingdom.[18] Although there was no evidence that the presence of the study locally influenced care in the control group practices, the proportion of patients with poorly

Key messages

- This trial assessed an intervention to coordinate preventive care in general practice of patients with newly diagnosed ischaemic heart disease
- Though the programme of intervention was effective in promoting follow up in general practice and rehabilitation, it did not improve objective measures of risk
- The emphasis of the educational programme for nurses in general practice and rehabilitation, which highlighted the importance of motivating behaviour change and the likelihood of full recovery after myocardial infarction, was at odds with patients' experiences
- Simply coordinating and supporting existing NHS care seems insufficient
- Angina and myocardial infarction merit the same systematic approach to secondary prevention as that given to other chronic diseases such as diabetes

controlled hypertension in the control group was low (3%) and validated smoking cessation in the control group was higher than anticipated. Conversely, the overall rates of prescribing of angiotensin converting enzyme inhibitors and cholesterol lowering agents in the control group were similar to those anticipated at the design stage, and symptom control was worse than anticipated in both groups.

Limitations of intervention

Another reason for the apparent lack of effect of the intervention is the failure of the given advice to relate to a patients' perspective. The training provided to both rehabilitation and primary care nurses was based on a model emphasising the importance of motivating change, which the Health Education Authority has promoted nationally.[15] Data from the 1 month follow up clearly show that this model is of limited relevance to follow up care; most patients were highly motivated and the task was to help them to sustain and make more effective the lifestyle changes they thought they had already made.[9] It also became clear through the parallel qualitative study that some patients thought that the initial advice and literature that they were given, such as the British Heart Foundation's booklet *Back to Normal*, implied that recovery would be complete in about 3 months.[14] As both the quantitative and qualitative results showed, this implication conflicted with the continuing symptoms experienced by many patients.

The most important explanation for the lack of a demonstrable effect of the intervention, however, seems to lie in the limitations of a liaison service focusing on coordination of services and incorporating discretionary training and use of resources. The nurse liaison service formed the core of the intervention and was entirely facilitating. After initial notification of discharge, collaboration with the liaison service was discretionary. The service sought to mobilise rather than augment existing NHS resources. These existing resources were often inadequate, and there were no agreed quality standards against which the acute or community services were trying to measure their performance. The liaison nursing service could not influence local service provision within the framework of the programme when it became clear during the study (for example) that the position of practice nurses within some primary care teams limited their effectiveness in coordinating and monitoring prescribing, that access to rehabilitation services was difficult for some patients, and that hospital discharge care was sometimes less than optimal.

Implications for practice

The results are not entirely without hope for preventive cardiology. Overall, the management of blood pressure and the prescribing of aspirin in both groups were encouraging. The higher rate of reported interference with activity caused by shortness of breath in patients in the intervention group may reflect an appropriately increased expectation of activity. Some of the results raise further questions. For example, we do not know why the intervention was more effective in reducing blood pressure in patients with angina (perhaps reflecting use of β blockers in the myocardial infarction control group) and why it was associated with higher hospital anxiety and depression subscores in patients with angina but not myocardial infarction (preventive advice cannot necessarily be given without psychological cost). Findings from the qualitative research also provide pointers for the way forward.[13 14] However, about 40% of patients with blood cholesterol concentrations ⩾5.5 mmol/l remained untreated and 80% of smokers did not stop smoking, and control of symptoms could probably also have been improved. The effectiveness of the coordination of services seems to be limited by the effectiveness of the services coordinated. This was also the conclusion from a randomised trial in general practice of an intervention to coordinate the care of terminally ill patients with cancer.[19]

The secondary prevention of all cardiovascular disease merits the same systematic approach as we have to other chronic diseases such as diabetes. This implies a register, a recall system, and routine audit of care.[20] Furthermore, it implies clear quality standards and appropriate local organisation and staff training to ensure the necessary team work across professions and sectors, including purchasers, providers, and patients.[21] Until this systematic approach is achieved nationally, audit of routine care is likely to continue to record the unpalatable fact that many patients with diagnosed symptomatic cardiovascular disease do not receive the quality of follow up care they deserve.

We thank the patients and staff of the participating general practices; members of the local coordinating committee (J Bigg, P Christmas, S Gilbert, R Grimes, L Rogers); and our administrators, L Watson and H Heitmann. We are grateful to M Alston for his assistance in the data management of this study.

The SHIP Collaborative Group is M Buxton, A Davies (Brunel University); K Done, K Enright, K Jolly, V Speller, D Waller, R Wiles, L Wright (University of Southampton); M Johnston, D Johnston (University of St Andrews); D Wood (department of cardiac medicine, National Heart and Lung Institute), and the authors of this paper. The parallel qualitative research group are M Blaxter (University of East Anglia); M Gantley, J Robison, A Spackman (University of Southampton), and Ann-Louise Kinmonth.

Contributors: K Done, K Enright, and L Wright were the liaison nurses who led the intervention. DM, A-LK, SS, ST, David Wood, Martin Buxton, Viv Speller, Marie Johnston, Derek Johnston, and Derek Waller all contributed to the study design. A-LK, Mildred Blaxter, Madeline Gantley, Angela Spackman, and Rose Wiles designed the qualitative study. Fiona Bradley was the first medical coordinator (responsible for day to day management of

the trial) and put the initial protocol into operation; KJ took over this role in March 1966. DM oversaw the trial as principal investigator; HS deputised in this role for much of 1997-8. ST and SS designed and carried out the statistical analysis. Andrew Davies and Martin Buxton designed and carried out the economic analysis. Derek Johnston and Marie Johnston designed the psychological assessment. Viv Speller was responsible for designing behavioural change aspects of the intervention and for organising initial nurse training and support. Derek Waller coordinated the hospital based element of the intervention. David Wood chaired the steering group. KJ and DM drafted the text of the paper with the support of a writing group consisting of the other authors listed. DM is guarantor for the study.

Funding: The study was funded by a research and development national programme grant from the NHS Executive, with service support from Southampton and South West Hampshire Health Authority. Rose Wiles was in receipt of a NHS South and West Region research and development research training fellowship.

Competing interests: None declared.

1 Moher M, Schofield T, Fullard E. Managing established coronary heart disease. *BMJ* 1997;315:69-70.
2 Audit Commission. *Dear to our hearts? Commissioning services for the treatment and prevention of coronary heart disease*. London: HMSO, 1995.
3 Bradley F, Morgan S, Smith H, Mant D. Preventive care for patients following myocardial infarction. *Fam Pract* 1997;14:220-6.
4 ASPIRE Steering Group. A British Cardiac Society survey of the potential for the secondary prevention of coronary heart disease: ASPIRE (action on secondary prevention through intervention to reduce events) principal results. *Heart* 1996;75:334-42.
5 Campbell N, Thain J, Deans H, Ritchie L, Rawles J, Squair J. Secondary prevention clinics for coronary heart disease: randomised trial of effect on health. *BMJ* 1998;316:1434-7.
6 Cupples M, McKnight A. Randomised controlled trial of health promotion in general practice for patients at high cardiovascular risk. *BMJ* 1994;309:993-6.
7 Van der Weijden T, Grol R. Preventing recurrent coronary heart disease. *BMJ* 1998;316:1400-1.
8 Wright L, Done K. Cardiac liaison crossing the primary-secondary care interface. *Br J Comm Nurs* 1998;3:118-23
9 SHIP Collaborative Group. Follow-up care in general practice of patients with myocardial infarction or angina pectoris: initial results of the SHIP trial. *Fam Pract* (in press).
10 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361-70.
11 EuroQol Group. EuroQol: a new facility for the measurement of health related quality of life. *Health Pol* 1990;16:199-208.
12 Guyett GH, Sullivan MJ, Thompson PJ, Fallen EL, Pugsley SO, Taylor DW, et al. The six minute walk: a new measure of exercise capacity in patients with chronic heart failure. *Can Med J* 1985;132:919-23.
13 Wiles R. Empowering practice nurses in the follow-up of patients with established heart disease: lessons from patients' experiences. *J Adv Nurs* 1997;26:729-35.
14 Wiles R. Patients' perceptions of their heart attack and recovery: the influence of epidemiological evidence and personal experience. *Soc Sci Med* 1998;46:1477-86.
15 Mason P, Hunt R, Raw M, Sils M. *Helping people change: a trainers' manual*. London: Health Education Authority, 1994.
16 Kerry SM, Bland JM. Analysis of a trial randomised in clusters. *BMJ* 1998;316:54.
17 Donner A. Some aspects of the design and analysis of cluster randomised trials. *Appl Stat* 1988;47:95-113.
18 Carney AJ, Carney TA. Use of aspirin in secondary prevention of coronary heart disease is rising. *BMJ* 1996;312:846.
19 Addington-Hall J, MacDonald L, Anderson H, Chamberlain J, Freeling P, Bland J, et al. Randomised controlled trial of effects of co-ordinating care for terminally ill patients. *BMJ* 1992;305:1317-22.
20 Marks L. Counting the cost: the real impact of non-insulin dependent diabetes. London: Kings' Fund, British Diabetic Association, 1996:25-31.
21 Apfel J. Training and professional development in diabetes care. *Diabet Med* 1996:13(suppl 4);65-76.

(Accepted 4 December 1998)

Development and evaluation of complex interventions in health services research: case study of the Southampton heart integrated care project (SHIP)

F Bradley, R Wiles, A-L Kinmonth, D Mant, M Gantley for the SHIP Collaborative Group

The development and evaluation of complex interventions within randomised controlled designs is a challenging area in health services research. The process usually entails a pilot phase to confirm the feasibility and potential effectiveness of the design before embarking on large and costly trials. However, the focus is often more on the study design and measures than on the theoretical base and extent to which the intervention can be appropriately applied. In this article, we use a case study to describe an approach to pilot work that addresses this gap.

Summary points

- Interventions are often defined pragmatically and lack any clear theoretical basis, which limits generalisability
- Implementation is rarely described, which limits understanding of why an intervention is or is not locally successful
- Integration of qualitative methods within pilot trials can help interpret the quantitative result by clarifying process and testing theory
- This approach defines three levels of understanding: the evidence and theory which inform the intervention, the tasks and processes involved in applying the theoretical principles, and people with whom, and context within which, the intervention is operationalised
- A case study shows how this novel method of programme development and evaluation can be applied

Background

Compared with drug trials or trials of surgical procedures, the design and development of a health service intervention is highly complex. In practice such interventions are often defined pragmatically, according to local circumstance, rather than building on any specific theoretical approach.[1] Even if an approach or technology can be clearly grounded in theory and evidence, it must still be operationalised and evaluated among specific practitioners and patients. There is thus a tension between evaluation of complex interventions and generalisability of results. Randomised trials alone can not tell us why an intervention was or was not

Department of Community Health and General Practice, Trinity College, Dublin 2, Ireland
Fiona Bradley, *lecturer*
Health Research Unit, School of Occupational Therapy and Physiotherapy, University of Southampton, Southampton SO17 1BJ
Rose Wiles, *senior research fellow*

continued over

BMJ 1999;318:711–5